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Medical electrical equipment –
Part 1: General requirements for basic safety and essential performance

Appareils électromédicaux –
Partie 1: Exigences générales pour la sécurité de base et les performances essentielles



IEC 60601-1:2005-07+AMD1:2012-08 CSV(en-fr)

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Publication IEC 60601-1 (Third edition – 2005) I-SH 01

MEDICAL ELECTRICAL EQUIPMENT – Part 1: General requirements for basic safety and essential performance

INTERPRETATION SHEET 1

This interpretation sheet has been prepared by SC 62A: Common aspects of electrical equipment used in medical practice

The text of this interpretation sheet is based on the following documents:

ISH	Report on voting
62A/599/ISH	62A/613/RVD

Full information on the voting for the approval of this interpretation sheet can be found in the report on voting indicated in the above table.

Subclause 1.1

This subclause is clarified by the following:

IEC 60601-1 does not apply to medical gas pipeline systems covered by ISO 7396-1, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum.*

NOTE Subclause 6.3 of ISO 7396-1 applies the requirement of IEC 60601-1-8 to certain monitoring and alarm signals.

This clarification will remain valid until a new version of IEC 60601-1 is published.

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Publication IEC 60601-1 (Third edition – 2005) I-SH 02

MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

INTERPRETATION SHEET 2

This interpretation sheet has been prepared by subcomittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this interpretation sheet is based on the following documents:

ISH	Report on voting
62A/634/ISH	62A/640/RVD

Full information on the voting for the approval of this interpretation sheet can be found in the report on voting indicated in the above table.

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Subclause 11.3

This subclause is clarified by the following:

As stated in the rationale for this subclause, fire ENCLOSURES are intended to be used only where there is a significant likelihood of fire due to the presence of a source of ignition (as described in the subclause) *and* a *significant* source of fuel. Most materials used in the construction of ME EQUIPMENT are not considered to be such a source of fuel unless they are in the presence of an OXYGEN RICH ENVIRONMENT. MANUFACTURERS should determine, through analyses documented in the RISK MANAGEMENT FILE, whether the ME EQUIPMENT contains combustible materials (fuel) in sufficient quantities to support combustion in conjunction with ignition sources (capable of releasing greater than 900 J).

Subclause 13.1.2

This subclause is clarified by the following:

As stated in subclause 4.7, it is the MANUFACTURER'S RISK ANALYSIS that determines which components are subject to failure testing based on the associated RISK. Where the associated RISK of fire exceeds the MANUFACTURER'S criteria for RISK acceptability, the MANUFACTURER'S simulation analysis (such as FMEAs) should be accepted in lieu of physical testing. As also stated in 4.7, component reliability and ratings are to be considered in such failure simulation analyses. Common electronic components that have a history of use without causing equipment fires should not be considered a likely source of ignition.

Where the subclause identifies "emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities;" as a hazardous situation, this refers to emissions from *the ENCLOSURE* not from components themselves. Where it identifies "exceeding the allowable values for 'other components and materials' identified in Table 22 times 1,5 minus 12,5 °C", this applies only where doing so would result in an unacceptable RISK (as identified in the MANUFACTURER'S RISK ANALYSIS according to 4.7). Typically, this would be cases where

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ESSENTIAL PERFORMANCE would not be maintained or where greater than 900 J of energy would be released in the presence of flammable materials that could sustain combustion.

The first exemption to fault analysis or testing identified in subclause 13.1.2 ("The construction or the supply circuit limits the power dissipation in SINGLE FAULT CONDITION to less than 15 W or the energy dissipation to less than 900 J.") is intended to apply where the component design itself ("The construction") or fusing (or other current limiting devices) in the supply circuit ("or the supply circuit") assure the energy released during failures will not exceed the limits. For most common signal level components rated for operation below 5 Watts, the energy released by short-circuiting of outputs will not exceed the 900 J limit.

This clarification will remain valid until a new version of IEC 60601-1 is published.

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SC 62A/Publication IEC 60601-1:2005, including Amendment 1:2012, Third edition/I-SH 03

MEDICAL ELECTRICAL EQUIPMENT –
Part 1: General requirements for basic safety and essential performance

INTERPRETATION SHEET 3

This interpretation sheet has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this interpretation sheet is based on the following documents:

ISH	Report on voting
62A/858/ISH	62A/875/RVD

Full information on the voting for the approval of this interpretation sheet can be found in the report on voting indicated in the above table.

Subclause 13.1.2 fourth dash (Emissions, deformation of ENCLOSURE or exceeding maximum temperature)

This subclause states the following:

The following HAZARDOUS SITUATIONS shall not occur:

– ....

– temperatures of ME EQUIPMENT parts that are not APPLIED PARTS but are likely to be touched, exceeding the allowable values in Table 23 when measured and adjusted as described in 11.1.3;

This is clarified by the following:

The above requirement is regarded as fulfilled in accordance with Subclause 4.5 for temperatures at the surfaces of the enclosure, if the following conditions are fulfilled:

– The maximum allowed temperature on OPERATOR accessible surfaces in SINGLE FAULT CONDITION is 105 °C; and

– the instructions for use contain a warning that, under some SINGLE FAULT CONDITIONS, the temperature of: (*indicate the surface of concern*) could get hot and there is a possible RISK of a burn if touched, and

– if the RISK ANALYSIS demonstrates a need for a warning symbol on the ENCLOSURE, safety sign ISO 7010-W018 () shall be used on or adjacent to the hot spot on the ENCLOSURE; and

– the RISK ASSESSMENT demonstrates that the temperature attained in the SINGLE FAULT CONDITION is acceptable, and

– the RISK ASSESSMENT demonstrates that applying the alternative RISK CONTROL measures in this Interpretation Sheet results in a RESIDUAL RISK that is comparable to the RESIDUAL RISK resulting from applying the requirement of the standard.

NOTE 1 This Interpretation Sheet is intended to be used with both Edition 3.0 and Edition 3.1 of IEC 60601-1.

NOTE 2 An example of an analysis that demonstrates an adequately low probability of occurrence of HARM is shown below.

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Example RISK ASSESSMENT:

The sum failure rate for parts that could increase the surface temperature of parts of the enclosure of XYZ device touchable only by the OPERATOR to values above those of Table 23 calculates to be 60 FIT (1 FIT = 1E-9/h) according to the standard MIL-HDBK-217F where FIT stands for "failure in time". In case of such failures, the device would emit an odour and would no longer function properly. It is estimated, that only in one of 3 cases the device would not be switched off immediately and the hot surface would be resulting in a burn.

The resulting overall probability of such HARM where adequate warning is provided in the instructions for use in combination with warning sign ISO 7010 W018 would be: probability = 1/3 * 60 FIT = 2 E-8/h =approx. 0,0002 per year.

In this example, the WXW Company's RISK acceptance criteria require that a HARM of that severity must have a probability of less than 0,0003 per year for the associated RISK to be considered acceptable. Based on that RISK acceptance criterion, the RISK associated with overtemperature of the ENCLOSURE caused by single faults in the circuitry is acceptable.

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MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

INTERPRETATION SHEET 1

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This interpretation sheet has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this interpretation sheet is based on the following documents:

DISH	Report on voting
62A/1403/DISH	62A/1414/RVDISH

Full information on the voting for the approval of this interpretation sheet can be found in the report on voting indicated in the above table.

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Interpretation of Subclauses 4.3 of IEC 60601-1:2005/AMD1:2012 and 4.7 of IEC 60601-1:2005

This interpretation sheet is intended to clarify the requirements which are needed to maintain ESSENTIAL PERFORMANCE in SINGLE FAULT CONDITION.

Subclause 4.3 * ESSENTIAL PERFORMANCE

The requirements in this subclause of IEC 60601-1:2005/AMD1:2012 are clarified by the following.

aa) IEC 60601-1:2005/AMD1:2012 requires that both the NORMAL CONDITION and the SINGLE FAULT CONDITIONS are to be considered in the identification of ESSENTIAL PERFORMANCE, because:

IEC 60601-1:2005-12/AMD1:2012-07/ISH1:2021-03(en)

ICS 11.040.01

1) ESSENTIAL PERFORMANCE is defined in terms of the performance of a clinical function (see 3.27);

NOTE 1 ESSENTIAL PERFORMANCE can have multiple aspects.

2) in particular, SINGLE FAULT CONDITIONS can cause or contribute to the loss or degradation of such a clinical function that results in unacceptable RISK; and

3) according to IEC 60601-1:2005, 4.7, ME EQUIPMENT is required to remain SINGLE FAULT SAFE or the RISK remains acceptable and this also applies to ESSENTIAL PERFORMANCE.

bb) The subclause requires the MANUFACTURER to:

NOTE 2 Many particular standards specify performance limits, RISK CONTROL measures and VERIFICATION methods for some aspects of ESSENTIAL PERFORMANCE.

1) identify performance of clinical functions, other than that related to BASIC SAFETY, that is necessary to achieve the INTENDED USE or that could affect safety;

2) specify performance limits between fully functional and total loss of the identified performance in both

   i) NORMAL CONDITION, and

   ii) SINGLE FAULT CONDITION;

   NOTE 3 The specified performance limits can be different in NORMAL CONDITION and SINGLE FAULT CONDITION.

3) evaluate the RISK from loss or degradation of the identified performance beyond the specified limits;

   i) Where the resulting RISK is unacceptable, the identified performance is ESSENTIAL PERFORMANCE.

4) implement RISK CONTROL measures to reduce these RISKS to an acceptable level for both

   i) NORMAL CONDITION, and

   ii) SINGLE FAULT CONDITION;

5) assess and determine which RISK CONTROL measures need VERIFICATION of effectiveness; and

6) specify methods for the VERIFICATION of the effectiveness of the RISK CONTROL measures.

cc) The requirements of IEC 60601-1:2005/AMD1:2012 4.3 as clarified in items 4.3 bb) 1) to 4.3 bb) 6) above include documentation of the relevant results in the RISK MANAGEMENT FILE. The documentation is intended to serve as OBJECTIVE EVIDENCE that the required activities have been performed.

dd) The compliance statement refers to “inspection of the RISK MANAGEMENT FILE”. Inspection means the careful examination or scrutiny of the contents of the RISK MANAGEMENT FILE. Only confirming the existence of a RISK MANAGEMENT FILE is insufficient. Inspection can include functional tests as clarified in IEC 60601-1:2005/AMD1:2012/ISH1 items 4.3 bb) 5) and 4.3 bb) 6). This is similar to the other uses of “inspection” throughout this standard.

Subclause 4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT

The requirements in this subclause of IEC 60601-1:2005 are clarified by the following.

aa) IEC 60601-1:2005 requires that ME EQUIPMENT remains SINGLE FAULT SAFE or the RISK remains acceptable according to 4.2 during the EXPECTED SERVICE LIFE and this also applies to ESSENTIAL PERFORMANCE.

bb) SINGLE FAULT CONDITION (as defined in 3.116) describes the condition where “a single means for reducing a RISK is defective or a single abnormal condition is present”. Either condition anticipates the failure or fault of one component [other than those indicated in 4.7 a), e.g. a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS].

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Component failure or fault can relate to:

1) a single part (e.g. resistor, capacitor, wire, mechanical part),

2) a subassembly (e.g. battery block, power supply unit, line filter, PESS), or

3) a device with a specified function (e.g. protective unit, control unit, monitoring unit).

Any SINGLE FAULT CONDITION that could result in a HAZARDOUS SITUATION, including those mentioned in 13.1, needs to be simulated, physically or theoretically. Care needs to be taken to adequately determine the worst case situation when analysing failure or fault of subassemblies and functional units.

cc) It can be necessary to investigate the consequences of a second independent fault or failure. This is relevant when the initial fault or failure remains undetected during NORMAL USE for the EXPECTED SERVICE LIFE or when the fault or failure is so likely that it is considered to be a NORMAL CONDITION. See 4.7 b) and 5.1 and their rationales in Annex A.

dd) The RISK ASSESSMENT is used to determine which SINGLE FAULT CONDITIONS are to be tested in agreement with 4.3, 4.7 and 5.1. This includes consideration of a second independent fault or failure following an initial SINGLE FAULT CONDITION that remains undetected during NORMAL USE for the EXPECTED SERVICE LIFE. This also applies to the VERIFICATION of the effectiveness of the RISK CONTROL measures needed to maintain ESSENTIAL PERFORMANCE [see IEC 60601-1/AMD1:2012/ISH1 4.3 bb) 5) and 4.3 bb) 6)].

ee) The requirements of 4.7 include documentation of the relevant tests in the RISK MANAGEMENT FILE. The documentation is intended to serve as OBJECTIVE EVIDENCE that the required activities have been performed.

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CONTENTS

FOREWORD 10
INTRODUCTION 13
INTRODUCTION TO THE AMENDMENT 15
1 Scope, object and related standards 16
1.1 * Scope 16
1.2 Object 16
1.3 * Collateral standards 16
1.4 * Particular standards 17
2 * Normative references 17
3 * Terminology and definitions 21
4 General requirements 42
4.1 * Conditions for application to ME EQUIPMENT or ME SYSTEMS 42
4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS 42
4.3 * ESSENTIAL PERFORMANCE 45
4.4 * EXPECTED SERVICE LIFE 46
4.5 * ~~Equivalent safety~~ Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS 46
4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT 47
4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT 47
4.8 * Components of ME EQUIPMENT 48
4.9 * Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT 48
4.10 * Power supply 49
4.11 Power input 50
5 * General requirements for testing ME EQUIPMENT 50
5.1 * TYPE TESTS 50
5.2 * Number of samples 51
5.3 Ambient temperature, humidity, atmospheric pressure 51
5.4 Other conditions 51
5.5 Supply voltages, type of current, nature of supply, frequency 51
5.6 Repairs and modifications 52
5.7 * Humidity preconditioning treatment 52
5.8 Sequence of tests 53
5.9 * Determination of APPLIED PARTS and ACCESSIBLE PARTS 53
6 * Classification of ME EQUIPMENT and ME SYSTEMS 56
6.1 General 56
6.2 * Protection against electric shock 56
6.3 * Protection against harmful ingress of water or particulate matter 56
6.4 Method(s) of sterilization 56
6.5 Suitability for use in an OXYGEN RICH ENVIRONMENT 56
6.6 * Mode of operation 56
7 ME EQUIPMENT identification, marking and documents 57
7.1 General 57
7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.1) 58
7.3 Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.2) 63

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7.4 Marking of controls and instruments (see also Table C.3) 64
7.5 Safety signs 66
7.6 Symbols 66
7.7 Colours of the insulation of conductors 67
7.8 * Indicator lights and controls 67
7.9 ACCOMPANYING DOCUMENTS 68
8 * Protection against electrical HAZARDS from ME EQUIPMENT 74
8.1 Fundamental rule of protection against electric shock 74
8.2 Requirements related to power sources 75
8.3 Classification of APPLIED PARTS 76
8.4 Limitation of voltage, current or energy 76
8.5 Separation of parts 79
8.6 * Protective earthing, functional earthing and potential equalization of ME EQUIPMENT 89
8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS 92
8.8 Insulation 114
8.9 * CREEPAGE DISTANCES and AIR CLEARANCES 120
8.10 Components and wiring 137
8.11 MAINS PARTS, components and layout 139
9 * Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS 145
9.1 MECHANICAL HAZARDS of ME EQUIPMENT 145
9.2 * MECHANICAL HAZARDS associated with moving parts 145
9.3 * MECHANICAL HAZARD associated with surfaces, corners and edges 151
9.4 * Instability HAZARDS 151
9.5 * Expelled parts HAZARD 156
9.6 Acoustic energy (including infra- and ultrasound) and vibration 157
9.7 * Pressure vessels and parts subject to pneumatic and hydraulic pressure 158
9.8 * MECHANICAL HAZARDS associated with support systems 161
10 * Protection against unwanted and excessive radiation HAZARDS 167
10.1 X-Radiation 167
10.2 Alpha, beta, gamma, neutron and other particle radiation 168
10.3 Microwave radiation 168
10.4 * Lasers ~~and light emitting diodes (LEDs)~~ 169
10.5 Other visible electromagnetic radiation 169
10.6 Infrared radiation 169
10.7 Ultraviolet radiation 169
11 Protection against excessive temperatures and other HAZARDS 169
11.1 * Excessive temperatures in ME EQUIPMENT 169
11.2 * Fire prevention 174
11.3 * Constructional requirements for fire ENCLOSURES of ME EQUIPMENT 178
11.4 * ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics 180
11.5 * ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents 181
11.6 Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT 181
11.7 Biocompatibility of ME EQUIPMENT and ME SYSTEMS 183
11.8 * Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT 183

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

12 * Accuracy of controls and instruments and protection against hazardous outputs 183
12.1 Accuracy of controls and instruments 183
12.2 USABILITY of ME EQUIPMENT 183
12.3 ALARM SYSTEMS 184
12.4 Protection against hazardous output 184
13 * HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT 185
13.1 Specific HAZARDOUS SITUATIONS 185
13.2 SINGLE FAULT CONDITIONS 187
14 * PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 192
14.1 * General 192
14.2 * Documentation 192
14.3 * RISK MANAGEMENT plan 193
14.4 * PEMS DEVELOPMENT LIFE-CYCLE 193
14.5 * Problem resolution 193
14.6 RISK MANAGEMENT PROCESS 193
14.7 * Requirement specification 194
14.8 * Architecture 194
14.9 * Design and implementation 194
14.10 * VERIFICATION 195
14.11 * PEMS VALIDATION 195
14.12 * Modification 195
14.13 * ~~Connection of PEMS by NETWORK/DATA COUPLING to other equipment~~
PEMS intended to be incorporated into an IT-NETWORK 196
15 Construction of ME EQUIPMENT 197
15.1 * Arrangements of controls and indicators of ME EQUIPMENT 197
15.2 * Serviceability 197
15.3 Mechanical strength 197
15.4 ME EQUIPMENT components and general assembly 201
15.5 * MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5 206
16 * ME SYSTEMS 210
16.1 * General requirements for the ME SYSTEMS 210
16.2 * ACCOMPANYING DOCUMENTS of an ME SYSTEM 211
16.3 * Power supply 212
16.4 ENCLOSURES 212
16.5 * SEPARATION DEVICES 212
16.6 * LEAKAGE CURRENTS 213
16.7 * Protection against MECHANICAL HAZARDS 214
16.8 Interruption of the power supply to parts of an ME SYSTEM 214
16.9 ME SYSTEM connections and wiring 214
17 * Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 216
Annex A (informative) General guidance and rationale 217
Annex B (informative) Sequence of testing 327
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS 331
Annex D (informative) Symbols on marking (see Clause 7) 334
Annex E (informative) Examples of the connection of the measuring device (MD) for measurement of the PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT (see 8.7) 343

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Annex F (informative) Suitable measuring supply circuits 345
Annex G (normative) Protection against HAZARDS of ignition of flammable anaesthetic mixtures 348
Annex H (informative) Pems structure, PEMS DEVELOPMENT LIFE-CYCLE and documentation 363
Annex I (informative) ME SYSTEMS aspects 376
Annex J (informative) Survey of insulation paths 382
Annex K (informative) Simplified PATIENT LEAKAGE CURRENT diagrams 385
Annex L (normative) Insulated winding wires for use without interleaved insulation 388
Annex M (normative) Reduction of pollution degrees 391
Bibliography 392
INDEX OF ABBREVIATIONS AND ACRONYMS 396
INDEX 398

Figure 1 – Detachable mains connection 23
Figure 2 – Example of the defined terminals and conductors 24
Figure 3 – Example of a CLASS I ME EQUIPMENT 25
Figure 4 – Example of a metal-enclosed CLASS II ME EQUIPMENT 25
Figure 5 – Schematic flow chart for component qualification 49
Figure 6 – Standard test finger 54
Figure 7 – Test hook 55
Figure 8 – Test pin 78
Figure 9 – Application of test voltage to bridged PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS 85
Figure 10 – Application of test voltage to individual PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS 87
Figure 11 – Application of test voltage to test the delivered defibrillation energy 89
Figure 12 – Example of a measuring device and its frequency characteristics 94
Figure 13 – Measuring circuit for ~~the~~ EARTH LEAKAGE CURRENT of CLASS I ME EQUIPMENT, with or without APPLIED PART 97
Figure 14 – Measuring circuit for ~~the~~ TOUCH CURRENT 99
Figure 15 – Measuring circuit for ~~the~~ PATIENT LEAKAGE CURRENT from the PATIENT CONNECTION to earth 101
Figure 16 – Measuring circuit for ~~the~~ PATIENT LEAKAGE current via the PATIENT CONNECTION(s) of an F-TYPE APPLIED PART to earth caused by an external voltage on the PATIENT CONNECTION(s) 103
Figure 17 – Measuring circuit for ~~the~~ PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(s) to earth caused by an external voltage on a SIGNAL INPUT/OUTPUT PART 105
Figure 18 – Measuring circuit for ~~the~~ PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(s) to earth caused by an external voltage on a metal ACCESSIBLE PART that is not PROTECTIVELY EARTHED 107
Figure 19 – Measuring circuit for ~~the~~ PATIENT AUXILIARY CURRENT 108
Figure 20 – Measuring circuit for ~~the~~ total PATIENT LEAKAGE CURRENT with all PATIENT CONNECTIONS of all APPLIED PARTS of the same type (TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS) connected together 109
Figure 21 – Ball-pressure test apparatus 120
Figure 22 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 1 132

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Figure 23 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 2 132
Figure 24 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 3 133
Figure 25 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 4 133
Figure 26 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 5 133
Figure 27 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 6 134
Figure 28 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 7 134
Figure 29 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 8 135
Figure 30 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 9 136
Figure 31 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 10 137
Figure 32 – Ratio between hydraulic test pressure and maximum permissible working pressure 160
Figure 33 – ~~Human body test mass~~ Body upper-carriage module 166
Figure 34 – Spark ignition test apparatus 175
Figure 35 – Maximum allowable current I as a function of the maximum allowable voltage U measured in a purely resistive circuit in an OXYGEN RICH ENVIRONMENT 176
Figure 36 – Maximum allowable voltage U as a function of the capacitance C measured in a capacitive circuit used in an OXYGEN RICH ENVIRONMENT 176
Figure 37 – Maximum allowable current I as a function of the inductance L measured in an inductive circuit in an OXYGEN RICH ENVIRONMENT 177
Figure 38 – Baffle 180
Figure 39 – Area of the bottom of an ENCLOSURE as specified in 11.3 b) 1) 180
Figure A.1 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in an ECG monitor 223
Figure A.2 – Example of the insulation of an F-TYPE APPLIED PART with the insulation incorporated in the ME EQUIPMENT 223
Figure A.3 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a PATIENT monitor with invasive pressure monitoring facility 224
Figure A.4 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a multifunction PATIENT monitor with invasive pressure monitoring facilities 225
Figure A.5 – Identification of APPLIED PARTS and PATIENT CONNECTIONS in an X-ray me system 226
Figure A.6 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a transcutaneous electronic nerve stimulator (TENS) intended to be worn on the patient's belt and connected to electrodes applied to the PATIENT'S upper arm 227
Figure A.7 – Identification of ME EQUIPMENT or ME SYSTEM, APPLIED PARTS and PATIENT CONNECTIONS in a personal computer with an ECG module 228
Figure A.8 – Pictorial representation of the relationship of HAZARD, sequence of events, HAZARDOUS SITUATION and HARM 231
Figure A.9 – Example of PATIENT ENVIRONMENT 236
Figure A.10 – Floating circuit 255
Figure A.11 – Interruption of a power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES 256
Figure A.12 – Identification of MEANS OF PATIENT PROTECTION and MEANS OF OPERATOR PROTECTION 261
Figure A.13 – Allowable protective earth impedance where the fault current is limited 267
Figure A.14 – Probability of ventricular fibrillation 273
Figure A.15 – Example of a measuring circuit for the PATIENT LEAKAGE CURRENT from a PATIENT CONNECTION to earth for ME EQUIPMENT with multiple PATIENT CONNECTIONS 278

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Figure A.16 – Instability test conditions 289
Figure A.17 – Example of determining TENSILE SAFETY FACTOR using Table 21 296
Figure A.18 – Example of determining design and test loads 297
Figure A.19 – Example of human body mass distribution 297
Figure A.20 – Relationship of the terms used to describe equipment, ACCESSORIES or equipment parts 233
Figure A.21 – Example of ME EQUIPMENT having two different functions on one common APPLIED PART circuit 265
Figure A.22 – Maximum allowable temperature for surfaces and APPLIED PARTS at higher altitudes 302
Figure A.23 – Example of the needed MEANS OF OPERATOR PROTECTION between the terminals of an INTERNAL ELECTRICAL POWER SOURCE and a subsequent protective device 319
Figure E.1 – TYPE B APPLIED PART 343
Figure E.2 – TYPE BF APPLIED PART 343
Figure E.3 – TYPE CF APPLIED PART 344
Figure E.4 – PATIENT AUXILIARY CURRENT 344
Figure E.5 – Loading of the PATIENT CONNECTIONS if specified by the MANUFACTURER 344
Figure F.1 – Measuring supply circuit with one side of the SUPPLY MAINS at approximately earth potential 345
Figure F.2 – Measuring supply circuit with SUPPLY MAINS approximately symmetrical to earth potential 345
Figure F.3 – Measuring supply circuit for polyphase me equipment specified for connection to a polyphase supply mains 346
Figure F.4 – Measuring supply circuit for single-phase me equipment specified for connection to a polyphase supply mains 346
Figure F.5 – Measuring supply circuit for me equipment having a separate power supply unit or intended to receive its power from another equipment in an me system 347
Figure G.1– Maximum allowable current IZR as a function of the maximum allowable voltage UZR measured in a purely resistive circuit with the most flammable mixture of ether vapour with air 354
Figure G.2 – Maximum allowable voltage UZC as a function of the capacitance Cmax measured in a capacitive circuit with the most flammable mixture of ether vapour with air 355
Figure G.3 – Maximum allowable current IZL as a function of the inductance Lmax measured in an inductive circuit with the most flammable mixture of ether vapour with air 355
Figure G.4 – Maximum allowable current IZR as a function of the maximum allowable voltage UZR measured in a purely resistive circuit with the most flammable mixture of ether vapour with oxygen 359
Figure G.5 – Maximum allowable voltage UZC as a function of the capacitance Cmax measured in a capacitive circuit with the most flammable mixture of ether vapour with oxygen 360
Figure G.6 – Maximum allowable current IZL as a function of the inductance Lmax measured in an inductive circuit with the most flammable mixture of ether vapour with oxygen 360
Figure G.7 – Test apparatus 362
Figure H.1 – Examples of PEMS/ PESS structures 364
Figure H.2 – A PEMS DEVELOPMENT LIFE-CYCLE model 365
IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Figure H.3 – ~~PEMS documentation requirements from Clause 14 and ISO 14971:2000~~ Not used 369
Figure H.4 – Example of potential parameters required to be specified for ~~NETWORK/DATA COUPLING~~ an IT-NETWORK 375
Figure I.1 – Example of the construction of a MULTIPLE SOCKET-OUTLET (MSO) 380
Figure I.2 – Examples of application of MULTIPLE SOCKET-OUTLETS (MSO) 381
Figure J.1 – Insulation example 1 382
Figure J.2 – Insulation example 2 382
Figure J.3 – Insulation example 3 382
Figure J.4 – Insulation example 4 383
Figure J.5 – Insulation example 5 383
Figure J.6 – Insulation example 6 384
Figure J.7 – Insulation example 7 384
Figure K.1 – ME EQUIPMENT with an ENCLOSURE made of insulating material 385
Figure K.2 – ME EQUIPMENT with an F-TYPE APPLIED PART 385
Figure K.3 – ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART 386
Figure K.4 – Me equipment with a PATIENT CONNECTION of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED 386
Figure K.5 – Me equipment with a PATIENT CONNECTION of a TYPE BF APPLIED PART that is not PROTECTIVELY EARTHED 387

Table 1 – Units outside the SI units system that may be used on ME EQUIPMENT 65
Table 2 – Colours of indicator lights and their meaning for ME EQUIPMENT 68
Table 3 – * Allowable values of PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL CONDITION and SINGLE FAULT CONDITION 95
Table 4 – * Allowable values of PATIENT LEAKAGE CURRENTS under the special test conditions identified in 8.7.4.7 96
Table 5 – Legends of symbols for Figure 9 to Figure 11, Figure 13 to Figure 20, Figure A.15, Annexes E and F 110
Table 6 – Test voltages for solid insulation forming a MEANS OF PROTECTION 117
Table 7 – Test voltages for MEANS OF OPERATOR PROTECTION 118
Table 8 – Multiplication factors for AIR CLEARANCES for altitudes up to 5 000 m 121
Table 9 – Material group classification 121
Table 10 – MAINS TRANSIENT VOLTAGE 123
Table 11 – ~~Minimum CREEPAGE DISTANCES and AIR CLEARANCES between parts of opposite polarity of the MAINS PART~~ Not used 124
Table 12 – Minimum CREEPAGE DISTANCES and AIR CLEARANCES providing MEANS OF PATIENT PROTECTION 125
Table 13 – Minimum AIR CLEARANCES providing MEANS OF OPERATOR PROTECTION from the MAINS PART 126
Table 14 – Additional AIR CLEARANCES for insulation in MAINS PARTS with PEAK WORKING VOLTAGES exceeding the peak value of the NOMINAL MAINS VOLTAGE [a] 127
Table 15 – Minimum AIR CLEARANCES for MEANS OF OPERATOR PROTECTION in SECONDARY CIRCUITS 128
Table 16 – Minimum CREEPAGE DISTANCES providing MEANS OF OPERATOR PROTECTION [a] 129
Table 17 – NOMINAL cross-sectional area of conductors of a POWER SUPPLY CORD 141
Table 18 – Testing of cord anchorages 142

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Table 19 – MECHANICAL HAZARDS covered by this clause 145
Table 20 – Acceptable gaps [a] 147
Table 21 – Determination of TENSILE SAFETY FACTOR 162
Table 22 – Allowable maximum temperatures of parts 170
Table 23 – Allowable maximum temperatures for ME EQUIPMENT parts that are likely to be touched 170
Table 24 – Allowable maximum temperatures for skin contact with ME EQUIPMENT APPLIED PARTS 171
Table 25 – Acceptable perforation of the bottom of an ENCLOSURE 179
Table 26 – * Temperature limits of motor windings 189
Table 27 – Maximum motor winding steady-state temperature 191
Table 28 – Mechanical strength test applicability 198
Table 29 – Drop height 199
Table 30 – Test torques for rotating controls 205
Table 31 – Maximum allowable temperatures of transformer windings under overload and short-circuit conditions at 25 °C (± 5 °C) ambient temperature 207
Table 32 – Test current for transformers 208
Table 33 – Test conditions for overtravel end stop test 150
Table A.1 – Values of AIR CLEARANCE and CREEPAGE DISTANCE derived from Table 7 of IEC 61010-1:2001 and Table 12 281
Table A.2 – CREEPAGE DISTANCES to avoid failure due to tracking from IEC 60664-1 282
Table A.3 – Instability test conditions 289
Table A.4 – Allowable time exposure for level of acceleration 292
Table A.5 – Guidance on surface temperatures for ME EQUIPMENT that creates low temperatures (cools) for therapeutic purposes or as part of its operation 301
Table C.1– Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts 331
Table C.2 – Marking on the inside of ME EQUIPMENT, ME SYSTEMS or their parts 332
Table C.3 – Marking of controls and instruments 332
Table C.4 – ACCOMPANYING DOCUMENTS, general 332
Table C.5 – ACCOMPANYING DOCUMENTS, instructions for use 333
Table D.1 – General symbols 335
Table D.2 – Safety signs 340
Table D.3 – General codes 342
Table G.1 – Gas-tightness of cord inlets 357
Table H.1 – ~~NETWORK/DATA COUPLING classification~~ Not used 373
Table I.1 – Some examples of ME SYSTEMS for illustration 378
Table L.1– Mandrel diameter 389
Table L.2 – Oven temperature 389
Table M.1 – Reduction of the pollution degree of internal environment through the use of additional protection 391

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

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FOREWORD

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DISCLAIMER
This Consolidated version is not an official IEC Standard and has been prepared for user convenience. Only the current versions of the standard and its amendment(s) are to be considered the official documents.

This Consolidated version of IEC 60601-1 bears the edition number 3.1. It consists of the third edition (2005-12) [documents 62A/505A/FDIS and 62A/512/RVD] and its amendment 1 (2012-07) [documents 62A/805/FDIS and 62A/820/RVD]. The technical content is identical to the base edition and its amendment.

This Consolidated version includes the contents of the corrigenda 1 (2006-12) and 2 (2007-12), the contents of the corrigendum to Amendment 1 (2014-07), as well as the interpretation sheets 1 (2008-04), 2 (2009-01), 3 (2013-05) and the Interpretation Sheet 1 to Amendment 1 (2021-03).

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

International Standard IEC 60601-1 has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 1988, its Amendment 1 (1991) and Amendment 2 (1995), the second edition of IEC 60601-1-1 published in 2000 and the first edition of IEC 60601-1-4 published in 1996 and its Amendment 1 (1999). This edition constitutes a technical revision. This edition has been significantly restructured. Requirements in the electrical section have been further aligned with those for information technology equipment covered by IEC 60950-1 and a requirement for including a RISK MANAGEMENT PROCESS has been added. For an expanded description of this revision, see Annex A.3.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard the following print types are used:

- Requirements and definitions: in roman type.
- *Test specifications: in italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS USED THROUGHOUT THIS STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 3 AND ALSO GIVEN IN THE INDEX: IN SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex G of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

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The committee has decided that the contents of the base publication and its amendment will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The "colour inside" logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.

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INTRODUCTION

In 1976, IEC subcommittee 62A published the first edition of IEC/TR 60513, *Basic aspects of the safety philosophy for electrical equipment used in medical practice*. The first edition of IEC/TR 60513 provided the basis for developing:

– the first edition of IEC 60601-1 (the parent safety standard for MEDICAL ELECTRICAL EQUIPMENT);

– the IEC 60601-1-xx series of collateral standards for MEDICAL ELECTRICAL EQUIPMENT;

– the IEC 60601-2-xx series of particular standards for particular types of MEDICAL ELECTRICAL EQUIPMENT; and

– the IEC 60601-3-xx series of performance standards for particular types of MEDICAL ELECTRICAL EQUIPMENT.

Aware of the need and the urgency for a standard covering electrical equipment used in medical practice, the majority of National Committees voted in 1977 in favour of the first edition of IEC 60601-1, based on a draft that at the time represented a first approach to the problem. The extent of the scope, the complexity of the equipment concerned, and the specific nature of some of the protective measures and the corresponding tests for verifying them, required years of effort in order to prepare this first standard, which can now be said to have served as a universal reference since its publication.

However, the frequent application of the first edition revealed room for improvement. These improvements were all the more desirable in view of the considerable success that this standard has enjoyed since its publication.

The careful work of revision subsequently undertaken and continued over a number of years resulted in the publication of the second edition in 1988. This edition incorporated all the improvements that could be reasonably expected up to that time. Further developments remained under constant study. The second edition was amended in 1991 and then again in 1995.

The original IEC approach was to prepare separate BASIC SAFETY and performance standards for MEDICAL ELECTRICAL EQUIPMENT. This was a natural extension of the historical approach taken at the national and international level with other electrical equipment standards (e.g. those for domestic equipment), where BASIC SAFETY is regulated through mandatory standards but other performance specifications are regulated by market pressure. In this context, it has been said that, “The ability of an electric kettle to boil water is not critical to its safe use!”

It is now recognized that this is not the situation with many items of MEDICAL ELECTRICAL EQUIPMENT, and RESPONSIBLE ORGANIZATIONS have to depend on standards to ensure ESSENTIAL PERFORMANCE as well as BASIC SAFETY. Such areas include the accuracy with which the equipment controls the delivery of energy or therapeutic substances to the PATIENT, or processes and displays physiological data that will affect PATIENT management.

This recognition means that separating BASIC SAFETY and performance is somewhat inappropriate in addressing the HAZARDS that result from inadequate design of MEDICAL ELECTRICAL EQUIPMENT. Many particular standards in the IEC 60601-2-xx series address a range of ESSENTIAL PERFORMANCE requirements that cannot be directly evaluated by the RESPONSIBLE ORGANIZATION without applying such standards. (However, the current IEC 60601 series includes fewer requirements for ESSENTIAL PERFORMANCE than for BASIC SAFETY).

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In anticipation of a third edition of IEC 60601-1, IEC subcommittee 62A prepared a second edition of IEC/TR 60513 [12][1)] in 1994. It was intended that the second edition of IEC/TR 60513 would provide guidance for developing this edition of IEC 60601-1, and for the further development of the IEC 60601-1-xx and IEC 60601-2-xx series.

In order to achieve consistency in international standards, address present expectations in the health care community and align with developments in IEC 60601-2-xx, the second edition of IEC/TR 60513 includes two major new principles:

– the first change is that the concept of "SAFETY" has been broadened from the BASIC SAFETY considerations in the first and second editions of IEC 60601-1 to include ESSENTIAL PERFORMANCE matters, (e.g. the accuracy of physiological monitoring equipment). Application of this principle leads to the change of the title of this publication from "Medical electrical equipment, Part 1: General requirements for safety" in the second edition, to "Medical electrical equipment, Part 1: General requirements for basic safety and essential performance";

– the second change is that, in specifying minimum safety requirements, provision is made for assessing the adequacy of the design PROCESS when this is the only practical method of assessing the safety of certain technologies such as programmable electronic systems. Application of this principle is one of the factors leading to introduction of a general requirement to carry out a RISK MANAGEMENT PROCESS. In parallel with the development of the third edition of IEC 60601-1, a joint project with ISO/TC 210 resulted in the publication of a general standard for RISK MANAGEMENT of medical devices. Compliance with this edition of IEC 60601-1 requires that the MANUFACTURER have in place a RISK MANAGEMENT PROCESS complying with parts of ISO 14971 (see 4.2).

This standard contains requirements concerning BASIC SAFETY and ESSENTIAL PERFORMANCE that are generally applicable to MEDICAL ELECTRICAL EQUIPMENT. For certain types of MEDICAL ELECTRICAL EQUIPMENT, these requirements are either supplemented or modified by the special requirements of a collateral or particular standard. Where particular standards exist, this standard should not be used alone.

Amendment 1 to this standard is intended to address:

– issues identified by National Committees and other interested parties since the publication of IEC 60601-1:2005;

– the way in which RISK MANAGEMENT has been introduced into IEC 60601-1:2005; and

– the way the concept of ESSENTIAL PERFORMANCE is used in IEC 60601-1:2005.

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1) Figures in square brackets refer to the Bibliography.

INTRODUCTION TO THE AMENDMENT

The third edition of IEC 60601-1 was published in 2005. At the time of publication, there were 94 National Committee comments on the 2nd CDV and the FDIS that were deferred to a future amendment/revision. Each of their deferred comments was captured in an Issue Sheet by the SC 62A secretariat. By the time of the Auckland meeting in April 2008, the Subcommittees had developed two Interpretation Sheets and the SC 62A secretariat has received an additional 15 issues from National Committees and other interested parties.

At the Auckland meeting, IEC/TC 62 approved a project to develop the 1st amendment to IEC 60601-1:2005 based on the issues outstanding at the time. The TC approved developing the 1st amendment with a view to addressing outstanding issues, including but not limited to:

– those listed in 62A/593/DC and 62A/602/INF;
– the way in which risk management has been introduced into IEC 60601-1:2005; and
– the way the concept of essential performance is used in IEC 60601-1:2005.

Since the Auckland meeting, the secretariat has received 73 additional issues from National Committees or other interested parties for a total of 182 Issues Sheets. This amendment is intended to address those issues.

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MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

1 Scope, object and related standards

1.1 * Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1.

NOTE 1 See also 4.2.

~~This standard can also be applied to equipment used for compensation or alleviation of disease, injury or disability.~~

~~In vitro diagnostic equipment that does not fall within the definition of ME EQUIPMENT is covered by the IEC 61010 series [2]. This standard does not apply to the implantable parts of active implantable medical devices covered by ISO 14708-1 [3].~~

The IEC 60601 series does not apply to:

– in vitro diagnostic equipment that does not fall within the definition of ME EQUIPMENT, which is covered by the IEC 61010 series [61];

– implantable parts of active implantable medical devices covered by the ISO 14708 series [69]; or

– medical gas pipeline systems covered by ISO 7396-1 [68].

NOTE 2 ISO 7396-1 applies the requirement of IEC 60601-1-8 to certain monitoring and ALARM SIGNALS.

1.2 Object

The object of this standard is to specify general requirements and to serve as the basis for particular standards.

1.3 * Collateral standards

In the IEC 60601 series, collateral standards specify general requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE applicable to:

– a subgroup of ME EQUIPMENT (e.g. radiological equipment);

– a specific characteristic of all ME EQUIPMENT not fully addressed in this standard.

Applicable collateral standards become normative at the date of their publication and shall apply together with this standard.

~~2) IEC 61010 (all parts), *Safety requirements for electrical equipment for measurement, control, and laboratory use*~~

~~3) ISO 14708-1, *Implants for surgery – Active implantable medical devices – Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*~~

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NOTE 1 When evaluating compliance with IEC 60601-1, it is permissible to independently assess compliance with the collateral standards.

NOTE 2 When declaring compliance with IEC 60601-1, the declarer should specifically list the collateral standards that have been applied. This allows the reader of the declaration to understand which collateral standards were part of the evaluation.

NOTE 3 Collateral standards in the IEC 60601 family are numbered IEC 60601-1-xx. ~~Members of~~ The IEC maintains a ~~register~~ catalogue of valid International Standards. Users of this standard should consult this ~~register~~ catalogue at "http://webstore.iec.ch" to determine which collateral standards have been published.

If a collateral standard applies to ME EQUIPMENT for which a particular standard exists, then the particular standard takes priority over the collateral standard.

1.4 * Particular standards

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in this standard as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

NOTE ~~Members of IEC and ISO maintain registers of valid International Standards. Users of this standard should consult these registers to determine which particular standards have been published.~~ Particular standards in the IEC 60601 family that are developed by IEC committees are numbered IEC 60601-2-xx. In addition, particular standards developed by joint projects between ISO and IEC can be numbered either IEC 80601-2-xx or ISO 80601-2-xx depending on which committee administered the project. IEC and ISO maintain catalogues of valid International Standards. Users of this standard should consult these catalogues at "http://webstore.iec.ch" and "http://www.iso.org/iso/store.htm" to determine which particular standards have been published.

A requirement of a particular standard takes priority over this standard.

2 * Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ATTENTION: Additional collateral standards of the IEC 60601 series, which are issued subsequent to publication of this standard, become normative at the date of their publication and shall be considered as being included among the normative references below. See 1.3.

NOTE Informative references are listed in the Bibliography on page 396.

IEC 60065:2001, *Audio, video and similar electronic apparatus – Safety requirements* [4)]
Amendment 1:2005
Amendment 2:2010

IEC 60068-2-2:~~1974~~ 2007, *Environmental testing – Part 2-2: Tests – Test B: Dry heat*
~~Amendment 1 (1993)~~
~~Amendment 2 (1994)~~

IEC 60079-0, *Electrical apparatus for explosive gas atmospheres – Part 0: General requirements*

IEC 60079-2, *Electrical apparatus for explosive gas atmospheres – Part 2: Pressurized enclosures "p"*

IEC 60079-5, *Electrical apparatus for explosive gas atmospheres – Part 5: Powder filling "q"*

IEC 60079-6, *Electrical apparatus for explosive gas atmospheres – Part 6: Oil-immersion "o"*

IEC 60083, *Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC*

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4) There exists a consolidated edition 7.2 including IEC 60065:2001 and its Amendment 1 (2005) and Amendment 2 (2010).

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IEC 60085, *Electrical insulation – Thermal classification*

IEC 60086-4, *Primary batteries – Part 4: Safety of lithium batteries*

IEC 60112, *Method for the determination of the proof and the comparative tracking indices of solid insulating materials*

IEC 60127-1, *Miniature fuses – Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links*

IEC 60227-1:~~1993~~ 2007, *Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V – Part 1: General requirements* ~~5)~~
~~Amendment 1 (1995)~~
~~Amendment 2 (1998)~~

IEC 60245-1:2003, *Rubber insulated cables – Rated voltages up to and including 450/750 V – Part 1: General requirements*[6]
Amendment 1:2007

IEC 60252-1, *AC motor capacitors – Part 1: General – Performance, testing and rating – Safety requirements – Guide for installation and operation*

IEC 60320-1, *Appliance couplers for household and similar general purposes – Part 1: General requirements*

IEC 60335-1:~~2001~~ 2010, *Household and similar electrical appliances – Safety – Part 1: General requirements*

IEC 60364-4-41, *Electrical installations of buildings – Part 4-41: Protection for safety – Protection against electric shock*

IEC 60384-14:2005, *Fixed capacitors for use in electronic equipment – Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains*

~~IEC 60417-DB:2002, *Graphical symbols for use on equipment* 7)~~

IEC 60417, *Graphical symbols for use on equipment.* Available from: <http://www.graphical-symbols.info/equipment>

IEC 60445, *Basic and safety principles for man-machine interface, marking and identification – Identification of equipment terminals and of terminations of certain designated conductors, including general rules for an alphanumeric system*

IEC 60447, *Basic and safety principles for man-machine interface, marking and identification – Actuating principles*

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)* [8)]
Amendment 1 (1999)

IEC 60601-1-2, *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests*

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~~5) There exists a consolidated edition 2.2 including IEC 60227-1:1993 and its Amendment 1 (1995) and Amendment 2 (1998).~~

6) There exists a consolidated edition 4.1 including IEC 60245-1:2003 and its Amendment 1 (2007).

~~7) "DB" refers to the joint ISO-IEC on-line database.~~

8) There exists a consolidated version 2.1, including IEC 60529:1989 and its Amendment 1 (1999).

IEC 60601-1-3, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance. Collateral standard: ~~General requirements for~~ Radiation protection in diagnostic X-ray equipment*

IEC 60601-1-6, *Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability*

IEC 60601-1-8, *Medical electrical equipment – Part 1-8: General requirements for safety –- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 60664-1:~~1992~~ 2007, *Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests* ~~9)~~
~~Amendment 1 (2000)~~
~~Amendment 2 (2002)~~

IEC 60695-11-10, *Fire hazard testing – Part 11-10: Test flames – 50 W horizontal and vertical flame test methods*

IEC 60730-1:~~1999~~ 2010, *Automatic electrical controls for household and similar use – Part 1: General requirements* ~~10)~~
~~Amendment 1 (2003)~~

IEC 60825-1:~~1993~~ 2007, *Safety of laser products – Part 1: Equipment classification and requirements ~~and user's guide~~* ~~11)~~
~~Amendment 1 (1997)~~
~~Amendment 2 (2001)~~

IEC 60851-3:~~1996~~ 2009, *Winding wires – Test methods – Part 3: Mechanical properties* ~~12)~~
~~Amendment 1 (1997)~~
~~Amendment 2 (2003)~~

IEC 60851-5:~~1996~~ 2008, *Winding wires – Test methods – Part 5: Electrical properties* ~~13)~~
~~Amendment 1 (1997)~~
~~Amendment 2 (2004)~~

IEC 60851-6:1996, *Winding wires – Test methods – Part 6: Thermal properties*
Amendment 1 (1997)

~~IEC 60878:2003, *Graphical symbols for electrical equipment in medical practice*~~

IEC 60884-1, *Plugs and socket-outlets for household and similar purposes - Part 1: General requirements*

IEC 60950-1:2001, *Information technology equipment – Safety – Part 1: General requirements*

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~~9) There exists a consolidated edition 1.2 including IEC 60664-1:1992 and its Amendment 1 (2000) and Amendment 2 (2002).~~

~~10) There exists a consolidated edition 3.1, including IEC 60730-1:1999 and its Amendment 1 (2003)~~

~~11) There exists a consolidated edition 1.2, including IEC 60825-1:1993 and its Amendment 1 (1997) and Amendment 2 (2001).~~

~~12) There exists a consolidated edition 2.1, including IEC 60851-3:1996 and its Amendment 1 (1997).~~

~~13) There exists a consolidated edition 3.2, including IEC 60851-5:1996 and its Amendment 1 (1997) and Amendment 2 (2004).~~

IEC 61058-1:2000, *Switches for appliances – Part 1: General requirements* [14)]
Amendment 1:2001
Amendment 2:2007

~~IEC 61558-1:1997, *Safety of power transformers, power supply units and similar – Part 1: General requirements and tests* [15)]~~
~~Amendment 1 (1998)~~

IEC 61558-2-1, *Safety transformers, power supply units and similar – Part 2: Particular requirements for separating transformers for general use*

IEC 61672-1, *Electroacoustics – Sound level meters – Part 1: Specifications*

IEC 61672-2, *Electroacoustics – Sound level meters – Part 2: Pattern evaluation tests*

IEC 61965, *Mechanical safety of cathode ray tubes*

IEC 62133, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications*

IEC 62304:2006, *Medical device software – Software lifecycle processes*

~~ISO 31 (all parts), *Quantities and units*~~

ISO 780, *Packaging – Pictorial marking for handling of goods*

~~ISO 1000, *SI units and recommendations for the use of their multiples and of certain other units*~~

ISO 1853, *Conducting and dissipative rubbers, vulcanized or thermoplastic – Measurement of resistivity*

ISO 2878, *Rubber, vulcanized – Antistatic and conductive products – Determination of electrical resistance*

ISO 2882 [16)], *Rubber, vulcanized – Antistatic and conductive products for hospital use – Electrical resistance limits*

ISO 3746, *Acoustics – Determination of sound power levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane*

ISO 3864-1:2002, *Graphical symbols – Safety colours and safety signs – Part 1: Design principles for safety signs in workplaces and public areas*

ISO 5349-1, *Mechanical vibration – Measurement and evaluation of human exposure to hand-transmitted vibration – Part 1: General requirements*

ISO 7000-DB:2004 [17)], *Graphical symbols for use on equipment – Collection of symbols*

ISO 7010:~~2003~~ 2011, *Graphical symbols – Safety colours and safety signs – Registered safety signs ~~used in workplaces and public areas~~*

ISO 9614-1, *Acoustics – Determination of sound power levels of noise sources using sound intensity – Measurement at discrete points*

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14) There exists a consolidated edition ~~3.1~~ 3.2, including IEC 61058-1:2000 and its Amendment 1 (2001) and Amendment 2 (2007)

~~15) There exists a consolidated edition 1.1, including IEC 61558-1:1997 and its Amendment 1 (1998).~~

16) ISO 2882 was withdrawn on 1 February 2005 and no replacement standard has been identified.

17) "DB" refers to the joint ISO-IEC on-line database.

ISO 10993 (all parts), *Biological evaluation of medical devices*

~~ISO 11134, *Sterilization of health care products – Requirements for validation and routine control – Industrial moist heat sterilization*~~

~~ISO 11135, *Medical devices – Validation and routine control of ethylene oxide sterilization*~~

ISO 11135-1:2007, *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

~~ISO 11137, *Sterilization of health care products – Requirements for validation and routine control – Radiation sterilization*~~

ISO 11137-1:2006, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

~~ISO 13852, *Safety of machinery – Safety distances to prevent danger zones being reached by the upper limbs*~~

ISO 13857:2008, *Safety of machinery – Safety distances to prevent hazard zones being reached by the upper and lower limbs*

ISO 14971:~~2000~~ 2007, *Medical devices – Application of risk management to medical devices*

~~ISO 15223, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied*~~

ISO 15223-1:2012, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*

ISO 17665-1:2006, *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 23529, *Rubber – General procedures for preparing and conditioning test pieces for physical test methods*

ISO 80000-1:2009, *Quantities and units – Part 1: General*

3 * Terminology and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE 1 Where the terms “voltage” and “current” are used in this document, they mean the r.m.s. values of an alternating, direct or composite voltage or current unless stated otherwise.

NOTE 2 The term “electrical equipment” is used to mean ME EQUIPMENT (see 3.63) or other electrical equipment. This standard also uses the term “equipment” to mean ME EQUIPMENT or other electrical or non-electrical equipment in the context of an ME SYSTEM (see 3.64).

NOTE 3 When the term "safety" is used in this document in roman or italic type, it does not mean "safety" as defined in ISO 14971, but rather is used to mean "the state of being protected from or guarded against hurt or injury; freedom from danger".

NOTE ~~3~~ 4 An index is found beginning on page 402.

3.1
ACCESS COVER
part of an ENCLOSURE or GUARD providing the possibility of access to electrical equipment parts for the purpose of adjustment, inspection, replacement or repair

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3.2
ACCESSIBLE PART
part of electrical equipment other than an APPLIED PART that can be touched by means of the standard test finger

NOTE See also 5.9.2.1.

3.3
ACCESSORY
additional part for use with equipment in order to:

– achieve the INTENDED USE,
– adapt it to some special use,
– facilitate its use,
– enhance its performance, or
– enable its functions to be integrated with those of other equipment

[IEC 60788:2004, rm-83-06 modified]

3.4
ACCOMPANYING DOCUMENT
document accompanying ME EQUIPMENT, an ME SYSTEM, equipment or an ACCESSORY and containing information for the RESPONSIBLE ORGANIZATION or OPERATOR, particularly regarding BASIC SAFETY and ESSENTIAL PERFORMANCE

3.5
AIR CLEARANCE
shortest path in air between two conductive parts

NOTE Adapted from IEC 60664-1:2007, definition ~~1.~~3.2.

3.6
APPLIANCE COUPLER
means enabling the connection of a flexible cord to electrical equipment without the use of a TOOL, consisting of two parts: a MAINS CONNECTOR and an APPLIANCE INLET

NOTE See Figure 1.

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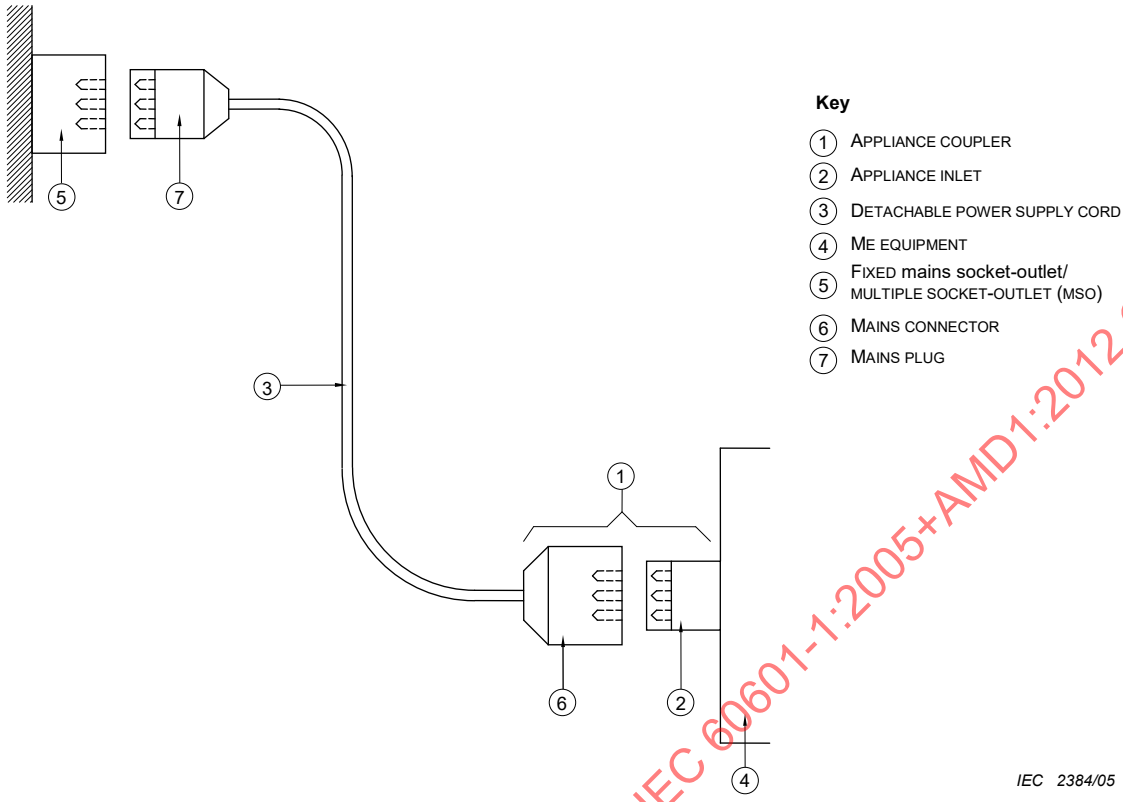


Figure 1 – Detachable mains connection
(see definitions)

3.7
APPLIANCE INLET
part of an APPLIANCE COUPLER either integrated in or FIXED to electrical equipment

NOTE See Figure 1 and Figure 2.

3.8
*** APPLIED PART**
part of ME EQUIPMENT that in NORMAL USE necessarily comes into physical contact with the PATIENT for ME EQUIPMENT or an ME SYSTEM to perform its function

NOTE 1 See Figure 3, Figure 4 and Figure A.1 to Figure A.7 (inclusive).

NOTE 2 See also 4.6 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be treated as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

NOTE 3 See also 3.78 for the definition of the associated term PATIENT CONNECTION.

3.9
*** BASIC INSULATION**
insulation providing basic protection against electric shock

[IEV 826-12-14, modified]

NOTE BASIC INSULATION provides one MEANS OF PROTECTION.

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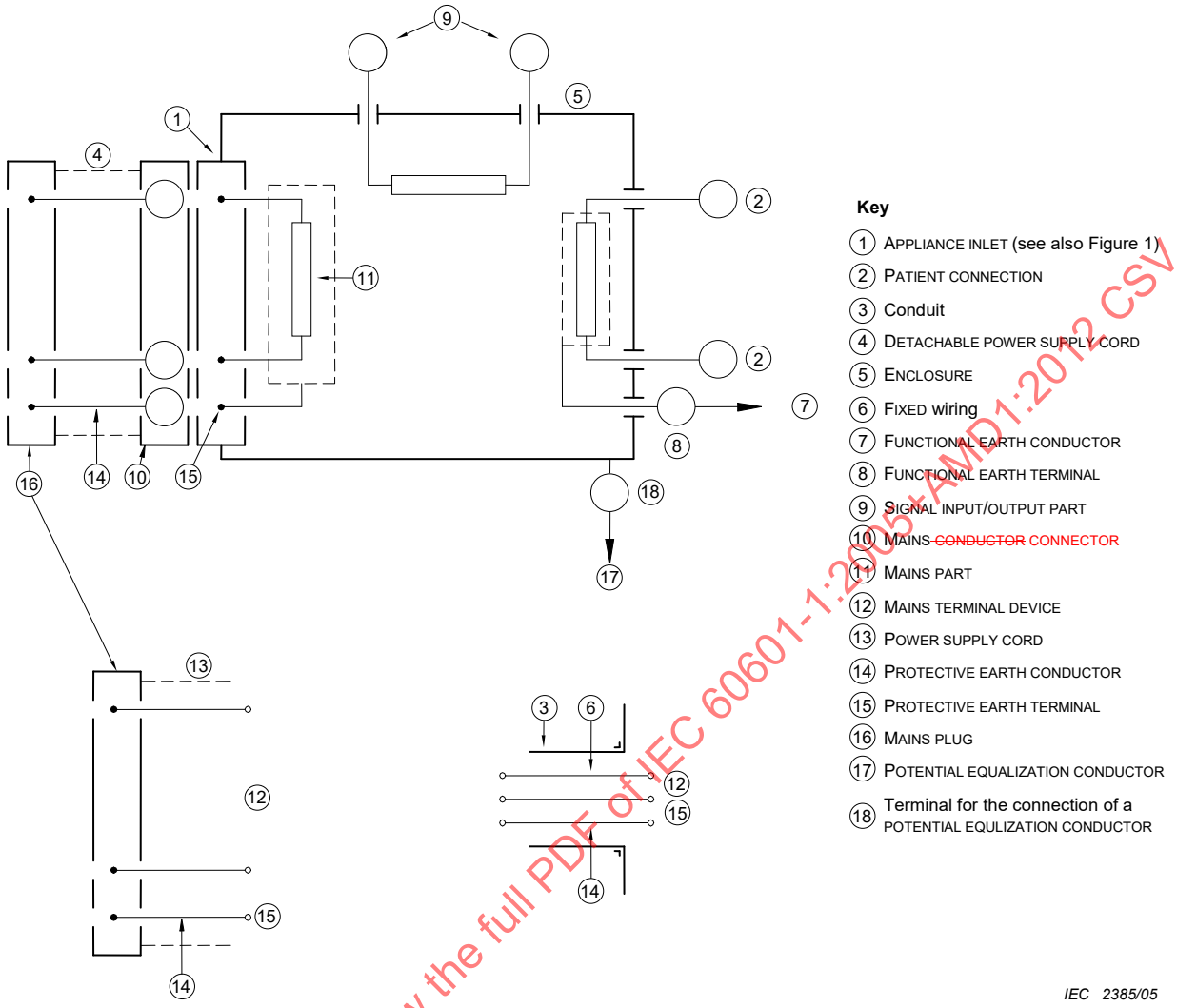
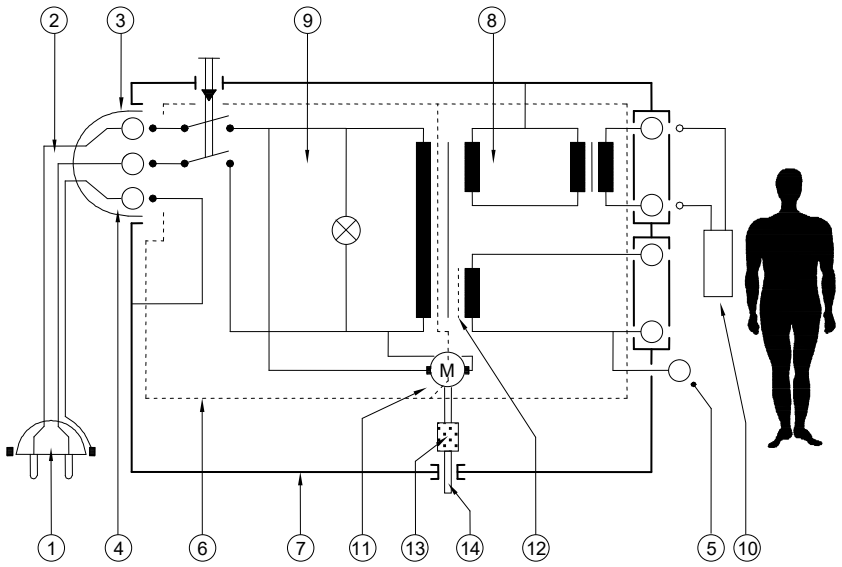


Figure 2 – Example of the defined terminals and conductors
(see definitions)

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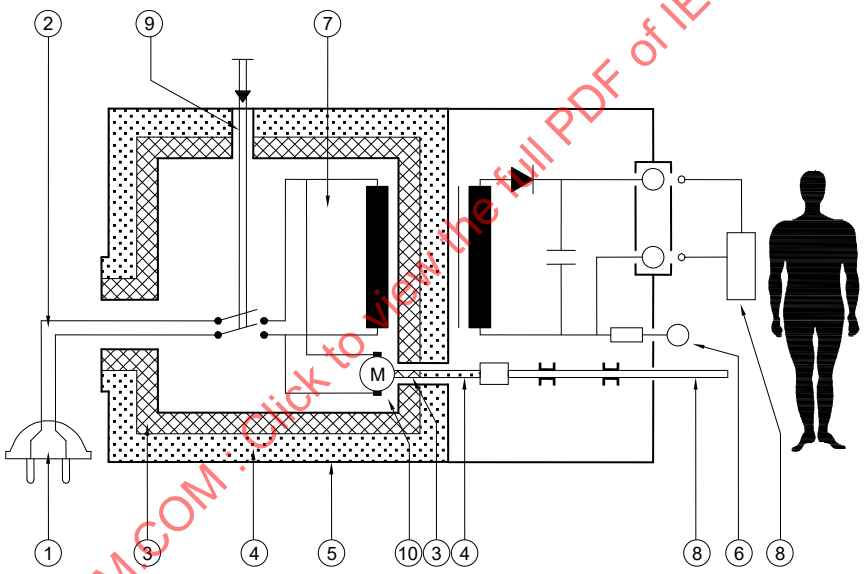


Key

1 MAINS PLUG with protective earth contact
2 DETACHABLE POWER SUPPLY CORD
3 APPLIANCE COUPLER
4 Protective earth contact and pin
5 FUNCTIONAL EARTH TERMINAL
6 BASIC INSULATION
7 ENCLOSURE
8 SECONDARY CIRCUIT
9 MAINS PART
10 APPLIED PART
11 Motor
12 PROTECTIVELY EARTHED screen
13 SUPPLEMENTARY INSULATION
14 Shaft that is an ACCESSIBLE PART

IEC 2386/05

Figure 3 – Example of a CLASS I ME EQUIPMENT
(see definitions)



Key

1 MAINS PLUG
2 POWER SUPPLY CORD
3 BASIC INSULATION
4 SUPPLEMENTARY INSULATION
5 ENCLOSURE
6 FUNCTIONAL EARTH TERMINAL
7 MAINS PART
8 APPLIED PART
9 REINFORCED INSULATION
10 Motor

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Figure 4 – Example of a metal-enclosed CLASS II ME EQUIPMENT
(see definitions)

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3.10
*** BASIC SAFETY**
freedom from unacceptable RISK directly caused by physical HAZARDS when ME EQUIPMENT is used under NORMAL CONDITION and SINGLE FAULT CONDITION

3.11
CATEGORY AP
rating for ME EQUIPMENT or an ME EQUIPMENT part complying with specified requirements on construction, marking and documentation in order to avoid sources of ignition in a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR

3.12
CATEGORY APG
rating for ME EQUIPMENT or an ME EQUIPMENT part complying with specified requirements on construction, marking and documentation in order to avoid sources of ignition in a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE

3.13
CLASS I
term referring to electrical equipment in which protection against electric shock does not rely on BASIC INSULATION only, but which includes an additional safety precaution in that means are provided for ACCESSIBLE PARTS of metal or internal parts of metal to be PROTECTIVELY EARTHED

NOTE See Figure 3.

3.14
CLASS II
term referring to electrical equipment in which protection against electric shock does not rely on BASIC INSULATION only, but in which additional safety precautions such as DOUBLE INSULATION or REINFORCED INSULATION are provided, there being no provision for protective earthing or reliance upon installation conditions

NOTE 1 See Figure 4.

NOTE 2 CLASS II equipment can be provided with a FUNCTIONAL EARTH TERMINAL or a FUNCTIONAL EARTH CONDUCTOR. See also 8.6.8 and 8.6.9.

3.15
*** CLEARLY LEGIBLE**
capable of being read by a person with normal vision

NOTE See ~~also~~ the test in 7.1.2.

3.16
COLD CONDITION
condition obtained if electrical equipment is de-energized for a sufficiently long time to attain the ambient temperature

3.17
*** COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS**
component where one or more characteristics ensure that its function is fault-free in relation to the safety requirements of this standard during the EXPECTED SERVICE LIFE of the ME EQUIPMENT in NORMAL USE and reasonably foreseeable misuse

3.18
*** CONTINUOUS OPERATION**
operation in NORMAL USE for an unlimited period of time without the specified limits of temperature being exceeded

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3.19
CREEPAGE DISTANCE
shortest distance along the surface of the insulating material between two conductive parts

[IEV 151-15-50, modified]

3.20
*** DEFIBRILLATION-PROOF APPLIED PART**
APPLIED PART that is protected against the effects of a discharge of a cardiac defibrillator to the PATIENT

3.21
*** DETACHABLE POWER SUPPLY CORD**
flexible cord intended to be connected to electrical equipment by means of a suitable APPLIANCE COUPLER for mains supply purposes

NOTE See Figure 1, Figure 2 and Figure 3.

3.22
*** DIRECT CARDIAC APPLICATION**
use of APPLIED PART that can come in direct contact with the PATIENT'S heart

3.23
*** DOUBLE INSULATION**
insulation comprising both BASIC INSULATION and SUPPLEMENTARY INSULATION

[IEV 195-06-08]

NOTE DOUBLE INSULATION provides two MEANS OF PROTECTION.

3.24
*** DUTY CYCLE**
maximum activation (on) time followed by minimum deactivation (off) time necessary for the safe operation of the ME EQUIPMENT

3.25
EARTH LEAKAGE CURRENT
current flowing from the MAINS PART through or across the insulation into the PROTECTIVE EARTH CONDUCTOR or a functional earthed connection according to 8.6.9

3.26
*** ENCLOSURE**
exterior surface of electrical equipment or parts thereof

NOTE For the purpose of testing to this standard, metal foil, with specified dimensions, applied in contact with parts of the exterior surface made of material with low conductivity or made of insulating material is considered a part of the ENCLOSURE (see Figure 2, Figure 3 and Figure 4).

3.27
*** ESSENTIAL PERFORMANCE**
~~performance necessary to achieve freedom from unacceptable RISK~~
performance of a clinical function, other than that related to BASIC SAFETY, where loss or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable RISK

NOTE ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or degradation would result in an unacceptable RISK.

3.28
EXPECTED SERVICE LIFE
~~maximum period of useful life as defined by the MANUFACTURER~~ time period specified by the MANUFACTURER during which the ME EQUIPMENT or ME SYSTEM is expected to remain safe for use (i.e. maintain BASIC SAFETY and ESSENTIAL PERFORMANCE)

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NOTE Maintenance can be necessary during the EXPECTED SERVICE LIFE.

3.29
F-TYPE ISOLATED (FLOATING) APPLIED PART (herein F-TYPE APPLIED PART)
APPLIED PART in which the PATIENT CONNECTIONS are isolated from other parts of the ME EQUIPMENT to such a degree that no current higher than the allowable PATIENT LEAKAGE CURRENT flows if an unintended voltage originating from an external source is connected to the PATIENT, and thereby applied between the PATIENT CONNECTION and earth

NOTE F-TYPE APPLIED PARTS are either TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.

3.30
FIXED
term meaning fastened or otherwise secured at a specific location either permanently or so that it can only be detached by means of a TOOL

EXAMPLE 1 Permanently affixed by welding, etc.

EXAMPLE 2 Affixed by means of fasteners (screws, nuts, etc.) making removal/opening impossible without using a TOOL.

NOTE See the taxonomy in the rationale for definition 3.63.

3.31
FLAMMABLE ANAESTHETIC MIXTURE WITH AIR
mixture of a flammable anaesthetic vapour with air in such a concentration that ignition can occur under specified conditions

3.32
FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE
mixture of a flammable anaesthetic vapour with oxygen or with nitrous oxide in such a concentration that ignition can occur under specified conditions

3.33
*** FUNCTIONAL CONNECTION**
connection, electrical or otherwise, including those intended to transfer signals, data, power or substances

NOTE Connection to a FIXED SUPPLY MAINS socket-outlet, whether single or multiple, is not considered to result in a FUNCTIONAL CONNECTION.

3.34
FUNCTIONAL EARTH CONDUCTOR
conductor to be connected to a FUNCTIONAL EARTH TERMINAL

NOTE See Figure 2.

3.35
*** FUNCTIONAL EARTH TERMINAL**
terminal, directly connected to a circuit or to a screening part, that is intended to be earthed for functional purposes

NOTE See Figure 2, Figure 3 and Figure 4.

3.36
GUARD
part of equipment specifically used to provide protection by means of a physical barrier

NOTE Depending on its construction, a GUARD can be called a casing, cover, screen, door, enclosing guard, etc. A GUARD can act:

– alone; it is then only effective when it is in place;

– in conjunction with an interlocking device with or without guard locking; in this case, protection is ensured whatever the position of the GUARD.

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3.37
HAND-HELD
~~term referring to electrical equipment intended to be supported by the hand during NORMAL USE~~ term referring to equipment that, once installed and placed into service, is intended to be supported by the hand

NOTE 1 Equipment can refer to ACCESSORIES or equipment parts.

NOTE 2 See the taxonomy in the rationale for definition 3.63.

3.38
*** HARM**
physical injury or damage to the health of people or animals, or damage to property or the environment

[ISO 14971:~~2000~~2007, definition 2.2, modified]

3.39
HAZARD
potential source of HARM

[ISO 14971:~~2000~~2007, definition 2.3]

3.40
*** HAZARDOUS SITUATION**
circumstance in which people, property, or the environment are exposed to one or more HAZARD(S)

[~~ISO/IEC Guide 51:1999, definition 3.6~~ ISO 14971:2007, definition 2.4]

3.41
HIGH VOLTAGE
voltage over 1 000 V a.c. or over 1 500 V d.c. or over 1 500 V peak value

3.42
HYDRAULIC TEST PRESSURE
pressure applied to test a vessel or part of it

NOTE See 9.7.5.

3.43
INSULATION CO-ORDINATION
mutual correlation of insulation characteristics of electrical equipment taking into account the expected micro-environment and other influencing stresses

NOTE This includes insulation types, CREEPAGE DISTANCES, AIR CLEARANCES, distance through insulation, coatings, encapsulation, environmental aspects, etc.

3.44
~~*~~ **INTENDED USE**
INTENDED PURPOSE
use ~~of~~ for which a product, PROCESS or service ~~in accordance with~~ is intended according to the specifications, instructions and information provided by the MANUFACTURER

[ISO 14971:~~2000~~2007, definition 2.5]

NOTE INTENDED USE should not be confused with NORMAL USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance~~, service~~, transport, etc. as well.

3.45
INTERNAL ELECTRICAL POWER SOURCE
electrical power source for operating equipment that is a part of the equipment and which produces electrical current from some other form of energy

EXAMPLE Chemical, mechanical, solar, or nuclear

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NOTE An INTERNAL ELECTRICAL POWER SOURCE can be inside the principal part of equipment, attached to the outside, or contained in a separate ENCLOSURE.

3.46
INTERNALLY POWERED
term referring to electrical equipment that is able to operate from an INTERNAL ELECTRICAL POWER SOURCE

3.47
LEAKAGE CURRENT
current that is not functional

NOTE The following LEAKAGE CURRENTS are defined: EARTH LEAKAGE CURRENT, TOUCH CURRENT and PATIENT LEAKAGE CURRENT.

3.48
MAINS CONNECTOR
part of an APPLIANCE COUPLER integral with or intended to be attached to a flexible cord that is intended to be connected to the SUPPLY MAINS

NOTE A MAINS CONNECTOR is intended to be inserted into the APPLIANCE INLET of electrical equipment (see Figure 1 and Figure 2).

3.49
*** MAINS PART**
~~electrical circuit~~ part of electrical equipment forming a circuit that is intended to be connected to the SUPPLY MAINS

NOTE 1 The MAINS PART includes all conductive parts that are not separated from the SUPPLY MAINS by at least one MEANS OF PROTECTION.

NOTE 2 For the purpose of this definition, the PROTECTIVE EARTH CONDUCTOR is not regarded as a part of the MAINS PART (see Figure 2 and Figure 3).

3.50
*** MAINS PLUG**
part, integral with or intended to be attached to a POWER SUPPLY CORD of electrical equipment, to be inserted into a mains socket-outlet

NOTE 1 See Figure 1.

NOTE 2 See also IEC 60083 and IEC 60309-1 [8].

3.51
MAINS SUPPLY TRANSFORMER
static piece of equipment with two or more windings which, by electro-magnetic induction, transforms an alternating voltage and current from a SUPPLY MAINS into a voltage and current usually of different values at the same frequency

3.52
MAINS TERMINAL DEVICE
TERMINAL DEVICE by which the electrical connection to the SUPPLY MAINS is made

NOTE See Figure 2.

3.53
MAINS TRANSIENT VOLTAGE
highest peak voltage expected at the power input to the electrical equipment, arising from external transients on the SUPPLY MAINS

3.54
MAINS VOLTAGE
voltage of a SUPPLY MAINS between two line conductors of a polyphase system or voltage between the line conductor and the neutral conductor of a single-phase system

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3.55
MANUFACTURER
natural or legal person with responsibility for the design, manufacture, packaging, or labelling of ME EQUIPMENT, assembling an ME SYSTEM, or adapting ME EQUIPMENT or an ME SYSTEM, regardless of whether these operations are performed by that person or on that person's behalf by a third party

NOTE 1 ISO 13485 [30] defines "labelling" as written, printed or graphic matter

– affixed to a medical device or any of its containers or wrappers, or

– accompanying a medical device,

related to identification, technical description, and use of the medical device, but excluding shipping documents. In this standard, that material is described as markings and ACCOMPANYING DOCUMENTS.

NOTE 2 "Adapting" includes making substantial modifications to ME EQUIPMENT or an ME SYSTEM already in use.

NOTE 3 In some jurisdictions, the RESPONSIBLE ORGANIZATION can be considered a MANUFACTURER when involved in the activities described.

NOTE 4 Adapted from ISO 14971:~~2000~~ 2007, definition ~~2.6~~ 2.8.

3.56
*** MAXIMUM MAINS VOLTAGE**
voltage used for test purposes related to the voltage of the SUPPLY MAINS and connected to certain ME EQUIPMENT parts

NOTE The value for MAXIMUM MAINS VOLTAGE is determined according to 8.5.3.

3.57
*** MAXIMUM PERMISSIBLE WORKING PRESSURE**
maximum pressure permitted on a component according to a declaration of the manufacturer of such component

3.58
*** MEANS OF OPERATOR PROTECTION**
MOOP
MEANS OF PROTECTION for reducing the RISK due to electric shock to persons other than the PATIENT

3.59
*** MEANS OF PATIENT PROTECTION**
MOPP
MEANS OF PROTECTION for reducing the RISK due to electric shock to the PATIENT

3.60
*** MEANS OF PROTECTION**
MOP
means for reducing the RISK due to electric shock in accordance with the requirements of this standard

NOTE MEANS OF PROTECTION include insulation, AIR CLEARANCES, CREEPAGE DISTANCES, impedances, and PROTECTIVE EARTH CONNECTIONS.

3.61
MECHANICAL HAZARD
HAZARD connected with or produced by physical force

3.62
MECHANICAL PROTECTIVE DEVICE
device that eliminates or reduces mechanical RISK to an acceptable level and which operates in the case of SINGLE FAULT CONDITION

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3.63
*** MEDICAL ELECTRICAL EQUIPMENT**
ME EQUIPMENT
electrical equipment having an APPLIED PART or transferring energy to or from the PATIENT or detecting such energy transfer to or from the PATIENT and which is:

a) provided with not more than one connection to a particular SUPPLY MAINS; and

b) intended by its MANUFACTURER to be used:

1) in the diagnosis, treatment, or monitoring of a PATIENT; or

2) for compensation or alleviation of disease, injury or disability

NOTE 1 ME EQUIPMENT includes those ACCESSORIES as defined by the MANUFACTURER that are necessary to enable the NORMAL USE of the ME EQUIPMENT.

NOTE 2 Not all electrical equipment used in medical practice falls within this definition (e.g. some in vitro diagnostic equipment).

NOTE 3 The implantable parts of active implantable medical devices can fall within this definition, but they are excluded from the scope of this standard by appropriate wording in Clause 1.

NOTE 4 This standard uses the term "electrical equipment" to mean ME EQUIPMENT or other electrical equipment.

NOTE 5 See also 4.10.1, 8.2.1 and 16.3.

3.64
*** MEDICAL ELECTRICAL SYSTEM**
ME SYSTEM
combination, as specified by its MANUFACTURER, of items of equipment, at least one of which is ME EQUIPMENT to be inter-connected by FUNCTIONAL CONNECTION or by use of a MULTIPLE SOCKET-OUTLET

NOTE Equipment, when mentioned in this standard, should be taken to include ME EQUIPMENT.

3.65
MOBILE
term referring to TRANSPORTABLE equipment that, once installed and placed into service, is intended to be moved from one location to another while supported by its own wheels or equivalent means

NOTE See the taxonomy in the rationale for definition 3.63.

3.66
*** MODEL OR TYPE REFERENCE**
combination of figures, letters or both used to identify a particular model of equipment or ACCESSORY

3.67
*** MULTIPLE SOCKET-OUTLET**
MSO
one or more socket-outlets intended to be connected to, or integral with, flexible cables, ~~or~~ cords or ME EQUIPMENT ~~for~~ providing SUPPLY MAINS or equivalent voltage

NOTE A MULTIPLE SOCKET-OUTLET can be a separate item or an integral part of equipment.

3.68
*** NETWORK/DATA COUPLING**
any means to transmit or receive information to or from other equipment in accordance with the MANUFACTURER'S specifications

3.69
NOMINAL (value)
value quoted for reference purposes that is subject to agreed tolerances

EXAMPLE NOMINAL MAINS VOLTAGE or NOMINAL diameter of a screw

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3.70
NORMAL CONDITION
condition in which all means provided for protection against HAZARDS are intact

3.71
NORMAL USE
operation, including routine inspection and adjustments by any OPERATOR, and stand-by, according to the instructions for use

NOTE NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance~~, service~~, transport, etc. as well.

3.72
OBJECTIVE EVIDENCE
~~information which can be proven true, based on facts obtained through observation, measurement, test or other means~~ data supporting the existence or verity of something

NOTE Objective evidence can be obtained through observation, measurement, testing or other means.

[ISO 14971:~~2000~~ 2007, definition ~~2.8~~ 2.10]

3.73
*** OPERATOR**
person handling equipment

NOTE See also 3.101.

3.74
OVER-CURRENT RELEASE
protective device that causes a circuit to open, with or without time-delay, when the current in the device exceeds a predetermined value

[IEV 441-16-33, modified]

3.75
*** OXYGEN RICH ENVIRONMENT**
environment in which the concentration of oxygen is:

a) greater than 25 % for ambient pressures up to 110 kPa; or

b) the partial pressure of oxygen is greater than 27,5 kPa at ambient pressures exceeding 110 kPa

3.76
PATIENT
living being (person or animal) undergoing a medical, surgical or dental procedure

NOTE A PATIENT can be an OPERATOR.

3.77
*** PATIENT AUXILIARY CURRENT**
current flowing in the PATIENT in NORMAL USE between any PATIENT CONNECTION and all other PATIENT CONNECTIONS and not intended to produce a physiological effect

3.78
*** PATIENT CONNECTION**
individual point on the APPLIED PART through which current can flow between the PATIENT and the ME EQUIPMENT in NORMAL CONDITION or SINGLE FAULT CONDITION

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3.79
*** PATIENT ENVIRONMENT**
any volume in which intentional or unintentional contact can occur between a PATIENT and parts of the ME EQUIPMENT or ME SYSTEM or between a PATIENT and other persons touching parts of the ME EQUIPMENT or ME SYSTEM

3.80
PATIENT LEAKAGE CURRENT
current:

– flowing from the PATIENT CONNECTIONS via the PATIENT to earth; or

– originating from the unintended appearance of a voltage from an external source on the PATIENT and flowing from the PATIENT via the PATIENT CONNECTIONS of an F-TYPE APPLIED PART to earth

3.81
*** PEAK WORKING VOLTAGE**
highest peak or d.c. value of a WORKING VOLTAGE, including repetitive peak impulses generated in the electrical equipment, but not including external transients

[IEC 60950-1:~~2001~~ 2005, definition ~~1.2.9.7~~ 1.2.9.8, modified]

3.82
PEMS DEVELOPMENT LIFE-CYCLE
necessary activities occurring during a period of time that starts at the concept phase of a project and finishes when the PEMS VALIDATION is complete

NOTE See also 3.90.

3.83
PEMS VALIDATION
PROCESS of evaluating a PEMS or a component of a PEMS during or at the end of the development PROCESS, to determine whether it satisfies the requirements for its INTENDED USE

NOTE See also 3.90.

3.84
PERMANENTLY INSTALLED
term meaning electrically connected to the SUPPLY MAINS by means of a permanent connection that can only be detached by the use of a TOOL

3.85
PORTABLE
term referring to TRANSPORTABLE equipment that, once installed and placed into service, is intended to be moved from one location to another while being carried by one or more persons

NOTE 1 Equipment can refer to ACCESSORIES or equipment parts.

NOTE 2 See the taxonomy in the rationale for definition 3.63.

3.86
POTENTIAL EQUALIZATION CONDUCTOR
conductor other than a PROTECTIVE EARTH CONDUCTOR or a neutral conductor, providing a direct connection between electrical equipment and the potential equalization busbar of the electrical installation

NOTE See Figure 2.

3.87
POWER SUPPLY CORD
flexible cord, FIXED to or assembled with electrical equipment for connection to SUPPLY MAINS

NOTE See Figure 1 to Figure 4 (inclusive).

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3.88
PROCEDURE
specifi~~c~~ed way to ~~perform~~ carry out an activity or a PROCESS

[ISO 14971:~~2000~~ 2007, definition ~~2.9~~ 2.12]

3.89
PROCESS
set of inter~~-~~related or interacting ~~resources and~~ activities which transforms inputs into outputs

[ISO 14971:~~2000~~ 2007, definition ~~2.10~~ 2.13]

3.90
PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM
PEMS
ME EQUIPMENT or an ME SYSTEM containing one or more PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS)

3.91
PROGRAMMABLE ELECTRONIC SUBSYSTEM
PESS
system based on one or more central processing units, including their software and interfaces

3.92
PROPERLY INSTALLED
installed in accordance with the ACCOMPANYING DOCUMENTS

3.93
PROTECTIVE EARTH CONDUCTOR
conductor to be connected between the PROTECTIVE EARTH TERMINAL and an external protective earthing system

NOTE See Figure 2.

3.94
PROTECTIVE EARTH CONNECTION
connection to the PROTECTIVE EARTH TERMINAL provided for protective purposes and complying with the requirements of this standard

3.95
PROTECTIVE EARTH TERMINAL
terminal connected to conductive parts of CLASS I equipment for safety purposes. This terminal is intended to be connected to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR

NOTE See Figure 2.

3.96
PROTECTIVELY EARTHED
connected to the PROTECTIVE EARTH TERMINAL for protective purposes by means complying with the requirements of this standard

3.97
RATED (value)
term referring to a value assigned by the MANUFACTURER for a specified operating condition

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3.98
RECORD
~~document which furnishes OBJECTIVE EVIDENCE of activities performed or results achieved~~
document stating results achieved or providing evidence of activities performed

[ISO 14971:~~2000~~ 2007, definition ~~2.11~~ 2.14]

3.99
*** REINFORCED INSULATION**
single insulation system that provides two MEANS OF PROTECTION

3.100
RESIDUAL RISK
RISK remaining after ~~protective~~ RISK CONTROL measures have been taken

[ISO 14971:~~2000~~ 2007, definition ~~2.12~~ 2.15]

3.101
RESPONSIBLE ORGANIZATION
entity accountable for the use and maintenance of an ME EQUIPMENT or an ME SYSTEM

NOTE 1 The accountable entity can be, for example, a hospital, an individual clinician or a layperson. In home use applications, the PATIENT, OPERATOR and RESPONSIBLE ORGANIZATION can be one and the same person.

NOTE 2 Education and training is included in "use."

3.102
RISK
combination of the probability of occurrence of HARM and the SEVERITY of that HARM

[ISO 14971:~~2000~~ 2007, definition ~~2.13~~ 2.16]

3.103
RISK ANALYSIS
systematic use of available information to identify HAZARDS and to estimate the RISK

[ISO 14971:~~2000~~ 2007, definition ~~2.14~~ 2.17]

3.104
RISK ASSESSMENT
overall PROCESS comprising a RISK ANALYSIS and a RISK EVALUATION

[ISO 14971:~~2000~~ 2007, definition ~~2.15~~ 2.18]

3.105
RISK CONTROL
~~PROCESS through which decisions are reached and protective measures are implemented for reducing RISKS to, or maintaining RISKS within, specified levels~~ PROCESS in which decisions are made and measures implemented by which RISKS are reduced to, or maintained within, specified levels

[ISO 14971:~~2000~~ 2007, definition ~~2.16~~ 2.19]

3.106
RISK EVALUATION
~~judgement, on the basis of RISK ANALYSIS, of whether a RISK which is acceptable has been achieved in a given context based on the current values of society~~ PROCESS of comparing the estimated RISK against given RISK criteria to determine the acceptability of the RISK

[ISO 14971:~~2000~~ 2007, definition ~~2.17~~ 2.21]

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3.107
RISK MANAGEMENT
systematic application of management policies, PROCEDURES and practices to the tasks of analyzing, evaluating and controlling RISK

[ISO 14971:~~2000~~ 2007, definition ~~2.18~~ 2.22]

NOTE For the purposes of this standard, RISK MANAGEMENT does not include planning for or monitoring of production and post-production information; whereas this is required for compliance with ISO 14971 (see 4.2.2).

3.108
RISK MANAGEMENT FILE
set of RECORDS and other documents~~, not necessarily contiguous,~~ that are produced by ~~a~~ RISK MANAGEMENT ~~PROCESS~~

[ISO 14971:~~2000~~ 2007, definition ~~2.19~~ 2.23]

NOTE All safety related information including MANUFACTURER'S calculations, test results, etc. is considered to be part of the RISK MANAGEMENT FILE. See also 4.2.

3.109
SAFE WORKING LOAD
maximum external mechanical load (mass) on equipment or an equipment part that is permitted in NORMAL USE

3.110
*** SECONDARY CIRCUIT**
circuit which is separated from the MAINS PART by at least one MEANS OF PROTECTION and derives its power from a transformer, converter or equivalent isolation device, or from an INTERNAL ELECTRICAL POWER SOURCE

NOTE See also 8.9.1.12.

3.111
SELF-RESETTING THERMAL CUT-OUT
THERMAL CUT-OUT that automatically restores the current after the relevant part of electrical equipment has cooled

3.112
*** SEPARATION DEVICE**
component or arrangement of components with input parts and output parts that, for safety reasons, prevents a transfer of unwanted voltage or current between parts of an ME SYSTEM

3.113
SERVICE PERSONNEL
individuals or entity accountable to the RESPONSIBLE ORGANIZATION that install, assemble, maintain or repair ME EQUIPMENT, ME SYSTEMS or equipment

3.114
SEVERITY
measure of the possible consequences of a HAZARD

[ISO 14971:~~2000~~ 2007, definition ~~2.21~~ 2.25]

3.115
*** SIGNAL INPUT/OUTPUT PART**
SIP/SOP
part of ME EQUIPMENT, not being an APPLIED PART, intended to deliver or receive signals to or from other electrical equipment, for example, for display, recording or data processing

NOTE See Figure 2.

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3.116
SINGLE FAULT CONDITION
condition of ME EQUIPMENT in which a single means for reducing a RISK is defective or a single abnormal condition is present

NOTE See 4.7 and 13.2.

3.117
SINGLE FAULT SAFE
characteristic of ME EQUIPMENT or its parts whereby it remains free of unacceptable RISK during its EXPECTED SERVICE LIFE under SINGLE FAULT CONDITIONS

NOTE See 4.7.

3.118
STATIONARY
term referring to equipment that, once installed and placed into service, is not intended to be moved from one place to another

NOTE See the taxonomy in the rationale for definition 3.63.

3.119
SUPPLEMENTARY INSULATION
independent insulation applied in addition to BASIC INSULATION in order to provide protection against electric shock in the event of a failure of BASIC INSULATION

[IEV 826-12-15, modified]

NOTE SUPPLEMENTARY INSULATION provides one MEANS OF PROTECTION.

3.120
*** SUPPLY MAINS**
source of electrical energy not forming part of ME EQUIPMENT or ME SYSTEM

NOTE This also includes battery systems and converter systems in ambulances and the like.

3.121
TENSILE SAFETY FACTOR
ratio between TENSILE STRENGTH and the stress corresponding to the TOTAL LOAD

3.122
TENSILE STRENGTH
maximum tensile stress a test piece will withstand before rupturing

3.123
TERMINAL DEVICE
part of electrical equipment by which electrical connection is made

NOTE A TERMINAL DEVICE can contain several individual contacts.

3.124
THERMAL CUT-OUT
device that, during an abnormal condition, limits the temperature of electrical equipment or of part of it, by automatically opening the circuit or by reducing the current, and that is so constructed that its setting cannot be altered except by qualified SERVICE PERSONNEL

3.125
THERMAL STABILITY
condition under which the temperature of an object does not increase by more than 2 °C over a period of 1 h

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3.126
THERMOSTAT
temperature sensing control that is intended to keep a temperature within a specific range or above/below a preset value

3.127
TOOL
extra-corporeal object that can be used to secure or release fasteners or to make adjustments

NOTE Coins and keys are considered TOOLS within the context of this standard.

3.128
TOTAL LOAD
maximum total loading of a part including the maximum SAFE WORKING LOAD, where applicable, and the static and dynamic forces occurring in NORMAL USE

NOTE 1 Examples of dynamic forces include forces caused by acceleration or deceleration of masses.

NOTE 2 Where a load is divided over several parallel supporting parts and the distribution over these parts is not determined unequivocally, the least favourable possibility is to be considered.

3.129
TOUCH CURRENT
LEAKAGE CURRENT flowing from the ENCLOSURE or from parts thereof, excluding PATIENT CONNECTIONS, accessible to any OPERATOR or PATIENT in NORMAL USE, through an external path other than the PROTECTIVE EARTH CONDUCTOR, to earth or to another part of the ENCLOSURE

NOTE The meaning of this term is the same as that of "enclosure leakage current" in the first and second editions of this standard. The term has been changed to align with IEC 60950-1 and to reflect the fact that the measurement now applies also to parts that are normally PROTECTIVELY EARTHED.

3.130
TRANSPORTABLE
term referring to equipment that, once installed and placed into service, is intended to be moved from one place to another whether or not connected to a supply and without an appreciable restriction of range

EXAMPLE MOBILE equipment, ~~and~~ PORTABLE equipment. and BODY-WORN equipment

NOTE See the taxonomy in the rationale for definition 3.63.

3.131
TRAPPING ZONE
accessible location on or within the ME EQUIPMENT, ME SYSTEM or in the equipment environment where a human body or a part of the human body is exposed to a trapping, crushing, shearing, impact, cutting, entanglement, drawing in, stabbing or abrasion HAZARD

3.132
*** TYPE B APPLIED PART**
APPLIED PART complying with the specified requirements of this standard to provide protection against electric shock, particularly regarding allowable PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT

NOTE 1 A TYPE B APPLIED PART is marked with symbol IEC 60417-5840 (~~DB:~~2002-10) (see Table D.1, symbol 19) or, when applicable, with symbol IEC 60417-5841 (~~DB:~~2002-10) (see Table D.1, symbol 25). See also 3.20.

NOTE 2 TYPE B APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

NOTE 3 See also 4.6 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be considered as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

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3.133
*** TYPE BF APPLIED PART**
F-TYPE APPLIED PART complying with the specified requirements of this standard to provide a higher degree of protection against electric shock than that provided by TYPE B APPLIED PARTS

NOTE 1 A TYPE BF APPLIED PART is marked with symbol IEC 60417-5333 (~~DB:~~2002-10) (see Table D.1, symbol 20) or, when applicable, with symbol 60417-5334 (~~DB:~~2002-10) (see Table D.1, symbol 26). See also 3.20.

NOTE 2 TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

NOTE 3 See also 4.6 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be considered as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

3.134
*** TYPE CF APPLIED PART**
F-TYPE APPLIED PART complying with the specified requirements of this standard to provide a higher degree of protection against electric shock than that provided by TYPE BF APPLIED PARTS

NOTE 1 A TYPE CF APPLIED PART is marked with symbol IEC 60417-5335 (~~DB:~~2002-10) (see Table D.1, symbol 21) or, when applicable, with symbol 60417-5336 (~~DB:~~2002-10) (see Table D.1, symbol 27). See also 3.20.

NOTE 2 See also 4.6 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be considered as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

NOTE 3 See the rationale for the definition of DIRECT CARDIAC APPLICATION (3.22) concerning the applied parts that need to be TYPE CF APPLIED PARTS.

3.135
TYPE TEST
test on a representative sample of the equipment with the objective of determining if the equipment, as designed and manufactured, can meet the requirements of this standard

3.136
USABILITY
characteristic of the OPERATOR interface that establishes effectiveness, efficiency, ease of OPERATOR learning and OPERATOR ~~learnability and~~ satisfaction

[~~IEC 60601-1-6:2004, definition 2.211~~ IEC 62366:2007, definition 3.17, modified]

3.137
USABILITY ENGINEERING
application of knowledge about human behaviour, abilities, limitations, and other characteristics to the design of tools~~, machines, equipment~~, devices, systems, tasks, jobs, and environments to achieve adequate USABILITY

[~~IEC 60601-1-6:2004, definition 2.212~~ IEC 62366:2007, definition 3.18]

3.138
VERIFICATION
confirmation ~~by examination and~~, through the provision of OBJECTIVE EVIDENCE that specified requirements have been fulfilled

~~NOTE In design and development, VERIFICATION concerns the PROCESS of examining the result of a given activity to determine conformity with the stated requirements for that activity.~~

NOTE 1 The term "verified" is used to designate the corresponding status.

NOTE 2 Confirmation can comprise activities such as:

– performing alternative calculations;
– comparing a new design specification with a similar proven design specification;
– undertaking tests and demonstrations;
– reviewing documents prior to issue.

[ISO 14971:~~2000~~ 2007, definition ~~2.22~~ 2.28]

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3.139
*** WORKING VOLTAGE**
highest voltage to which the insulation or the component under consideration is, or can be, subjected when the electrical equipment is operating under conditions of NORMAL USE

[IEC 60950-1:~~2001~~2005, definition 1.2.9.6]

3.140
AIR KERMA
K
quotient of dE_{tr} by dm, where dE_{tr} is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of air, thus

$$K = \frac{dE_{tr}}{dm}$$

Unit: J kg^{-1}

The special name for the unit of AIR KERMA is gray (Gy) (ICRU 60)

[IEC 60601-1-3:2008, definition 3.4]

3.141
ALARM CONDITION
state of the ALARM SYSTEM when it has determined that a potential or actual HAZARDOUS SITUATION exists for which OPERATOR awareness or response is required

NOTE 1 An ALARM CONDITION can be invalid, i.e. a false positive ALARM CONDITION.

NOTE 2 An ALARM CONDITION can be missed, i.e. a false negative ALARM CONDITION.

[IEC 60601-1-8:2006 / Amendment 1 (2012), definition 3.1]

3.142
ALARM SIGNAL
type of signal generated by the ALARM SYSTEM to indicate the presence (or occurrence) of an ALARM CONDITION

[IEC 60601-1-8:2006, definition 3.9]

3.143
ALARM SYSTEM
parts of ME EQUIPMENT or a ME SYSTEM that detect ALARM CONDITIONS and, as appropriate, generate ALARM SIGNALS

[IEC 60601-1-8:2006, definition 3.11]

3.144
BODY-WORN
term referring to TRANSPORTABLE equipment whose INTENDED USE includes operation while being worn by a PATIENT or attached to a PATIENT'S clothing

NOTE 1 TRANSPORTABLE equipment can be both BODY-WORN and HAND-HELD.

[IEC 60601-1-11:2010, definition 3.1]

NOTE 2 See the taxonomy in the rationale for definition 3.63.

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3.145
IT-NETWORK
INFORMATION TECHNOLOGY NETWORK
a system or systems composed of communicating nodes and transmission links to provide physically linked or wireless transmission between two or more specified communication nodes

[IEC 80001-1:2010, definition 2.12]

3.146
PRIMARY OPERATING FUNCTION
function that involves OPERATOR interaction that is frequently used or related to the safety of the ME EQUIPMENT

[IEC 62366:2007, definition 3.14, modified]

3.147
USABILITY ENGINEERING FILE
set of RECORDS and other documents that are produced by the USABILITY ENGINEERING PROCESS

[IEC 62366:2007, definition 3.19]

4 General requirements

4.1 * Conditions for application to ME EQUIPMENT or ME SYSTEMS

Unless otherwise specified, the requirements of this standard shall apply in NORMAL USE and reasonably foreseeable misuse.

When applying this standard to ME EQUIPMENT or ME SYSTEMS intended for the compensation or alleviation of disease, injury or disability, the definitions and requirements that use the term PATIENT shall be considered as applying to the person for whom the ME EQUIPMENT or ME SYSTEM is intended.

4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

~~A RISK MANAGEMENT PROCESS complying with ISO 14971 shall be performed.~~

~~In applying ISO 14971:~~

- ~~The term "medical device" shall assume the same meaning as ME EQUIPMENT or ME SYSTEM.~~
- ~~The term "fault conditions" referred to in ISO 14971 shall include, but shall not be limited to, SINGLE FAULT CONDITIONS identified in this standard.~~
- ~~The policy for determining acceptable RISK and the acceptability of the RESIDUAL RISK(S) shall be established by the MANUFACTURER.~~
- ~~Where this standard or any of its collateral or particular standards specify verifiable requirements addressing particular RISKS, and these requirements are complied with, the RESIDUAL RISKS addressed by these requirements shall be presumed to be acceptable unless there is OBJECTIVE EVIDENCE to the contrary.~~

~~NOTE 1 This standard specifies requirements that are generally applicable to RISKS associated with ME EQUIPMENT or ME SYSTEMS, and is intended to serve as a tool during the RISK MANAGEMENT PROCESS. The RISK MANAGEMENT PROCESS should identify not only those HAZARDS addressed by this standard, but all HAZARDS, their associated RISKS and RISK CONTROL measures.~~

~~NOTE 2 Conditions or faults that can give rise to HAZARDS are identified in the clauses of this standard. In these cases, it will often be necessary to carry out a RISK MANAGEMENT PROCESS to determine what the actual HAZARDS are and the tests that need to be done to show that the identified HAZARDS do not arise in the specified circumstances.~~

~~NOTE 3 It is recognized that the MANUFACTURER might not be able to follow all the PROCESSES identified in this standard for each constituent component of the ME EQUIPMENT or ME SYSTEM, such as proprietary components,~~

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~~subsystems of non-medical origin, and legacy devices. In this case, the MANUFACTURER should take special account of the need for additional RISK CONTROL measures.~~

~~NOTE 4 Where requirements of this standard refer to freedom from unacceptable RISK, acceptability or unacceptability of this RISK is determined by the MANUFACTURER in accordance with the MANUFACTURER'S policy for determining acceptable RISK.~~

~~NOTE 5 Not all the RISKS associated with ME EQUIPMENT and ME SYSTEMS are subject to specific requirements of this standard (see 1.1).~~

~~*Compliance is checked by inspection of the RISK MANAGEMENT FILE. The requirements of this clause and all requirements of this standard referring to inspection of the RISK MANAGEMENT FILE are considered to be satisfied if the MANUFACTURER has:*~~

- ~~*established a RISK MANAGEMENT PROCESS;*~~
- ~~*established acceptable levels of RISK; and*~~
- ~~*demonstrated that the RESIDUAL RISK(S) is acceptable (in accordance with the policy for determining acceptable RISK).*~~

4.2.1 Introduction to RISK MANAGEMENT

Subclause 4.2 specifies the RISK MANAGEMENT PROCESS that is required for compliance with this standard. This RISK MANAGEMENT PROCESS is intended to serve the following purposes:

a) To identify whether the normative requirements specified in Clauses 5 to 17 of this standard, together with the requirements of applicable collateral and particular standards, address all the HAZARDS associated with the particular ME EQUIPMENT or ME SYSTEM under consideration.

b) To identify the way in which some particular tests specified in this standard should be applied to a particular ME EQUIPMENT or ME SYSTEM.

c) To identify whether particular HAZARDS or HAZARDOUS SITUATIONS for which this standard does not provide specific acceptance criteria result in any RISKS for a particular ME EQUIPMENT or ME SYSTEM, and, if so, to establish acceptable RISK levels and evaluate the RESIDUAL RISKS.

d) To evaluate the acceptability of alternative RISK CONTROL strategies by comparing RESIDUAL RISK with that achieved by applying the full requirements of this standard.

Although the RISK MANAGEMENT PROCESS specified in this standard is required to comply with the relevant requirements of ISO 14971, it is not as extensive as and does not include all of the elements required for compliance with ISO 14971. For example, the RISK MANAGEMENT PROCESS required for compliance with this standard does not include the production and post-production monitoring required in ISO 14971. Furthermore, verification of compliance with the RISK MANAGEMENT requirements of this standard can be accomplished by examination of the RECORDS and other documentation required by this standard and assessment of the processes cited in this standard and does not require auditing of the RISK MANAGEMENT PROCESS.

4.2.2 General requirement for RISK MANAGEMENT

A RISK MANAGEMENT PROCESS complying with ISO 14971 shall be performed. For compliance with this standard, all elements of the ISO 14971:2007 RISK MANAGEMENT PROCESS shall be applied except:

– the planning for and execution of production and post-production monitoring (subclause 3.1, fourth dash, subclause 3.4, item f), and Clause 9 of ISO 14971:2007), and

– periodic reviews of the suitability of the RISK MANAGEMENT PROCESS (subclause 3.2, fourth dash, of ISO 14971:2007).

When applying any of the requirements of ISO 14971:

– the term “medical device” shall assume the same meaning as ME EQUIPMENT or ME SYSTEM; and

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– the term “fault conditions” referred to in ISO 14971 shall include, but shall not be limited to, SINGLE FAULT CONDITIONS identified in this standard.

NOTE 1 This standard specifies requirements that are generally applicable to RISKS associated with the ME EQUIPMENT or ME SYSTEMS. Those requirements are intended to facilitate the RISK MANAGEMENT PROCESS. The RISK MANAGEMENT PROCESS is aimed at identifying not only those HAZARDS addressed by this standard, but all HAZARDS, their associated RISKS and RISK CONTROL measures.

NOTE 2 Conditions or faults that can give rise to HAZARDOUS SITUATIONS are identified in the clauses of this standard. In these cases, it will often be necessary to carry out a RISK MANAGEMENT PROCESS to determine what the actual HAZARDOUS SITUATIONS are and the tests that need to be done to show that the identified HAZARDOUS SITUATIONS do not arise in the specified circumstances.

NOTE 3 It is recognized that the MANUFACTURER might not be able to follow all the PROCESSES identified in this standard for each constituent component of the ME EQUIPMENT or ME SYSTEM, such as proprietary components, subsystems of non-medical origin, and legacy devices. In this case, the MANUFACTURER would need to take special account of the need for additional RISK CONTROL measures.

NOTE 4 Where requirements of this standard refer to freedom from unacceptable RISK, acceptability or unacceptability of this RISK is determined by the MANUFACTURER in accordance with the MANUFACTURER'S policy for determining acceptable RISK.

NOTE 5 Not all the RISKS associated with the ME EQUIPMENT or ME SYSTEM are subject to specific requirements of this standard (see 1.1).

Compliance is checked by:

– *inspection of the MANUFACTURER'S policy for determining criteria for RISK acceptability;*

– *inspection of the RISK MANAGEMENT plan for the particular ME EQUIPMENT or ME SYSTEM under consideration; and*

– *confirming the MANUFACTURER has prepared a RISK MANAGEMENT FILE containing the RISK MANAGEMENT RECORDS and other documentation required by this standard for the particular ME EQUIPMENT or ME SYSTEM under consideration.*

NOTE 6 It is helpful to keep an index containing references or pointers to the RISK MANAGEMENT RECORDS and other documentation required by this standard.

4.2.3 Evaluating RISK

4.2.3.1 HAZARDS identified in the IEC 60601-series

The requirements of this standard shall be applied in the following way when evaluating RISK:

a) Where this standard or its collateral or particular standards specify requirements addressing particular HAZARDS or HAZARDOUS SITUATIONS, together with specific acceptance criteria, compliance with these requirements is presumed to establish that the RESIDUAL RISKS have been reduced to acceptable levels unless there is OBJECTIVE EVIDENCE to the contrary.

EXAMPLE 1 Subclause 8.5.1.2, MEANS OF PATIENT PROTECTION (MOPP)

EXAMPLE 2 Subclause 9.4.2.1, Instability in transport position

Compliance is checked by satisfying the relevant requirements of this standard and its collateral and particular standards.

b) Where this standard or its collateral or particular standards specify requirements addressing particular HAZARDS or HAZARDOUS SITUATIONS but do not provide specific acceptance criteria, the MANUFACTURER shall provide the acceptance criteria defined in the RISK MANAGEMENT plan. These acceptance criteria shall ensure that the RESIDUAL RISK is acceptable according to the criteria for RISK acceptability recorded in the RISK MANAGEMENT plan.

EXAMPLE 3 Subclause 9.8.3.3, Dynamic forces due to loading from persons

EXAMPLE 4 Subclause 11.6.3, Spillage on ME EQUIPMENT and ME SYSTEMS

Compliance is checked by confirming that the RECORDS in the RISK MANAGEMENT FILE demonstrate that, after applying the specific requirements of this standard, the acceptance criteria determined by the MANUFACTURER are satisfied. Only the relevant parts of the RISK

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MANAGEMENT FILE need to be reviewed, e.g. the *MANUFACTURER'S calculations or test results, or the determination of RISK acceptability.*

c) Where this standard or its collateral or particular standards identify particular HAZARDS or HAZARDOUS SITUATIONS that have to be investigated without providing specific technical requirements:

- the MANUFACTURER shall determine whether such HAZARDS or HAZARDOUS SITUATIONS exist for the particular ME EQUIPMENT or ME SYSTEM, and
- where such HAZARDS or HAZARDOUS SITUATIONS exist for the particular ME EQUIPMENT or ME SYSTEM, the MANUFACTURER shall evaluate and (if necessary) control these RISKS following the RISK MANAGEMENT PROCESS specified in 4.2.2.

EXAMPLE 5 Subclause 10.2, Alpha, beta, gamma, neutron and other particle radiation

Compliance is checked by confirming that the RECORDS in the RISK MANAGEMENT FILE demonstrate that the RESIDUAL RISK is acceptable using the criteria for RISK acceptability recorded in the RISK MANAGEMENT plan, i.e. no unacceptable RISK remains. Only the relevant parts of the RISK MANAGEMENT FILE need to be reviewed, e.g. the MANUFACTURER'S calculations or test results, or the determination of RISK acceptability.

NOTE When ME EQUIPMENT or an ME SYSTEM has been designed in such way that for a certain type of HAZARDS no HAZARDOUS SITUATION exists, no further RISK ASSESSMENT for that HAZARD is necessary. This can be verified by tests or inspections.

4.2.3.2 HAZARDS not identified in the IEC 60601 series

For HAZARDS or HAZARDOUS SITUATIONS that are identified for the particular ME EQUIPMENT or ME SYSTEM but are not specifically addressed in this standard or its collateral or particular standards, the MANUFACTURER shall address those HAZARDS in the RISK MANAGEMENT PROCESS as specified in 4.2.2.

EXAMPLE ME EQUIPMENT or an ME SYSTEM for which there are particular RISKS but no particular standard.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

4.3 * ESSENTIAL PERFORMANCE

~~The MANUFACTURER shall identify which functions of the ME EQUIPMENT and ME SYSTEMS are ESSENTIAL PERFORMANCE. Where this standard specifies that ESSENTIAL PERFORMANCE is to be maintained following a particular test, these functions shall be used and compliance shall be checked by inspection, and if necessary, by functional test.~~

~~NOTE Where requirements of this standard refer to ESSENTIAL PERFORMANCE, that ESSENTIAL PERFORMANCE is determined by the MANUFACTURER in accordance with the MANUFACTURER's policy for RISK acceptability.~~

~~*Compliance is checked by inspection of the RISK MANAGEMENT FILE.*~~

During RISK ANALYSIS, the MANUFACTURER shall identify the performance of the clinical function(s) of the ME EQUIPMENT or ME SYSTEM, other than that related to BASIC SAFETY, that is necessary to achieve its INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM.

The MANUFACTURER shall then specify performance limits between fully functional and total loss of the identified performance in both NORMAL CONDITION and SINGLE FAULT CONDITION.

The MANUFACTURER shall then evaluate the RISK from the loss or degradation of the identified performance beyond the limits specified by the MANUFACTURER. If the resulting RISK is unacceptable, then the identified performance constitutes an ESSENTIAL PERFORMANCE of the ME EQUIPMENT or ME SYSTEM.

The MANUFACTURER shall implement RISK CONTROL measures to reduce the RISK from the loss or degradation of the identified performance to an acceptable level.

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NOTE 1 The performance of the RISK CONTROL measure might well become an aspect of the ESSENTIAL PERFORMANCE of the ME EQUIPMENT or ME SYSTEM. For example, the generation of the ALARM SIGNAL to indicate the interruption of the SUPPLY MAINS could be "essential" if an interruption of the SUPPLY MAINS could result in an unacceptable RISK if it went unattended.

The MANUFACTURER shall specify the methods used to verify the effectiveness of the RISK CONTROL measures. This shall include any assessment made to determine whether verification is needed.

NOTE 2 Following the principles of RISK MANAGEMENT, the MANUFACTURER is required to verify the effectiveness of each RISK CONTROL measure. This can involve demonstrating that the RISK CONTROL measure will operate in the presence of the conditions that result in the loss or degradation of the identified performance.

EXAMPLE 1 If ESSENTIAL PERFORMANCE is lost because of an interruption of the SUPPLY MAINS, an ALARM SYSTEM intended to notify the OPERATOR that the SUPPLY MAINS has been interrupted would need to have a backup power source so that the generation of the ALARM SIGNAL would not depend on the SUPPLY MAINS.

EXAMPLE 2 If the failure of a component results in the loss of ESSENTIAL PERFORMANCE, the design of the ME EQUIPMENT or ME SYSTEM would need to be such that the component failure does not compromise the effectiveness of any RISK CONTROL measures put in place to mitigate the RISK from the loss of the ESSENTIAL PERFORMANCE.

NOTE 3 Each collateral standard or particular standard in the IEC 60601 or the IEC/ISO 80601 series can list potential ESSENTIAL PERFORMANCES to guide the MANUFACTURER to identify particular ESSENTIAL PERFORMANCE in accordance with 4.3.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

Where this standard requires that ESSENTIAL PERFORMANCE is to be maintained following a particular test, compliance is checked by inspection and, if necessary, by functional test(s) that demonstrate the MANUFACTURER'S specified limits are maintained or the ME EQUIPMENT or ME SYSTEM transitions to a safe state as defined by the MANUFACTURER.

4.4 * EXPECTED SERVICE LIFE

The MANUFACTURER shall state the EXPECTED SERVICE LIFE of the ME EQUIPMENT or ME SYSTEM in the RISK MANAGEMENT FILE.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

4.5 ~~* Equivalent safety for ME EQUIPMENT or ME SYSTEMS~~ * Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS

~~Where this standard specifies requirements addressing particular RISKS, alternative means of addressing these RISKS are acceptable provided that the MANUFACTURER can justify that the RESIDUAL RISKS that result from applying the alternative means are equal to or less than the RESIDUAL RISKS that result from applying the requirements of this standard.~~

~~*Compliance is checked by inspection of the RISK MANAGEMENT FILE.*~~

Where this standard specifies a particular RISK CONTROL measure or test method, an alternative RISK CONTROL measure or test method is acceptable, provided that the MANUFACTURER can demonstrate through scientific data or clinical opinion or comparative studies that the RESIDUAL RISK that results from applying the alternative RISK CONTROL measure or test method remains acceptable and is comparable to the RESIDUAL RISK that results from applying the requirements of this standard.

Comparative studies in this context mean studies comparing the effect of the alternative RISK CONTROL measure or test method with the RISK CONTROL measure or test method specified in this standard.

NOTE Alternative RISK CONTROL measures can allow for exceeding limits specified in this standard or in its collateral or particular standards if additional measures for compensation are provided.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

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4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

~~The RISK MANAGEMENT PROCESS shall include an assessment of whether parts that can come into contact with the PATIENT but fall outside of the definition of APPLIED PARTS shall be subject to the requirements for APPLIED PARTS. If the RISK MANAGEMENT PROCESS determines that such parts are subject to the requirements for APPLIED PARTS, then all the relevant requirements and tests of this standard shall apply, except that 7.2.10 does not apply to such parts.~~

~~*Compliance is checked by inspection of the RISK MANAGEMENT FILE.*~~

The RISK MANAGEMENT PROCESS shall include an assessment of whether parts that can come into contact with the PATIENT but fall outside of the definition of APPLIED PARTS need to be subject to the requirements for APPLIED PARTS. For the parts concerned, the requirements for TYPE B APPLIED PART shall be applied unless the assessment identifies a need for the requirements for a TYPE BF APPLIED PART or TYPE CF APPLIED PART to apply.

If the RISK MANAGEMENT PROCESS determines that such parts are subject to the requirements for APPLIED PARTS, then all the relevant requirements and tests of this standard and of relevant collateral and particular standards shall apply, except that 7.2.10 does not apply to such parts.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT

ME EQUIPMENT shall be so designed and manufactured that it remains SINGLE FAULT SAFE, or the RISK remains acceptable as determined through application of 4.2.

NOTE 1 The NORMAL CONDITIONS identified in 8.1 a) are taken into consideration during evaluation of compliance with any requirement of this standard that they might affect.

ME EQUIPMENT is considered SINGLE FAULT SAFE if:

a) it employs a single means for reducing a RISK that has a negligible probability of failure (e.g. REINFORCED INSULATION, suspended masses without MECHANICAL PROTECTIVE DEVICES employing a TENSILE SAFETY FACTOR of 8X, COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS), or

b) a SINGLE FAULT CONDITION occurs, but:

- the initial fault will be detected during the EXPECTED SERVICE LIFE of the ME EQUIPMENT and before a second means for reducing a RISK fails (e.g. suspended masses with MECHANICAL PROTECTIVE DEVICES); or
- the probability that the second means of reducing the RISK will fail during the EXPECTED SERVICE LIFE of the ME EQUIPMENT is negligible.

Where a SINGLE FAULT CONDITION causes another SINGLE FAULT CONDITION, the two failures are considered as one SINGLE FAULT CONDITION.

During any test under SINGLE FAULT CONDITION, only one fault at a time shall be applied.

NOTE 2 Faults are generally divided into 3 probability categories:

a) so remote that they can be ignored. The RISKS arising from these faults are considered acceptable;

b) probable enough that they need to be considered, but improbable enough that they need only be considered one at a time (single fault). Faults of this category include all those identified as SINGLE FAULT CONDITIONS in this standard, and any other faults identified in applying ISO 14971 that meet the SINGLE FAULT CONDITION criteria;

c) so likely, so unpredictable or undetectable that they are considered to be a NORMAL CONDITION and need to be considered individually and collectively.

The results of the RISK ANALYSIS shall be used to determine which failures shall be tested. The failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those mentioned in 13.1, shall be simulated, physically or theoretically. The evaluation of whether a component is subject to failure simulation shall take into account the RISK

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associated with the failure of the component during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. This evaluation shall be accomplished by applying the principles of RISK MANAGEMENT. The evaluation shall take into account issues such as reliability, TENSILE SAFETY FACTORS and rating of components. Additionally, during the simulation of SINGLE FAULT CONDITIONS, component failures that are highly probable or undetectable shall be simulated.

NOTE 3 See also Note 2 in 4.2.

This requirement and relevant tests shall not be applied to failures of DOUBLE or REINFORCED INSULATION or COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS.

Compliance is determined by applying the specific requirements and tests associated with the SINGLE FAULT CONDITIONS identified in 13.2, and tests for the failures identified from evaluation of the results of the RISK ANALYSIS. Compliance is confirmed if the introduction of any of the SINGLE FAULT CONDITIONS described in 13.2, one at a time, does not lead directly to the HAZARDOUS SITUATIONS described in 13.1, or any other outcome that results in an unacceptable RISK.

4.8 * Components of ME EQUIPMENT

All components, including wiring, the failure of which could result in a HAZARDOUS SITUATION shall be used in accordance with their specified ratings unless a specific exception is made in this standard or through the RISK MANAGEMENT PROCESS. The reliability of components that are used as MEANS OF PROTECTION shall be assessed for the conditions of use in the ME EQUIPMENT. They shall comply with one of the following (see also 4.5):

a) the applicable safety requirements of a relevant IEC or ISO standard;

NOTE 1 For the components, it is not necessary to carry out identical or equivalent tests already performed to check compliance with the component standard.

b) where there is no relevant IEC or ISO standard, the requirements of this standard have to be applied.

NOTE 2 If there are neither requirements in this standard nor in an IEC or ISO standard, any other applicable source (e.g. standards for other types of devices, national standards) could be used to demonstrate compliance with the RISK MANAGEMENT PROCESS.

See Figure 5 for a schematic flow chart for a) and b).

Compliance is checked by inspection and, where necessary, by test. The tests of this standard for motors (see 13.2.8 and 13.2.13.3) and transformers (see 15.5.3) are considered to be comprehensive and together with the evaluation of the motor or transformer insulation system according to Table 22 represent all testing required by this standard. ME SYSTEM components that provide isolation from non-ME EQUIPMENT are evaluated to Clause 16.

4.9 * Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT

A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS shall be used when a fault in a particular component can generate an unacceptable RISK. COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS shall be selected and evaluated consistent with their conditions of use and reasonably foreseeable misuse during the EXPECTED SERVICE LIFE of the ME EQUIPMENT.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the selection criteria for the COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS.

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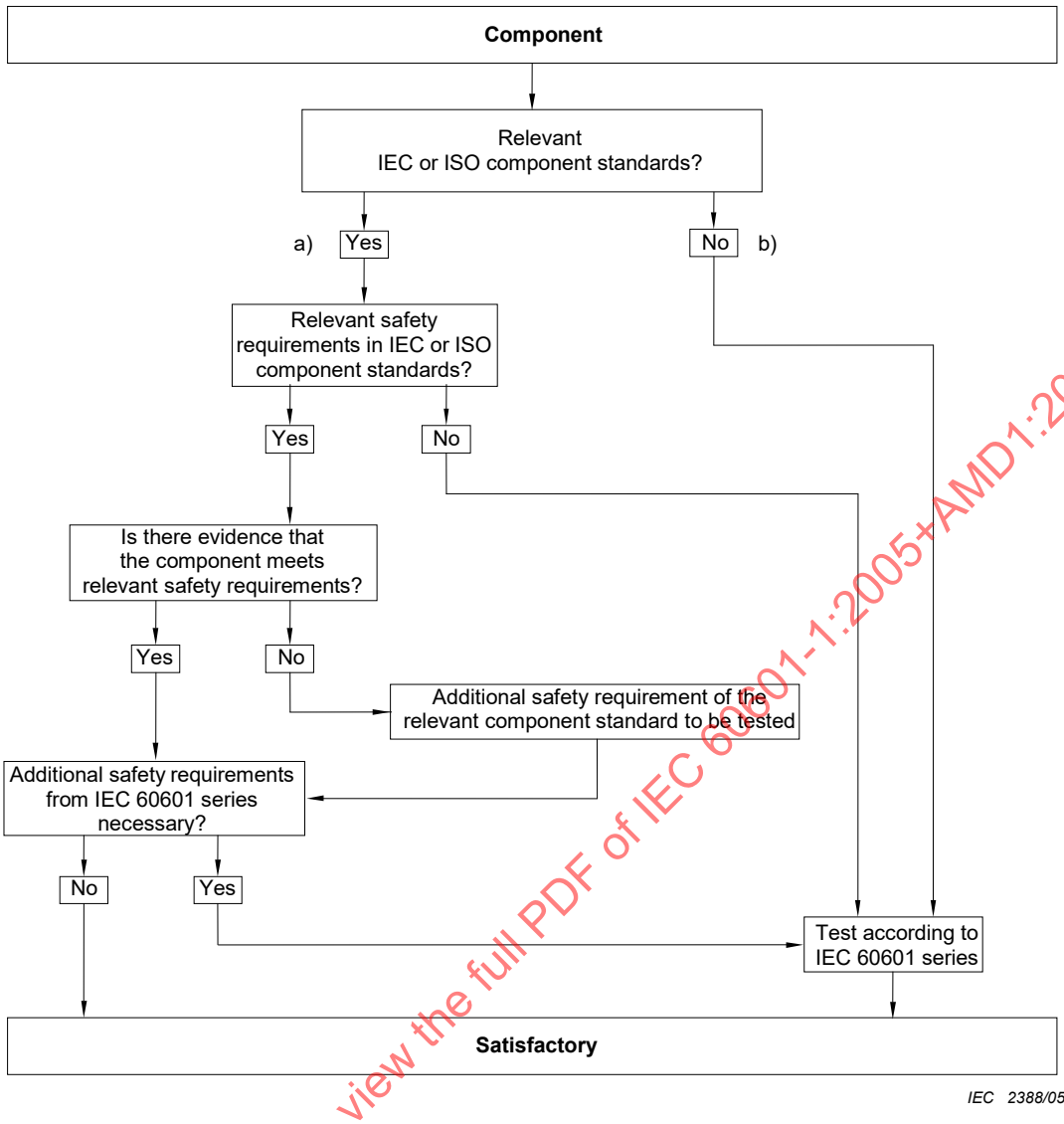


Figure 5 – Schematic flow chart for component qualification
(see 4.8)

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4.10 * Power supply

4.10.1 Source of power for ME EQUIPMENT

ME EQUIPMENT shall be suitable for connection to a SUPPLY MAINS, be specified for connection to a separate power supply or be powered by an INTERNAL ELECTRICAL POWER SOURCE. Alternatively, a combination of these sources may be used.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

4.10.2 SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

For ME EQUIPMENT intended to be connected to SUPPLY MAINS, the following RATED voltages shall not be exceeded:

– 250 V for HAND-HELD ME EQUIPMENT;

– 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA; or

– 500 V for all other ME EQUIPMENT and ME SYSTEMS.

SUPPLY MAINS in this standard shall be assumed to have the following characteristics:

– overvoltage category II for mains transients unless a higher category is specified by the MANUFACTURER;

– no voltage in excess of 110 % or lower than 90 % of the NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth (see 7.9.3.1);

NOTE 1 IEC 60601-1-2 contains requirements and tests for voltage dips, short interruptions and voltage variations on the SUPPLY MAINS. See also 1.3.

– voltages that are practically sinusoidal and forming a practically symmetrical supply system in case of polyphase supply;

– a frequency of ≤ 1 kHz;

– a frequency deviation of ≤ 1 Hz from the NOMINAL frequency up to 100 Hz and ≤ 1 % from the NOMINAL frequency from 100 Hz to 1 kHz;

– the protective measures as described in IEC 60364-4-41;

NOTE 2 If ME EQUIPMENT or an ME SYSTEM is intended to be operated from a SUPPLY MAINS with characteristics different from the SUPPLY MAINS described in this subclause, additional safety measures could be necessary.

– a d.c. voltage (as measured by a moving coil meter or equivalent method) having a peak-to-peak ripple not exceeding 10 % of the average value.

Where peak-to-peak ripple exceeds 10 % of the average value, the peak voltage has to be applied.

4.11 Power input

The steady-state measured input of the ME EQUIPMENT or ME SYSTEM at RATED voltage and at operating settings indicated in the instructions for use shall not exceed the marked rating by more than 10 % (see 7.2.7).

Compliance is checked by inspection and by the following tests.

– *The ME EQUIPMENT or ME SYSTEM is operated as specified in the instructions for use until the input has reached a stable value. Input is measured and compared with markings and the contents of the technical description.*

– *ME EQUIPMENT or an ME SYSTEM marked with one or more RATED voltage ranges is tested at both upper and lower limits of the range, unless each marking of RATED input is related to the mean value of the relevant voltage range, in which case the test is performed at a voltage equal to the mean value of that range.*

– *The steady state current is measured with a true r.m.s. reading instrument.*

Power input, if expressed in volt-amperes, is either measured with a volt-ampere meter or determined as the product of the steady state current (measured as described above) and the supply voltage.

NOTE 1 Technical details of a true r.m.s. meter can be found in IEC 62354 [66].

~~A supplier certification may be used in place of the above measurement as the basis for steady-state current or power input specification.~~

NOTE 2 Supplier information can be used to supplement the above measurement as a power input specification.

5 * General requirements for testing ME EQUIPMENT

5.1 * TYPE TESTS

The tests described in this standard are TYPE TESTS. The tests to be performed are determined taking into consideration the requirements of Clause 4, in particular 4.2.

A test need not be performed if analysis shows that the condition being tested has been adequately evaluated by other tests or methods.

~~The results of the RISK ANALYSIS are used to determine which combination(s) of simultaneous faults are to be tested.~~

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The combination of simultaneous independent faults that could result in a HAZARDOUS SITUATION shall be documented in the RISK MANAGEMENT FILE (see also 4.7). When testing is necessary to demonstrate that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained under such simultaneous independent faults, the related testing may be limited to worst case situations.

NOTE 1 The test results might necessitate a revision of the RISK ANALYSIS.

NOTE 2 When considering use of tests described in this standard as routine tests, see Annex K of IEC/TR 62354 (production line tests) or see IEC 62353 (recurrent tests).

5.2 * Number of samples

TYPE TESTS are performed on a representative sample of the item being tested.

NOTE Multiple samples can be utilized simultaneously if the validity of the results is not significantly affected.

5.3 Ambient temperature, humidity, atmospheric pressure

a) After the ME EQUIPMENT to be tested has been set up for NORMAL USE (according to 5.7), tests are performed within the range of environmental conditions indicated in the technical description (see 7.9.3.1).

b) ME EQUIPMENT is shielded from other influences (for example, draughts), that might affect the validity of the tests.

c) In cases where ambient temperatures cannot be maintained, the test conditions are to be consequently modified and results adjusted accordingly.

5.4 Other conditions

a) a) Unless otherwise specified in this standard, ME EQUIPMENT is to be tested under the least favourable working conditions ~~as specified in the instructions for use that are identified during RISK ANALYSIS~~. The working conditions are specified in the ACCOMPANYING DOCUMENTS. The least favourable working conditions shall be documented for every test where they apply.

b) ME EQUIPMENT having operating values that can be adjusted or controlled by anyone other than SERVICE PERSONNEL shall be adjusted as part of the tests to values least favourable for the relevant test, but in accordance with the instructions for use.

c) If the test results are influenced by the inlet pressure and flow or chemical composition of a cooling liquid, the test is performed within the limits for these characteristics as prescribed in the technical description.

d) Where cooling water is required, potable water is used.

5.5 Supply voltages, type of current, nature of supply, frequency

a) Where test results are influenced by deviations of ~~the supply voltage~~ the characteristics of the SUPPLY MAINS from ~~its~~ their RATED values, the effect of such deviations is taken into account.

The ~~supply voltage~~ values used during ~~tests is~~ testing are according to 4.10.2 or according to that marked on the ME EQUIPMENT (see 7.2.6), whichever is least favourable.

NOTE 1 For the RATED value(s) given on the ME EQUIPMENT, deviations of the SUPPLY MAINS as provided in 4.10.2 are only to be tested if the deviations have a negative impact on BASIC SAFETY or ESSENTIAL PERFORMANCE.

b) ME EQUIPMENT having a MAINS PART intended for connection to a.c. SUPPLY MAINS is only tested with a.c. at RATED frequency ~~(if marked) ± 1 Hz up to and including 100 Hz and~~

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~~± 1 % above 100 Hz.~~ ME EQUIPMENT marked with a RATED frequency range is tested at the least favourable frequency within that range.

c) ME EQUIPMENT designed for more than one RATED voltage, ~~or~~ for both a.c. and d.c., or for both external power and an INTERNAL ELECTRICAL POWER SOURCE, is tested in conditions (described in 5.4) related to the least favourable voltage and nature of supply, for example, number of phases (except for single-phase supply) and type of current. It could be necessary to perform some tests more than once in order to establish which supply configuration is least favourable.

d) ME EQUIPMENT having a MAINS PART intended for connection to d.c. SUPPLY MAINS is only tested with d.c. When performing the tests, the possible influence of polarity on the operation of the ME EQUIPMENT is taken into consideration, according to the instructions for use. See also 8.2.2.

e) ME EQUIPMENT for which alternative ACCESSORIES or components specified in the ACCOMPANYING DOCUMENTS (see 7.9.2.14 and 7.9.3.2) are available is tested with those ACCESSORIES or components that give the least favourable conditions.

f) If the instructions for use specify that ME EQUIPMENT is intended to receive its power from a separate power supply, it is connected to such a power supply. See also 7.2.5 and 8.2.1.

NOTE 2 What was referred to in the first and second editions of this standard as a "specified power supply" is now considered either as another part of the same ME EQUIPMENT or as another equipment in an ME SYSTEM.

5.6 Repairs and modifications

In the event of the necessity for repairs or modifications after a failure or a probability of future failure during the sequence of tests, the testing laboratory and the supplier of the ME EQUIPMENT for the test can agree, either upon the presentation of a new sample on which all tests influencing the result are performed again or, preferably, upon making all the necessary repairs or modifications after which only relevant tests are repeated.

5.7 * Humidity preconditioning treatment

Prior to the tests of 8.7.4 and 8.8.3, all ME EQUIPMENT or its parts shall be subjected to a humidity preconditioning treatment.

ME EQUIPMENT or its parts shall be set up complete (or where necessary partially). Covers used during transport and storage are detached.

This treatment is applied only to those ME EQUIPMENT parts which are influenced by the climatic conditions that are simulated by the test.

Parts that can be detached without the use of a TOOL are detached but are treated simultaneously with the major part.

ACCESS COVERS that can be opened or detached without the use of a TOOL are opened and detached.

The humidity preconditioning treatment is performed in a humidity cabinet containing air with a relative humidity of 93 % ± 3 % where the ME EQUIPMENT or its parts under test are located. The humidity conditions at other locations in the chamber may vary by ± 6 %. The temperature of the air in the cabinet, at all places where ME EQUIPMENT or its parts can be located, ~~is~~ shall be maintained within 2 °C of any convenient value T in the range of + 20 °C to + ~~32~~ 30 °C. Before being placed in the humidity cabinet, ME EQUIPMENT or its parts ~~shall~~ are be brought to a temperature between T and T + 4 °C, and kept at this temperature for at least 4 h before the humidity treatment starts.

KEEP ME EQUIPMENT and its parts, where the ENCLOSURE is classified as IPX0, ~~is kept~~ in the humidity cabinet for 48 h.

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Keep ME EQUIPMENT and its parts, where the ENCLOSURE is designed to provide higher ingress protection against liquids, in the humidity cabinet for 168 h.

~~Where the RISK MANAGEMENT PROCESS suggests that the ME EQUIPMENT can be exposed to high humidity for extended periods (such as ME EQUIPMENT intended for out-door use), the period is extended appropriately.~~

After the treatment, the ME EQUIPMENT is reassembled, if necessary.

5.8 Sequence of tests

Unless stated otherwise, the tests in this standard are sequenced in such a way that the results of any test do not influence the results of a subsequent test.

NOTE It is recommended that all tests be performed in the sequence given in Annex B.

5.9 * Determination of APPLIED PARTS and ACCESSIBLE PARTS

5.9.1 APPLIED PARTS

APPLIED PARTS are identified by inspection and by reference to the ACCOMPANYING DOCUMENTS See also 4.6.

5.9.2 ACCESSIBLE PARTS

5.9.2.1 * Test finger

Parts of ME EQUIPMENT that are to be regarded as ACCESSIBLE PARTS are identified by inspection and where necessary by test. In case of doubt, accessibility is determined by a test with the standard test finger shown in Figure 6, applied in a bent or straight position:

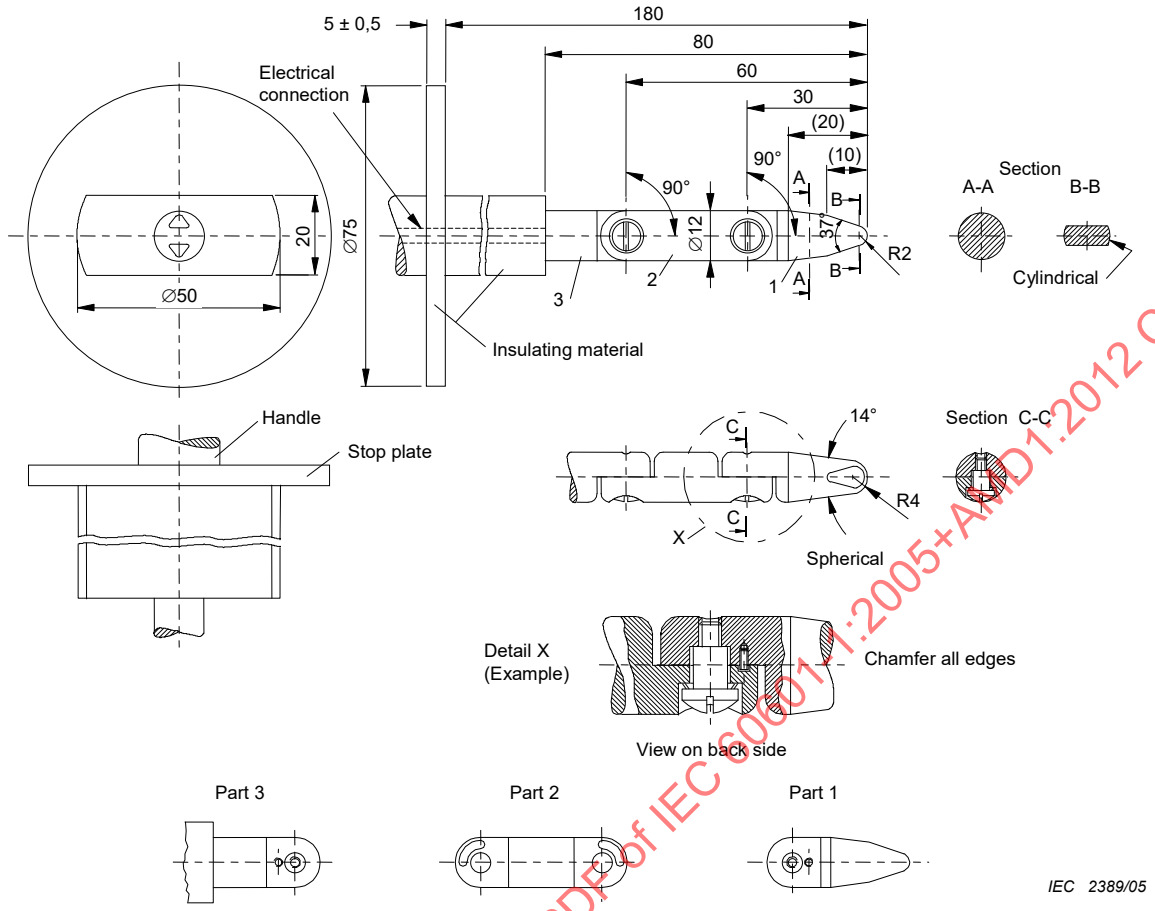
– for all positions of ME EQUIPMENT when operated as in NORMAL USE,

– even after opening of ACCESS COVERS and removal of parts, including lamps, fuses and fuseholders, without the use of a TOOL or according to the instructions for use.

The standard test finger is applied without appreciable force in every possible position, except that ME EQUIPMENT intended to be used on the floor and having a mass in any operational condition exceeding 45 kg is not tilted. ME EQUIPMENT which, according to the technical description, is intended for mounting into a cabinet, is tested in its final mounting position.

Openings preventing the entry of the standard test finger of Figure 6 are mechanically tested by means of a straight unjointed test finger of the same dimensions, which is applied with a force of 30 N. If this finger enters, the test with the standard test finger of Figure 6 is repeated, the finger being pushed through the opening if necessary.

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Linear dimensions in millimetres

Tolerances on dimensions without specific tolerances:

– 14° and 37° angles: ± 15′

– on radii: ± 0,1 mm

– on linear dimensions:

  ≤ 15 mm: $^{0}_{0,1}$ mm

  > 15 mm ≤ 25 mm: ± 0,1 mm

  > 25 mm: ± 0,3 mm

Material of finger: heat-treated steel, for example.

Both joints of this finger can be bent through an angle of 90 $^{+10°}_{0°}$ but in one and the same direction only.

NOTE 1 Using the pin and groove solution is only one of the possible approaches in order to limit the bending angle to 90°. For this reason, dimensions and tolerances of these details are not given in the drawing. The actual design must insure a 90° bending angle with a 0° to + 10° tolerance.

NOTE 2 Dimensions in parentheses are for information only.

NOTE 3 The test finger is taken from IEC 60950-1, Figure 2A. That test finger is based on IEC 61032[18)], Figure 2, test probe B. In some cases, the tolerances are different.

Figure 6 – Standard test finger
(see 5.9.2.1)

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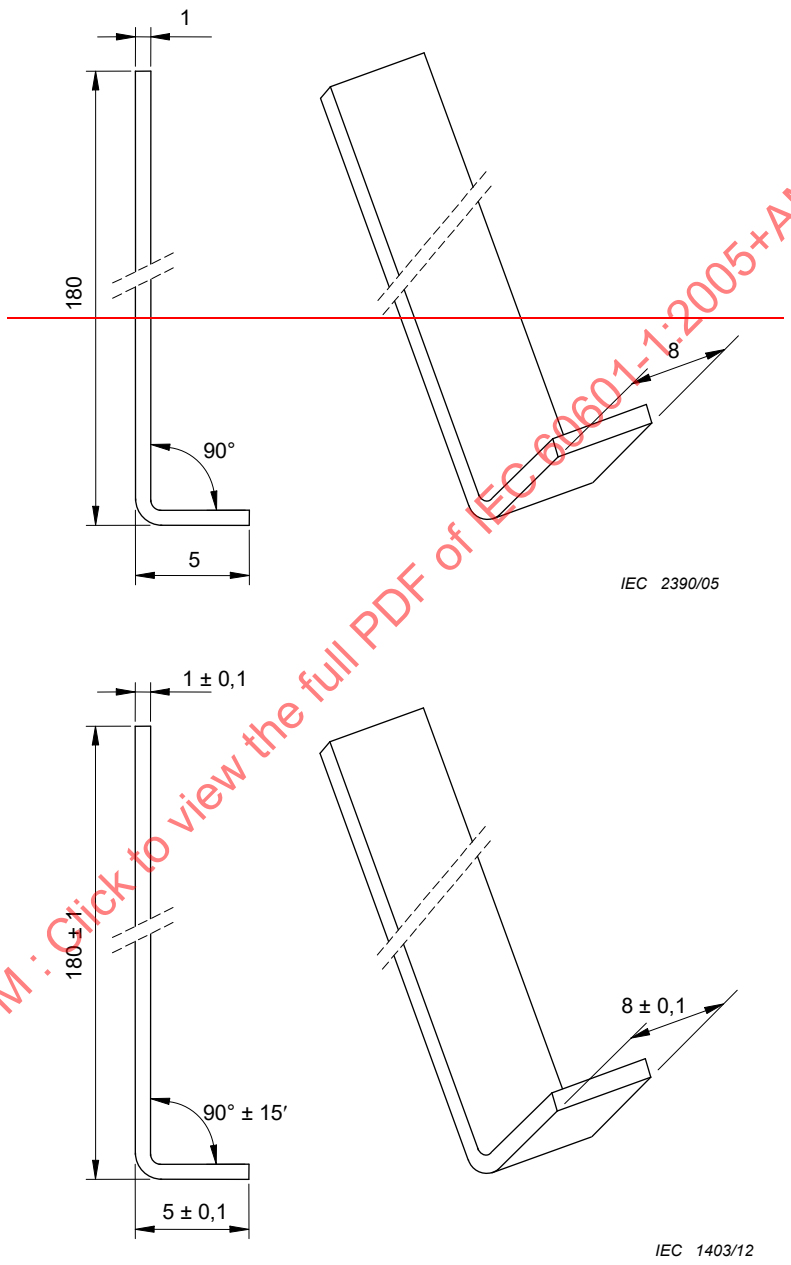
18) IEC 61032:1997, *Protection of persons and equipment by enclosures - Probes for verification*

5.9.2.2 Test hook

ME EQUIPMENT openings are mechanically tested by means of the test hook (see Figure 7), if the hook can be inserted.

The test hook is inserted in all openings in question and is subsequently pulled with a force of 20 N for 10 s and in a direction substantially perpendicular to the surface in which the relevant opening is present. Any additional parts that have become accessible are identified by using the standard test finger of Figure ~~7~~ 6 and by inspection.

Dimensions in millimetres



Material: steel

Figure 7 – Test hook
(see 5.9.2.2)

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5.9.2.3 Actuating mechanisms

Conductive parts of actuating mechanisms of electrical controls that are accessible after the removal of handles, knobs, levers and the like are regarded as ACCESSIBLE PARTS. Conductive parts of actuating mechanisms are not considered ACCESSIBLE PARTS if removal of handles, knobs, etc. requires the use of a TOOL ~~and inspection of the RISK MANAGEMENT FILE demonstrates that the relevant part is unlikely to become detached unintentionally during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. See also 15.4.6.1~~.

Compliance is checked by tests according to 5.9.2.1 and 15.4.6.1.

6 * Classification of ME EQUIPMENT and ME SYSTEMS

6.1 General

For purposes of this standard, ME EQUIPMENT, or parts thereof, including APPLIED PARTS, shall be classified as follows.

6.2 * Protection against electric shock

ME EQUIPMENT energized from an external electrical power source shall be classified as CLASS I ME EQUIPMENT or CLASS II ME EQUIPMENT (see 7.2.6). Other ME EQUIPMENT shall be classified as INTERNALLY POWERED ME EQUIPMENT.

INTERNALLY POWERED ME EQUIPMENT having a means of connection to a SUPPLY MAINS shall comply with the requirements for CLASS I ME EQUIPMENT or CLASS II ME EQUIPMENT while so connected, and with the requirements for INTERNALLY POWERED ME EQUIPMENT while not so connected.

APPLIED PARTS shall be classified as TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS (see 7.2.10 and 8.3). APPLIED PARTS may be classified as DEFIBRILLATION-PROOF APPLIED PARTS (see 8.5.5).

6.3 * Protection against harmful ingress of water or particulate matter

ENCLOSURES shall be classified according to the degree of protection against harmful ingress of water and particulate matter as detailed in IEC 60529 (see 7.2.9 and 11.6.5).

NOTE 1 This classification is IPN_1N_2, where:

– N_1 is an integer indicating degree of protection against particulate matter or the letter "X".

– N_2 is an integer indicating the degree of protection against ingress of water or the letter "X".

NOTE 2 See also Table D.3.

6.4 Method(s) of sterilization

ME EQUIPMENT or its parts intended to be sterilized shall be classified according to the method(s) of sterilization as indicated in the instructions for use (see 7.9.2.12 and 11.6.7).

EXAMPLE 1 By ethylene oxide gas

EXAMPLE 2 By irradiation such as gamma ray

EXAMPLE 3 By moist heat such as by autoclave

EXAMPLE 4 By other methods validated and described by the MANUFACTURER

6.5 Suitability for use in an OXYGEN RICH ENVIRONMENT

ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT shall be classified for such use (see 11.2.2).

6.6 * Mode of operation

ME EQUIPMENT shall be classified for either CONTINUOUS OPERATION or non-CONTINUOUS OPERATION (see 7.2.11).

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7 ME EQUIPMENT identification, marking and documents

NOTE Annex C contains a guide to assist the reader in locating the marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS contained in other clauses of this standard.

7.1 General

7.1.1 * USABILITY of the identification, marking and documents

~~The MANUFACTURER shall address in a USABILITY ENGINEERING PROCESS the RISK of poor USABILITY associated with the design of the ME EQUIPMENT's identification, marking and documents. See IEC 60601-1-6 and also see 1.3 and 12.2.~~

~~*Compliance is checked by inspection of the results of the USABILITY ENGINEERING PROCESS.*~~

See 12.2.

7.1.2 * Legibility of markings

The markings required by 7.2, 7.3, 7.4, 7.5 and 7.6 shall be CLEARLY LEGIBLE under the following conditions:

– for warning statements, instructive statements, safety signs and drawings on the outside of ME EQUIPMENT: from the intended position of the person performing the related function;

– for FIXED ME EQUIPMENT: when the ME EQUIPMENT is mounted in its position of NORMAL USE;

– for TRANSPORTABLE ME EQUIPMENT and for STATIONARY ME EQUIPMENT that is not FIXED ME EQUIPMENT: in NORMAL USE or after dislodging the ME EQUIPMENT from a wall against which it has been positioned, or after turning the ME EQUIPMENT from its position of NORMAL USE and, in the case of dismountable rack units, after their removal from the rack;

– for markings on the inside of ME EQUIPMENT or ME EQUIPMENT parts: when viewed from the intended position of the person performing the related function.

Compliance for clear legibility is checked by the following test:

The ME EQUIPMENT or its part is positioned so that the viewpoint is the intended position of the OPERATOR~~; or~~. If the intended position of the OPERATOR is not specified and the position is not obvious, the viewpoint is at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m. The ambient ~~illuminance~~ illumination is the least favourable level in the range of 100 lx to 1 500 lx.

The observer has a visual acuity, corrected if necessary, of:

– *0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20); and*

– *is able to read N6 of the Jaeger test card;*

in normal room lighting conditions (approximately 500 lx).

The observer correctly reads the marking from the viewpoint.

7.1.3 * Durability of markings

The markings required by 7.2, 7.3, 7.4, 7.5 and 7.6 shall be removable only with a TOOL or by appreciable force and shall be sufficiently durable to remain CLEARLY LEGIBLE during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. In considering the durability of the markings, the effect of NORMAL USE shall be taken into account.

Compliance is checked by inspection and the following tests:

a) *After all the tests of this standard have been performed (see the recommended sequence of tests in Annex B):*

– *markings are tested to the requirements of 7.1.2; and*

– *adhesive labels are not to have worked loose or become curled at the edges.*

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b) *For markings required by 7.2, 7.4, 7.5 and 7.6, an additional test for durability is to be performed. Markings are rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ~~methylated spirit~~ ethanol 96 % and then for 15 s with a cloth rag soaked with isopropyl alcohol.*

7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.1)

7.2.1 Minimum requirements for marking on ME EQUIPMENT and on interchangeable parts

If the size of the ME EQUIPMENT, an ME EQUIPMENT part or an ACCESSORY, or the nature of its ENCLOSURE, does not allow affixation of all markings specified in 7.2.2 to 7.2.20 (inclusive), then at least the markings as indicated in 7.2.2, 7.2.5, 7.2.6 (not for PERMANENTLY INSTALLED ME EQUIPMENT), 7.2.10 and 7.2.13 (if applicable) shall be affixed and the remaining markings shall be recorded in full in the ACCOMPANYING DOCUMENTS. Where no marking of the ME EQUIPMENT is practicable, these markings may be affixed to the individual packaging.

Any material, component, ACCESSORY or ME EQUIPMENT that is intended for a single use or its packaging shall be marked "Single Use Only", "Do Not Reuse" or with symbol ISO 7000-1051 (~~DB:~~2004-01) (see Table D.1, symbol 28).

NOTE See also 7.9.2.12.

7.2.2 * Identification

~~ME EQUIPMENT and its detachable components shall be marked with the name or trademark of the MANUFACTURER, and with a MODEL OR TYPE REFERENCE unless misidentification does not present an unacceptable RISK.~~

ME EQUIPMENT shall be marked with:

– the name or trademark and contact information of the MANUFACTURER;

– a MODEL OR TYPE REFERENCE;

– a serial number or lot or batch identifier; and

– the date of manufacture or use by date, if applicable.

NOTE See ISO 15223-1 for symbols for MANUFACTURER, serial number, lot or batch, year of manufacture and use by date.

The serial number, lot or batch identifier, and the date of manufacture may be provided in a human readable code or through automatic identification technology such as barcodes or RFID.

Detachable components of the ME EQUIPMENT shall be marked with:

– the name or trademark of the MANUFACTURER; and

– a MODEL OR TYPE REFERENCE;

unless misidentification does not result in an unacceptable RISK.

Software that forms part of a PEMS shall be identified with a unique identifier, such as revision level or date of release/issue. The identification shall be available to designated persons, e.g. SERVICE PERSONNEL. The identification ~~does not need to~~ need not be on the outside of the ME EQUIPMENT.

7.2.3 * Consult ACCOMPANYING DOCUMENTS

When appropriate, symbol ISO 7000-1641 (~~DB:~~2004-01) (see Table D.1, symbol 11) may be used to advise the OPERATOR to consult the ACCOMPANYING DOCUMENTS. When consulting the ACCOMPANYING DOCUMENTS is a mandatory action, safety sign ISO 7010-M002 (see Table D.2, safety sign 10) shall be used instead of symbol ISO 7000-1641.

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7.2.4 * ACCESSORIES

~~ACCESSORIES shall be marked with the name or trade-mark of their MANUFACTURER or supplier, and with a MODEL OR TYPE REFERENCE. Where no marking of the ACCESSORIES is practicable, these markings may be affixed to the individual packaging.~~

ACCESSORIES shall be marked with:

– the name or trade-mark and contact information of their MANUFACTURER

– a MODEL OR TYPE REFERENCE;

– a serial number or lot or batch identifier; and

– the date of manufacture or use by date, if applicable.

NOTE See ISO 15223-1 for symbols for MANUFACTURER, serial number, lot or batch, year of manufacture and use by date.

The serial number, lot or batch identifier, and the date of manufacture may be provided in a human readable code or through automatic identification technology such as barcodes or RFID.

Where no marking of the ACCESSORIES is practicable, these markings may be affixed to the individual packaging.

7.2.5 ME EQUIPMENT intended to receive power from other equipment

~~If ME EQUIPMENT is intended to receive its power from other equipment including ME EQUIPMENT in an ME SYSTEM and connection to another source could result in an unacceptable RISK, the MODEL OR TYPE REFERENCE of the specified other equipment shall be marked adjacent to the relevant connection point. See also 7.9.2.3, 8.2.1 and 16.3.~~

If ME EQUIPMENT is intended to receive its power from other electrical equipment in an ME SYSTEM and compliance with the requirements of this standard is dependent on that other equipment, one of the following shall be provided:

– the name or trademark of the manufacturer of the other electrical equipment with a MODEL OR TYPE REFERENCE of the specified other equipment adjacent to the relevant connection point;

– placing safety sign ISO 7010-M002 (see Table D.2, safety sign 10) adjacent to the relevant connection point and listing of the required details in the instructions for use; or

– using a special connector style that is not commonly available on the market and listing of the required details in the instructions for use.

See also 7.9.2.3, 8.2.1 and 16.3.

7.2.6 Connection to the SUPPLY MAINS

ME EQUIPMENT shall be marked with the following information:

– the RATED supply voltage(s) or RATED voltage range(s) to which it may be connected. A RATED supply voltage range shall have a hyphen (-) between the minimum and maximum voltages. Where multiple RATED supply voltages or multiple RATED supply voltage ranges are given, they shall be separated by a solidus (/);

EXAMPLE 1 RATED supply voltage range: 100-240 V. This means that the ME EQUIPMENT is designed to be connected to a SUPPLY MAINS having a NOMINAL voltage between 100 V and 240 V.

EXAMPLE 2 Multiple RATED supply voltage: 120/220/240 V. This means that the ME EQUIPMENT is designed to be switched to allow connection to a SUPPLY MAINS having a NOMINAL voltage of 120 V or 220 V or 240 V.

NOTE 1 Marking of RATED supply voltage is taken from IEC 61293[19].

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[19] IEC 61293:1994, *Marking of electrical equipment with ratings related to electrical supply - Safety requirements*

– nature of supply, for example, number of phases (except for single-phase supply) and type of current. Symbols IEC 60417-5032, 5032-1, 5032-2, 5031, and 5033 (all ~~DB:~~2002-10) may be used for this purpose (see Table D.1, symbols 1, 2, 3, 4 and 5);

NOTE 2 For alternating current, the RATED frequency in hertz is sufficient to identify the type of current.

– the RATED supply frequency or RATED frequency range in hertz;

EXAMPLE 3 RATED supply frequency range: 50-60 Hz. This means that the ME EQUIPMENT is designed to be connected to a SUPPLY MAINS having a NOMINAL frequency between 50 Hz and 60Hz.

– For CLASS II ME EQUIPMENT, symbol IEC 60417-5172 (~~DB:~~2003-02) (see Table D.1, symbol 9).

Except for PERMANENTLY INSTALLED ME EQUIPMENT, these markings shall appear on the outside of the part that contains the SUPPLY MAINS connection and preferably adjacent to the connection point. For PERMANENTLY INSTALLED ME EQUIPMENT, the NOMINAL supply voltage or voltage range to which it can be connected may be marked on the inside or the outside of the ME EQUIPMENT, preferably adjacent to the ~~supply connection terminals~~ SUPPLY MAINS connection.

7.2.7 Electrical input power from the SUPPLY MAINS

~~The RATED input shall be given in amperes or volt-amperes or where the power factor exceeds 0,9, in watts.~~

The RATED input from the SUPPLY MAINS shall be marked on the ME EQUIPMENT. The RATED input shall be given in:

– amperes or volt-amperes, or

– if the power factor exceeds 0,9, in amperes, volt-amperes or watts.

In the case of ME EQUIPMENT for one or several RATED voltage ranges, the RATED input shall always be given for the upper and lower limits of the range or ranges, if the range(s) is/are greater than ± 10 % of the mean value of the given range.

In the case of range limits which do not differ by more than 10 % from the mean value, marking of the input at the mean value of the range is sufficient.

If the rating of ME EQUIPMENT includes both long-time and momentary current or volt-ampere ratings, the marking shall include both long-time and the most relevant momentary volt-ampere ratings, each plainly identified and indicated in the ACCOMPANYING DOCUMENTS.

The marked input of ME EQUIPMENT provided with means for the connection of supply conductors of other electrical equipment shall include the RATED (and marked) output of such means.

7.2.8 Output connectors

7.2.8.1 Mains power output

For MULTIPLE SOCKET-OUTLETS that are integral with ME EQUIPMENT, see 16.9.2.1 b).

7.2.8.2 Other power sources

With the exception of MULTIPLE SOCKET-OUTLETS or connectors intended only for specified equipment, equipment parts or ACCESSORIES, output connectors of ME EQUIPMENT intended to deliver power shall be marked with the following information:

– RATED output voltage;

– RATED current or power (when applicable);

– output frequency (when applicable).

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7.2.9 IP classification

ME EQUIPMENT or its parts shall be marked with a symbol, using the letters IP followed by the designations described in IEC 60529, according to the classification in 6.3 (see Table D.3, Code 2).

ME EQUIPMENT classified IPX0 or IP0X need not be marked as such.

7.2.10 * APPLIED PARTS

This requirement does not apply to parts that have been identified according to 4.6.

The degree of protection against electric shock as classified in 6.2 for all APPLIED PARTS shall be marked with the relevant symbol, i.e., TYPE B APPLIED PARTS with symbol IEC 60417-5840, TYPE BF APPLIED PARTS with symbol IEC 60417-5333 or TYPE CF APPLIED PARTS with symbol IEC 60417-5335 (all ~~DB:~~2002-10) (see Table D.1, symbols 19, 20 and 21).

For DEFIBRILLATION-PROOF APPLIED PARTS, symbols IEC 60417-5841, IEC 60417-5334, or IEC 60417-5336 shall be used as applicable (all ~~DB:~~2002-10) (see Table D.1, symbols 25, 26 and 27).

The relevant symbol shall be marked adjacent to or on the connector for the APPLIED PART, unless either:

– there is no such connector, in which case the marking shall be on the APPLIED PART; or

– the connector is used for more than one APPLIED PART and the different APPLIED PARTS have different classifications, in which case each APPLIED PART shall be marked with the relevant symbol.

For clear differentiation with symbol IEC 60417-5333, symbol IEC 60417-5840 shall not be applied in such a way as to give the impression of being inscribed within a square (see Table D.1, symbols 19 and 20).

If the protection against the effect of the discharge of a cardiac defibrillator is partly in the PATIENT cable, safety sign ISO 7010-W001, shall be placed near the relevant outlet (see Table D.2, safety sign 2). The instructions for use shall explain that protection of the ME EQUIPMENT against the effects of the discharge of a cardiac defibrillator is dependent upon the use of appropriate cables.

7.2.11 Mode of operation

If no marking is provided, ME EQUIPMENT is assumed to be suitable for CONTINUOUS OPERATION. For ME EQUIPMENT intended for non-CONTINUOUS OPERATION, the DUTY CYCLE shall be indicated using an appropriate marking giving the maximum activation (on) time and the minimum deactivation (off) time.

7.2.12 * Fuses

Where the fuse-holder is an ACCESSIBLE PART, the type and full rating of the fuse (voltage, current, operating speed and breaking capacity) shall be marked adjacent to the fuse-holder.

7.2.13 Physiological effects (safety signs and warning statements)

ME EQUIPMENT producing physiological effects that are not obvious to the OPERATOR and can cause HARM to the PATIENT or OPERATOR shall bear a suitable safety sign (see 7.5). The safety sign shall appear in a prominent location so that it will be CLEARLY LEGIBLE in NORMAL USE after the ME EQUIPMENT has been PROPERLY INSTALLED.

The instructions for use shall describe the nature of the HAZARD and the precautions for avoiding it or minimising the associated RISK.

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7.2.14 HIGH VOLTAGE TERMINAL DEVICES

HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT that are accessible without the use of a TOOL shall be marked with symbol IEC 60417-5036 (~~DB:~~2002-10) (see Table D.1, symbol 24).

NOTE CREEPAGE DISTANCES and AIR CLEARANCES between the high voltage contacts and the standard test finger are subject to the requirements in 8.9.

7.2.15 Cooling conditions

Requirements for cooling provisions for ME EQUIPMENT (for example, supply of water or air) shall be marked.

7.2.16 Mechanical stability

For requirements on ME EQUIPMENT with a limited stability, see 9.4.

7.2.17 Protective packaging

If special handling measures have to be taken during transport or storage, the packaging shall be marked accordingly (see ISO 780).

The permissible environmental conditions for transport and storage shall be marked on the outside of the packaging (see 7.9.3.1 and ISO 15223-1).

Where premature unpacking of ME EQUIPMENT or its parts could result in an unacceptable RISK, the packaging shall be marked with a suitable safety sign (see 7.5).

EXAMPLE 1 Humidity sensitive ME EQUIPMENT.

EXAMPLE 2 ME EQUIPMENT containing hazardous substances and materials.

The packaging of ME EQUIPMENT or ACCESSORIES supplied sterile shall be marked as sterile and indicate the method of sterilization (see ISO 15223-1).

7.2.18 External pressure source

~~The RATED maximum supply pressure from an external source shall be marked on the ME EQUIPMENT adjacent to each input connector.~~

Adjacent to each input connector, the ME EQUIPMENT shall be marked with:

– the RATED maximum supply pressure from an external source, and

– the RATED flow rate if required to maintain BASIC SAFETY or ESSENTIAL PERFORMANCE.

7.2.19 FUNCTIONAL EARTH TERMINALS

A FUNCTIONAL EARTH TERMINAL shall be marked with symbol IEC 60417-5017 (~~DB:2002-10~~ 2006-08) (see Table D.1, symbol 7).

7.2.20 Removable protective means

If ME EQUIPMENT has alternative applications that require the removal of a protective means to use a particular function, the protective means shall be marked to indicate the necessity for replacement when the relevant function is no longer needed. No marking is required when an interlock is provided.

Compliance with the requirements of 7.2 is checked by inspection and by application of the tests and criteria in 7.1.2 and 7.1.3.

7.2.21 * Mass of MOBILE ME EQUIPMENT

MOBILE ME EQUIPMENT shall be marked with its mass including its SAFE WORKING LOAD in kilograms. The marking shall be done in a way that it is obvious that it applies to the whole of

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the MOBILE ME EQUIPMENT when loaded with its SAFE WORKING LOAD and is separate and distinct from any markings related to maximum bin, shelf or drawer loading requirements.

7.3 Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.2)

7.3.1 Heating elements or lampholders

The maximum power loading of heating elements or lampholders designed for use with heating lamps shall be marked near the heater or in the heater itself.

For heating elements or lampholders designed for use with heating lamps that can be changed only by SERVICE PERSONNEL with the use of a TOOL, an identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS is sufficient.

7.3.2 * HIGH VOLTAGE parts

The presence of HIGH VOLTAGE parts shall be marked with symbol IEC 60417-5036 (~~DB:~~2002-10) (see Table D.1, symbol 24) or with safety sign 3 (see Table D.2, safety sign 3). See also 7.5.

7.3.3 Batteries

The type of battery and the mode of insertion (if applicable) shall be marked (see 15.4.3.2).

For batteries intended to be changed only by SERVICE PERSONNEL with the use of a TOOL, an identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS is sufficient.

Where lithium batteries or fuel cells are incorporated and where incorrect replacement would result in an unacceptable RISK, a warning indicating that replacement by inadequately trained personnel could result in a HAZARD (such as excessive temperatures, fire or explosion) shall be given in addition to the identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS.

7.3.4 * Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES

Fuses and replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES that are accessible only by the use of a TOOL shall be identified either by ~~type and full rating~~ specification adjacent to the component (voltage, current, operating speed, size, breaking capacity), or by a reference to information in the ACCOMPANYING DOCUMENTS.

The nomenclature of IEC 60127-1 may be used.

7.3.5 * PROTECTIVE EARTH TERMINALS

PROTECTIVE EARTH TERMINALS shall be marked with symbol IEC 60417-5019 (~~DB:2002-10~~ 2006-08) (see Table D.1, symbol 6) unless the PROTECTIVE EARTH TERMINAL is in an APPLIANCE INLET according to IEC 60320-1.

Markings that are on or adjacent to PROTECTIVE EARTH TERMINALS shall not be affixed to parts that have to be removed to make the connection. They shall remain visible after the connection has been made.

7.3.6 FUNCTIONAL EARTH TERMINALS

FUNCTIONAL EARTH TERMINALS shall be marked with symbol IEC 60417-5017 (~~DB:2002-10~~ 2006-08) (see Table D.1, symbol 7).

7.3.7 Supply terminals

Terminals for supply conductors shall be marked adjacent to the terminals unless it can be demonstrated that no ~~HAZARDOUS SITUATION~~ unacceptable RISK an result if connections are interchanged.

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If ME EQUIPMENT is so small that the terminal markings cannot be affixed, they shall be included in the ACCOMPANYING DOCUMENTS.

Terminals that are provided exclusively for the connection of the neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT shall be marked with the appropriate code from IEC 60445 (see Table D.3, Code 1).

If marking for connection to a three-phase supply is necessary, it shall be according to IEC 60445.

Markings that are on or adjacent to electrical connection points shall not be affixed to parts that have to be removed to make the connection. They shall remain visible after the connection has been made.

7.3.8 Temperature of supply terminals

If any point within a terminal box or wiring compartment intended for connection of the power supply conductors for PERMANENTLY INSTALLED ME EQUIPMENT (including such conductors themselves), attains a temperature of more than 75 °C during NORMAL USE and NORMAL CONDITION at the maximum ambient operating temperature as indicated in the technical description (see 7.9.3.1), the ME EQUIPMENT shall be marked with the following or an equivalent statement:

"For supply connections, use wiring materials suitable for at least X °C."

where "X" is greater than the maximum temperature measured in the terminal box or wiring compartment in NORMAL USE and NORMAL CONDITION. This statement shall be located at or near the point where the supply connections are to be made. This statement shall not be affixed to parts that have to be removed to make the connection. It shall be CLEARLY LEGIBLE after the connections have been made.

Compliance with the requirements of 7.3 is checked by inspection and by application of the tests and criteria in 7.1.2 and 7.1.3.

7.4 Marking of controls and instruments (see also Table C.3)

7.4.1 * Power switches

Switches used to control power to ME EQUIPMENT or its parts, including mains switches, shall have their "on" and "off" positions:

– marked with symbols IEC 60417-5007 (~~DB:~~2002-10) and IEC 60417-5008 (~~DB:~~2002-10) (see Table D.1, symbols 12 and 13); or
– indicated by an adjacent indicator light; or
– indicated by other unambiguous means.

If a push button with bistable positions is used:

– it shall be marked with symbol IEC 60417-5010 (~~DB:~~2002-10) (see Table D.1, symbol 14); and
– the status shall be indicated by an adjacent indicator light; or
– the status shall be indicated by other unambiguous means.

If a push button with momentary on position is used:

– it shall be marked with symbol 60417-5011 (~~DB:~~2002-10) (see Table D.1, symbol 15); or
– the status shall be indicated by an adjacent indicator light; or
– the status shall be indicated by other unambiguous means.

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7.4.2 * Control devices

Different positions of control devices and different positions of switches on ME EQUIPMENT shall be indicated by figures, letters or other visual means, e.g. by use of symbols IEC 60417-5264 (~~DB:~~2002-10) and IEC 60417-5265 (~~DB:~~2002-10) (see Table D.1, symbols 16 and 17).

If in NORMAL USE, the change of setting of a control could result in an unacceptable RISK to the PATIENT, such controls shall be provided with either:

– an associated indicating device, e.g. instruments or scale, or

– an indication of the direction in which the magnitude of the function changes. See also 15.4.6.2.

A control device or switch that brings the ME EQUIPMENT into the "stand-by" condition may be indicated by use of symbol IEC 60417-5009 (2002-10) (see Table D.1, Symbol 29).

7.4.3 Units of ~~measure~~ measurement

Numeric indications of parameters on ME EQUIPMENT shall be expressed in SI units according to ISO ~~31~~ 80000-1 except the base quantities listed in Table 1 may be expressed in the indicated units, which are outside the SI units system.

For application of SI units, their multiples and certain other units, ISO ~~1000~~ 80000-1 applies.

Compliance with the requirements of 7.4 is checked by inspection and by application of the tests and criteria in 7.1.2 and 7.1.3.

Table 1 – Units outside the SI units system that may be used on ME EQUIPMENT

Base quantity	Unit	
	Name	Symbol
Plane angle	revolution	r
	gon	gon or grade
	degree	°
	minute of angle	′
	second of angle	″
Time	minute	min
	hour	h
	day	d
Energy	electron volt	eV
Volume	litre	l [a]
Pressure of respiratory gases, blood, and other body fluids	millimetres of mercury	mmHg
	centimetres of water	cmH_2O
Pressure of gases	bar	bar
	millibar	mbar

[a] For consistency, in international standards only the symbol "l" is used for litre, although the symbol "L" is also given in ISO ~~31~~ 80000-1.

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7.5 Safety signs

For the purpose of this clause, markings used to convey a warning, prohibition or mandatory action that mitigates a RISK that is not obvious to the OPERATOR shall be a safety sign selected from ISO 7010. If a safety sign with an established meaning is appropriately used, the use of the general warning sign ISO 7010:2003-W001 (see Table D.2, safety sign 2) is not required.

NOTE 1 In this context, warning is used to mean, "There is certain danger"; prohibition is used to mean, "You must not..."; and mandatory action is used to mean, "You must...".

Where a safety sign is not available to indicate a particular desired meaning, the meaning may be obtained by one of the following methods.

a) Constructing a safety sign according to ISO 3864-1:2002, Clause 7 (for the corresponding templates, see Table D.2, safety signs 1, 4 and 8).

b) Using the general warning sign ISO 7010:2003-W001 (see Table D.2, safety sign 2) placed together with a supplementary symbol or text. The text associated with the general warning sign shall be an affirmative statement (i.e., a safety notice) describing the principal RISK(S) foreseen (e.g. "Causes burns", "Risk of explosion", etc.).

c) Using the general prohibition sign ISO 7010:2003-P001 (see Table D.2, safety sign 4) placed together with a supplementary symbol or text. The text associated with the general prohibition sign shall be a statement (i.e. a safety notice) describing what is prohibited (e.g. "Do not open", "Do not drop", etc.).

d) Using the general mandatory action sign ISO 7010:2003-M001 (see Table D.2, safety sign 9) placed together with a supplementary symbol or text. The text associated with the general mandatory action sign shall be a command (i.e. a safety notice) describing required action (e.g. "Wear protective gloves", "Scrub before entering", etc.).

If there is insufficient space to place the affirmative statement together with the safety sign on the ME EQUIPMENT, it may be placed in the instructions for use.

NOTE 2 The colours for safety signs are specified in ISO 3864-1 and it is important to use the specified colour.

NOTE 3 A safety notice should include the appropriate precautions or include instructions on how to reduce the RISK (e.g. "Do not use for . . . ", "Keep away from . . .", etc.).

Safety signs, including any supplementary symbol or text, shall be explained in the instructions for use (see 7.9.2).

When supplementary text is placed together with safety signs, the supplementary text shall be in a language that is acceptable to the intended OPERATOR.

NOTE 4 In some countries, more than one language is required.

Compliance is checked by inspection.

7.6 Symbols

7.6.1 Explanation of symbols

The meanings of the symbols used for marking shall be explained in the instructions for use.

7.6.2 Symbols from Annex D

Symbols required by this standard shall conform to the requirements in the referenced IEC or ISO publication. Annex D provides the symbol graphic and description for these symbols as a quick reference.

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7.6.3 Symbols for controls and performance

Symbols used for controls and performance shall conform to the requirements of the IEC or ISO publication where the symbol is defined, when applicable. See also 7.2.13.

NOTE IEC 60878 [60] provides a survey of titles, descriptions and graphical representations of symbols for electrical equipment used in medical practice.

Compliance with the requirements of 7.6 is checked by inspection.

7.7 Colours of the insulation of conductors

7.7.1 PROTECTIVE EARTH CONDUCTOR

A PROTECTIVE EARTH CONDUCTOR shall be identified throughout its length by green and yellow coloured insulation.

7.7.2 PROTECTIVE EARTH CONNECTIONS

Any insulation on conductors inside ME EQUIPMENT that form PROTECTIVE EARTH CONNECTIONS shall be identified by the colours green and yellow at least at the termination of the conductors.

EXAMPLE Conductors of a multi-conductor cord that are connected in parallel, where the maximum allowed resistance of the PROTECTIVE EARTH CONNECTIONS would be exceeded if only the green and yellow coloured conductor were used.

7.7.3 Green and yellow insulation

Identification by green and yellow insulation shall only be used for:

– PROTECTIVE EARTH CONDUCTORS (see 8.6.2);

– conductors as specified in 7.7.2;

NOTE In other safety standards such as IEC 60950-1, internal connections between conductive parts and the main protective earth are called protective bonding conductors.

– POTENTIAL EQUALIZATION CONDUCTORS (see 8.6.7);

– FUNCTIONAL EARTH CONDUCTORS (see 8.6.9).

7.7.4 Neutral conductor

Conductors in POWER SUPPLY CORDS intended to be connected to the neutral conductor of the supply system shall be coloured “light blue” as specified in IEC 60227-1 or in IEC 60245-1.

7.7.5 POWER SUPPLY CORD conductors

Colours of conductors in POWER SUPPLY CORDS shall be in accordance with IEC 60227-1 or with IEC 60245-1.

Compliance with the requirements of 7.7 is checked by inspection.

7.8 * Indicator lights and controls

7.8.1 Colours of indicator lights

The colours of indicator lights and their meanings shall comply with Table 2.

NOTE IEC 60601-1-8 contains specific requirement for the colour, flashing frequency and DUTY CYCLE of alarm indicator lights.

Dot-matrix and other alphanumeric displays are not considered to be indicator lights.

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Table 2 – Colours of indicator lights and their meaning for ME EQUIPMENT

Colour	Meaning
Red	Warning – immediate response by the OPERATOR is required
Yellow	Caution – prompt response by the OPERATOR is required
Green	Ready for use
Any other colour	Meaning other than that of red, yellow or green

7.8.2 Colours of controls

The colour red shall be used only for a control by which a function is interrupted in case of emergency.

Compliance with the requirements of 7.8 is checked by inspection. See also 15.4.4.

7.9 ACCOMPANYING DOCUMENTS

7.9.1 * General (see also Table C.4)

ME EQUIPMENT shall be accompanied by documents containing at least the instructions for use and a technical description. The ACCOMPANYING DOCUMENTS shall be regarded as a part of the ME EQUIPMENT.

NOTE The purpose of the ACCOMPANYING DOCUMENTS is to promote the safe use of the ME EQUIPMENT during its EXPECTED SERVICE LIFE.

The ACCOMPANYING DOCUMENTS shall identify the ME EQUIPMENT by including, as applicable, the following:

– name or trade-name of the MANUFACTURER and ~~an address~~ contact information to which the RESPONSIBLE ORGANIZATION can refer;

– MODEL OR TYPE REFERENCE (see 7.2.2).

ACCOMPANYING DOCUMENTS may be provided electronically, e.g. electronic file format on CD-ROM. If the ACCOMPANYING DOCUMENTS are provided electronically, the ~~RISK MANAGEMENT PROCESS~~ USABILITY ENGINEERING PROCESS shall include consideration of which information also needs to be provided as hard copy or as markings on the ME EQUIPMENT~~, e.g. to cover emergency operation~~ (see 12.2).

EXAMPLE Information to cover emergency operation

NOTE ACCOMPANYING DOCUMENTS provided electronically might not be acceptable in all jurisdictions.

The ACCOMPANYING DOCUMENTS shall specify any special skills, training and knowledge required of the intended OPERATOR or the RESPONSIBLE ORGANIZATION and any restrictions on locations or environments in which the ME EQUIPMENT can be used.

The ACCOMPANYING DOCUMENTS shall be written at a level consistent with the education, training and any special needs of the person(s) for whom they are intended.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS, and, when provided electronically, as specified in IEC 60601-1-6.

7.9.2 Instructions for use (see also Table C.5)

7.9.2.1 * General

The instructions for use shall document:

– the use of the ME EQUIPMENT as intended by the MANUFACTURER,

– the frequently used functions; ~~and~~

– any known contraindication(s) to the use of the ME EQUIPMENT; and

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– those parts of the ME EQUIPMENT that shall not be serviced or maintained while in use with a PATIENT.

Where the PATIENT is an intended OPERATOR, the instructions for use shall indicate:

– the PATIENT is an intended OPERATOR;
– a warning against servicing and maintenance while the ME EQUIPMENT is in use;
– which functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and
– which maintenance the PATIENT can perform (e.g. changing batteries).

NOTE 1 For ME EQUIPMENT where the INTENDED USE includes the PATIENT partially or fully operating the ME EQUIPMENT, the PATIENT becomes an OPERATOR.

NOTE 2 For ME EQUIPMENT where the PATIENT is allowed to perform restricted maintenance, the PATIENT becomes SERVICE PERSONNEL.

The instructions for use shall indicate:

– the name or trademark and address of the MANUFACTURER;
– the MODEL OR TYPE REFERENCE.

The instructions for use shall include all applicable classifications specified in Clause 6, all markings specified in 7.2, and the explanation of safety signs and symbols (marked on the ME EQUIPMENT).

NOTE ~~1~~ 3 The instructions for use are intended for the OPERATOR and the RESPONSIBLE ORGANIZATION and should contain only the information most likely to be useful to the OPERATOR or RESPONSIBLE ORGANIZATION. Additional details can be contained in the technical description. See also 7.9.3.

NOTE ~~2~~ 4 Guidance on the preparation of instructions for use is found in IEC 62079 [25]. Guidance on the preparation of educational materials for ME EQUIPMENT is found in IEC/TR 61258 [24].

The instructions for use shall be in a language that is acceptable to the intended OPERATOR.

NOTE 5 In some countries, more than one language is required.

7.9.2.2 * Warning and safety notices

The instructions for use shall include all warning and safety notices.

NOTE General warnings and safety notices should be placed in a specifically identified section of the instructions for use. A warning or safety notice that applies only to a specific instruction or action should precede the instruction to which it applies.

For CLASS I ME EQUIPMENT, the instructions for use shall include a warning statement to the effect: “WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.”

The instructions for use shall provide the OPERATOR or RESPONSIBLE ORGANIZATION with warnings regarding any significant RISKS of reciprocal interference posed by the presence of the ME EQUIPMENT during specific investigations or treatments.

The instructions for use shall include information regarding potential electromagnetic or other interference between the ME EQUIPMENT and other devices together with advice on ways to avoid or minimize such interference.

If the ME EQUIPMENT is provided with an integral MULTIPLE SOCKET-OUTLET, the instructions for use shall provide a warning statement that connecting electrical equipment to the MSO effectively leads to creating an ME SYSTEM and the result can be a reduced level of safety. For the requirements that are applicable to an ME SYSTEM, the RESPONSIBLE ORGANIZATION shall be referred to this standard.

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7.9.2.3 ME EQUIPMENT specified for connection to a separate power supply

If ME EQUIPMENT is intended for connection to a separate power supply, either the power supply shall be specified as part of the ME EQUIPMENT or the combination shall be specified as an ME SYSTEM. The instructions for use shall state this specification.

7.9.2.4 Electrical power source

For mains-operated ME EQUIPMENT with an additional power source not automatically maintained in a fully usable condition, the instructions for use shall include a warning statement referring to the necessity for periodic checking or replacement of such an additional power source.

If leakage from a battery would result in an unacceptable RISK, the instructions for use shall include a warning to remove the battery if the ME EQUIPMENT is not likely to be used for some time.

If an INTERNAL ELECTRICAL POWER SOURCE is replaceable, the instructions for use shall state its specification.

If loss of the power source would result in an unacceptable RISK, the instructions for use shall contain a warning that the ME EQUIPMENT must be connected to an appropriate power source.

EXAMPLE Internal or external battery, uninterruptible power supply (UPS) or institutional stand-by generator.

7.9.2.5 ME EQUIPMENT description

The instructions for use shall include:

– a brief description of the ME EQUIPMENT;

– how the ME EQUIPMENT functions; and

– the significant physical and performance characteristics of the ME EQUIPMENT.

If applicable, this description shall include the expected positions of the OPERATOR, PATIENT and other persons near the ME EQUIPMENT in NORMAL USE (see 9.2.2.3).

The instructions for use shall include information on the materials or ingredients to which the PATIENT or OPERATOR is exposed if such exposure can constitute an unacceptable RISK (see 11.7).

The instructions for use shall specify any restrictions on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected.

The instructions for use shall indicate any APPLIED PART.

7.9.2.6 * Installation

If installation of the ME EQUIPMENT or its parts is required, the instructions for use shall contain:

– a reference to where the installation instructions are to be found (e.g. the technical description), or

– contact information for persons designated by the MANUFACTURER as qualified to perform the installation.

7.9.2.7 * Isolation from the SUPPLY MAINS

If an APPLIANCE COUPLER or MAINS PLUG or other separable plug is used as the isolation means to satisfy 8.11.1 a), the instructions for use shall contain an instruction not to position the ME EQUIPMENT so that it is difficult to operate the disconnection device.

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7.9.2.8 Start-up PROCEDURE

The instructions for use shall contain the necessary information for the OPERATOR to bring the ME EQUIPMENT into operation including such items as any initial control settings, connection to or positioning of the PATIENT, etc.

The instructions for use shall detail any treatment or handling needed before the ME EQUIPMENT, its parts, or ACCESSORIES can be used.

EXAMPLE A pre-use checklist.

7.9.2.9 Operating instructions

The instructions for use shall contain all information necessary to operate the ME EQUIPMENT in accordance with its specification. This shall include explanation of the functions of controls, displays and signals, the sequence of operation, and connection and disconnection of detachable parts and ACCESSORIES, and replacement of material that is consumed during operation.

The meanings of figures, symbols, warning statements, abbreviations and indicator lights on ME EQUIPMENT shall be explained in the instructions for use.

7.9.2.10 Messages

The instructions for use shall list all system messages, error messages and fault messages that are generated, unless these messages are self-explanatory.

NOTE 1 These lists can be identified in groups.

The list shall include an explanation of messages including important causes, and possible action(s) by the OPERATOR, if any, that are necessary to resolve the situation indicated by the message.

NOTE 2 Requirements and guidelines for messages generated by an alarm system are found in IEC 60601-1-8.

7.9.2.11 Shutdown PROCEDURE

The instructions for use shall contain the necessary information for the OPERATOR to safely terminate the operation of the ME EQUIPMENT.

7.9.2.12 Cleaning, disinfection and sterilization

For ME EQUIPMENT parts or ACCESSORIES that can become contaminated through contact with the PATIENT or with body fluids or expired gases during NORMAL USE, the instructions for use shall contain:

– details about cleaning and disinfection or sterilization methods that may be used; and

– list the applicable parameters such as temperature, pressure, humidity, time limits and number of cycles that such ME EQUIPMENT parts or ACCESSORIES can tolerate.

See also 11.6.6 and 11.6.7.

This requirement does not apply to any material, component, ACCESSORY or ME EQUIPMENT that is marked as intended for a single use unless the MANUFACTURER specifies that the material, component, ACCESSORY or ME EQUIPMENT is to be cleaned, disinfected or sterilized before use (see 7.2.1).

7.9.2.13 Maintenance

The instructions for use shall instruct the OPERATOR or RESPONSIBLE ORGANIZATION in sufficient detail concerning preventive inspection, maintenance and calibration to be performed by them, including the frequency of such maintenance.

The instructions for use shall provide information for the safe performance of such routine maintenance necessary to ensure the continued safe use of the ME EQUIPMENT.

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Additionally, the instructions for use shall identify the parts on which preventive inspection and maintenance shall be performed by SERVICE PERSONNEL, including the periods to be applied, but not necessarily including details about the actual performance of such maintenance.

For ME EQUIPMENT containing rechargeable batteries that are intended to be maintained by anyone other than SERVICE PERSONNEL, the instructions for use shall contain instructions to ensure adequate maintenance.

7.9.2.14 ACCESSORIES, supplementary equipment, used material

The instructions for use shall include a list of ACCESSORIES, detachable parts and materials that the MANUFACTURER has determined are intended for use with the ME EQUIPMENT.

If ME EQUIPMENT is intended to receive its power from other equipment in an ME SYSTEM, the instructions for use shall sufficiently specify such other equipment to ensure compliance with the requirements of this standard (e.g. part number, RATED voltage, maximum or minimum power, protection class, intermittent or continuous ~~service~~ duty).

NOTE What was referred to in the first and second editions of this standard as a "specified power supply" is considered either as another part of the same ME EQUIPMENT or as other equipment in an ME SYSTEM. Similarly, a battery charger is considered either as part of the ME EQUIPMENT or as other equipment in an ME SYSTEM.

7.9.2.15 Environmental protection

~~The instructions for use shall:~~

~~– identify any RISKS associated with the disposal of waste products, residues, etc. and of the ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE; and~~

~~– provide advice on minimizing these RISKS.~~

The instructions for use shall provide advice on the proper disposal of waste products, residues, etc. and of the ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE.

7.9.2.16 Reference to the technical description

The instructions for use shall contain the information specified in 7.9.3 or a reference to where the material specified in 7.9.3 is to be found (e.g. in a service manual).

7.9.2.17 ME EQUIPMENT emitting radiation

For ME EQUIPMENT emitting radiation for medical purposes, when appropriate, the instructions for use shall indicate the nature, type, intensity and distribution of this radiation.

7.9.2.18 ME EQUIPMENT and ACCESSORIES supplied sterile

The instructions for use for ME EQUIPMENT or ACCESSORIES supplied sterile shall indicate that they have been sterilized and indicate the method of sterilization.

The instructions for use shall indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization (see also 7.9.2.12).

7.9.2.19 * Unique version identifier

The instructions for use shall contain a unique version identifier such as its date of issue.

EXAMPLE Month and year.

Compliance with the requirements of 7.9.2 is checked by inspection of the instructions for use in a language of an intended OPERATOR.

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7.9.3 Technical description (see also Table C.6)

7.9.3.1 * General

The technical description shall provide all data that is essential for safe operation, transport and storage, and measures or conditions necessary for installing the ME EQUIPMENT, and preparing it for use. This shall include:

– the permissible environmental conditions of use including conditions for transport and storage. See also 7.2.17;

– all characteristics of the ME EQUIPMENT, including range(s), accuracy, and precision of the displayed values or an indication where they can be found;

– any special installation requirements such as the maximum permissible apparent impedance of SUPPLY MAINS;

NOTE 1 The apparent impedance of the SUPPLY MAINS is the sum of the impedance of the distribution network plus the impedance of the power source.

– if liquid is used for cooling, the permissible range of values of inlet pressure and flow, and the chemical composition of the cooling liquid;

– a description of the means of isolating the ME EQUIPMENT from the SUPPLY MAINS, if such means is not incorporated in the ME EQUIPMENT (see 8.11.1 b));

– if applicable, a description of the means for checking the oil level in partially sealed oil-filled ME EQUIPMENT or its parts (see 15.4.9);

– a warning statement that addresses the HAZARDS that can result from unauthorized modification of the ME EQUIPMENT, e.g. a statement to the effect:

- "WARNING: No modification of this equipment is allowed."
- "WARNING: Do not modify this equipment without authorization of the manufacturer."
- "WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment."

– information pertaining to ESSENTIAL PERFORMANCE and any necessary recurrent ESSENTIAL PERFORMANCE and BASIC SAFETY testing including details of the means, methods and recommended frequency.

NOTE 2 This information is directly derived from the ESSENTIAL PERFORMANCE identified by the MANUFACTURER in 4.3.

If the technical description is separable from the instructions for use, it shall contain:

– all applicable classifications specified in Clause 6, any warning and safety notices and the explanation of safety signs (marked on the ME EQUIPMENT);

– a brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and

– a unique version identifier such as its date of issue.

NOTE ~~2~~ 3 The technical description is intended for the RESPONSIBLE ORGANIZATION and SERVICE PERSONNEL.

The MANUFACTURER may designate the minimum qualifications for SERVICE PERSONNEL. If present, these requirements shall be documented in the technical description.

NOTE ~~3~~ 4 Some authorities with jurisdiction impose additional requirements for qualification of SERVICE PERSONNEL.

7.9.3.2 Replacement of fuses, POWER SUPPLY CORDS and other parts

The technical description shall contain, as applicable, the following:

– the required type and full rating of fuses used in the SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT, if the type and rating of these fuses are not apparent from the information concerning RATED current and mode of operation of ME EQUIPMENT;

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– for ME EQUIPMENT having a non-DETACHABLE POWER SUPPLY CORD, a statement as to whether the POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and if so, instructions for correct connection and anchoring to ensure that the requirements of 8.11.3 will continue to be met;

– instructions for correct replacement of interchangeable or detachable parts that the MANUFACTURER specifies as replaceable by SERVICE PERSONNEL; and

– where replacement of a component could result in an unacceptable RISK, appropriate warnings that identify the nature of the HAZARD and, if the MANUFACTURER specifies the component as replaceable by SERVICE PERSONNEL, all information necessary to safely replace the component.

7.9.3.3 Circuit diagrams, component part lists, etc.

The technical description shall contain a statement that the MANUFACTURER will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist SERVICE PERSONNEL to repair those parts of ME EQUIPMENT that are designated by the MANUFACTURER as repairable by SERVICE PERSONNEL.

7.9.3.4 * Mains isolation

The technical description shall clearly identify any means used to comply with the requirements of 8.11.1.

Compliance with the requirements of 7.9.3 is checked by inspection of the technical description.

8 * Protection against electrical HAZARDS from ME EQUIPMENT

8.1 Fundamental rule of protection against electric shock

The limits specified in 8.4 shall not be exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL CONDITION or SINGLE FAULT CONDITION. For other HAZARDOUS SITUATIONS in SINGLE FAULT CONDITION, see 13.1.

a) * NORMAL CONDITION includes all of the following simultaneously:

– the presence on any SIGNAL INPUT/OUTPUT PART of any voltage or current from other electrical equipment that is permitted to be connected according to the ACCOMPANYING DOCUMENTS as specified in 7.9, or, if the ACCOMPANYING DOCUMENTS place no restrictions on such other electrical equipment, the presence of the MAXIMUM MAINS VOLTAGE as specified in 8.5.3;

– transposition of supply connections, for ME EQUIPMENT intended for connection to a SUPPLY MAINS by means of a MAINS PLUG;

– short circuit of any or all insulation that does not comply with the requirements of 8.8;

– short circuit of any or all CREEPAGE DISTANCES or AIR CLEARANCES that do not comply with the requirements of 8.9;

– open circuit of any or all earth connections that do not comply with the requirements of 8.6, including any functional earth connection.

b) * SINGLE FAULT CONDITION includes:

– short circuit of any one insulation that complies with the requirements for one MEANS OF PROTECTION as specified in 8.8;

NOTE This includes short circuiting of either constituent part of DOUBLE INSULATION that complies with 8.8.

– short circuit of any one CREEPAGE DISTANCE or AIR CLEARANCE that complies with the requirements for one MEANS OF PROTECTION as specified in 8.9;

– short circuit and open circuit of any component other than a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS that is connected in parallel with insulation, with an AIR

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CLEARANCE or with a CREEPAGE DISTANCE unless shorting can be shown not to be a failure mode for the component (see also 4.8 and 4.9);

– open circuit of any one PROTECTIVE EARTH CONDUCTOR or internal PROTECTIVE EARTH CONNECTION that complies with the requirements of 8.6: this does not apply to a PROTECTIVE EARTH CONDUCTOR of PERMANENTLY INSTALLED ME EQUIPMENT, which is considered unlikely to become disconnected;

– interruption of any one supply conductor, except for the neutral conductor of polyphase ME EQUIPMENT or PERMANENTLY INSTALLED ME EQUIPMENT;

– interruption of any one power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES, if ~~the RISK ANALYSIS indicates that~~ this condition might cause permitted limits to be exceeded;

– unintended movement of a component~~; but only if the component is not mounted securely enough to ensure that such movement will be very unlikely to occur during the EXPECTED SERVICE LIFE of the ME EQUIPMENT, as determined by the RISK MANAGEMENT PROCESS~~ (see ~~also~~ 8.10.1);

– accidental detachment of conductors and connectors where breaking free could lead to a HAZARDOUS SITUATION. See also 8.10.2.

Determination of which parts are ACCESSIBLE PARTS is performed in accordance with 5.9.

LEAKAGE CURRENTS are measured in accordance with 8.7.

8.2 Requirements related to power sources

8.2.1 Connection to a separate power source

If ME EQUIPMENT is specified for connection to a separate power source, other than the SUPPLY MAINS, either the separate power source shall be considered as part of the ME EQUIPMENT and all relevant requirements of this standard shall apply, or the combination shall be considered as an ME SYSTEM. See also 7.2.5, 7.9.2.14, 5.5 f) and Clause 16.

NOTE What was formerly referred to, in the first and second editions of this standard, as a "specified power supply" is now considered either as another part of the same ME EQUIPMENT or as another electrical equipment in an ME SYSTEM.

Compliance is checked by inspection and by testing as specified in 5.5 f). If a particular separate power supply is specified then the relevant tests are performed with the ME EQUIPMENT connected to it. If a generic separate power supply is specified, then the specification in the ACCOMPANYING DOCUMENTS is inspected.

8.2.2 Connection to an external d.c. power source

If ME EQUIPMENT is specified for power supplied from an external d.c. power source, ~~no HAZARDOUS SITUATION, other than absence of its intended function, shall develop when a connection with the wrong polarity is made~~ then a connection with the wrong polarity shall not lead to the HAZARDOUS SITUATIONS described in 13.1. The ME EQUIPMENT, when connection is subsequently made with the correct polarity, shall ~~provide freedom from unacceptable RISK~~ maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.

Protective devices that can be reset by anyone without the use of a TOOL are acceptable provided ~~that these restore correct operation~~ the ME EQUIPMENT returns to NORMAL CONDITION on reset.

NOTE 1 See also 11.8.

NOTE 2 The external d.c. power source can be a SUPPLY MAINS or another item of electrical equipment. In the latter case, the combination is considered to be an ME SYSTEM as specified in 8.2.1.

~~*Compliance is checked by inspection and, if necessary, by functional tests.*~~

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8.3 Classification of APPLIED PARTS

a) * An APPLIED PART that is specified in the ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION shall be a TYPE CF APPLIED PART.

NOTE See the rationale for the definition of DIRECT CARDIAC APPLICATION (3.22) concerning the APPLIED PARTS that need to be TYPE CF APPLIED PARTS. Other restrictions can apply for cardiac applications.

Compliance is checked by inspection.

b) * An APPLIED PART that includes a PATIENT CONNECTION that is intended to deliver electrical energy or an electrophysiological signal to or from the PATIENT shall be a TYPE BF APPLIED PART or TYPE CF APPLIED PART.

Compliance is checked by inspection.

c) An APPLIED PART not covered by a) or b) shall be a TYPE B APPLIED PART, TYPE BF APPLIED PART or TYPE CF APPLIED PART.

Compliance is checked by inspection.

~~d) * For a part that is identified according to 4.6 as needing to be subject to the requirements for an APPLIED PART (except for marking), the requirements for a TYPE B APPLIED PART shall apply unless the RISK MANAGEMENT PROCESS identifies a need for the requirements for a TYPE BF APPLIED PART or TYPE CF APPLIED PART to apply.~~

8.4 Limitation of voltage, current or energy

8.4.1 * PATIENT CONNECTIONS intended to deliver current

The limits specified in 8.4.2 do not apply to currents that are intended to flow through the body of the PATIENT to produce a physiological effect during NORMAL USE.

8.4.2 ACCESSIBLE PARTS ~~including~~ and APPLIED PARTS

a) The currents from, to or between PATIENT CONNECTIONS shall not exceed the limits for PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT specified in Table 3 and Table 4 when measured as specified in 8.7.4.

Compliance is checked by measurement according to 8.7.4.

b) * The LEAKAGE CURRENTS from, to or between ACCESSIBLE PARTS ~~other than PATIENT CONNECTIONS~~ shall not exceed the limits for TOUCH CURRENT specified in 8.7.3 c) when measured as specified in 8.7.4.

Compliance is checked by measurement according to 8.7.4.

c) * The limits specified in b) above do not apply to the following parts if the probability of a connection to a PATIENT, either directly or through the body of the OPERATOR, through which a current exceeding the allowable TOUCH CURRENT could flow, is negligible in NORMAL USE, and the instructions for use instruct the OPERATOR not to touch the relevant part and the PATIENT simultaneously:

– accessible contacts of connectors;
– contacts of fuseholders that are accessible during replacement of the fuse;
– contacts of lampholders that are accessible after removal of the lamp;
– parts inside an ACCESS COVER that can be opened without the use of a TOOL, or where a TOOL is needed but the instructions for use instruct any OPERATOR other than SERVICE PERSONNEL to open the relevant ACCESS COVER.

EXAMPLE 1 Illuminated push-buttons

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EXAMPLE 2 Indicator lamps

EXAMPLE 3 Recorder pens

EXAMPLE 4 Parts of plug-in modules

EXAMPLE 5 Batteries

For such parts, the voltage to earth or to other ACCESSIBLE PARTS shall not exceed 42,4 V peak a.c. or 60 V d.c. in NORMAL CONDITION or in SINGLE FAULT CONDITION. The d.c. limit of 60 V applies to d.c. with not more than 10 % peak-to-peak ripple. If the ripple exceeds that amount, the 42,4 V peak limit applies. The energy shall not exceed 240 VA for longer than 60 s or the stored energy available shall not exceed 20 J at a potential ~~up to 2 V~~ of 2 V or more.

NOTE If voltages higher than the limits specified in 8.4.2 c) are present, the LEAKAGE CURRENT limits referred to in 8.4.2 b) apply.

Compliance is checked by inspection of ~~the RISK MANAGEMENT FILE, by reference to~~ the instructions for use and by measurement.

d) * The voltage and energy limits specified in c) above also apply to:

– internal parts, other than contacts of plugs, connectors and socket-outlets, that can be touched by the test pin shown in Figure 8 inserted through an opening in an ENCLOSURE; and

– internal parts that can be touched by a metal test rod with a diameter of $4\ ^{0}_{-0,05}$ mm and a length of $100\ ^{+0,5}_{0}$ mm, inserted through any opening in the top of an ENCLOSURE or through any opening provided for the adjustment of pre-set controls that ~~may~~ can be adjusted by the RESPONSIBLE ORGANIZATION in NORMAL USE by using a TOOL.

See also 8.9.4 concerning the measurement of CREEPAGE DISTANCES and AIR CLEARANCES through slots or openings in external parts to the standard test finger.

Compliance is checked by inserting the test pin or the test rod through relevant openings. The test pin is inserted in every possible position with minimal force (not more than 1 N).

The test rod is inserted in every possible position through openings provided for the adjustment of pre-set controls that can be adjusted by the RESPONSIBLE ORGANIZATION in NORMAL USE, in case of doubt with a force of 10 N.

If the instructions for use specify that a particular TOOL is to be used, the test is repeated with that TOOL.

The test rod is also freely and vertically suspended through any opening in the top of an ENCLOSURE.

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Dimensions in millimetres

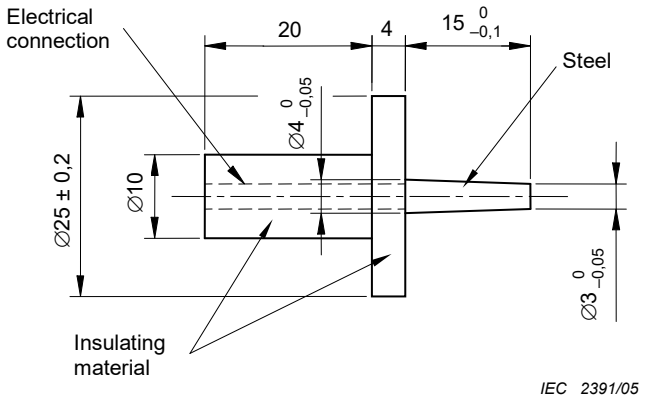


Figure 8 – Test pin
(see 8.4.2 d)

e) Where an ACCESS COVER that can be opened without the use of a TOOL gives access to parts that are at voltages above the levels permitted by this subclause, but these parts are automatically de-energized when the ACCESS COVER is opened, the device(s) used to de-energize the parts shall meet the requirements specified in 8.11.1 for mains isolating switches and shall remain effective in SINGLE FAULT CONDITION. If it is possible to prevent these devices from operating, a TOOL shall be required.

Compliance is checked by inspection.

8.4.3 * ME EQUIPMENT intended to be connected to a power source by a plug

ME EQUIPMENT or its parts intended to be connected to a power source by means of a plug shall be so designed that 1 s after disconnection of the plug the voltage between the pins of the plug and between either supply pin and the ENCLOSURE does not exceed 60 V or, if this value is exceeded, the stored charge does not exceed 45 μC.

Compliance is checked by the following test:

ME EQUIPMENT is operated at RATED voltage or at the upper limit of the RATED voltage range.

ME EQUIPMENT is disconnected from the power source with any relevant switch in the "On" and "Off" positions.

Either the ME EQUIPMENT is disconnected from the power source by means of the plug, in which case the test is performed as many times as necessary to allow the worst case to be measured, or a triggering circuit is used to ensure that disconnection occurs at the peak of the supply voltage waveform.

The voltage between the pins of the plug and between any pin and the ENCLOSURE is measured 1 s after disconnection with an instrument the internal impedance of which does not affect the test significantly.

NOTE An example of a measuring arrangement that is considered acceptable is an oscilloscope and probe having an input impedance consisting of a resistance of 100 MΩ ± 5 MΩ in parallel with an input capacitance of 20 pF ± 5 pF.

The stored charge can be measured or calculated by any convenient method.

Where appropriate, a d.c. input voltage equal to the peak of the RATED SUPPLY MAINS voltage may be used.

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8.4.4 * Internal capacitive circuits

Conductive parts of capacitive circuits that become accessible after ME EQUIPMENT has been de-energized and ACCESS COVERS as present in NORMAL USE have been removed immediately thereafter, shall not have a residual voltage exceeding 60 V, or, if this value is exceeded, shall not have a stored charge exceeding 45 μC.

If automatic discharging is not reasonably possible and ACCESS COVERS can be removed only with the aid of a TOOL, a device that is included and which permits manual discharging is acceptable. The capacitor(s) or the connected circuitry shall then be marked with symbol IEC 60417-5036 (~~DB:~~2002-10) (see Table D.1, symbol 24) and the non-automatic discharging device shall be specified in the technical description.

Compliance is checked by the following test:

ME EQUIPMENT is operated at RATED voltage and then de-energized. Any ACCESS COVERS present in NORMAL USE are removed as quickly as normally possible. Immediately thereafter, the residual voltage on any accessible capacitors or circuit parts is measured and the stored charge calculated.

If a non-automatic discharging device is specified in the technical description, its inclusion and marking are ascertained by inspection.

8.5 Separation of parts

8.5.1 * MEANS OF PROTECTION (MOP)

8.5.1.1 General

ME EQUIPMENT shall have two MEANS OF PROTECTION to prevent APPLIED PARTS and other ACCESSIBLE PARTS from exceeding the limits specified in 8.4.

Each MEANS OF PROTECTION shall be categorized as a MEANS OF PATIENT PROTECTION or a MEANS OF OPERATOR PROTECTION, taking account of 4.6. See also Figure A.12.

Varnishing, enamelling, oxidation and similar protective finishes, as well as covering with sealing compounds that can replasticize at temperatures to be expected during operation (including sterilization), shall not be regarded as a MEANS OF PROTECTION.

NOTE Coatings and other insulation that are intended as a MEANS OF PROTECTION and that comply with IEC 60950-1:~~2001~~2005 ~~are acceptable~~ may be used as a MEANS OF OPERATOR PROTECTION but not automatically as a MEANS OF PATIENT PROTECTION. For MEANS OF PATIENT PROTECTION, considerations can arise as a result of the RISK MANAGEMENT PROCESS.

Components and wiring forming a MEANS OF PROTECTION shall comply with the relevant requirements of 8.10.

Any insulation, CREEPAGE DISTANCE, AIR CLEARANCES, component or earth connection that does not comply with the requirements of 8.5.1.2 and 8.5.1.3 shall not be considered as a MEANS OF PROTECTION. Failure of any or all such parts shall be regarded as NORMAL CONDITION.

Compliance is checked by the test in 8.5.1.3.

8.5.1.2 * MEANS OF PATIENT PROTECTION (MOPP)

Solid insulation forming a MEANS OF PATIENT PROTECTION shall comply with the dielectric strength test according to 8.8 at the test voltage specified in Table 6.

CREEPAGE DISTANCES and AIR CLEARANCES forming a MEANS OF PATIENT PROTECTION shall comply with the limits specified in Table 12.

PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION shall comply with the requirements and tests of 8.6.

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~~A Y1 capacitor complying with IEC 60384-14 is considered equivalent to one MEANS OF PATIENT PROTECTION provided that it will pass the dielectric strength test for two MEANS OF PATIENT PROTECTION. Where two capacitors are used in series, they shall each be RATED for the total WORKING VOLTAGE across the pair and shall have the same NOMINAL capacitance.~~

A Y capacitor (Y1 or Y2 only) complying with IEC 60384-14 is considered equivalent to one MEANS OF PATIENT PROTECTION. Where two capacitors are used in series, they shall be identical in type (either both Y1 or both Y2) and shall have the same NOMINAL capacitance. The capacitor(s) shall meet the dielectric strength for the type of protection for which they are being used (i.e. one or two MEANS OF PATIENT PROTECTION).

Where the working voltage across a barrier forming a MEANS OF PATIENT PROTECTION is less than 42,4 V peak a.c. or 60 V d.c., a single Y1 capacitor is acceptable for two MEANS OF PATIENT PROTECTION.

Compliance is checked by the test in 8.5.1.3.

8.5.1.3 MEANS OF OPERATOR PROTECTION (MOOP)

Solid insulation forming a MEANS OF OPERATOR PROTECTION shall:

– comply with the dielectric strength test according to 8.8 at the test voltage specified in Table 6; or

– comply with the requirements of IEC 60950-1 for INSULATION CO-ORDINATION.

CREEPAGE DISTANCES and AIR CLEARANCES forming a MEANS OF OPERATOR PROTECTION shall:

– comply with the limits specified in Table 13 to Table 16 (inclusive); or

– comply with the requirements of IEC 60950-1 for INSULATION CO-ORDINATION.

PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION shall either:

– comply with the requirements of 8.6; or

– comply with the requirements and tests of IEC 60950-1 for protective earthing.

~~A Y2 capacitor complying with IEC 60384-14 is considered equivalent to one MEANS OF OPERATOR PROTECTION provided that it will pass the dielectric strength test for one MEANS OF OPERATOR PROTECTION. A Y1 capacitor complying with IEC 60384-14 is considered equivalent to two MEANS OF OPERATOR PROTECTION provided that it will pass the dielectric strength test for two MEANS OF OPERATOR PROTECTION. Where two capacitors are used in series, they shall each be RATED for the total WORKING VOLTAGE across the pair and shall have the same NOMINAL capacitance.~~

A Y capacitor (Y1 or Y2 only) complying with IEC 60384-14 is considered equivalent to one MEANS OF OPERATOR PROTECTION. Where two capacitors are used in series, they shall be identical in type (either both Y1 or both Y2) and shall have the same NOMINAL capacitance. The capacitor(s) shall meet the dielectric strength for the type of protection for which they are being used (i.e. one or two MEANS OF OPERATOR PROTECTION). A Y1 capacitor can be used for two MEANS OF OPERATOR PROTECTION.

Compliance ~~with 8.5.1.1 to 8.5.1.3 (inclusive)~~ is checked by examination of the physical and electrical configuration of the ME EQUIPMENT to identify points at which insulation, CREEPAGE DISTANCES, AIR CLEARANCES, impedances of components or PROTECTIVE EARTH CONNECTIONS prevent ACCESSIBLE PARTS or APPLIED PARTS from exceeding the limits specified in 8.4.

NOTE Such points typically include insulation between parts different from earth potential and ACCESSIBLE PARTS or APPLIED PARTS but can also include, for example, insulation between a floating circuit and earth or other circuits. A survey of insulation paths is found in Annex J.

For each such point, it is determined whether:

– *solid insulation complies with the dielectric strength test according to 8.8 or, for a MEANS OF OPERATOR PROTECTION, with the requirements of IEC 60950-1 for INSULATION CO-ORDINATION;*

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– *CREEPAGE DISTANCES and AIR CLEARANCES are as specified in 8.9 or, for a MEANS OF OPERATOR PROTECTION, with the requirements of IEC 60950-1 for INSULATION CO-ORDINATION;*

– *components that are connected in parallel with an insulation, with an AIR CLEARANCE or with a CREEPAGE DISTANCE comply with 4.8 and 8.10.1;*

– *PROTECTIVE EARTH CONNECTIONS comply with the requirements of 8.6 or, for a MEANS OF OPERATOR PROTECTION, with the requirements of IEC 60950-1 for protective earthing;*

and hence whether a failure at that point is to be regarded as a NORMAL CONDITION or as a SINGLE FAULT CONDITION.

Each MEANS OF PROTECTION is categorized in relation to the ME EQUIPMENT part(s) which it protects from exceeding permitted limits. It is a MEANS OF PATIENT PROTECTION if it protects APPLIED PARTS or parts that are identified according to 4.6 as needing to be subject to the same requirements as APPLIED PARTS. Otherwise it is a MEANS OF OPERATOR PROTECTION.

The WORKING VOLTAGE is determined by inspection, calculation or measurement, according to 8.5.4.

The voltage, current or energy that can appear between any ACCESSIBLE PART or APPLIED PART and any other ACCESSIBLE PART, APPLIED PART or earth in NORMAL CONDITION and in SINGLE FAULT CONDITION is determined by inspection or calculation or, where necessary, by measurement in the relevant conditions.

8.5.2 Separation of PATIENT CONNECTIONS

8.5.2.1 * F-TYPE APPLIED PARTS

The PATIENT CONNECTION(S) of any F-TYPE APPLIED PART shall be separated from all other parts, including the PATIENT CONNECTION(S) of other APPLIED PARTS, by means equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAXIMUM MAINS VOLTAGE and shall comply with the specified limit for PATIENT LEAKAGE CURRENT with 110 % of the MAXIMUM MAINS VOLTAGE applied.

A single F-TYPE APPLIED PART may include multiple functions, in which case separation between such functions is not required.

If there is no electrical separation between PATIENT CONNECTION(S) of the same or another function (e.g. between ECG electrode and pressure catheter), then these PATIENT CONNECTION(S) are treated as one APPLIED PART.

Whether multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS is as defined by the MANUFACTURER.

The classification as TYPE BF, TYPE CF or DEFIBRILLATION-PROOF applies to the whole of one APPLIED PART.

Compliance is checked by inspection, by the LEAKAGE CURRENT tests of 8.7.4, by the dielectric strength test of 8.8.3 and by measurement of relevant CREEPAGE DISTANCES and AIR CLEARANCES.

NOTE The separation means between an F-TYPE APPLIED PART and other parts are subject both to these tests, related to the MAXIMUM MAINS VOLTAGE, and to tests related to the voltages present within the respective circuits as specified in 8.5.4. Depending on the magnitude of the latter voltages, one set of tests or the other could be more stringent.

Any protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and the ENCLOSURE for the purpose of providing protection against excessive voltages shall not operate below 500 V r.m.s.

Compliance is checked by testing the operating voltage of the protective device.

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8.5.2.2 * TYPE B APPLIED PARTS

The PATIENT CONNECTION(S) of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED shall be separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS that are not PROTECTIVELY EARTHED, unless:

– the metal ACCESSIBLE PART is physically contiguous with the APPLIED PART and can be regarded as a part of the APPLIED PART; and

– the RISK that the metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low.

Compliance is checked by inspection, by the LEAKAGE CURRENT tests of 8.7.4, by the dielectric strength test of 8.8.3, by measurement of relevant CREEPAGE DISTANCES and AIR CLEARANCES, and by reference to the RISK MANAGEMENT FILE.

8.5.2.3 * PATIENT leads or PATIENT cables

Any connector for electrical connections on a PATIENT lead that:

– is at the end of the lead or cable that is remote from the PATIENT; and

– contains a conductive part that is not separated from all PATIENT CONNECTION(S) by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAXIMUM MAINS VOLTAGE.

shall be constructed so that the said part cannot become connected to earth or possible hazardous voltage while the PATIENT CONNECTION(S) contact the PATIENT.

NOTE Where the phrase "said part" is mentioned in this subclause, it refers to the "...conductive part of the connector that is not separated from all PATIENT CONNECTIONS...." from the first sentence of this subclause.

In particular:

– the said part shall not come into contact with a flat conductive plate of not less than 100 mm diameter;

– the AIR CLEARANCE between connector pins and a flat surface shall be at least 0,5 mm;

– if able to be plugged into a mains socket, the said part shall be protected from making contact with parts at MAINS VOLTAGE by insulating means providing a CREEPAGE DISTANCE of at least 1,0 mm and a dielectric strength of 1 500 V and complying with 8.8.4.1;

– the straight unjointed test finger with the same dimensions as the standard test finger of Figure 6 shall not make electrical contact with the said part if applied in the least favourable position against the access openings with a force of 10 N, unless the RISK MANAGEMENT PROCESS demonstrates that no unacceptable RISK exists from contact with objects other than a mains socket or a flat surface (e.g. corners or edges).

Compliance is checked by inspection and test as required.

8.5.3 * MAXIMUM MAINS VOLTAGE

The MAXIMUM MAINS VOLTAGE shall be determined as follows:

– for single-phase or d.c. SUPPLY MAINS powered ME EQUIPMENT, including INTERNALLY POWERED ME EQUIPMENT that also has a means of connection to a SUPPLY MAINS, the MAXIMUM MAINS VOLTAGE is the highest RATED supply voltage; unless this is less than 100 V, in which case the MAXIMUM MAINS VOLTAGE is 250 V;

– for polyphase ME EQUIPMENT, the MAXIMUM MAINS VOLTAGE is the highest RATED phase to neutral supply voltage;

– for other INTERNALLY POWERED ME EQUIPMENT, the MAXIMUM MAINS VOLTAGE is 250 V.

8.5.4 * WORKING VOLTAGE

The WORKING VOLTAGE for each MEANS OF PROTECTION shall be determined as follows:

– The input supply voltage to the ME EQUIPMENT shall be the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value.

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– For d.c. voltages with superimposed ripple, the WORKING VOLTAGE is the average value if the peak-to-peak ripple does not exceed 10 % of the average value or the peak voltage if the peak-to-peak ripple exceeds 10 % of the average value.

– The WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION is the voltage to which the DOUBLE INSULATION as a whole is subjected.

– For WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth, the situation in which the PATIENT is earthed (intentionally or accidentally) is regarded as a NORMAL CONDITION.

– The WORKING VOLTAGE between the PATIENT CONNECTION(S) of an F-TYPE APPLIED PART and the ENCLOSURE is taken as the highest voltage appearing across the insulation in NORMAL USE including earthing of any part of the APPLIED PART. See also 8.5.2.1.

– For DEFIBRILLATION-PROOF APPLIED PARTS, the WORKING VOLTAGE is determined without regard to the possible presence of defibrillation voltages. See also 8.5.5 and 8.9.1.15.

– In the case of motors provided with capacitors where a resonance voltage can occur between the point where a winding and a capacitor are connected together on the one hand and any terminal for external conductors on the other hand, the WORKING VOLTAGE shall be equal to the resonance voltage.

8.5.5 DEFIBRILLATION-PROOF APPLIED PARTS

8.5.5.1 * Defibrillation protection

The classification DEFIBRILLATION-PROOF APPLIED PART shall apply to the whole of one APPLIED PART.

~~NOTE 1 This requirement does not apply to separate functions of the same APPLIED PART but the possibility of an OPERATOR receiving a shock from such parts should be considered in the RISK MANAGEMENT PROCESS.~~

See 8.9.1.15 for the requirements for CREEPAGE DISTANCES and AIR CLEARANCES associated with a DEFIBRILLATION-PROOF APPLIED PART.

Arrangements used to isolate the PATIENT CONNECTION(S) of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT shall be so designed that:

a) During a discharge of a cardiac defibrillator to a PATIENT connected to a DEFIBRILLATION-PROOF APPLIED PART, hazardous electrical energies, as determined by the peak voltage measured between the points Y_1 and Y_2 of Figure 9 and Figure 10 exceeding 1 V, do not appear on:

   – the ENCLOSURE, including connectors in PATIENT leads and cables when connected to the ME EQUIPMENT;

     NOTE ~~2~~ 1 This requirement does not apply to a connecting lead from a DEFIBRILLATION-PROOF APPLIED PART or its connector when it is disconnected from the ME EQUIPMENT.

   – any SIGNAL INPUT/OUTPUT PART;

   – metal foil for test on which the ME EQUIPMENT is placed and which has an area at least equal to the base of the ME EQUIPMENT; ~~or~~

   – PATIENT CONNECTIONS of any other APPLIED PART (whether or not classified as a DEFIBRILLATION-PROOF APPLIED PART); or

   – any unused or disconnected connections of the APPLIED PART under test or any function of the same APPLIED PART. ME EQUIPMENT that is completely BODY-WORN (e.g. a Holter monitor) is exempt from this requirement.

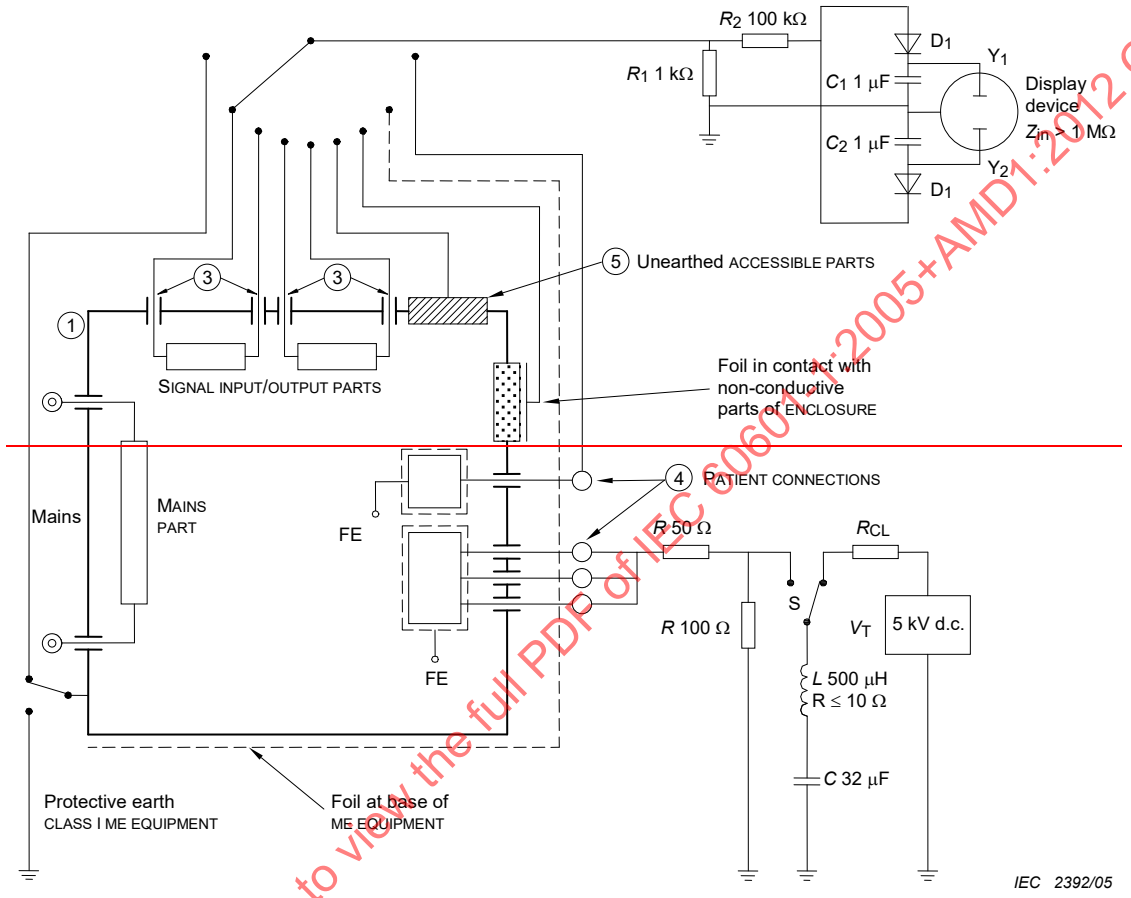
b) Following exposure to the defibrillation voltage, and any necessary recovery time stated in the ACCOMPANYING DOCUMENTS, the ME EQUIPMENT shall comply with relevant requirements of this standard and shall continue to provide BASIC SAFETY and ESSENTIAL PERFORMANCE.

Compliance is checked by the following tests, for each DEFIBRILLATION-PROOF APPLIED PART in turn.

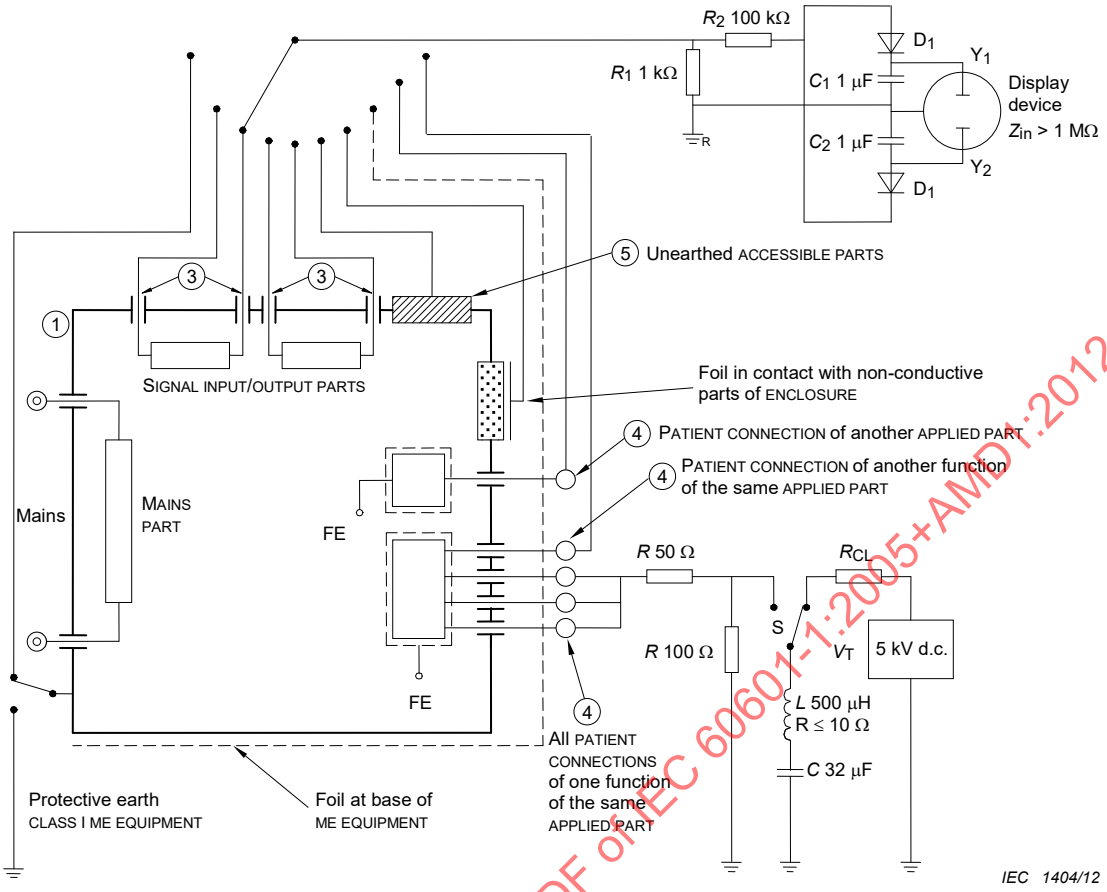
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- ***Common-mode test***

The ME EQUIPMENT is connected to the test circuit as shown in Figure 9. The test voltage is applied to all the PATIENT CONNECTIONS of the DEFIBRILLATION-PROOF APPLIED PART connected together, excluding any that are PROTECTIVELY EARTHED or functionally earthed. If an APPLIED PART has multiple functions, the test voltage is applied to all the PATIENT CONNECTIONS of one function at a time with the other functions disconnected.



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For legends, see Table 5.

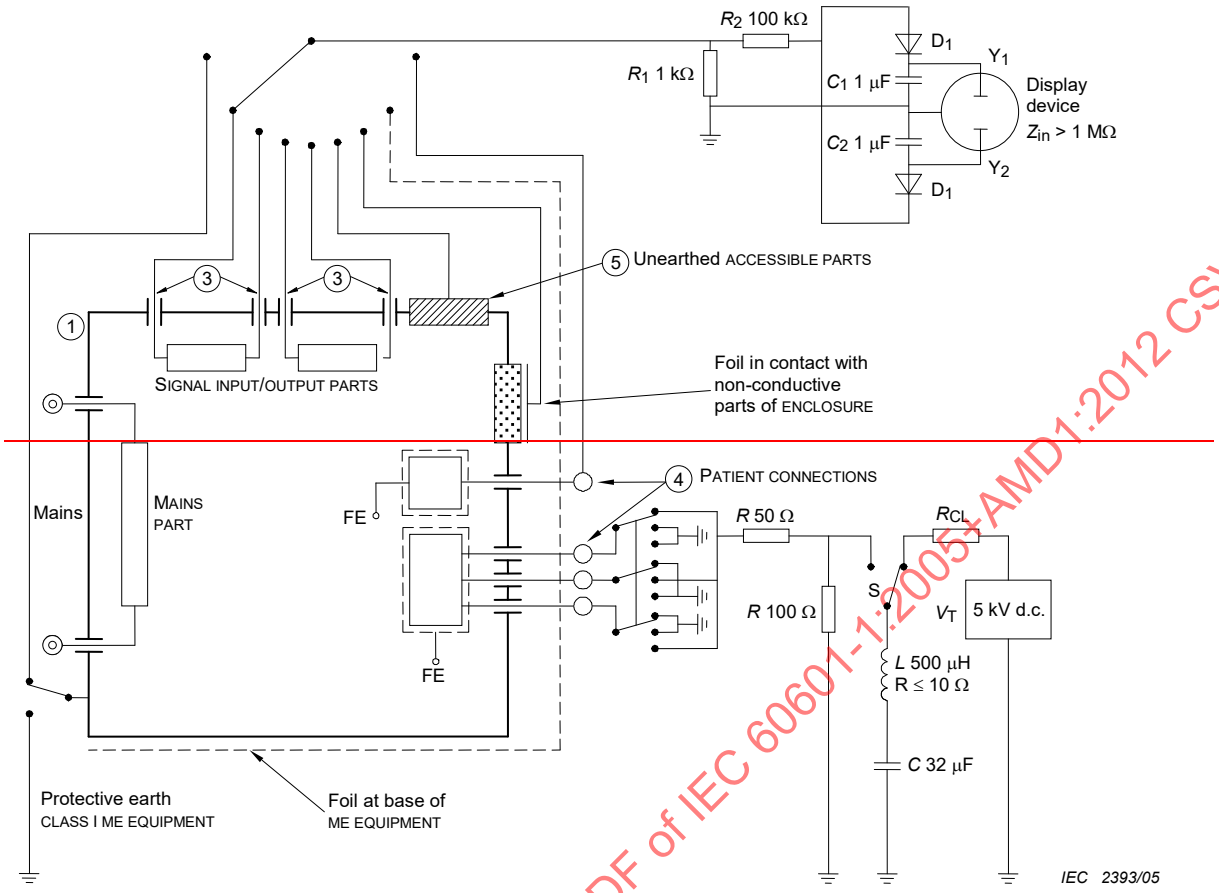
Components

V_T	Test voltage
S	Switch for applying the test voltage
R_1, R_2	Tolerance at ± 2 %, not less than 2 kV
R_{CL}	Current limiting resistor
D_1, D_2	Small signal silicon diodes

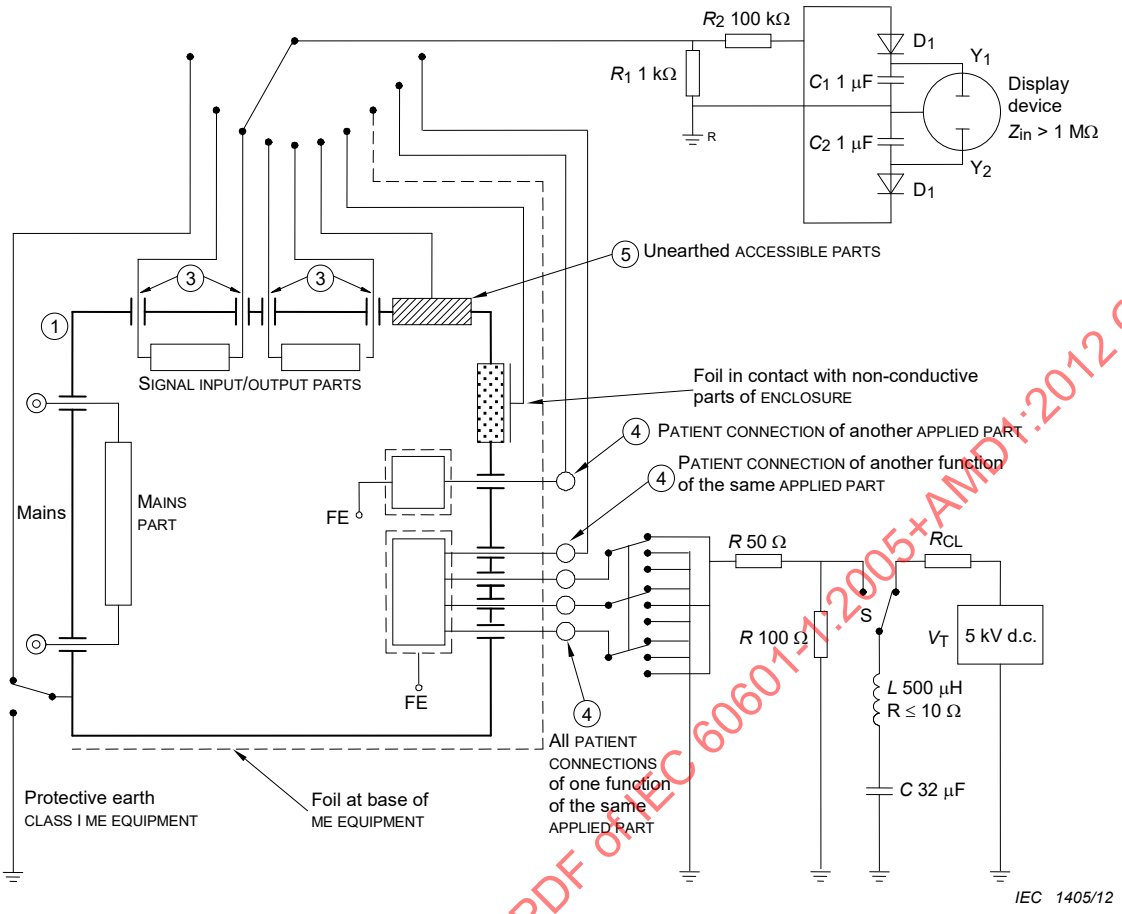
Other components toleranced at ± 5 %

Figure 9 – Application of test voltage to bridged PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS
(see 8.5.5.1)

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For legends, see Table 5.

Components

V_T	Test voltage
S	Switch for applying the test voltage
R_1, R_2	Tolerance at ± 2 %, not less than 2 kV
R_{CL}	Current limiting resistor
D_1, D_2	Small signal silicon diodes

Other components toleranced at ± 5 %

Figure 10 – Application of test voltage to individual PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS
(see 8.5.5.1)

- ***Differential-mode test***

The ME EQUIPMENT is connected to the test circuit as shown in Figure 10. The test voltage is applied to each PATIENT CONNECTION of the DEFIBRILLATION-PROOF APPLIED PART in turn with all the remaining PATIENT CONNECTIONS of the same DEFIBRILLATION-PROOF APPLIED PART being connected to earth.

NOTE 2 The differential-mode test is not used when the APPLIED PART consists of a single PATIENT CONNECTION.

During the above tests:

– *except for PERMANENTLY INSTALLED ME EQUIPMENT, the ME EQUIPMENT is to be tested with and without the PROTECTIVE EARTH CONDUCTOR connected (i.e. two separate tests);*

– *insulating surfaces of APPLIED PARTS are covered with metal foil or, where appropriate, immersed in a 0,9 % saline solution;*

– *any external connection to a FUNCTIONAL EARTH TERMINAL is removed;*

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– *parts specified 8.5.5.1 a) that are not PROTECTIVELY EARTHED are connected in turn to a display device;*

– *the ME EQUIPMENT is connected to the SUPPLY MAINS and operated in accordance with the instructions for use.*

After the operation of S, the peak voltage between the points Y_1 and Y_2 is measured. Each test is repeated with V_T reversed.

After any recovery time stated in the ACCOMPANYING DOCUMENTS, determine that the ME EQUIPMENT continues to provide BASIC SAFETY and ESSENTIAL PERFORMANCE.

8.5.5.2 Energy reduction test

DEFIBRILLATION-PROOF APPLIED PARTS or PATIENT CONNECTIONS of DEFIBRILLATION-PROOF APPLIED PARTS shall incorporate a means so that the defibrillator energy delivered to a 100 Ω load is at least 90 % of the energy delivered to this load with the ME EQUIPMENT disconnected.

Compliance is checked by the following test:

The test circuit is shown in Figure 11. For this test, the ACCESSORIES such as cables, electrodes and transducers that are recommended in the instructions for use (see 7.9.2.14) are used. The test voltage is applied to each PATIENT CONNECTION or APPLIED PART in turn with all the remaining PATIENT CONNECTIONS of the same APPLIED PART being connected to earth (differential mode). Other DEFIBRILLATION PROOF APPLIED PARTS, if any, are tested separately, in turn.

The PROCEDURE is as follows.

a) *Connect the APPLIED PART or PATIENT CONNECTION to the test circuit. The parts described in 8.5.5.1 a) are connected to earth.*

b) *Charge capacitor C to 5 kV d.c. with switch S in position A.*

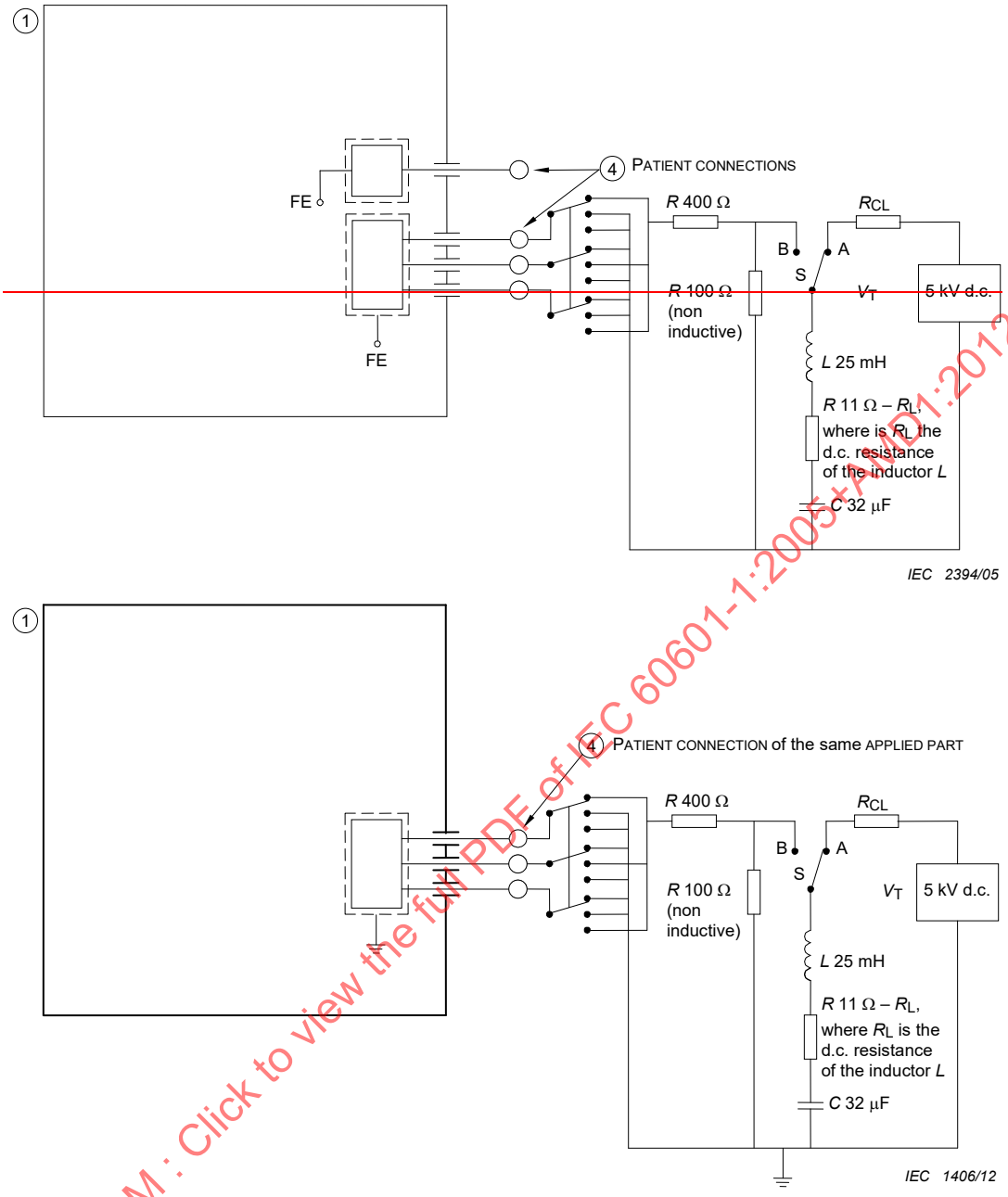
c) *Discharge capacitor C by actuating the switch S to position B, and measure the energy E_1 delivered to the 100 Ω load.*

d) *Remove the ME EQUIPMENT under test from the test circuit and repeat steps b) and c) above, measuring the energy E_2 delivered to the 100 Ω load.*

e) *Verify that the energy E_1 is at least 90 % of E_2.*

f) *Repeat the test with V_T reversed.*

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For legends, see Table 5.

Components

S Switch for applying the test energy

A, B Switch positions

R_{CL} Current limiting resistor

Components toleranced at ± 5 %

Figure 11 – Application of test voltage to test the delivered defibrillation energy
(see 8.5.5.2)

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8.6 * Protective earthing, functional earthing and potential equalization of ME EQUIPMENT

8.6.1 * Applicability of requirements

The requirements of 8.6.2 to 8.6.8 (inclusive) apply unless the parts concerned comply with the requirements and tests of IEC 60950-1 for protective earthing and serve as MEANS OF OPERATOR PROTECTION but not as MEANS OF PATIENT PROTECTION.

8.6.2 * PROTECTIVE EARTH TERMINAL

The PROTECTIVE EARTH TERMINAL of ME EQUIPMENT shall be suitable for connection to an external protective earthing system either by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and, where appropriate, by a suitable plug, or by a FIXED PROTECTIVE EARTH CONDUCTOR.

The clamping means of the PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS shall comply with the requirements of 8.11.4.3. It shall not be possible to loosen the clamping means without the aid of a TOOL.

Screws for internal PROTECTIVE EARTH CONNECTIONS shall be completely covered or protected against accidental loosening from the outside of ME EQUIPMENT.

Where an APPLIANCE INLET forms the supply connection to ME EQUIPMENT, the earth pin of the APPLIANCE INLET shall be regarded as the PROTECTIVE EARTH TERMINAL.

The PROTECTIVE EARTH TERMINAL shall not be used for the mechanical connection between different parts of the ME EQUIPMENT or the fixing of any component not related to protective earthing or functional earthing.

Compliance is checked by inspection of materials and construction, by manual tests, and by the test of 8.11.4.3.

8.6.3 * Protective earthing of moving parts

Any PROTECTIVE EARTH CONNECTION shall not be used for a moving part unless the MANUFACTURER demonstrates that the connection will remain reliable during the EXPECTED SERVICE LIFE of the ME EQUIPMENT.

Compliance is checked by inspection of the ME EQUIPMENT and if necessary inspection of the RISK MANAGEMENT FILE.

8.6.4 Impedance and current-carrying capability

a) * PROTECTIVE EARTH CONNECTIONS shall be able to carry fault currents reliably and without excessive voltage drop.

For PERMANENTLY INSTALLED ME EQUIPMENT, the impedance between the PROTECTIVE EARTH TERMINAL and any part that is PROTECTIVELY EARTHED shall not exceed 100 mΩ, except as allowed by 8.6.4 b).

For ME EQUIPMENT with an APPLIANCE INLET the impedance between the earth pin in the APPLIANCE INLET and any part that is PROTECTIVELY EARTHED shall not exceed 100 mΩ, except as allowed by 8.6.4 b).

For ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD the impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED shall not exceed 200 mΩ, except as allowed by 8.6.4 b).

Additionally, the impedance between the protective earth pin in the MAINS PLUG of any DETACHABLE POWER SUPPLY CORD supplied or specified by the MANUFACTURER, when attached to the ME EQUIPMENT, and any part of the ME EQUIPMENT that is PROTECTIVELY EARTHED shall not exceed 200 mΩ, except as allowed by 8.6.4 b).

Where a DETACHABLE POWER SUPPLY CORD is neither supplied nor specified, testing shall be carried out using a 3 m long cord of appropriate cross sectional area based on 8.11.3.3 and Table 17.

Compliance is checked by the following test:

A current of 25 A or 1,5 times the highest RATED current of the relevant circuit(s), whichever is greater (± 10 %), from a current source with a frequency of 50 Hz or 60 Hz

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and with a no-load voltage not exceeding 6 V, is passed for 5 s to 10 s through the PROTECTIVE EARTH TERMINAL or the protective earth contact in the APPLIANCE INLET or the protective earth pin in the MAINS PLUG and each PROTECTIVELY EARTHED part.

Alternatively, d.c. may be used for this test.

The voltage drop between the parts described is measured and the impedance determined from the current and voltage drop.

Where the product of the test current as specified above and the total impedance (i.e. the impedance being measured plus the impedance of the test leads and the contact impedances) would exceed 6 V, the impedance is first measured with a no-load voltage not exceeding 6 V.

If the measured impedance is within the permitted limit, either the impedance measurement is then repeated using a current source with a no-load voltage sufficient to deliver the specified current into the total impedance, or the current-carrying ability of the relevant protective earth conductor and protective earth connection is confirmed by checking that their cross sectional area is at least equal to that of the relevant current-carrying conductors.

b) * The impedance of PROTECTIVE EARTH CONNECTIONS is allowed to exceed the values specified above if the relevant circuits have limited current capability such that, in case of short circuit of relevant insulation, the allowable values of the TOUCH CURRENT and the PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION are not exceeded.

Compliance is checked by inspection and if necessary by measurement of LEAKAGE CURRENT in the relevant SINGLE FAULT CONDITION. Transient currents occurring during the first 50 ms following the short circuit are disregarded.

8.6.5 Surface coatings

Conductive elements of ME EQUIPMENT that have surface coatings of poorly conducting material such as paint, and between which electrical contact is essential to a PROTECTIVE EARTH CONNECTION, shall have the coatings removed at the point of contact unless an investigation of the joint construction and the manufacturing PROCESS has demonstrated that the requirements for impedance and current-carrying capacity are assured without the removal of the surface coating.

Compliance is checked by inspection.

8.6.6 Plugs and sockets

Where the connection between the SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT that can be operated by persons other than SERVICE PERSONNEL is made via a plug and socket device, the PROTECTIVE EARTH CONNECTION shall be made before and interrupted after the supply connections are made or interrupted. This applies also where interchangeable parts are PROTECTIVELY EARTHED.

Compliance is checked by inspection.

8.6.7 * POTENTIAL EQUALIZATION CONDUCTOR

If ME EQUIPMENT is provided with a terminal for the connection of a POTENTIAL EQUALIZATION CONDUCTOR, the following requirements apply.

– The terminal shall be accessible to the OPERATOR with the ME EQUIPMENT in any position of NORMAL USE.

– ~~The RISK of~~ Accidental disconnection shall be ~~minimized~~ avoided in NORMAL USE.

– The terminal shall allow the conductor to be detached without the use of a TOOL.

– The terminal shall not be used for a PROTECTIVE EARTH CONNECTION.

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– The terminal shall be marked with symbol IEC 60417-5021 (~~DB:~~2002-10) (see Table D.1, symbol 8).
– The instructions for use shall contain information on the function and use of the POTENTIAL EQUALIZATION CONDUCTOR together with a reference to the requirements of this standard for ME SYSTEMS.

The POWER SUPPLY CORD shall not incorporate a POTENTIAL EQUALIZATION CONDUCTOR.

Compliance is checked by inspection.

8.6.8 FUNCTIONAL EARTH TERMINAL

A FUNCTIONAL EARTH TERMINAL of ME EQUIPMENT shall not be used to provide a PROTECTIVE EARTH CONNECTION.

Compliance is checked by inspection.

8.6.9 * CLASS II ME EQUIPMENT

If CLASS II ME EQUIPMENT with isolated internal screens is supplied with a POWER SUPPLY CORD having three conductors, the third conductor (connected to the protective earth contact of the MAINS PLUG) shall be used only as the functional earth connection to a FUNCTIONAL EARTH TERMINAL for these screens and shall be coloured green and yellow. In such a case, the ACCOMPANYING DOCUMENTS shall state that the third conductor in the POWER SUPPLY CORD is only a functional earth.

~~The insulation of such internal screens and all internal wiring connected to them shall provide two MEANS OF PROTECTION. In such case, there shall be an explanation in the technical description.~~

The insulation between internal screens, including internal wiring connected to them and ACCESSIBLE PARTS, shall provide two MEANS OF PROTECTION.

Compliance is checked by inspection and measurement. The insulation is tested as described in 8.8.

8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

8.7.1 General requirements

a) The electrical isolation providing protection against electric shock shall be of such quality that currents flowing through it are limited to the values specified in 8.7.3.

b) The specified values of the EARTH LEAKAGE CURRENT, the TOUCH CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT apply in any combination of the following conditions:
   – at operating temperature and following the humidity preconditioning treatment, as described in 5.7;
   – after any required sterilization PROCEDURE (see 11.6.7);
   – in NORMAL CONDITION and in the SINGLE FAULT CONDITIONS specified in 8.7.2;
   – with ME EQUIPMENT energized in stand-by condition and fully operating and with any switch in the MAINS PART in any position;
   – with the highest RATED supply frequency;
   – with a supply equal to 110 % of the highest RATED MAINS VOLTAGE.

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8.7.2 * SINGLE FAULT CONDITIONS

The allowable values specified in 8.7.3 apply in the SINGLE FAULT CONDITIONS specified in 8.1 b) except that:

– where insulation is used in conjunction with a PROTECTIVE EARTH CONNECTION, short circuit of the insulation applies only in the circumstances specified in 8.6.4 b);

– the only SINGLE FAULT CONDITION for the EARTH LEAKAGE CURRENT is the interruption of one supply conductor at a time;

– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT are not measured in the SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION.

SINGLE FAULT CONDITIONS shall not be applied at the same time as the special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS (8.7.4.7 b)) and non-PROTECTIVELY EARTHED parts of the ENCLOSURE (8.7.4.7 d)).

8.7.3 * Allowable values

a) The allowable values specified in 8.7.3 b), c) and d) apply to currents flowing through the network of Figure 12 a) and measured as shown in this figure (or by a device measuring the frequency contents of the currents as defined in Figure 12 b)). The values apply to d.c. and a.c. and composite waveforms. Unless stated otherwise they may be d.c. or r.m.s.

b) The allowable values of the PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS are stated in Table 3 and Table 4. The values of a.c. apply to currents having a frequency not less than 0,1 Hz.

c) The allowable values of the TOUCH CURRENT are 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION.

d) The allowable values of the EARTH LEAKAGE CURRENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION. For PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit that supplies only this ME EQUIPMENT, a higher value of EARTH LEAKAGE CURRENT is allowed.

NOTE 1 Local regulation can establish limits for protective earth currents of the installation. See also IEC 60364-7-710 [10].

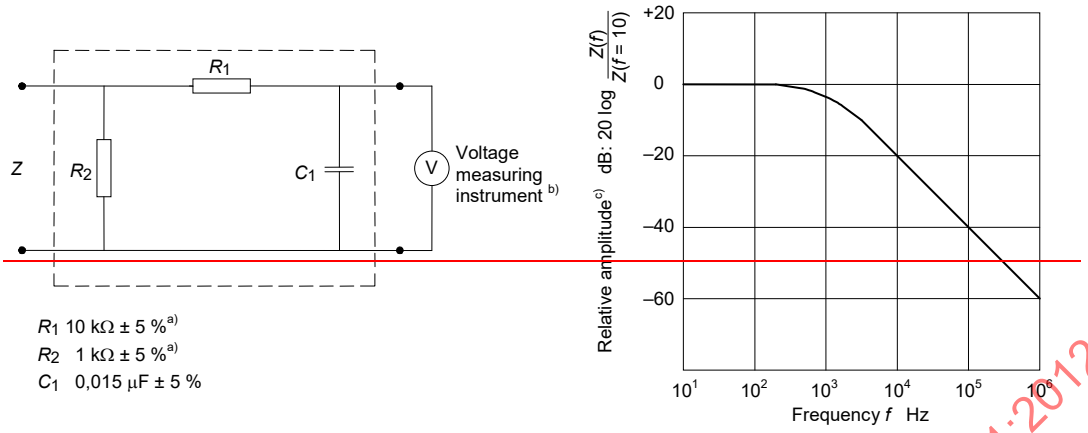
NOTE 2 The EARTH LEAKAGE CURRENT in NORMAL CONDITION can become TOUCH CURRENT in SINGLE FAULT CONDITION unless the ME EQUIPMENT is PERMANENTLY INSTALLED or the protective earth is not accessible from outside the ME EQUIPMENT.

e) Additionally, regardless of waveform and frequency, no LEAKAGE CURRENT shall exceed 10 mA r.m.s. in NORMAL CONDITION or in SINGLE FAULT CONDITION when measured with a non-frequency-weighted device.

f) *. The allowable values of LEAKAGE CURRENTS that can flow in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION.

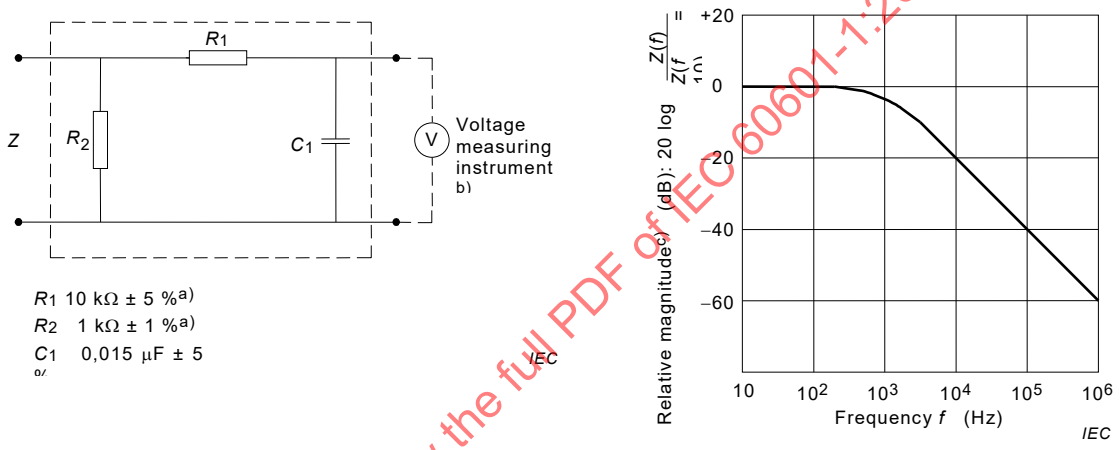
NOTE 3 Subclause 16.6.1 requires that when ME EQUIPMENT is included in an ME SYSTEM, the TOUCH CURRENTS from any part of the ME SYSTEM cannot exceed 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION.

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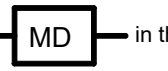
a) Measuring device

b) Frequency characteristics



a) Measuring device

b) Frequency characteristics

NOTE The network and voltage measuring instrument above are replaced by the symbol 

in the following figures.

a) Non-inductive components
b) Resistance ≥ 1 MΩ and capacitance ≤ 150 pF
c) $Z(f)$ is the transfer impedance of the network, i.e. V_{out}/I_{in}, for a current of frequency f.

Figure 12 – Example of a measuring device and its frequency characteristics
(see 8.7.3)

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Table 3 – * Allowable values of PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL CONDITION and SINGLE FAULT CONDITION

Current in μA

Current	Description	Reference	Measuring Circuit		TYPE B APPLIED PART		TYPE BF APPLIED PART		TYPE CF APPLIED PART	
					NC	SFC	NC	SFC	NC	SFC
PATIENT AUXILIARY CURRENT		8.7.4.8	Figure 19	d.c.	10	50	10	50	10	50
				a.c.	100	500	100	500	10	50
PATIENT LEAKAGE CURRENT	From PATIENT CONNECTION to earth	8.7.4.7 a)	Figure 15	d.c.	10	50	10	50	10	50
				a.c.	100	500	100	500	10	50
	Caused by an external voltage on a SIP/SOP	8.7.4.7 c)	Figure 17	d.c.	10	50	10	50	10	50
				a.c.	100	500	100	500	10	50
Total PATIENT LEAKAGE CURRENT [a]	With the same types of APPLIED PART connected together	8.7.4.7 a) and 8.7.4.7 h)	Figure 15 and Figure 20	d.c.	50	100	50	100	50	100
				a.c.	500	1 000	500	1 000	50	100
	Caused by an external voltage on a SIP/SOP	8.7.4.7 c) and 8.7.4.7 h)	Figure 17 and Figure 20	d.c.	50	100	50	100	50	100
				a.c.	500	1 000	500	1 000	50	100

Key
NC = NORMAL CONDITION
SFC = SINGLE FAULT CONDITION

NOTE 1 For EARTH LEAKAGE CURRENT see 8.7.3 d).

NOTE 2 For TOUCH CURRENT see 8.7.3 c).

[a] Total PATIENT LEAKAGE CURRENT values are only applicable to equipment having multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS shall comply with the PATIENT LEAKAGE CURRENT values.

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Table 4 – * Allowable values of PATIENT LEAKAGE CURRENTS under the special test conditions identified in 8.7.4.7

Current in μA

Current	Description [a]	Reference	Measuring Circuit	TYPE B APPLIED PART	TYPE BF APPLIED PART	TYPE CF APPLIED PART
PATIENT LEAKAGE CURRENT	Caused by an external voltage on the PATIENT CONNECTION of an F-TYPE APPLIED PART	8.7.4.7 b)	Figure 16	Not applicable	5 000	50
	Caused by an external voltage on a metal ACCESSIBLE PART not PROTECTIVELY EARTHED	8.7.4.7 d)	Figure 18	500	500	– [c]
Total PATIENT LEAKAGE CURRENT [b]	Caused by an external voltage on the PATIENT CONNECTION of an F-TYPE APPLIED PART	8.7.4.7 b) and 8.7.4.7 h)	Figure 16 and Figure 20	Not applicable	5 000	100
	Caused by an external voltage on a metal ACCESSIBLE PART not PROTECTIVELY EARTHED	8.7.4.7 d) and 8.7.4.7 h)	Figure 18 and Figure 20	1 000	1 000	– [c]

[a] The condition referred to in Table IV of the second edition as "MAINS VOLTAGE on APPLIED PART", and treated in that edition as a SINGLE FAULT CONDITION, is treated in this edition as a special test condition. The test with MAXIMUM MAINS VOLTAGE on a non-PROTECTIVELY EARTHED ACCESSIBLE PART is also a special test condition, but the allowable values are the same as for SINGLE FAULT CONDITION. See also the rationales for 8.5.2.2 and 8.7.4.7 d).

[b] Total PATIENT LEAKAGE CURRENT values are only applicable to equipment having multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS shall comply with the PATIENT LEAKAGE CURRENT values.

[c] This condition is not tested with TYPE CF APPLIED PARTS because it is covered by the test with MAXIMUM MAINS VOLTAGE on the APPLIED PART. See also the rationale for 8.7.4.7 d).

8.7.4 Measurements

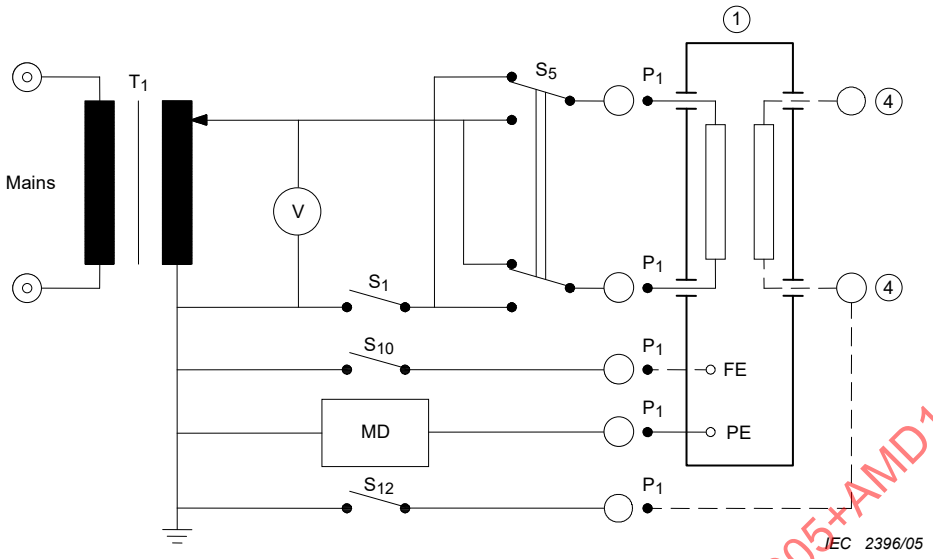
8.7.4.1 General

The LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT test figures referenced in 8.7.4.5 to 8.7.4.8 (Figure 13 to Figure 19 inclusive) show suitable test configurations for use in conjunction with the test PROCEDURES specified in these subclauses. It is recognized that other test figures can yield accurate results. However if the test results are close to the allowed values or if there is any doubt as to the validity of the test results, the applicable test figure is to be used as the deciding factor.

a) The EARTH LEAKAGE CURRENT, the TOUCH CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT are measured after the ME EQUIPMENT has been brought up to operating temperature in accordance with the requirements of 11.1.3 c).

b) Where examination of the circuit arrangement and the arrangement of components and material of the ME EQUIPMENT shows no possibility of any HAZARDOUS SITUATION described in 13.1, the number of tests can be reduced.

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For legends, see Table 5.

Key

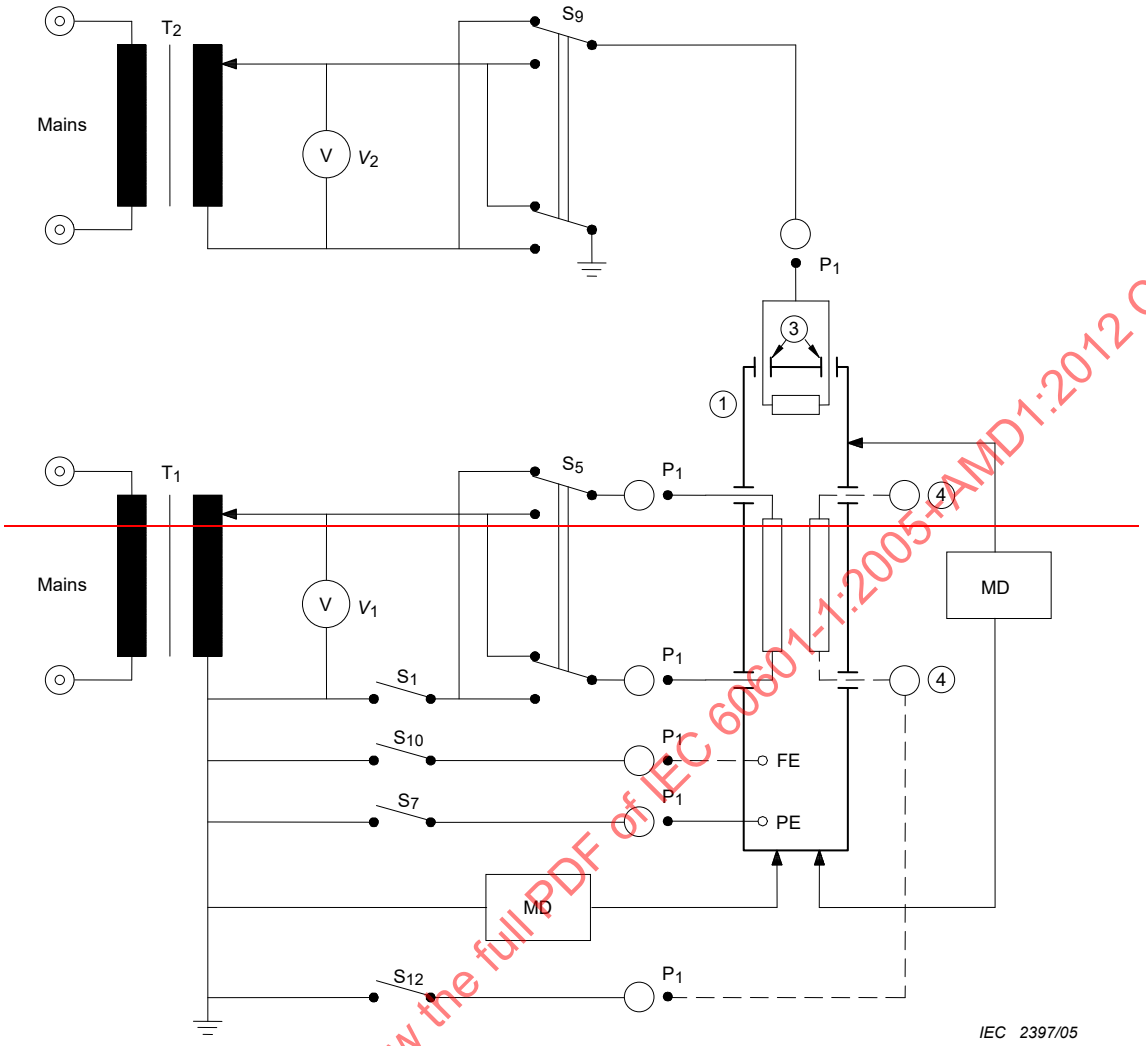
Measure in all possible combinations of positions of S_5, S_{10} and S_{12} with:

S_1 closed (NORMAL CONDITION), and
S_1 open (SINGLE FAULT CONDITION).

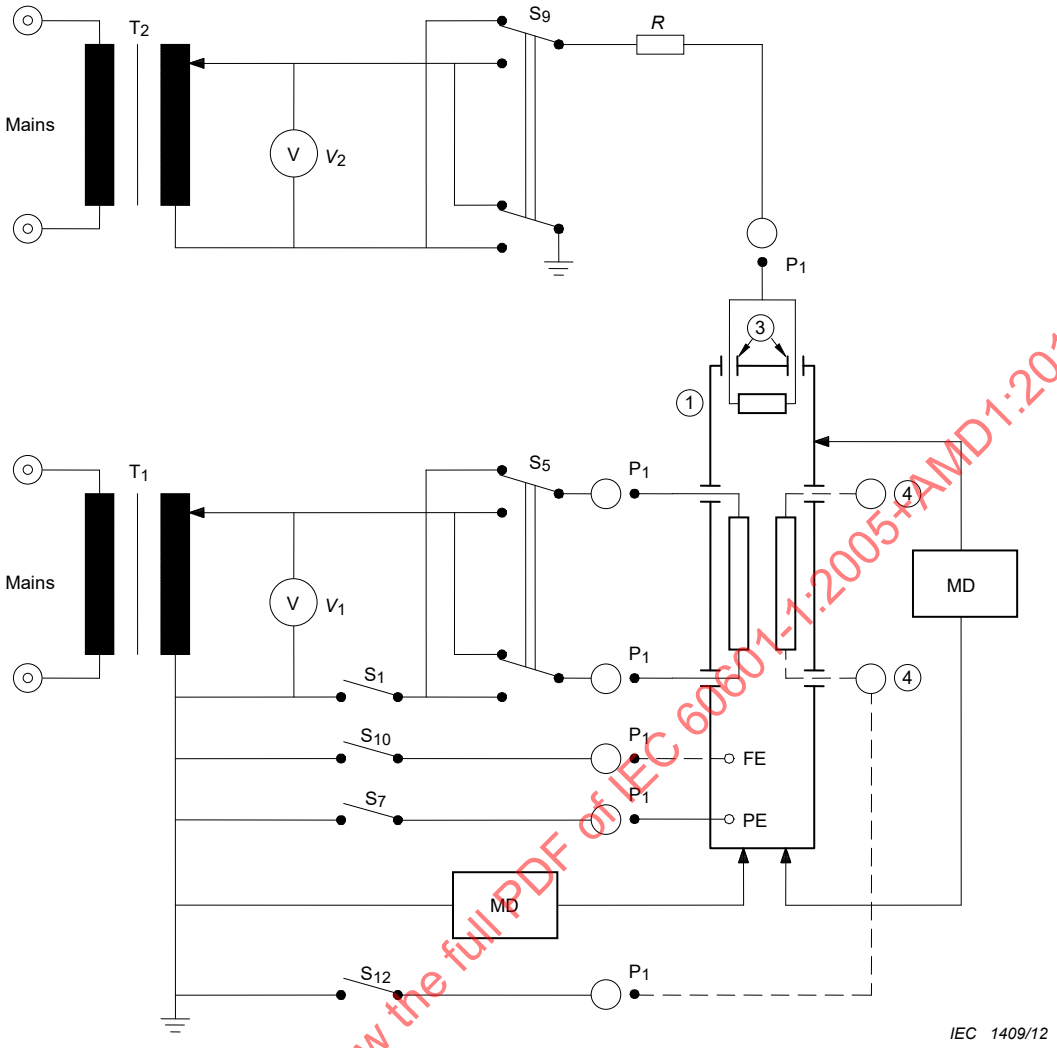
Example with the measuring supply circuit of Figure F.1

Figure 13 – Measuring circuit for ~~the~~ EARTH LEAKAGE CURRENT of CLASS I ME EQUIPMENT, with or without APPLIED PART
(see 8.7.4.5)

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For legends, see Table 5.

Key

Measure (with S_7 closed if CLASS I ME equipment) under all possible combinations of positions of S_1, S_5, S_9, S_{10}, and S_{12}.

S_1 open is SINGLE FAULT CONDITION.

CLASS I ME equipment only:
Measure with S_7 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of S_5, S_9, S_{10} and S_{12}.

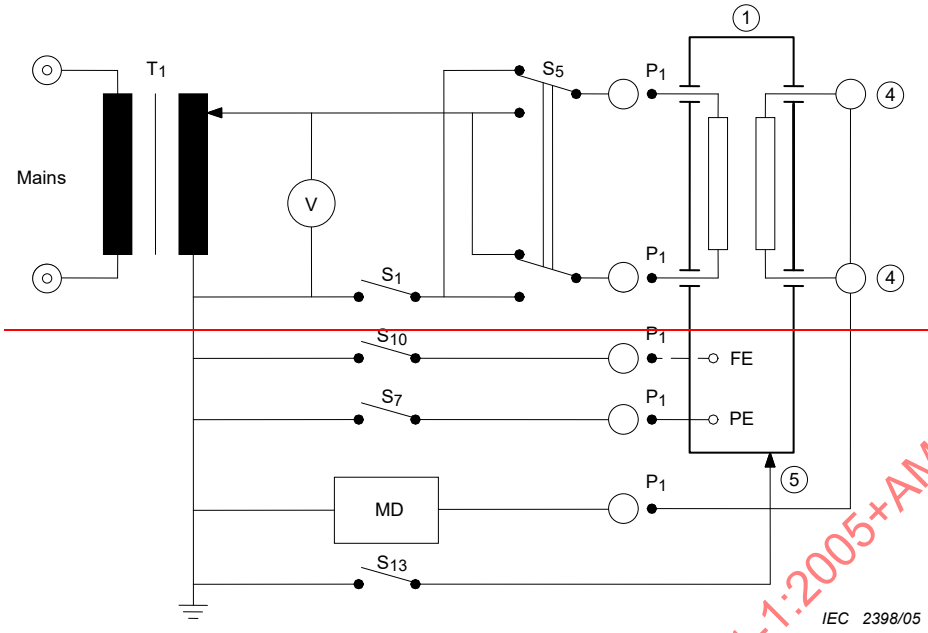
For CLASS II ME equipment, the PROTECTIVE EARTH CONNECTION and S_7 are not used.

Transformer T_2 is used if required (see 8.1 a))

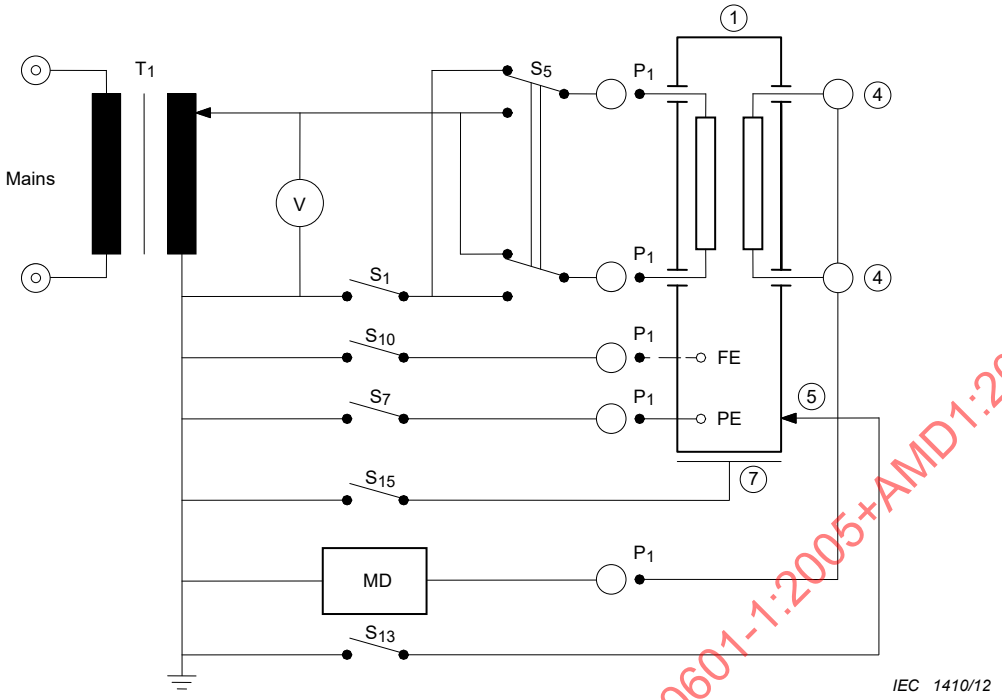
Example with the measuring supply circuit of Figure F.1.

Figure 14 – Measuring circuit for ~~the~~ TOUCH CURRENT
(see 8.7.4.6)

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For legends, see Table 5.

Key

Measure (with S_7 closed if CLASS I ME EQUIPMENT) under all possible combinations of positions of S_1, S_5, S_{10}, S_{13} and S_{15}.

S_1 open is SINGLE FAULT CONDITION.

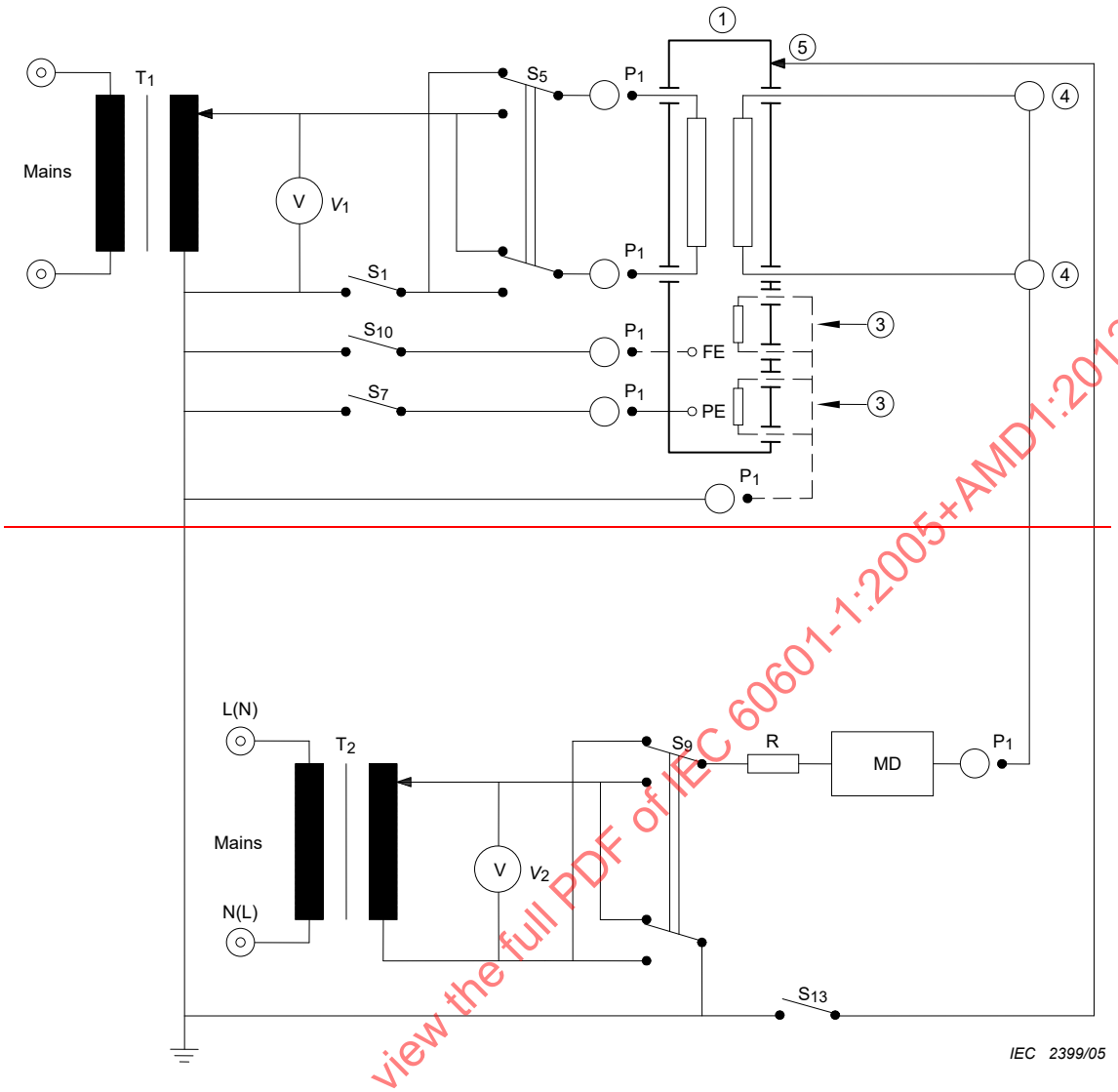
CLASS I ME EQUIPMENT only:
Measure with S_7 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of S_5, S_{10}, S_{13} and S_{15}.

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S_7 are not used.

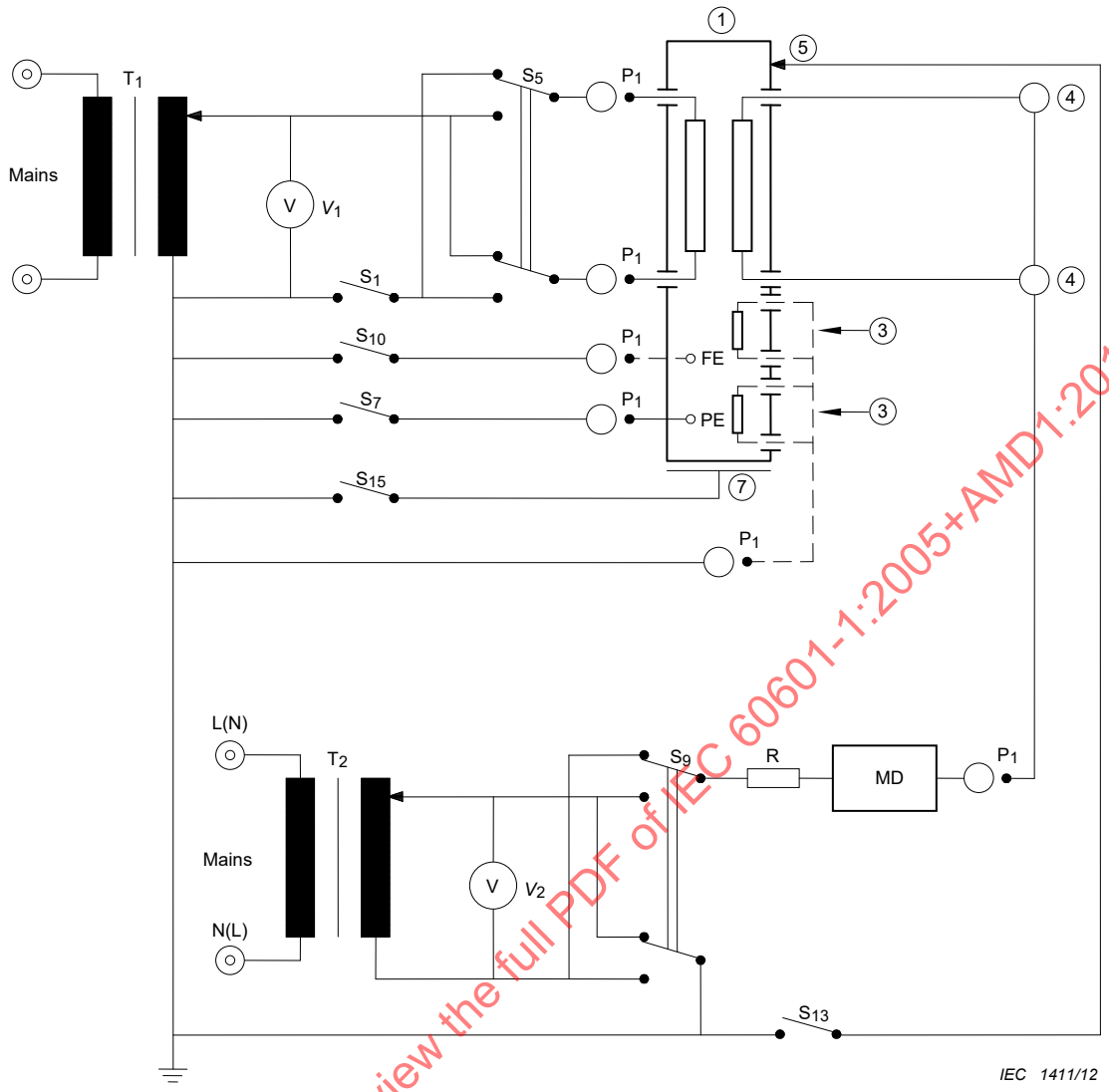
Example with the measuring supply circuit of Figure F.1.

Figure 15 – Measuring circuit for ~~the~~ PATIENT LEAKAGE CURRENT from the PATIENT CONNECTION to earth
(see 8.7.4.7 a))

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For legends, see Table 5.

Key

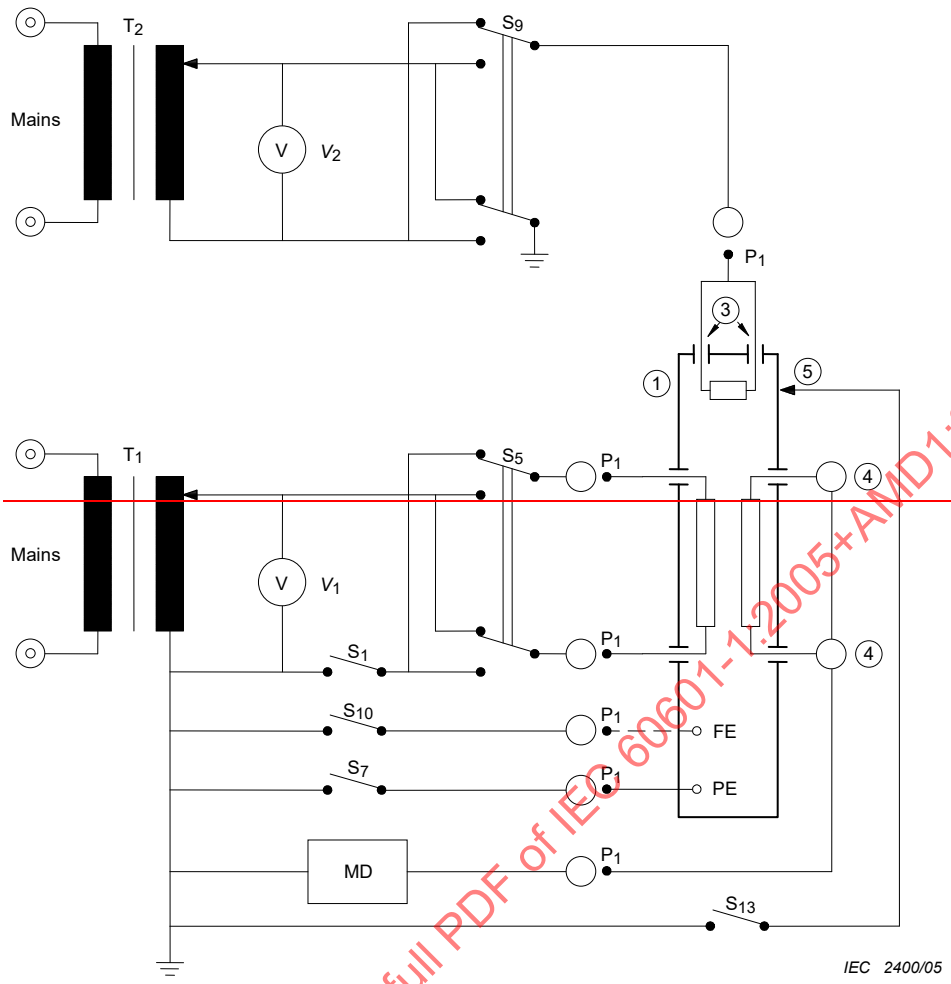
Measure (with S_7 closed, if CLASS I ME EQUIPMENT) WITH S_1 closed under all possible combinations of positions of S_5, S_9, S_{10} and S_{13}.

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S_7 are not used.

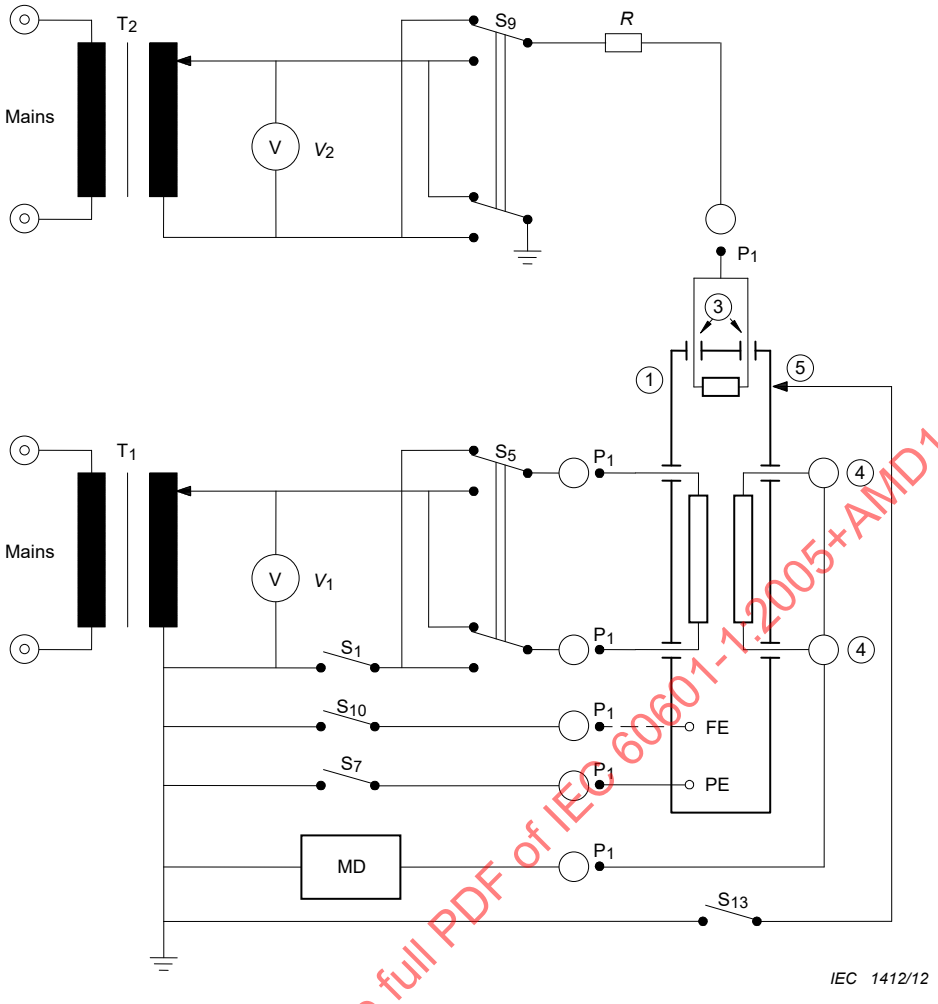
Example with the measuring supply circuit of Figure F.1.

Figure 16 – Measuring circuit for ~~the~~ PATIENT LEAKAGE CURRENT via the PATIENT CONNECTION(S) of an F-TYPE APPLIED PART to earth caused by an external voltage on the PATIENT CONNECTION(S)
(see 8.7.4.7 b))

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For legends, see Table 5.

Key

Measure (with S_7 closed, if CLASS I ME EQUIPMENT) under all possible combinations of positions of S_1, S_5, S_9, S_{10} and S_{13} (S_1 open is SINGLE FAULT CONDITION).

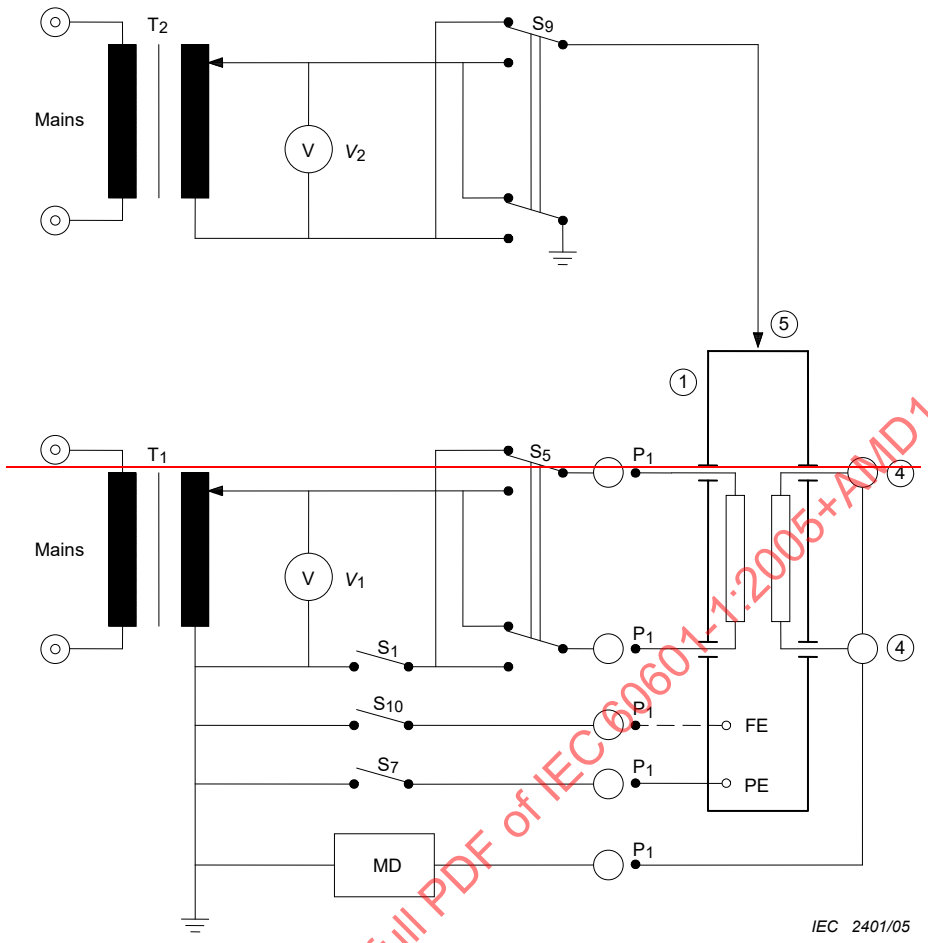
CLASS I ME EQUIPMENT only:
Measure with S_7 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of S_5, S_9, S_{10} and S_{13}.

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S_7 are not used.

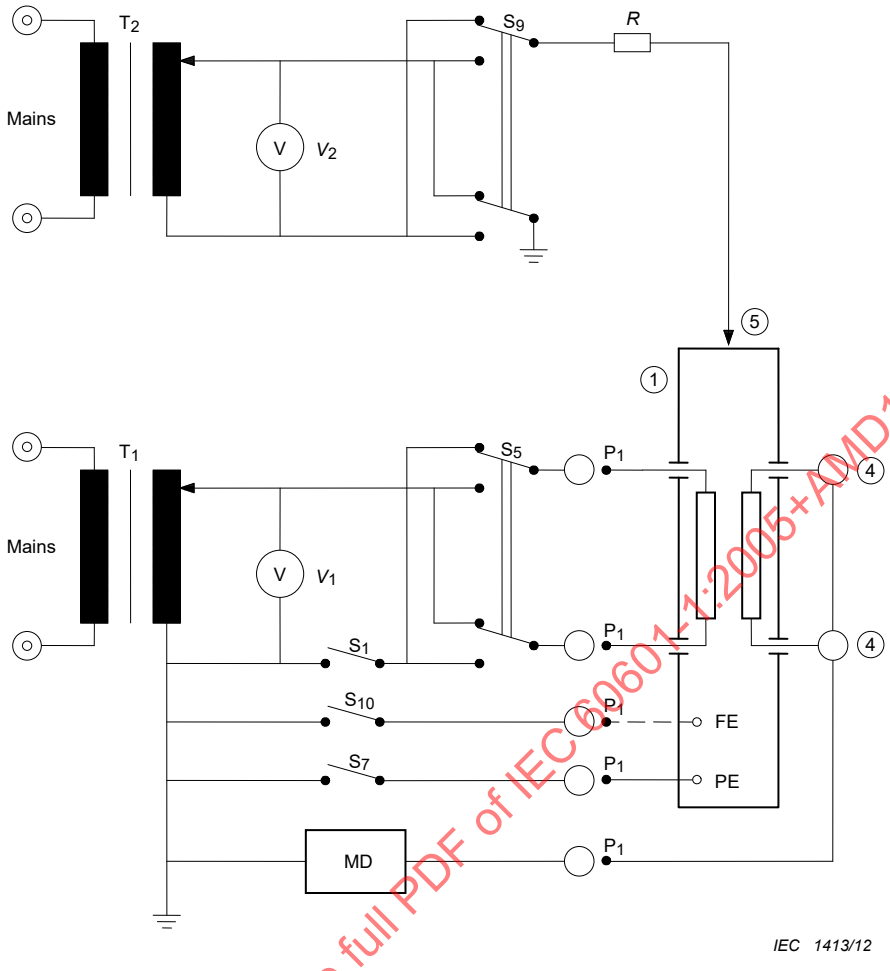
Example with the measuring supply circuit of Figure F.1.

Figure 17 – Measuring circuit for ~~the~~ PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(S) to earth caused by an external voltage on a SIGNAL INPUT/OUTPUT PART
(see 8.7.4.7 c))

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For legends, see Table 5.

Key

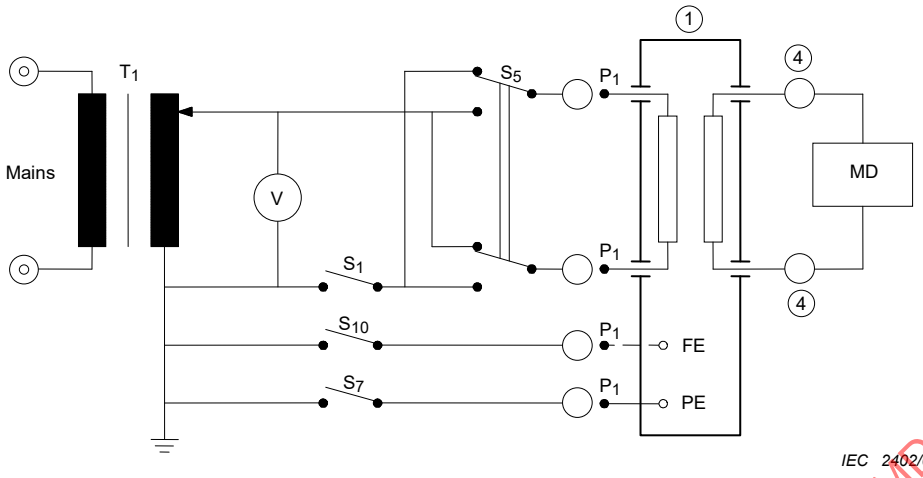
Measure with S_1 closed (and with S_7 closed, if CLASS I ME EQUIPMENT) under all possible combinations of positions of S_5, S_9 and S_{10}

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S_7 are not used.

Example with the measuring supply circuit of Figure F.1.

Figure 18 – Measuring circuit for ~~the~~ PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(S) to earth caused by an external voltage on a metal ACCESSIBLE PART that is not PROTECTIVELY EARTHED
(see 8.7.4.7 d))

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For legends, see Table 5.

Key

Measure (with S_7 closed if CLASS I ME EQUIPMENT) under all possible combinations of positions of S_1, S_5, and S_{10}.

S_1 open is a SINGLE FAULT CONDITION.

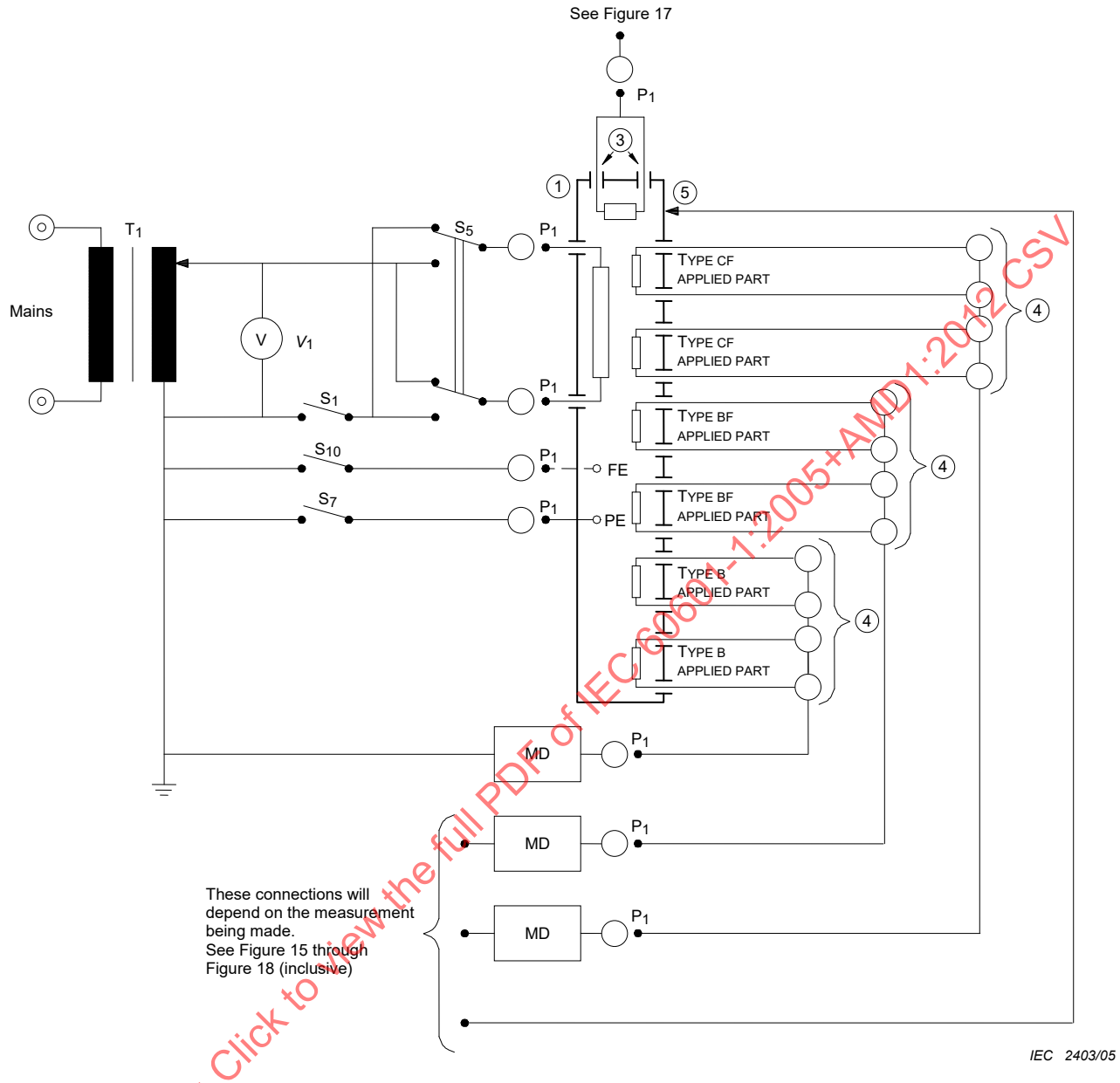
CLASS I ME EQUIPMENT only:
Measure with S_7 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of positions of S_5, and S_{10}.

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S_7 are not used.

Example with the measuring supply circuit of Figure F.1.

Figure 19 – Measuring circuit for ~~the~~ PATIENT AUXILIARY CURRENT
(see 8.7.4.8)

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For legends, see Table 5.

Key

For the position of S_1, S_5, S_7 and S_{10}, see Figure 15, Figure 16, Figure 17 or Figure 18

Figure 20 – Measuring circuit for ~~the~~ total PATIENT LEAKAGE CURRENT with all PATIENT CONNECTIONS of all APPLIED PARTS of the same type (TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS) connected together
(see 8.7.4.7 h))

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Table 5 – Legends of symbols for Figure 9 to Figure 11, Figure 13 to Figure 20, Figure A.15, Annexes E and F

1	ME EQUIPMENT ENCLOSURE
2	Separate power supply unit or other electrical equipment in an ME SYSTEM that supplies power to the ME EQUIPMENT (see 5.5 ~~g~~ f) and Annex F)
3	SIGNAL INPUT/OUTPUT PART short circuited or loaded
4	PATIENT CONNECTIONS
5	Metal ACCESSIBLE PART not PROTECTIVELY EARTHED In case of a non-conductive ENCLOSURE and PATIENT LEAKAGE CURRENT measurement, connection is replaced by a metal foil of maximum 20 cm × 10 cm in intimate contact with the ENCLOSURE or relevant parts of the ENCLOSURE and connected to the reference earth
6	PATIENT circuit
7	Metal plate under a non-conductive ENCLOSURE with dimensions at least equal to the plan projection of the ENCLOSURE connected to the reference earth
T_1, T_2	Single- or polyphase isolation transformers with sufficient power rating and adjustable output voltage (See also the rationale for 8.7.4.2 and 8.7.4.3.)
$V_{(1,2,3)}$	Voltmeter indicating r.m.s. value, using, if relevant and possible, one meter with a commutator switch
S_1, S_2, S_3	Single-pole switches, simulating the interruption of a power supply conductor (SINGLE FAULT CONDITION) (See Annex F)
S_5, S_9	Commutator switches to reverse the polarity of the MAINS VOLTAGE
S_7	Single-pole switch, simulating the interruption of a single PROTECTIVE EARTH CONDUCTOR to the ME EQUIPMENT (SINGLE FAULT CONDITION)
S_8	Single pole switch simulating the interruption of a single PROTECTIVE EARTH CONDUCTOR to a separate power supply unit or other electrical equipment in an ME SYSTEM that supplies power to the ME EQUIPMENT (SINGLE FAULT CONDITION) (see Figure F.5)
S_{10}	Switch for connecting a FUNCTIONAL EARTH TERMINAL to the earthed point of the measuring supply system
S_{12}	Switch for connecting a PATIENT CONNECTION to the earthed point of the measuring supply circuit
S_{13}	Switch for connecting to earth a metal ACCESSIBLE PART not PROTECTIVELY EARTHED
S_{14}	Switch to connect/disconnect PATIENT CONNECTION to/from earth
S_{15}	Switch for connecting to earth a metal plate under a non-conductive ENCLOSURE
P_1	Sockets, plugs or terminals for the supply connection of the ME EQUIPMENT
P_2	Sockets, plugs or terminals for the connection to a separate power supply or other electrical equipment in an ME SYSTEM that supplies power to the ME EQUIPMENT (see Figure F.5)
MD	Measuring device (see Figure 12)
FE	FUNCTIONAL EARTH TERMINAL
PE	PROTECTIVE EARTH TERMINAL
R	Impedance to protect the circuitry and the person performing the test, but low enough to accept currents higher than the allowable values of the LEAKAGE CURRENT to be measured (optional)
- - - -	Optional connection
	Reference earth (for LEAKAGE CURRENT and PATIENT AUXILLARY CURRENT measurements and for testing of DEFIBRILLATION-PROOF APPLIED PARTS, not connected to protective earth of the SUPPLY MAINS)
	SUPPLY MAINS voltage source

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8.7.4.2 * Measuring supply circuits

ME EQUIPMENT specified for connection to a SUPPLY MAINS is connected to an appropriate power source. For single-phase ME EQUIPMENT, the polarity of the supply is reversible and tests are conducted at both polarities. INTERNALLY POWERED ME EQUIPMENT is tested without any connection to a measuring supply circuit.

NOTE Figure F.1 to Figure F.5 (inclusive) show some suitable arrangements but do not cover all possibilities, for example, delta-connected 3-phase supplies.

8.7.4.3 * Connection to the measuring supply circuit

a) *ME EQUIPMENT provided with a POWER SUPPLY CORD is tested using this cord.*

b) *ME EQUIPMENT provided with an APPLIANCE INLET is tested while connected to the measuring supply circuit via a DETACHABLE POWER SUPPLY CORD having a length of 3 m or a length and type specified in the instructions for use.*

c) *PERMANENTLY INSTALLED ME EQUIPMENT is tested while connected to the measuring supply circuit by the shortest possible connection.*

d) *Measuring arrangement*

1) *APPLIED PARTS, including PATIENT cables (when present), are placed on an insulating surface with a dielectric constant of approximately 1 (for example, expanded polystyrene) and approximately 200 mm above an earthed metal surface.*

NOTE 1 The measuring supply circuit and the measuring circuit should be positioned as far as possible away from unscreened power source leads. Placing the ME EQUIPMENT on or near a large earthed metal surface should be avoided.

NOTE 2 Where APPLIED PARTS are such that the test results can depend upon how they are placed on the insulating surface, the test is repeated as necessary to determine the worst possible positioning.

2) *If an isolating transformer is not used for LEAKAGE CURRENT measurements (e.g. when measuring LEAKAGE CURRENT for very high input power ME EQUIPMENT), the reference earth of the measuring circuits is connected to protective earth of the SUPPLY MAINS.*

8.7.4.4 Measuring device (MD)

a) *The measuring device loads the source of LEAKAGE CURRENT or PATIENT AUXILIARY CURRENT with a resistive impedance of approximately 1 000 Ω for d.c., a.c. and composite waveforms with frequencies up to and including 1 MHz.*

b) *The evaluation of current or current components according to 8.7.3 a) is obtained automatically if a measuring device according to Figure 12 a) or a similar circuit with the same frequency characteristic is used. This allows measurement of the total effect of all frequencies with a single instrument.*

If currents or current components with frequencies exceeding 1 kHz might exceed the 10 mA limit specified in 8.7.3 *e), these are measured by other appropriate means such as a 1 kΩ non-inductive resistor and suitable measuring instrument.*

c) *The voltage measuring instrument as shown in Figure 12 a) has an input resistance of at least 1 MΩ and input capacitance of no more than 150 pF. It indicates the true r.m.s. value of the voltage being d.c., a.c. or a composite waveform having components with frequencies from 0,1 Hz up to and including 1 MHz, with an indicating error not exceeding ± 5 % of the indicated value.*

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The scale can indicate the current through the measuring device including automatic evaluation of components with frequencies above 1 kHz so as to enable direct comparison of the reading with the limit values specified in 8.7.3.

These requirements can be limited to a frequency range with an upper limit lower than 1 MHz if it can be proven (for example, by the use of an oscilloscope) that frequencies above such an upper limit do not occur in the measured current.

8.7.4.5 * Measurement of the EARTH LEAKAGE CURRENT and current in functional earth connection

a) *CLASS I ME EQUIPMENT is tested according to Figure 13. CLASS II ME EQUIPMENT with a functional earth connection according to 8.6.9 is tested as if it were CLASS I ME EQUIPMENT.*

b) *If ME EQUIPMENT has more than one PROTECTIVE EARTH CONDUCTOR (for example, one connected to the main ENCLOSURE and one to a separate power supply unit), then the current to be measured is the aggregate current that would flow into the protective earthing system of the installation.*

c) *For FIXED ME EQUIPMENT that can have connections to earth through the building structure, the MANUFACTURER specifies a suitable test PROCEDURE and configuration for measurement of EARTH LEAKAGE CURRENT.*

8.7.4.6 * Measurement of the TOUCH CURRENT

a) *ME EQUIPMENT is tested according to Figure 14, using an appropriate measuring supply circuit.*

Measure with MD between earth and each part of the ENCLOSURE(S) that is not PROTECTIVELY EARTHED.

Measure with MD between parts of the ENCLOSURE(S) that are not PROTECTIVELY EARTHED.

In the SINGLE FAULT CONDITION of interruption of any one PROTECTIVE EARTH CONDUCTOR (when applicable, see 8.1 b)), measure with MD between earth and any part of the ENCLOSURE(S) that is normally PROTECTIVELY EARTHED.

NOTE It is not necessary to make separate measurements from more than one part that is PROTECTIVELY EARTHED.

INTERNALLY POWERED ME EQUIPMENT is investigated for TOUCH CURRENT but only between parts of the ENCLOSURE, not between the ENCLOSURE and earth unless 8.7.4.6 c) applies.

b) *If ME EQUIPMENT has an ENCLOSURE or a part of the ENCLOSURE made of insulating material, metal foil of maximum 20 cm x 10 cm is applied in intimate contact with the ENCLOSURE or relevant part of the ENCLOSURE.*

The metal foil is shifted, if possible, to determine the highest value of the TOUCH CURRENT. The metal foil should not touch any metal parts of the ENCLOSURE that are possibly PROTECTIVELY EARTHED; however, metal parts of the ENCLOSURE that are not PROTECTIVELY EARTHED can be covered partly or totally by the metal foil.

Where it is intended to measure the TOUCH CURRENT in the SINGLE FAULT CONDITION of interruption of a PROTECTIVE EARTH CONDUCTOR, the metal foil is arranged to contact parts of the ENCLOSURE that are normally PROTECTIVELY EARTHED.

Where the surface of the ENCLOSURE contacted by the PATIENT or OPERATOR is larger than 20 cm x 10 cm, the size of the foil is increased corresponding to the area of contact.

c) *ME EQUIPMENT with a SIGNAL INPUT/OUTPUT PART is, when required (see 8.1 a)), additionally tested using transformer T_2.*

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The value of the voltage set at the transformer T_2 is equal to 110 % of the MAXIMUM MAINS VOLTAGE. The specific pin configuration used when applying the external voltage is determined to be worst case based on testing or circuit analysis.

8.7.4.7 Measurement of the PATIENT LEAKAGE CURRENT

See Annex K, which contains simplified PATIENT LEAKAGE CURRENT diagrams, for supplemental explanatory detail.

a) *ME EQUIPMENT with an APPLIED PART is tested according to Figure 15.*

An ENCLOSURE, other than an APPLIED PART, made of insulating material is placed in any position of NORMAL USE upon a flat metal surface connected to earth with dimensions at least equal to the plan-projection of the ENCLOSURE.

b) * *ME EQUIPMENT with an F-TYPE APPLIED PART is additionally tested according to Figure 16.*

SIGNAL INPUT/OUTPUT PARTS are connected to earth, if not already permanently earthed in the ME EQUIPMENT.

The value of the voltage to be set at the transformer T_2 in Figure 16 is equal to 110 % of the MAXIMUM MAINS VOLTAGE.

For this measurement, non-PROTECTIVELY EARTHED metal ACCESSIBLE PARTS including PATIENT CONECTIONS of other APPLIED PARTS (if present) are connected to earth.

c) * *ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART is, when required (see 8.1 a)), additionally tested according to Figure 17.*

The value of the voltage set at the transformer T_2 is equal to 110 % of the MAXIMUM MAINS VOLTAGE. The specific pin configuration used when applying the external voltage is to be worst case based on testing or circuit analysis.

d) * *ME EQUIPMENT with a PATIENT CONNECTION of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED or a TYPE BF APPLIED PART and with metal ACCESSIBLE PARTS that are not PROTECTIVELY EARTHED is additionally tested according to Figure 18.*

The value of the voltage set at the transformer T_2 is equal to 110 % of the MAXIMUM MAINS VOLTAGE.

This test need not be conducted if it can be demonstrated that there is adequate separation of the parts involved.

e) *An APPLIED PART consisting of a surface made of insulating material is tested using metal foil as mentioned under 8.7.4.6. Alternatively a 0,9 % saline solution is used in which the APPLIED PART is immersed.*

Where the surface of the APPLIED PART intended to contact the PATIENT is considerably larger than that of a foil of 20 cm x 10 cm, the size of the foil is increased to correspond to the area of contact.

Such metal foil or saline solution is considered as the only PATIENT CONNECTION for the APPLIED PART concerned.

f) *Where the PATIENT CONNECTION is formed by a fluid which contacts the PATIENT, the fluid is replaced by 0,9 % saline solution, an electrode is placed in the saline solution and this electrode is considered as the PATIENT CONNECTION for the APPLIED PART concerned.*

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g) *The PATIENT LEAKAGE CURRENT is measured (see also Annex E):*

~~– for TYPE B APPLIED PARTS and TYPE BF APPLIED PARTS, from and to all PATIENT CONNECTIONS of a single function either connected directly together or loaded as in NORMAL USE;~~

– *for TYPE B APPLIED PARTS, from all PATIENT CONNECTIONS connected directly together.*

– *for TYPE BF APPLIED PARTS, from and to all PATIENT CONNECTIONS of a single function either connected directly together or loaded as in NORMAL USE.*

– ~~in~~ *for TYPE CF APPLIED PARTS, from and to every PATIENT CONNECTION in turn.*

If the instructions for use specifies alternatives for a detachable part of the APPLIED PART (for example, PATIENT leads or PATIENT cables and electrodes), the PATIENT LEAKAGE CURRENT measurements are made with the least favourable specified detachable part. See also 7.9.2.14.

h) * *The total PATIENT LEAKAGE CURRENT is measured from and to all PATIENT CONNECTIONS of all APPLIED PARTS of the same type (TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS) connected together. See Figure 20. If necessary, a functional earth may be disconnected before conducting this test.*

NOTE Measurement of total PATIENT LEAKAGE CURRENT of TYPE B APPLIED PARTS is only necessary if there are two or more PATIENT CONNECTION that belong to different functions and that are not electrically connected directly together.

i) *If the PATIENT CONNECTIONS of the APPLIED PART are loaded in NORMAL USE, the measuring device is connected to each PATIENT CONNECTION in turn.*

8.7.4.8 Measurement of the PATIENT AUXILIARY CURRENT

ME EQUIPMENT with an APPLIED PART is tested according to Figure 19, using an appropriate measuring supply circuit unless the ME EQUIPMENT has only a single PATIENT CONNECTION.

The PATIENT AUXILIARY CURRENT is measured between any single PATIENT CONNECTION and all other PATIENT CONNECTIONS, either connected directly together or loaded as in NORMAL USE (see also Annex E).

8.7.4.9 * ME EQUIPMENT with multiple PATIENT CONNECTIONS

ME EQUIPMENT with multiple PATIENT CONNECTIONS is investigated to ensure that the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT do not exceed the allowable values for NORMAL CONDITION while one or more PATIENT CONNECTIONS are:

– disconnected from the PATIENT; and

– disconnected from the PATIENT and earthed.

Testing is performed if an examination of the ME EQUIPMENT circuit indicates that the PATIENT LEAKAGE CURRENT or the PATIENT AUXILIARY CURRENT can increase to excessive levels under the above conditions. Actual measurements should be limited to a representative number of combinations.

8.8 Insulation

8.8.1 * General

~~Only the following insulation shall be subject to testing:~~

~~– insulation that is relied upon as a MEANS OF PROTECTION, including REINFORCED INSULATION;~~

~~– insulation between parts of opposite polarity of the MAINS PART on the SUPPLY MAINS side of any mains fuse or OVER-CURRENT RELEASE, which shall be tested as one MEANS OF PROTECTION.~~

Only insulation that is relied upon as a MEANS OF PROTECTION, including REINFORCED INSULATION, shall be subject to testing.

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Insulation forming part of a component is exempt provided that the component complies with 4.8.

Insulation forming MEANS OF OPERATOR PROTECTION is exempt from the tests of 8.8 if it complies with the requirements and tests of IEC 60950-1 for INSULATION CO-ORDINATION.

8.8.2 * Distance through solid insulation or use of thin sheet material

Solid insulation which forms SUPPLEMENTARY INSULATION or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V shall either:

a) have a distance through insulation of at least 0,4 mm, or

b) not form part of an ENCLOSURE and not be subject to handling or abrasion during NORMAL USE, and comprise:
   - at least two layers of material, each of which will pass the appropriate dielectric strength test; or
   - three layers of material, for which all combinations of two layers together will pass the appropriate dielectric strength test.

The appropriate dielectric strength test for the one or two layers is the test for one MEANS OF PROTECTION in the case of SUPPLEMENTARY INSULATION or the test for two MEANS OF PROTECTION in the case of REINFORCED INSULATION, respectively.

NOTE 1 There is no minimum thickness requirement for BASIC INSULATION, nor for insulation operating at WORKING VOLTAGE up to 71 V.

NOTE 2 There is no requirement for all layers of insulation to be of the same material.

Compliance is checked by inspection, by measurement of thickness and by the dielectric strength test of 8.8.3.

For wound components, where BASIC INSULATION, SUPPLEMENTARY INSULATION or REINFORCED INSULATION is required between windings, they shall be separated by interleaved insulation complying with a) or b) immediately above, or both, unless one of the following wire constructions is used:

c) wire that has solid insulation, other than solvent based enamel, complying with a) above;

d) wire that has multi-layer extruded or spirally wrapped insulation (where the layers can be individually tested for dielectric strength) complying with b) above and passes the tests of Annex L;

e) wire that has multi-layer extruded or spirally wrapped insulation (where only the finished wire can be tested) and passes the tests of Annex L. The minimum number of constructional layers applied to the conductor shall be as follows:
   - BASIC INSULATION: two wrapped layers or one extruded layer;
   - SUPPLEMENTARY INSULATION: two layers, wrapped or extruded;
   - REINFORCED INSULATION: three layers, wrapped or extruded.

In both d) and e), for spirally wrapped insulation where the CREEPAGE DISTANCES between layers, as wrapped, are less than those given in Table 12 or Table 16 (for Pollution Degree 1) depending on the type of insulation in question, the path between layers shall be sealed as for a cemented joint in 8.9.3.3 and the test voltages of the TYPE TESTS in L.3 are increased to 1,6 times their normal values.

NOTE 3 One layer of material wound with more than 50 % overlap is considered to constitute two layers.

Where two insulated wires or one bare and one insulated wire are in contact inside the wound component, crossing each other at an angle between 45° and 90° and subject to winding tension, protection against mechanical stress shall be provided. This protection can be

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achieved, for example, by providing physical separation in the form of insulating sleeving or sheet material, or by using double the required number of insulation layers.

The finished component shall pass routine tests for dielectric strength using the appropriate test voltages in 8.8.3.

Compliance is checked by inspection and measurement and, if applicable, as specified in Annex L. However, the tests of Annex L are not repeated if the material data sheets confirm compliance.

8.8.3 * Dielectric strength

The dielectric strength of solid electrical insulation of ME EQUIPMENT shall be capable of withstanding the test voltages as specified in Table 6. Only insulation with a safety function need be subject to testing (see 8.8.1).

Compliance is checked by applying the test voltage specified in Table 6 for 1 min:

– *immediately after the humidity preconditioning treatment (as described in 5.7) with the ME EQUIPMENT de-energized during the test, and*

– *after any required sterilization PROCEDURE (see 11.6.7, 7.9.2.12 and the instructions for use) with the ME EQUIPMENT de-energized, and*

– *after reaching a temperature equivalent to the steady state operating temperature reached during the heating test of 11.1.1.*

Initially, not more than half the test voltage is applied, and then it is gradually raised over a period of 10 s to the full value, which is maintained for 1 min, after which it is gradually lowered over a period of 10 s to less than half the full value.

The test conditions are as follows:

a) * *The test voltage has a waveform and frequency such that the dielectric stress on the insulation is at least equal to that occurring in NORMAL USE. The waveform and frequency of the test voltage can differ from the voltage applied in NORMAL USE if it can be demonstrated that the dielectric stress on the insulation tested will not be diminished.*

Where the voltage to which the relevant insulation is subjected in NORMAL USE is non-sinusoidal a.c., the test may be performed using a sinusoidal 50 Hz or 60 Hz test voltage.

Alternatively, a d.c. test voltage equal to the peak value of the a.c. test voltage may be used.

The test voltage, for the WORKING VOLTAGE to which the insulation is subjected is greater than or equal to the value specified in Table 6.

b) *During the test, breakdown constitutes a failure. Insulation breakdown is considered to have occurred when the current which flows as a result of the application of the test voltage rapidly increases in an uncontrolled manner, that is, the insulation does not restrict the flow of the current. Corona discharge or a single momentary flashover is not regarded as insulation breakdown.*

c) *If it is not possible to test individual solid insulations, it is then necessary to test a large part of the ME EQUIPMENT or even the whole ME EQUIPMENT. In this case, it is important not to overstress different types and levels of insulation and the following must be taken into account.*

– *Where an ENCLOSURE or part of ENCLOSURE consists of non-conductive surfaces, metal foil is applied. Care is taken that the metal foil is positioned in such a manner that flashover does not occur at the edges of insulation linings. If applicable, the metal foil is moved so as to test all parts of the surface.*

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– *The circuits on either side of the insulation under test should be connected or short circuited such that components within these circuits do not get stressed during the test. For example, the terminals of the MAINS PART, the SIGNAL INPUT/OUTPUT PART and the PATIENT CONNECTION(S) (if applicable) respectively are short circuited during the test.*

– *Where there are capacitors across the insulation under test (e.g. radio-frequency filter capacitors), they may be disconnected during the test, if they are certified to IEC 60384-14.*

Table 6 – Test voltages for solid insulation forming a MEANS OF PROTECTION

PEAK WORKING VOLTAGE (*U*) V peak	PEAK WORKING VOLTAGE (*U*) V d.c.	A.C. test voltages in V r.m.s.							
		MEANS OF OPERATOR PROTECTION				MEANS OF PATIENT PROTECTION			
		Protection from MAINS PART		Protection from SECONDARY CIRCUITS		Protection from MAINS PART		Protection from SECONDARY CIRCUITS	
		One MOOP	Two MOOP	One MOOP	Two MOOP	One MOPP	Two MOPP	One MOPP	Two MOPP
U < 42,4	*U* < 60	1 000	2 000	No test	No test	1 500	3 000	500	1 000
42,4 < *U* ≤ 71	60 < *U* ≤ 71	1 000	2 000	See Table 7	See Table 7	1 500	3 000	750	1 500
71 < *U* ≤ 184	71 < *U* ≤ 184	1 000	2 000	See Table 7	See Table 7	1 500	3 000	1 000	2 000
184 < *U* ≤ 212	184 < *U* ≤ 212	1 500	3 000	See Table 7	See Table 7	1 500	3 000	1 000	2 000
212 < *U* ≤ 354	212 < *U* ≤ 354	1 500	3 000	See Table 7	See Table 7	1 500	4 000	1 500	3 000
354 < *U* ≤ 848	354 < *U* ≤ 848	See Table 7	3 000	See Table 7	See Table 7	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)
848 < *U* ≤ 1 414	848 < *U* ≤ 1 414	See Table 7	3 000	See Table 7	See Table 7	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)
1 414 < *U* ≤ 10 000	1 414 < *U* ≤ 10 000	See Table 7	See Table 7	See Table 7	See Table 7	$U/\sqrt{2}$ + 2 000	$\sqrt{2}U$ + 5 000	$U/\sqrt{2}$ + 2 000	$\sqrt{2}U$ + 5 000
10 000 < *U* ≤ 14 140	10 000 < *U* ≤ 14 140	1,06 x $U/\sqrt{2}$	1,06 x $U/\sqrt{2}$	1,06 x $U/\sqrt{2}$	1,06 x $U/\sqrt{2}$	$U/\sqrt{2}$ + 2 000	$\sqrt{2}U$ + 5 000	$U/\sqrt{2}$ + 2 000	$\sqrt{2}U$ + 5 000
U > 14 140	*U* > 14 140	If necessary, to be prescribed by particular standards							

NOTE 1 For a barrier according to:

– Figure J.6, use the column MEANS OF PATIENT PROTECTION – Protection from SECONDARY CIRCUITS – Two MOPP.

– 8.5.2.1 and Figure J.7, use the column MEANS OF PATIENT PROTECTION – Protection from MAINS PART – One MOPP.

NOTE 2 See the rationale for 8.8.3.

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Table 7 – Test voltages for MEANS OF OPERATOR PROTECTION

Test voltage in V r.m.s.

PEAK WORKING VOLTAGE (*U*) V peak or V d.c.	One MOOP	Two MOOP	PEAK WORKING VOLTAGE (*U*) V peak or V d.c.	One MOOP	Two MOOP	PEAK WORKING VOLTAGE (*U*) V peak or V d.c.	One MOOP	Two MOOP
34	500	800	250	1 261	2 018	1 750	3 257	3 257
35	507	811	260	1 285	2 055	1 800	3 320	3 320
36	513	821	270	1 307	2 092	1 900	3 444	3 444
38	526	842	280	1 330	2 127	2 000	3 566	3 566
40	539	863	290	1 351	2 162	2 100	3 685	3 685
42	551	882	300	1 373	2 196	2 200	3 803	3 803
44	564	902	310	1 394	2 230	2 300	3 920	3 920
46	575	920	320	1 414	2 263	2 400	4 034	4 034
48	587	939	330	1 435	2 296	2 500	4 147	4 147
50	598	957	340	1 455	2 328	2 600	4 259	4 259
52	609	974	350	1 474	2 359	2 700	4 369	4 369
54	620	991	360	1 494	2 390	2 800	4 478	4 478
56	630	1 008	380	1 532	2 451	2 900	4 586	4 586
58	641	1 025	400	1 569	2 510	3 000	4 693	4 693
60	651	1 041	420	1 605	2 567	3 100	4 798	4 798
62	661	1 057	440	1 640	2 623	3 200	4 902	4 902
64	670	1 073	460	1 674	2 678	3 300	5 006	5 006
66	680	1 088	480	1 707	2 731	3 400	5 108	5 108
68	690	1 103	500	1 740	2 784	3 500	5 209	5 209
70	699	1 118	520	1 772	2 835	3 600	5 309	5 309
72	708	1 133	540	1 803	2 885	3 800	5 507	5 507
74	717	1 147	560	1 834	2 934	4 000	5 702	5 702
76	726	1 162	580	1 864	2 982	4 200	5 894	5 894
78	735	1 176	588	1 875	3 000	4 400	6 082	6 082
80	744	1 190	600	1 893	3 000	4 600	6 268	6 268
85	765	1 224	620	1 922	3 000	4 800	6 452	6 452
90	785	1 257	640	1 951	3 000	5 000	6 633	6 633
95	805	1 288	660	1 979	3 000	5 200	6 811	6 811
100	825	1 319	680	2 006	3 000	5 400	6 987	6 987
105	844	1 350	700	2 034	3 000	5 600	7 162	7 162
110	862	1 379	720	2 060	3 000	5 800	7 334	7 334
115	880	1 408	740	2 087	3 000	6 000	7 504	7 504
120	897	1 436	760	2 113	3 000	6 200	7 673	7 673
125	915	1 463	780	2 138	3 000	6 400	7 840	7 840
130	931	1 490	800	2 164	3 000	6 600	8 005	8 005
135	948	1 517	850	2 225	3 000	6 800	8 168	8 168
140	964	1 542	900	2 285	3 000	7 000	8 330	8 330
145	980	1 568	950	2 343	3 000	7 200	8 491	8 491
150	995	1 593	1 000	2 399	3 000	7 400	8 650	8 650
152	1 000	1 600	1 050	2 454	3 000	7 600	8 807	8 807
155	1 000	1 617	1 100	2 508	3 000	7 800	8 964	8 964
160	1 000	1 641	1 150	2 560	3 000	8 000	9 119	9 119
165	1 000	1 664	1 200	2 611	3 000	8 200	9 273	9 273
170	1 000	1 688	1 250	2 661	3 000	8 400	9 425	9 425
175	1 000	1 711	1 300	2 710	3 000	8 600	9 577	9 577
180	1 000	1 733	1 350	2 758	3 000	8 800	9 727	9 727
184	1 000	1 751	1 400	2 805	3 000	9 000	9 876	9 876
185	1 097	1 755	1 410	2 814	3 000	9 200	10 024	10 024
190	1 111	1 777	1 450	2 868	3 000	9 400	10 171	10 171
200	1 137	1 820	1 500	2 934	3 000	9 600	10 317	10 317
210	1 163	1 861	1 550	3 000	3 000	9 800	10 463	10 463
220	1 189	1 902	1 600	3 065	3 065	10 000	10 607	10 607
230	1 214	1 942	1 650	3 130	3 130			
240	1 238	1 980	1 700	3 194	3 194			

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8.8.4 Insulation other than wire insulation

8.8.4.1 * Mechanical strength and resistance to heat

The resistance to heat shall be retained by all types of insulation, including insulating partition walls, during the EXPECTED SERVICE LIFE of the ME EQUIPMENT.

Compliance is checked by inspection of the ME EQUIPMENT and the design documentation, and, if necessary, inspection of the RISK MANAGEMENT FILE ~~and, if necessary,~~ in conjunction with the following tests:

– *resistance to moisture, etc. (see 11.6);*

– *dielectric strength (see 8.8.3);*

– *mechanical strength (see 15.3).*

Resistance to heat is established by the following tests, which need not be performed if satisfactory evidence of compliance is provided.

a) *For parts of the ENCLOSURE and other external insulating parts, the deterioration of which could result in an unacceptable RISK, by the ball-pressure test:*

ENCLOSURES and other external parts of insulating material, except the insulation of flexible cords and parts of ceramic material, are subjected to a ball-pressure test using the test apparatus shown in Figure 21. The surface of the part to be tested is placed in the horizontal position and a steel ball of 5 mm diameter is pressed against the surface with a force of 20 N. The test is performed in a heating cabinet at a temperature of 75 °C ± 2 °C or the ambient temperature indicated in the technical description (see 7.9.3.1) ± 2 °C plus the temperature rise of the relevant part of insulating material measured during the test of 11.1, whichever is the higher.

The ball is withdrawn after 1 h and the diameter of the impression made by the ball is measured. An impression greater than 2 mm in diameter constitutes a failure.

b) *For parts of insulating material that support uninsulated parts of the MAINS PART, the deterioration of which could influence the safety of the ME EQUIPMENT, by the ball-pressure test:*

A test is performed as described in a) above, but at a temperature of 125 °C ± 2 °C or at the ambient temperature indicated in the technical description (see 7.9.3.1) ± 2 °C plus the temperature rise that was determined during the test of 11.1 of the relevant part, whichever is the higher.

The test is not performed on parts of ceramic material, insulating parts of commutators, brush-caps and the like, and on coil formers not used as REINFORCED INSULATION.

NOTE For SUPPLEMENTARY INSULATION and REINFORCED INSULATION of thermoplastic materials, see also 13.1.2.

8.8.4.2 Resistance to environmental stress

The insulating characteristics and mechanical strength of any MEANS OF PROTECTION shall be so designed or protected that it is not likely to be impaired by environmental stresses including deposition of dirt or by dust resulting from wear of parts within the ME EQUIPMENT to such an extent that CREEPAGE DISTANCES and AIR CLEARANCES are reduced below the values specified in 8.9.

Ceramic material not tightly sintered, and the like, and beads alone shall not be used as SUPPLEMENTARY INSULATION or REINFORCED INSULATION.

Insulating material in which heating conductors are embedded may be considered as one MEANS OF PROTECTION but shall not be used as two MEANS OF PROTECTION.

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Compliance is checked by inspection, by measurement and for natural latex rubber by the following test:

Parts of natural latex rubber are aged in an atmosphere of oxygen under pressure. The samples are suspended freely in an oxygen cylinder, the effective capacity of the cylinder is at least 10 times the volume of the samples. The cylinder is filled with commercial oxygen not less than 97 % pure, to a pressure of 2,1 MPa ± 70 kPa.

The samples are kept in the cylinder at a temperature of 70 °C ± 2 °C for 96 h. Immediately afterwards, they are taken out of the cylinder and left at room temperature for at least 16 h. After the test, the samples are examined. Cracks visible to the naked eye constitute a failure.

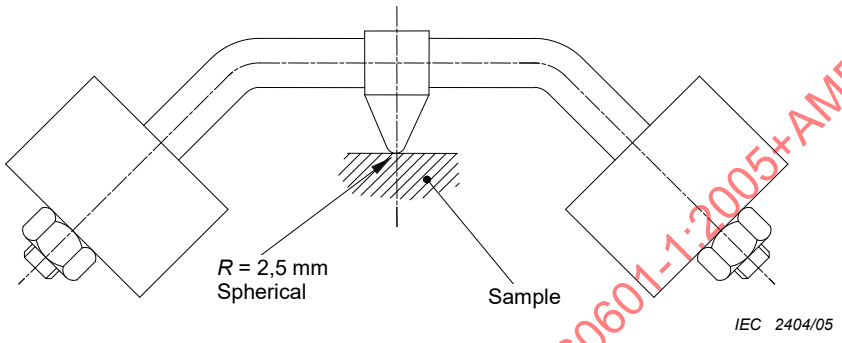


Figure 21 – Ball-pressure test apparatus
(see 8.8.4.1)

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8.9 * CREEPAGE DISTANCES and AIR CLEARANCES

8.9.1 * Values

8.9.1.1 General

CREEPAGE DISTANCES and AIR CLEARANCES of ME EQUIPMENT shall be equal to or greater than the values of ~~Table 11 to Table 16 (inclusive) except as specified in 8.9.1.2 to 8.9.1.15. See also 8.9.2 to 8.9.4.~~:

– for insulation between parts of opposite polarity of the MAINS PART on the SUPPLY MAINS side of any mains fuse or OVER-CURRENT RELEASE, one MEANS OF OPERATOR PROTECTION in accordance with Table 13, Table 14 and Table 16; and

– for insulation providing at least a MEANS OF PROTECTION, in accordance with Table 12 to Table 16 (inclusive) except as specified in 8.9.1.2 to 8.9.1.15. See also 8.9.2 to 8.9.4.

8.9.1.2 CREEPAGE DISTANCES and AIR CLEARANCES complying with IEC 60950-1

The values of Table ~~11~~ 12 to Table 16 (inclusive) do not apply to CREEPAGE DISTANCES and AIR CLEARANCES forming MEANS OF OPERATOR PROTECTION that comply with the requirements of IEC 60950-1 for INSULATION CO-ORDINATION and are used in the conditions (e.g. overvoltage category, pollution degree) under which compliance was tested.

8.9.1.3 CREEPAGE DISTANCES across glass, mica, ceramic and similar materials

For CREEPAGE DISTANCES across glass, mica, ceramic and other inorganic insulating materials with similar tracking characteristics, the specified minimum value of AIR CLEARANCE shall be applied as the minimum CREEPAGE DISTANCE.

8.9.1.4 Minimum CREEPAGE DISTANCE

If the minimum CREEPAGE DISTANCE derived from Table ~~11~~ 12 to Table 16 (inclusive) is less than the applicable minimum AIR CLEARANCE, that value of minimum AIR CLEARANCE shall be applied as the minimum CREEPAGE DISTANCE.

8.9.1.5 ME EQUIPMENT RATED for high altitudes

Unless otherwise declared by the MANUFACTURER, ME EQUIPMENT is RATED to operate at an altitude ≤ 2 000 m. Where ME EQUIPMENT is intended to be operated in a pressurized environment, e.g. aircraft, the operating altitude corresponding to the air pressure concerned shall be used in determining multiplication factor from Table 8. The AIR CLEARANCE is then multiplied by this factor. CREEPAGE DISTANCES are not subject to the multiplication factors but shall always be at least as large as the resulting value for AIR CLEARANCE.

Table 8 – Multiplication factors for AIR CLEARANCES for altitudes up to 5 000 m

RATED operating altitude (*a*) m	Normal barometric pressure kPa	Multiplication factor for MOOP	Multiplication factor for MOPP
a ≤ 2 000	80,0	1,00	1,00
2 000 < *a* ≤ 3 000	70,0	1,14	1,00
3 000 < *a* ≤ 4 000	62,0	1,29	1,14
4 000 < *a* ≤ 5 000	54,0	1,48	1,29
NOTE 1 The multiplication factors for MEANS OF OPERATOR PROTECTION relate to IEC 60950-1, which specifies AIR CLEARNACES for altitudes up to 2 000 m. NOTE 2 The multiplication factors for MEANS OF PATIENT PROTECTION relate to the second edition of IEC 60601-1, which specified spacing AIR CLEARANCES for altitudes up to 3 000 m. NOTE 3 The multiplication factors for MOOPs (column 3) are derived from IEC 60664-1:2007~~1992 as amended~~.			

8.9.1.6 * Interpolation

If the WORKING VOLTAGE has a value between those given in Table ~~11~~ 12 to Table 16 (inclusive):

– for determining CREEPAGE DISTANCES, linear interpolation is permitted between the nearest two values, the calculated spacing being rounded to the next higher 0,1 mm increment;

– for determining AIR CLEARANCES for PEAK WORKING VOLTAGES above 2 800 V peak or d.c., linear interpolation is permitted between the nearest two values, the calculated spacing being rounded to the next higher 0,1 mm increment;

– for determining AIR CLEARANCES for PEAK WORKING VOLTAGE up to 2 800 V peak or d.c., the higher of the two values shall be applied.

8.9.1.7 Material groups classification

Material groups are classified as shown in Table 9.

Table 9 – Material group classification

Material group	Comparative tracking index (CTI)
I	600 ≤ CTI
II	400 ≤ CTI < 600
IIIa	175 ≤ CTI < 400
IIIb	100 ≤ CTI < 175

The material group is verified by evaluation of the test data for the material according to IEC 60112 using 50 drops of solution A.

If the material group is not known, material group IIIb shall be assumed.

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8.9.1.8 Pollution degree classification

Pollution degrees are classified as follows:

– Pollution degree 1 is used to describe a micro-environment that is sealed so as to exclude dust and moisture.

NOTE 1 An example of such a micro-environment is a sealed or potted component or assembly.

– Pollution degree 2 is used to describe a micro-environment where only non-conductive pollution occurs except that occasionally a temporary conductivity caused by condensation is to be expected.

– Pollution degree 3 is used to describe a micro-environment that is subject to conductive pollution, or to dry non-conductive pollution that could become conductive due to expected condensation.

– Pollution degree 4 is used to describe a micro-environment where continuous conductivity occurs due to conductive dust, rain or other wet conditions.

NOTE 2 This type of environment can occur inside commutating motors which generate carbon dust from the brushes.

Pollution degree 4 is not acceptable for insulation providing a MEANS OF PROTECTION. However, in the case where insulation between the MAINS PART and earth might be compromised, it is necessary to provide measures, such as planned maintenance, to ensure that the micro-environment is mitigated to a lower pollution degree.

Annex M specifies measures that may be used to reduce the pollution degree.

8.9.1.9 Overvoltage category classification

The applicable value of the MAINS TRANSIENT VOLTAGE shall be determined from the overvoltage category according to IEC 60664-1 and the NOMINAL a.c. MAINS VOLTAGE using Table 10.

8.9.1.10 AIR CLEARANCE for MAINS PARTS

For MAINS PARTS operating on RATED MAINS VOLTAGES up to 300 V, the required AIR CLEARANCE shall be the value in Table 13 for the r.m.s. or d.c. RATED MAINS VOLTAGE plus the additional AIR CLEARANCE in Table 14 for the PEAK WORKING VOLTAGE.

8.9.1.11 SUPPLY MAINS overvoltage

This standard relates to overvoltage category II according to IEC 60664-1. If ME EQUIPMENT is intended to be used in locations where the SUPPLY MAINS is overvoltage category III, the values specified in Table 13 to Table 15 (inclusive) will be inadequate for clearance. Therefore the values given in the next MAINS TRANSIENT VOLTAGE column upwards shall be used. Whilst it is not envisaged that PATIENT protection (Table 12) will be required for use of ME EQUIPMENT on overvoltage category III SUPPLY MAINS, should this be necessary, guidance is given on the values required in the rationale for Subclause 8.9.

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Table 10 – MAINS TRANSIENT VOLTAGE

NOMINAL a.c. SUPPLY MAINS voltage line-to-neutral up to and including V r.m.s.	MAINS TRANSIENT VOLTAGE V peak			
	Overvoltage Category			
	I	II	III	IV
50	330	500	800	1 500
100	500	800	1 500	2 500
150 [a]	800	1 500	2 500	4 000
300 [b]	1 500	2 500	4 000	6 000
600 [c]	2 500	4 000	6 000	8 000
NOTE 1 In Norway, due to the IT power distribution system used, the a.c SUPPLY MAINS voltage is considered to be equal to the line-to-line voltage, and will remain 230 V in case of a single earth fault. NOTE 2 In Japan, the value of the MAINS TRANSIENT VOLTAGES for the NOMINAL a.c. SUPPLY MAINS voltage of 100 V is determined from columns applicable to the NOMINAL a.c. SUPPLY MAINS voltage of 150 V.				
[a] Including 120/208 or 120/240 V. [b] Including 230/400 or 277/480 V. [c] Including 400/690 V.				

8.9.1.12 SECONDARY CIRCUITS

A SECONDARY CIRCUIT derived from a SUPPLY MAINS will normally be overvoltage category I according to IEC 60664-1 if the MAINS PART is overvoltage category II; the maximum transients for various SUPPLY MAINS voltages in overvoltage category I are shown in the column headings of Table 15.

Where the SECONDARY CIRCUIT is earthed or the ME EQUIPMENT is INTERNALLY POWERED, Table 15 applies.

Where a SECONDARY CIRCUIT is not earthed and is derived from a SUPPLY MAINS, the circuit shall be subjected to the requirements for primary circuits in Table 13 and Table 14.

If the SECONDARY CIRCUIT is separated from the MAINS PART by a functionally earthed or PROTECTIVELY EARTHED metal screen or transients in the SECONDARY CIRCUIT are below the levels expected for overvoltage category I, (for example due to being attenuated by connecting a component, such as a capacitor, between the SECONDARY CIRCUIT and earth), the values in Table 15 apply.

The column for circuits not subject to transient overvoltages applies to:

– d.c. SECONDARY CIRCUITS that are reliably connected to earth and have capacitive filtering which limits the peak-to-peak ripple to 10 % of the d.c. voltage; and

– circuits in INTERNALLY POWERED ME EQUIPMENT.

8.9.1.13 PEAK WORKING VOLTAGES above 1 400 V peak or d.c.

The values in Table 15 for PEAK WORKING VOLTAGES above 1 400 V peak or d.c. do not apply if all the following conditions are satisfied:

– the AIR CLEARANCE is at least 5 mm;

– the insulation involved passes a dielectric strength test according to 8.8.3 using:

  • an a.c. test voltage whose r.m.s. value is equal to 1,06 times the PEAK WORKING VOLTAGE or

  • a d.c. test voltage equal to the peak value of the a.c. test voltage prescribed above;

  and

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– the AIR CLEARANCE path is partly or entirely through air or along the surface of an insulating material of material group I.

If the AIR CLEARANCE path is also partly along the surface of a material that is not material group I, the dielectric strength test is conducted only across the part(s) of the path that are through air.

8.9.1.14 Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION

Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION are obtained by doubling the values shown in Table 16 for one MEANS OF OPERATOR PROTECTION.

8.9.1.15 * CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS

CREEPAGE DISTANCES and AIR CLEARANCES needed to satisfy 8.5.5.1 for DEFIBRILLATION-PROOF APPLIED PARTS shall not be less than 4 mm.

NOTE In ~~Table 11 and~~ Table 12, which detail the spacing for PATIENT protection, the CREEPAGE DISTANCE and AIR CLEARANCE are both related to r.m.s. or d.c. WORKING VOLTAGES. In Table 13, Table 14 and Table 15, which detail the spacing for OPERATOR protection, the ~~clearance~~ AIR CLEARANCE is related to peak or d.c. WORKING VOLTAGE and the CREEPAGE DISTANCE is related to r.m.s. or d.c. WORKING VOLTAGE.

Table 11 – ~~Minimum CREEPAGE DISTANCES and AIR CLEARANCES between parts of opposite polarity of the MAINS PART~~ Not used

~~WORKING VOLTAGE V d.c. up to and including~~	~~WORKING VOLTAGE V r.m.s. up to and including~~	~~CREEPAGE DISTANCE mm~~	~~AIR CLEARANCE mm~~
~~17~~	~~12~~	~~0,8~~	~~0,4~~
~~43~~	~~30~~	~~1~~	~~0,5~~
~~85~~	~~60~~	~~1,3~~	~~0,7~~
~~177~~	~~125~~	~~2~~	~~1~~
~~354~~	~~250~~	~~3~~	~~1,6~~
~~566~~	~~400~~	~~4~~	~~2,4~~
~~707~~	~~500~~	~~5,5~~	~~3~~
~~934~~	~~660~~	~~7~~	~~4~~
~~1 061~~	~~750~~	~~8~~	~~4,5~~
~~1 414~~	~~1 000~~	~~11~~	~~6~~

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Table 12 – Minimum CREEPAGE DISTANCES and AIR CLEARANCES providing MEANS OF PATIENT PROTECTION

WORKING VOLTAGE V d.c. up to and including	WORKING VOLTAGE V r.m.s. up to and including	Spacing providing one MEANS OF PATIENT PROTECTION		Spacing providing two MEANS OF PATIENT PROTECTION	
		CREEPAGE DISTANCE mm	AIR CLEARANCE mm	CREEPAGE DISTANCE mm	AIR CLEARANCE mm
17	12	1,7	0,8	3,4	1,6
43	30	2	1	4	2
85	60	2,3	1,2	4,6	2,4
177	125	3	1,6	6	3,2
354	250	4	2,5	8	5
566	400	6	3,5	12	7
707	500	8	4,5	16	9
934	660	10,5	6	21	12
1 061	750	12	6,5	24	13
1 414	1 000	16	9	32	18
1 768	1 250	20	11,4	40	22,8
2 263	1 600	25	14,3	50	28,6
2 828	2 000	32	18,3	64	36,6
3 535	2 500	40	22,9	80	45,8
4 525	3 200	50	28,6	100	57,2
5 656	4 000	63	36,0	126	72,0
7 070	5 000	80	45,7	160	91,4
8 909	6 300	100	57,1	200	114,2
11 312	8 000	125	71,4	250	142,8
14 140	10 000	160	91,4	320	182,8

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Table 13 – Minimum AIR CLEARANCES providing MEANS OF OPERATOR PROTECTION from the MAINS PART

AIR CLEARANCE in mm

WORKING VOLTAGE up to and including		NOMINAL MAINS VOLTAGE ≤ 150 V (MAINS TRANSIENT VOLTAGE 1 500 V)				150 V < NOMINAL MAINS VOLTAGE ≤ 300 V (MAINS TRANSIENT VOLTAGE 2 500 V)		300 V < NOMINAL MAINS VOLTAGE ≤ 600 V (MAINS TRANSIENT VOLTAGE 4 000V)	
Voltage peak or d.c.	Voltage r.m.s (sinusoidal)	Pollution degrees 1 and 2		Pollution degree 3		Pollution degrees 1, 2 and 3		Pollution degrees 1, 2 and 3	
V	V	One MOOP	Two MOOP	One MOOP	Two MOOP	One MOOP	Two MOOP	One MOOP	Two MOOP
210	150	1,0	2,0	1,3	2,6	2,0	4,0	3,2	6,4
420	300	1 MOOP 2,0 2 MOOP 4,0						3,2	6,4
840	600	1 MOOP 3,2 2 MOOP 6,4							
1 400	1 000	1 MOOP 4,2 2 MOOP 6,4							
2 800	2 000	1 or 2 MOOP 8,4							
7 000	5 000	1 or 2 MOOP 17,5							
9 800	7 000	1 or 2 MOOP 25							
14 000	10 000	1 or 2 MOOP 37							
28 000	20 000	1 or 2 MOOP 80							
AIR CLEARANCES for WORKING VOLTAGES above 20 kV r.m.s. or 28 kV d.c. can be prescribed by particular standards if necessary.									
NOTE AIR CLEARNACES are a function of peak voltage in the circuit. The r.m.s. voltage column is provided for the special case where the voltage has a sinusoidal waveform.									

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Table 14 – Additional AIR CLEARANCES for insulation in MAINS PARTS with PEAK WORKING VOLTAGES exceeding the peak value of the NOMINAL MAINS VOLTAGE [a]
(see 8.9.1.10)

NOMINAL MAINS VOLTAGE ≤ 150 V r.m.s. or 210 V d.c.		150 V r.m.s. or 210 V dc < NOMINAL MAINS VOLTAGE ≤ 300 V r.m.s. or 420 V d.c.	Additional AIR CLEARANCE mm	
Pollution degrees 1 and 2	Pollution degree 3	Pollution degrees 1, 2 and 3		
PEAK WORKING VOLTAGE V	PEAK WORKING VOLTAGE V	PEAK WORKING VOLTAGE V	One MOOP	Two MOOP
210	210	420	0	0
298	294	493	0,1	0,2
386	379	567	0,2	0,4
474	463	640	0,3	0,6
562	547	713	0,4	0,8
650	632	787	0,5	1,0
738	715	860	0,6	1,2
826	800	933	0,7	1,4
914		1 006	0,8	1,6
1 002		1 080	0,9	1,8
1 090		1 153	1,0	2,0
		1 226	1,1	2,2
		1 300	1,2	2,4

[a] When using this table, select the appropriate column for the RATED MAINS VOLTAGE and pollution degree and choose the row in that column which covers the actual PEAK WORKING VOLTAGE. Read the additional AIR CLEARANCE required from the relevant right hand column (for one or two MEANS OF OPERATOR PROTECTION and add this to the minimum AIR CLEARANCE from Table 13 to give the total minimum AIR CLEARANCE.

NOTE For voltage values above the PEAK WORKING VOLTAGE values given in the table, linear extrapolation is permitted.

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Table 15 – Minimum AIR CLEARANCES for MEANS OF OPERATOR PROTECTION in SECONDARY CIRCUITS
(see 8.9.1.12)

AIR CLEARANCES in mm

WORKING VOLTAGE up to and including		Transient value for SECONDARY CIRCUIT ≤ 800 V (NOMINAL MAINS VOLTAGE ≤ 150 V)				Transient value for SECONDARY CIRCUIT ≤ 1 500 V (150 V < NOMINAL MAINS VOLTAGE ≤ 300 V)				Transient value for SECONDARY CIRCUIT ≤ 2 500 V (300 V < NOMINAL MAINS VOLTAGE ≤600 V)		Circuit not subject to transient overvoltages	
Voltage V peak or V d.c.	Voltage V r.m.s. (sinu-soidal)	Pollution degrees 1 and 2		Pollution degree 3		Pollution degrees 1 and 2		Pollution degree 3		Pollution degrees 1, 2 and 3		Pollution degrees 1 and 2 only	
		One MOOP	Two MOOP	One MOOP	Two MOOP	One MOOP	Two MOOP	One MOOP	Two MOOP	One MOOP	Two MOOP	One MOOP	Two MOOP
71	50	0,7	1,4	1,3	2,6	1,0	2,0	1,3	2,6	2,0	4,0	0,4	0,8
140	100	0,7	1,4	1,3	2,6	1,0	2,0	1,3	2,6	2,0	4,0	0,7	1,4
210	150	0,9	1,8	1,3	2,6	1,0	2,0	1,3	2,6	2,0	4,0	0,7	1,4
280	200	One MOOP 1,4; two MOOP 2,8								2,0	4,0	1,1	2,2
420	300	One MOOP 1,9; two MOOP 3,8								2,0	4,0	1,4	2,8
700	500	One MOOP 2,5; two MOOP 5,0											
840	600	One MOOP 3,2; two MOOP 5,0											
1 400	1 000	One MOOP 4,2; two MOOP 5,0											
2 800	2 000	One or two MOOP 8,4, but see 8.9.1.13											
7 000	5 000	One or two MOOP 17,5, but see 8.9.1.13											
9 800	7 000	One or two MOOP 25, but see 8.9.1.13											
14 000	10 000	One or two MOOP 37, but see 8.9.1.13											
28 000	20 000	One or two MOOP 80, but see 8.9.1.13											
42 000	30 000	One or two MOOP 130, but see 8.9.1.13											

NOTE AIR CLEARANCES are a function of peak voltage in the circuit. The r.m.s voltage column is provided for the special case where the voltage has a sinusoidal waveform.

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Table 16 – Minimum CREEPAGE DISTANCES providing MEANS OF OPERATOR PROTECTION [a]

CREEPAGE DISTANCE in mm

WORKING VOLTAGE V r.m.s or d.c.	Spacing for one MEANS OF OPERATOR PROTECTION						
	Pollution degree 1	Pollution degree 2			Pollution degree 3		
	Material group	Material group			Material group		
	I, II, IIIa, IIIb	I	II	IIIa or IIIb	I	II	IIIa or IIIb
50	Use the AIR CLEARANCE from the appropriate table	0,6	0,9	1,2	1,5	1,7	1,9
100		0,7	1,0	1,4	1,8	2,0	2,2
125		0,8	1,1	1,5	1,9	2,1	2,4
150		0,8	1,1	1,6	2,0	2,2	2,5
200		1,0	1,4	2,0	2,5	2,8	3,2
250		1,3	1,8	2,5	3,2	3,6	4,0
300		1,6	2,2	3,2	4,0	4,5	5,0
400		2,0	2,8	4,0	5,0	5,6	6,3
600		3,2	4,5	6,3	8,0	9,6	10,0
800		4.0	5,6	8,0	10,0	11,0	12,5
1 000		5,0	7,1	10,0	12,5	14,0	16,0

NOTE Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION are obtained by doubling the values in this table.

[a] CREEPAGE DISTANCES within this table apply to all situations.

WORKING VOLTAGE V r.m.s or d.c.	Spacing for one MEANS OF OPERATOR PROTECTION						
	Pollution degree 1	Pollution degree 2			Pollution degree 3		
	Material group	Material group			Material group		
	I, II, IIIa, IIIb	I	II	IIIa or IIIb	I	II	IIIa or IIIb
25	Use the AIR CLEARANCE from the appropriate table	0,5	0.5	0,5	1,3	1,3	1,3
50		0,6	0,9	1,2	1,5	1,7	1,9
100		0,7	1,0	1,4	1,8	2,0	2,2
125		0,8	1,1	1,5	1,9	2,1	2,4
150		0,8	1,1	1,6	2,0	2,2	2,5
200		1,0	1,4	2,0	2,5	2,8	3,2
250		1,3	1,8	2,5	3,2	3,6	4,0
300		1,6	2,2	3,2	4,0	4,5	5,0
400		2,0	2,8	4,0	5,0	5,6	6,3
600		3,2	4,5	6,3	8,0	9,6	10,0
800		4.0	5,6	8,0	10,0	11,0	12,5
1 000		5,0	7,1	10,0	12,5	14,0	16,0

NOTE 1 Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION are obtained by doubling the values in this table.

NOTE 2 A CREEPAGE DISTANCE cannot be less than the required air clearance. See 8.9.1.4.

NOTE 3 For WORKING VOLTAGE values greater than 1 000 V, refer to Table A.2.

[a] CREEPAGE DISTANCES within this table apply to all situations.

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8.9.2 * Application

a) * For insulation in the MAINS PART between parts of opposite polarity, the minimum CREEPAGE DISTANCES and AIR CLEARANCES are not required if short circuiting of each single one of these CREEPAGE DISTANCES and AIR CLEARANCES in turn does not result in a HAZARDOUS SITUATION described in 13.1.

b) The contribution to the CREEPAGE DISTANCES of any groove or air gap less than 1 mm wide shall be limited to its width (see Figure 23 to Figure 31 [inclusive]).

c) If AIR CLEARANCE provides a MEANS OF PROTECTION, the relative positioning shall be such that the relevant parts are rigid and located by moulding or the design shall be otherwise such that there is no reduction of a distance below the specified value by deformation or movement of the parts.

Where limited movement of one of the relevant parts is normal or likely, this shall be taken into account when computing the minimum AIR CLEARANCE.

8.9.3 * Spaces filled by insulating compound

8.9.3.1 General

Where distances between conductive parts are filled with insulating compound, including where insulation is reliably cemented together with insulating compound, so that AIR CLEARANCES and CREEPAGE DISTANCES do not exist, only the requirements for solid insulation apply.

NOTE Examples of such treatment include potting, encapsulation and vacuum impregnation, components or subassemblies that are treated with an insulating compound that fills voids; and internal insulation between adjacent tracks on one layer of a multi-layer printed board.

Compliance is checked by inspection, measurement and test of samples. Requirements for CREEPAGE DISTANCES and AIR CLEARANCES do not apply if samples pass the thermal cycling, humidity preconditioning and dielectric strength tests specified in either 8.9.3.2 and 8.9.3.4 or 8.9.3.3 and 8.9.3.4.

8.9.3.2 Insulating compound forming solid insulation between conductive parts

For situations where insulating compound forms solid insulation between conductive parts, a single finished sample is tested. The sample is subjected to the thermal cycling PROCEDURE as specified in 8.9.3.4, followed by humidity preconditioning according to 5.7 except for 48 hours only, followed by a dielectric strength test according to 8.8.3 except that the test voltage is multiplied by 1,6. The tests are followed by inspection, including sectioning, and measurement. Cracks or voids in the insulating compound such as would affect the homogeneity of the material constitute a failure.

8.9.3.3 Insulating compound forming a cemented joint with other insulating parts

For situations where insulating compound forms a cemented joint with other insulating parts, the reliability of the joint is checked by testing three samples. If a winding of solvent-based enamelled wire is used, it is replaced for the test by a metal foil or by a few turns of bare wire, placed close to the cemented joint. The three samples are then tested as follows.

– *One of the samples is subjected to the thermal cycling PROCEDURE as specified in 8.9.3.4. Immediately after the last period at highest temperature during thermal cycling it is subjected to a dielectric strength test according to 8.8.3 except that the test voltage is multiplied by 1,6*;

– *The other two samples are subjected to humidity preconditioning according to 5.7 except for 48 hours only, followed by a dielectric strength test according to 8.8.3 except that the test voltage is multiplied by 1,6.*

8.9.3.4 Thermal cycling

The sample is subjected 10 times to the following sequence of temperature cycles:

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68 h at T_1 ± 2 °C;

1 h at 25 °C ± 2 °C;

2 h at 0 °C ± 2 °C;

not less than 1 h at 25 °C ± 2 °C,

where T_1 is the higher of

– *10 °C above the maximum temperature of the relevant part as determined according to 11.1.1; or*

– *85 °C.*

However, the 10 °C margin is not added if the temperature is measured by an embedded thermocouple.

The period of time taken for the transition from one temperature to another is not specified, but the transition is permitted to be gradual.

8.9.4 * Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES

Compliance is checked by measurement taking into account the rules in Figure 22 to Figure 31 (inclusive). In each figure, the dashed line (– – –) represents AIR CLEARANCE *and the shaded bar ( )represents* CREEPAGE DISTANCE.

The minimum spacing (X) for grooves transverse to the CREEPAGE DISTANCE in Figure 23 to Figure 25 and Figure 27 to Figure 31 (inclusive) that are considered a MEANS OF OPERATOR PROTECTION may be adjusted based on pollution degree if the minimum AIR CLEARANCE is 3 mm or more. The minimum width of the groove is:

– *0,25 mm for pollution degree 1*

– *1,0 mm for pollution degree 2*

– *1,5 mm for pollution degree 3*

If the specified minimum AIR CLEARANCE is less than 3 mm, the minimum spacing (X) for grooves transverse to the CREEPAGE DISTANCE is the lesser of:

– *the relevant value specified in the previous paragraph, or*

– *one third of the specified minimum AIR CLEARANCE.*

The minimum spacing (X) for a groove transverse to a CREEPAGE DISTANCE that is considered a MEANS OF PATIENT PROTECTION is 1 mm for pollution degree 1 and pollution degree 2, and 1,5 mm for pollution degree 3.

Any corner with included angle less than 80° is assumed to be bridged with an insulating link of 1 mm moved into the least favourable position (see Figure 25).

Where the distance across the top of a groove is 1 mm or more, no CREEPAGE DISTANCE exists across the air space (see Figure 24).

CREEPAGE DISTANCES and AIR CLEARANCES between parts moving relative to each other are measured with the parts in their least favourable positions.

Computed CREEPAGE DISTANCE is never less than measured AIR CLEARANCE.

Coatings of varnish, enamel or oxide are ignored. Coverings of any insulating material, however, are considered as insulation, if the covering is equivalent to a sheet of insulating material of equal thickness with respect to its electrical, thermal and mechanical properties.

If CREEPAGE DISTANCES or AIR CLEARANCES for one or two MEANS OF PROTECTION are interrupted by one or more floating conductive parts, the minimum values specified in Table ~~11~~ 12 to Table 16 (inclusive) apply to the sum of the sections, except that distances less than 1 mm are not taken into consideration.

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If there are grooves transverse to the CREEPAGE DISTANCE, the wall of the groove is counted as CREEPAGE DISTANCE only if the width of the groove is more than 1 mm (see Figure 24). In all other cases the groove is neglected.

In the case of a barrier placed on the surface of insulation or held in a recess, the CREEPAGE DISTANCES are measured over the barrier only if the latter is so affixed that dust and moisture cannot penetrate into the joint or recess.

For ME EQUIPMENT provided with an APPLIANCE INLET, the measurements are made with an appropriate connector inserted. For other ME EQUIPMENT incorporating POWER SUPPLY CORDS, they are made with supply conductors of the largest cross-sectional area specified by the MANUFACTURER and also without conductors.

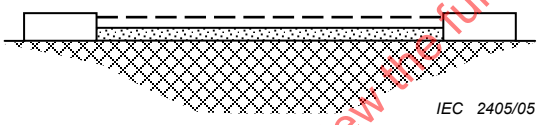
Movable parts are placed in the least favourable position; nuts and screws with non-circular heads are tightened in the least favourable position.

CREEPAGE DISTANCES and AIR CLEARANCES through slots or openings in external parts are measured to the standard test finger of Figure 6. If necessary, a force is applied to any point on bare conductors and to the outside of metal ENCLOSURES in an endeavour to reduce the CREEPAGE DISTANCES and AIR CLEARANCES while taking the measurements.

The force is applied by means of a standard test finger having a tip as shown in Figure 6 and has a value of:

2 N for bare conductors;
30 N for ENCLOSURES.

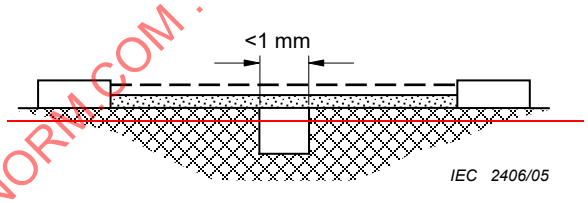
CREEPAGE DISTANCE and AIR CLEARANCES are measured after use of the test hook according to 5.9.2.2, if relevant.

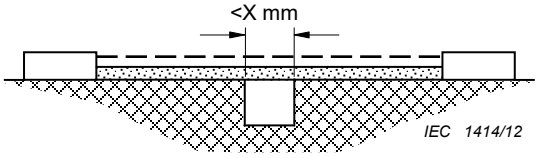


Condition: Path under consideration is a flat surface.

Rule: CREEPAGE DISTANCE and AIR CLEARANCE are measured directly across the surface.

Figure 22 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 1



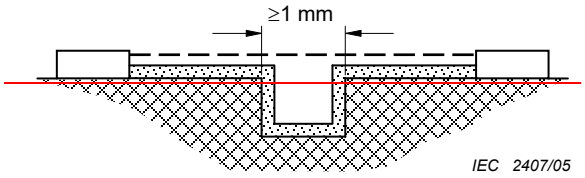


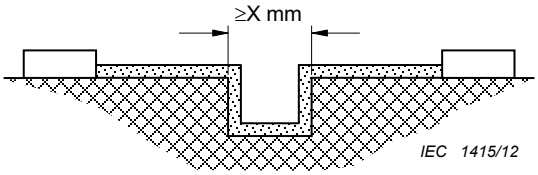
Condition: Path under consideration includes a parallel- or converging-sided groove of any depth with a width less than ~~1~~ X mm.

Rule: CREEPAGE DISTANCE and AIR CLEARANCE are measured directly across the groove as shown.

Figure 23 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 2

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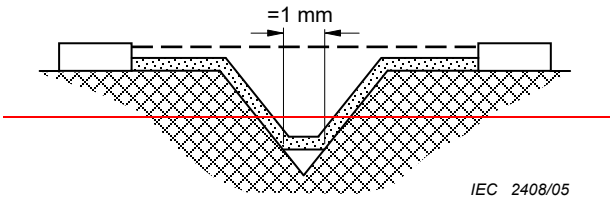


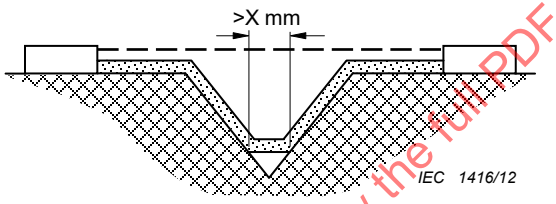


Condition: Path under consideration includes a parallel-sided groove of any depth and equal to or more than ~~1~~ X mm.

Rule: AIR CLEARANCE is the "line of sight" distance. CREEPAGE DISTANCE path follows the contour of the groove.

Figure 24 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 3

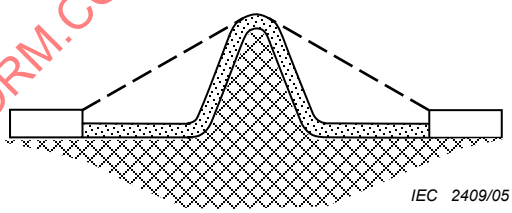




Condition: Path under consideration includes a V-shaped groove with a width greater than ~~1~~ X mm and an internal angle of less than 80°.

Rule: AIR CLEARANCE is the "line of sight" distance. CREEPAGE DISTANCE path follows the contour of the groove but "short circuits" the bottom of the groove by a ~~1~~ X mm link.

Figure 25 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 4

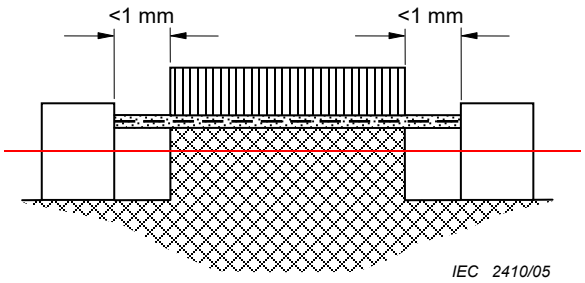


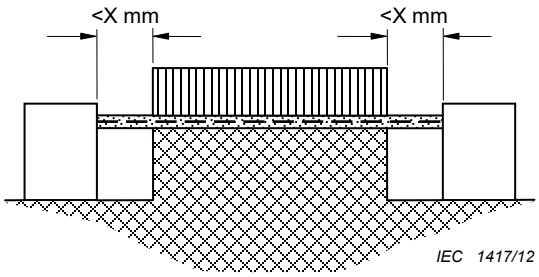
Condition: Path under consideration includes a rib.

Rule: AIR CLEARANCE is the shortest direct air path over the top of the rib. CREEPAGE DISTANCE path follows the contour of the rib.

Figure 26 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 5

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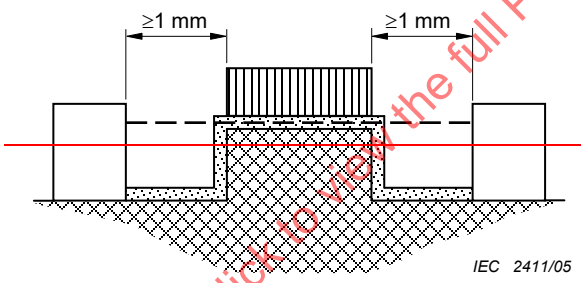


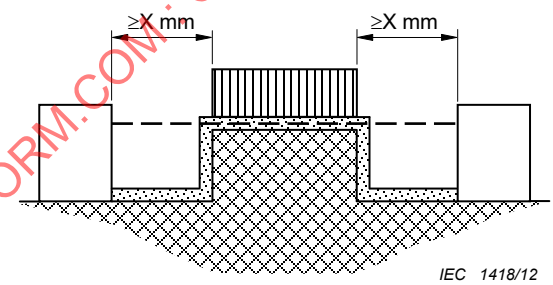


Condition: Path under consideration includes an uncemented joint (see 8.9.3) with grooves less than ~~1~~ X mm wide on each side.

Rule: CREEPAGE DISTANCE and AIR CLEARANCE path are the "line of sight" distance shown.

Figure 27 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 6



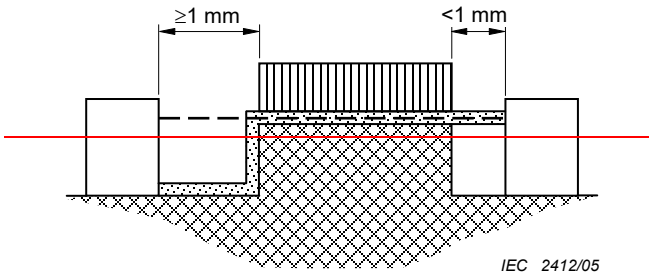


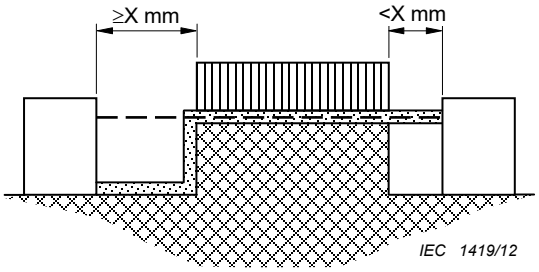
Condition: Path under consideration includes an uncemented joint (see 8.9.3) with grooves equal to or more that ~~1~~ X mm wide on each side.

Rule: AIR CLEARANCE is the "line of sight" distance. CREEPAGE DISTANCE path follows the contour of the groove.

Figure 28 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 7

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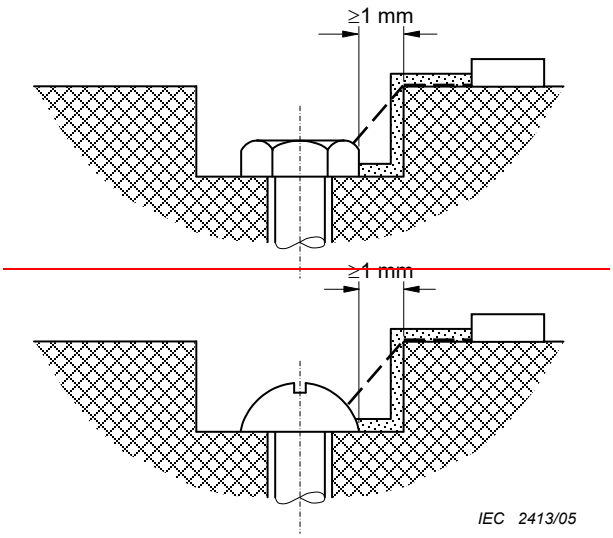


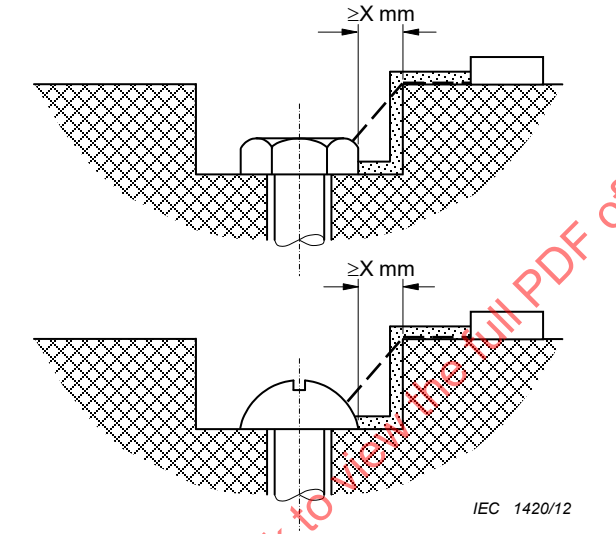


Condition:	Path under consideration includes an uncemented joint (see 8.9.3) with a groove on one side less than ~~1~~ X mm wide and the groove on the other side equal to or more than ~~1~~ X mm wide.
Rule:	AIR CLEARANCE and CREEPAGE DISTANCE are as shown.

Figure 29 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 8

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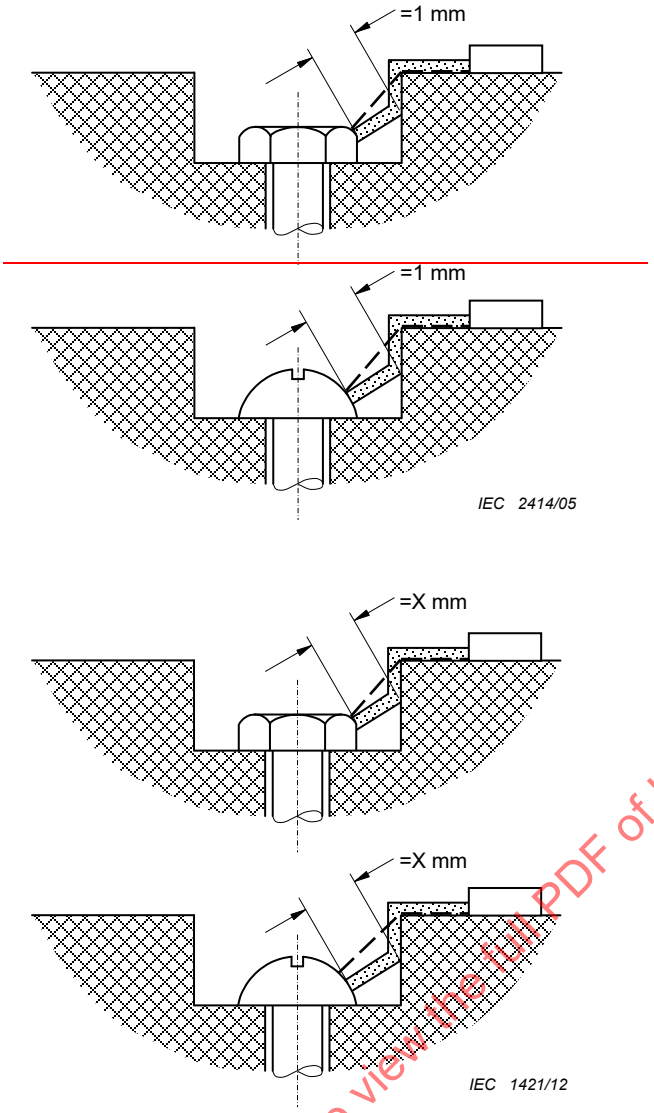


Condition: Gap between head of screw and wall of recess wide enough to be taken into account.

Rule: The AIR CLEARNACE is the shortest distance to any point on the head of the screw. CREEPAGE DISTANCE path follows the surface.

Figure 30 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 9

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Condition: Gap between head of screw and wall of recess too narrow to be taken into account.

Rule: Measurement of CREEPAGE DISTANCE is from screw to wall at any point where the distance is equal to ~~1~~ X mm. The AIR CLEARNACE is the shortest distance to any point on the head of the screw.

Figure 31 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 10

8.10 Components and wiring

8.10.1 * Fixing of components

Components of ME EQUIPMENT, the unwanted movement of which could result in an unacceptable RISK, shall be mounted securely to prevent such movement.

Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE.

8.10.2 * Fixing of wiring

Conductors and connectors of ME EQUIPMENT shall be so secured or insulated that accidental detachment shall not result in a HAZARDOUS SITUATION. They are not considered to be adequately secured if on breaking free at their joint and moving about their support point they are capable of touching ~~circuit points~~ parts resulting in a HAZARDOUS SITUATION described in 13.1.

Breaking free of one means of mechanical restraint shall be considered a SINGLE FAULT CONDITION.

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Stranded conductors shall not be solder-coated if they are affixed by any clamping means and poor contact could result in a HAZARDOUS SITUATION described in 13.1.

Compliance is checked by inspection of the ME EQUIPMENT ~~and the RISK MANAGEMENT FILE~~.

8.10.3 Connections between different parts of ME EQUIPMENT

Flexible cords detachable without the use of a TOOL that are used for interconnection of different parts of ME EQUIPMENT shall be provided with means for connection such that compliance of metal ACCESSIBLE PARTS with 8.4 is not compromised when a connection is loosened or broken due to the disengagement of one of the connecting means.

Compliance is checked by inspection and measurement and, if necessary, by a test with the standard test finger according to 5.9.2.1.

8.10.4 * Cord-connected HAND-HELD parts and cord-connected foot-operated control devices (see also 15.4.7)

8.10.4.1 Limitation of operating voltages

Cord-connected HAND-HELD and foot-operated control devices of ME EQUIPMENT and their associated connection cords shall contain only conductors and components operating at voltages not exceeding 42,4 V peak a.c. or 60 V d.c. in circuits isolated from the MAINS PART by two MEANS OF PROTECTION. The d.c. limit of 60 V applies to d.c. with not more than 10 % peak-to-peak ripple. If the ripple exceeds that amount, the 42,4 V peak limit applies.

Compliance is checked by inspection and, if necessary, voltage measurements.

8.10.4.2 Connection cords

The connection and anchorage at both ends of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT~~, at both ends of the cable to the control device,~~ shall comply with the requirements specified for POWER SUPPLY CORDS in 8.11.3, if breaking free or shorting between the conductors could result in a HAZARDOUS SITUATION described in 13.1. This requirement also applies to other HAND-HELD parts if disturbance or breaking of one or more of the connections could result in a HAZARDOUS SITUATION described in 13.1.

Compliance is checked by performance of the tests of 8.11.3.

8.10.5 * Mechanical protection of wiring

a) Internal cables and wiring shall be adequately protected against contact with a moving part or from friction at sharp corners and edges where damage to insulation could result in a HAZARDOUS SITUATION described in 13.1.

b) ME EQUIPMENT shall be so designed that wiring, cord forms or components are not likely to be damaged during assembly or the opening or closing of ACCESS COVERS where such damage could result in a HAZARDOUS SITUATION described in 13.1.

Compliance is checked by inspection and, where appropriate, by manual test ~~or reference to the RISK MANAGEMENT FILE~~.

8.10.6 Guiding rollers for insulated conductors

Guiding rollers of insulated conductors of ME EQUIPMENT shall be constructed in such a manner that movable insulated conductors in NORMAL USE are not bent round a radius of less than five times the outer diameter of the lead concerned.

Compliance is checked by inspection and measurement of the relevant dimensions.

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8.10.7 * Insulation of internal wiring

a) If insulating sleeving is needed on internal wiring of ME EQUIPMENT, it shall be adequately secured. Sleeving that can only be removed by breaking or cutting or that is secured at both ends may be used to satisfy this requirement.

b) Inside ME EQUIPMENT the sheath of a flexible cord shall not be used as a MEANS OF PROTECTION if it is subject to mechanical or thermal stresses outside its RATED characteristics.

c) Insulated conductors of ME EQUIPMENT that in NORMAL USE are subject to temperatures exceeding 70 °C shall have insulation of heat-resistant material if compliance with this standard is likely to be impaired by deterioration of the insulation.

Compliance is checked by inspection and, if necessary, by special tests. Temperatures are determined as indicated in 11.1.

8.11 MAINS PARTS, components and layout

8.11.1 Isolation from the SUPPLY MAINS

a) * ME EQUIPMENT shall have means to isolate its circuits electrically from the SUPPLY MAINS on all poles simultaneously.

PERMANENTLY INSTALLED ME EQUIPMENT connected to a polyphase SUPPLY MAINS may be provided with a device that does not interrupt the neutral conductor, provided that local installation conditions are such that in NORMAL CONDITION the voltage on the neutral conductor can be expected not to exceed the limits specified in 8.4.2 c).

For PERMANENTLY INSTALLED ME EQUIPMENT, the means provided to isolate its circuits electrically from the SUPPLY MAINS shall be capable of being locked in the off position if:

– reconnection would result in a HAZARDOUS SITUATION; or

– any OPERATOR including SERVICE PERSONNEL is unable to view the means of isolation from their intended position.

The locking mechanism may be in a SUPPLY MAINS switch provided by the RESPONSIBLE ORGANIZATION.

The requirements for the isolation device shall be specified in the ACCOMPANYING DOCUMENTS.

b) Means for isolation either shall be incorporated in ME EQUIPMENT or, if external, shall be described in the technical description (see 7.9.3.1).

c) * A SUPPLY MAINS switch that is used to comply with 8.11.1 a) shall comply with the CREEPAGE DISTANCES and AIR CLEARANCES as specified in IEC 61058-1 for a MAINS TRANSIENT VOLTAGE of 4 kV.

NOTE Table 22 in IEC 61058-1:2000 specifies different values for contact separation depending on the MAINS TRANSIENT VOLTAGE , which is referred to in that table as the “rated impulse withstand voltage.”

d) A SUPPLY MAINS switch shall not be incorporated in a POWER SUPPLY CORD or any other external, flexible lead.

e) The ~~direction of movement of the~~ actuator of a SUPPLY MAINS switch that is used to comply with 8.11.1 a) shall comply with IEC 60447.

f) In non-PERMANENTLY INSTALLED ME EQUIPMENT that has no SUPPLY MAINS switch, a suitable plug device used to isolate ME EQUIPMENT from the SUPPLY MAINS shall be considered as

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complying with the requirements of 8.11.1 a). An APPLIANCE COUPLER or a flexible cord with a MAINS PLUG may be used.

g) A fuse or a semiconductor device shall not be used as an isolating means in the sense of this subclause.

h) * ME EQUIPMENT shall not include a device that causes disconnection of the ME EQUIPMENT from the SUPPLY MAINS by producing a short circuit that results in operation of an over-current protection device.

i) * Any part within the ENCLOSURE of ME EQUIPMENT with a circuit voltage exceeding 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device that is accessible at all times shall be protected against being touched even after opening of the ENCLOSURE by an additional covering or, in the case of a spatially separated arrangement, shall be marked clearly as exceeding the permitted voltage for parts that can be touched. The use of the symbol ISO 7000-0434 (see Table D.1, symbol 10) is not sufficient. A warning notice on the outside of the ME EQUIPMENT may be used.

Compliance is checked by inspection.

For a part that cannot be disconnected from the supply by an external switch or a plug device that is accessible at all times, compliance is checked by inspection of the required cover or warning notice (if present) and, if necessary, by application of the standard test finger of Figure 6.

8.11.2 * MULTIPLE SOCKET-OUTLETS

MULTIPLE SOCKET-OUTLETS that are integral with ME EQUIPMENT shall comply with the requirements of 16.2 d), second dash, and 16.9.2.1.

Compliance is checked by inspection.

8.11.3 POWER SUPPLY CORDS

8.11.3.1 Application

The MAINS PLUG of ME EQUIPMENT shall not be fitted with more than one POWER SUPPLY CORD.

Compliance is checked by inspection.

8.11.3.2 Types

Any POWER SUPPLY CORD of ME EQUIPMENT shall be not less robust than ordinary tough rubber-sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, designation 53).

A polyvinyl chloride insulated POWER SUPPLY CORD shall not be used for ME EQUIPMENT having external metal parts with a temperature exceeding 75 °C and which can be touched in NORMAL USE by the cord, unless it is RATED for that temperature. See also Table 22.

Compliance is checked by inspection and measurement.

8.11.3.3 Cross-sectional area of POWER SUPPLY CORD conductors

The NOMINAL cross-sectional area of conductors of any POWER SUPPLY CORD of ME EQUIPMENT shall be not less than that shown in Table 17.

Compliance is checked by inspection.

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Table 17 – NOMINAL cross-sectional area of conductors of a POWER SUPPLY CORD

RATED current (*I*) of ME EQUIPMENT A	NOMINAL cross-sectional area mm² Cu
I ≤ 6	0,75
6 < *I* ≤ 10	1
10< *I* ≤ 16	1,5
16< *I* ≤ 25	2,5
25< *I* ≤ 32	4
32< *I* ≤ 40	6
40< *I* ≤ 63	10

8.11.3.4 * APPLIANCE COUPLERS

APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6.

Compliance is checked by inspection of the documentation demonstrating that the APPLIANCE COUPLER conforms to the requirements of IEC 60320-1.

8.11.3.5 * Cord anchorage

a) The conductors of a POWER SUPPLY CORD shall be relieved from strain, including twisting, and the insulation of the conductors shall be protected from abrasion at the point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage.

b) If a total insulation failure of the POWER SUPPLY CORD could cause conductive ACCESSIBLE PARTS that are not PROTECTIVELY EARTHED to exceed the limits specified in 8.4, the cord anchorage of a POWER SUPPLY CORD shall be made:

- of insulating material, or
- of metal, insulated from conductive ACCESSIBLE PARTS not PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or
- of metal provided with an insulating lining, which shall be affixed to the cord anchorage, unless it is a flexible bushing that forms part of the cord guard specified in 8.11.3.6, and which shall comply with the requirements for one MEANS OF PROTECTION.

c) The cord anchorage of a POWER SUPPLY CORD shall be so designed that the cord is not clamped by a screw that bears directly on the cord insulation.

d) Screws, if any, that have to be operated when replacing the POWER SUPPLY CORD shall not serve to fix any component other than parts of the cord anchorage.

e) Conductors of the POWER SUPPLY CORD shall be so arranged that if the cord anchorage fails the PROTECTIVE EARTH CONDUCTOR is not subject to strain as long as the phase conductors are in contact with their terminals.

f) The cord anchorage shall prevent the POWER SUPPLY CORD from being pushed into the ME EQUIPMENT or MAINS CONNECTOR.

Compliance is checked by inspection and by the following tests:

ME EQUIPMENT, if designed for a POWER SUPPLY CORD, is tested with the cord supplied by the MANUFACTURER.

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The POWER SUPPLY CORD conductors are, if possible, disconnected from the terminals or from the MAINS CONNECTOR.

The cord is subjected 25 times to a pull on the sheath of the value shown in Table 18. The pulls are applied in the most unfavourable direction without jerks, each time for 1 s.

Immediately afterwards, the cord is subjected for 1 min to a torque of the value shown in Table 18.

Table 18 – Testing of cord anchorages

Mass (*m*) of ME EQUIPMENT kg	**Pull** N	**Torque** Nm
$m \leq 1$	30	0,1
$1 < m \leq 4$	60	0,25
$m > 4$	100	0,35

A cord anchorage that allows the cord sheath to be longitudinally displaced by more than 2 mm or the conductor ends to move over a distance of more than 1 mm from their normally connected position is considered to fail.

CREEPAGE DISTANCES and AIR CLEARANCES that are reduced below the values specified in 8.9 constitutes a failure.

Attempt to push the cord into the ME EQUIPMENT or the MAINS CONNECTOR. If the cord can be pushed into the ME EQUIPMENT or the MAINS CONNECTOR to such an extent that the cord or internal parts are damaged, the cord anchorage is considered to fail.

8.11.3.6 * Cord guards

POWER SUPPLY CORDS of other than STATIONARY ME EQUIPMENT shall be protected against excessive bending at the inlet opening of the equipment or of the MAINS CONNECTOR by means of a cord guard of insulating material or by means of an appropriately shaped opening in the ME EQUIPMENT.

Compliance is checked by inspection and by either the test described in IEC 60335-1:2001, subclause 25.14 or the following test. An arrangement that passes either test is considered to comply with the requirement.

ME EQUIPMENT having a cord guard or opening is so placed that the axis of the cord guard, where the cord leaves it, projects at an angle of 45° when the cord is free from stress. A mass equal to 10 x D^2 gram is then attached to the free end of the cord, where D is the overall diameter of, or for flat cords, the minor overall dimension of the POWER SUPPLY CORD in millimetres.

If the cord guard is of temperature-sensitive material, the test is made at 23 °C ± 2 °C.

Flat cords are bent in the plane of least resistance.

If the radius of curvature of the cord, immediately after the mass has been attached, is anywhere less than 1,5 x D, the cord guard is considered to fail.

8.11.4 MAINS TERMINAL DEVICES

8.11.4.1 * General requirements for MAINS TERMINAL DEVICES

PERMANENTLY INSTALLED ME EQUIPMENT and ME EQUIPMENT having a non-DETACHABLE POWER SUPPLY CORD that is replaceable by SERVICE PERSONNEL shall be provided with MAINS TERMINAL DEVICES that ensure reliable connection.

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Reliance shall not be placed upon the terminals alone to maintain the conductors in position, unless barriers are provided such that CREEPAGE DISTANCES and AIR CLEARANCES that serve as a MEANS OF PROTECTION cannot be reduced to less than the values specified in 8.9, if any conductor breaks away. See also 8.10.2.

Terminals of components other than terminal blocks may be used as terminals intended for external conductors if they comply with the requirements of this subclause and are properly marked according to 7.3.7.

Screws and nuts that clamp external conductors shall not serve to fix any other component, except that they may also clamp internal conductors if these are so arranged that they are unlikely to be displaced when fitting the supply conductors.

Compliance is checked by inspection.

8.11.4.2 Arrangement of MAINS TERMINAL DEVICES

a) * For ME EQUIPMENT with rewirable cords where terminals are provided for the connection of external cords or POWER SUPPLY CORDS, these terminals together with any PROTECTIVE EARTH TERMINAL shall be closely grouped, so as to provide a convenient means of connection.

Compliance is checked by inspection.

b) For details of PROTECTIVE EARTH CONDUCTOR connections, see 8.6.

c) For marking of MAINS TERMINAL DEVICES, see 7.3.

d) MAINS TERMINAL DEVICES shall not be accessible without the use of a TOOL.

Compliance is checked by inspection.

e) MAINS TERMINAL DEVICES shall be so located or shielded that, if a wire of a stranded conductor escapes when the conductors are fitted, short circuiting a MEANS OF PROTECTION is unlikely.

Compliance is checked by inspection and, if necessary, by the following test:

The end of a flexible conductor having the NOMINAL cross-sectional area specified in Table 17 is stripped of its insulation for a length of 8 mm.

A single wire of the stranded conductor is left free and the rest of the conductor is secured to the terminal.

The free wire is bent in every possible direction without pulling back the insulating sheath and without making sharp bends around partitions.

Contact between the free wire and any other part such that a MEANS OF PROTECTION is short circuited constitutes a failure.

8.11.4.3 Fixing of mains terminals

Terminals shall be FIXED such that, when the means for clamping the conductors are tightened or loosened, the internal wiring is not subjected to stress and CREEPAGE DISTANCES and AIR CLEARANCES are not reduced below the values specified in 8.9.

Compliance is checked by inspection and by measurement after fastening and loosening a conductor of the largest cross-sectional area specified 10 times.

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8.11.4.4 * Connections to mains terminals

Terminals with clamping means for a rewirable flexible cord shall not require special preparation of the conductors in order to effect correct connection, and they shall be so designed or placed that the conductors are not damaged and cannot slip out when the clamping means are tightened. See also 8.10.2.

Compliance is checked by inspection of the terminals and of the conductors after the test of 8.11.3.4.

8.11.4.5 Accessibility of the connection

The space inside ME EQUIPMENT designed for FIXED wiring or a rewirable POWER SUPPLY CORD shall be adequate to allow conductors to be easily introduced and connected, and covers, if any, to be fitted without damage to the conductors or their insulation. It shall be possible to check that the conductors are correctly connected and positioned before the ACCESS COVER is fitted. See also 8.10.5.

Compliance is checked by inspection and by an installation test.

8.11.5 * Mains fuses and OVER-CURRENT RELEASES

A fuse or OVER-CURRENT RELEASE shall be provided in each supply lead for CLASS I ME EQUIPMENT and for CLASS II ME EQUIPMENT having a functional earth connection according to 8.6.9, and in at least one supply lead for other single-phase CLASS II ME EQUIPMENT, except that:

– for PERMANENTLY INSTALLED ME EQUIPMENT, the neutral conductor shall not be fused;

– if examination shows that two MEANS OF PROTECTION are present between all parts of opposite polarity within the MAINS PART, and between all parts of the MAINS PART and earth, then the fuses or OVER-CURRENT RELEASES may be omitted. These insulation requirements shall be continued up to and within any component. The effect of short-circuit fault conditions in other circuits shall be ~~considered~~ VERIFIED before eliminating fuses or OVER-CURRENT RELEASES.

A PROTECTIVE EARTH CONDUCTOR shall not incorporate a fuse or OVER-CURRENT RELEASE.

Protective devices shall have adequate breaking capacity to interrupt the maximum fault current (including short-circuit current) which can flow.

NOTE If fuses complying with IEC 60127[20)] are used and the prospective short-circuit current exceeds 35 A or 10 times the current rating of the fuse, whichever is greater, the fuses should have high breaking capacity (1 500 A).

Justification for omission of fuses or OVER-CURRENT RELEASES shall be ~~included in the RISK MANAGEMENT FILE~~ documented.

Compliance is checked by inspection of the ME EQUIPMENT and the ~~RISK MANAGEMENT FILE~~ MANUFACTURER'S documentation.

8.11.6 Internal wiring of the MAINS PART

a) Internal wiring in a MAINS PART between the MAINS TERMINAL DEVICE or the APPLIANCE INLET and the protective devices shall have a cross-sectional area not less than the minimum required for the POWER SUPPLY CORD as specified in 8.11.3.3.

Compliance is checked by inspection.

b) The cross-sectional area of other wiring in the MAINS PART and the sizes of tracks on printed wiring circuits of ME EQUIPMENT shall be sufficient to prevent fire in case of possible fault currents.

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20) IEC 60127 series, *Miniature fuses*

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When necessary, compliance is checked by connecting the ME EQUIPMENT to a specified SUPPLY MAINS from which the most unfavourable short-circuit current expected can be drawn in the event of a fault in the MAINS PART. Subsequently, a fault in a single insulation in the MAINS PART is simulated so that the fault current is the least favourable. The occurrence of any HAZARDOUS SITUATIONS listed in 13.1.2 constitutes a failure.

9 * Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

9.1 MECHANICAL HAZARDS of ME EQUIPMENT

For general requirements on design and manufacture of ME EQUIPMENT, see Clause 4 and 15.3.

Table 19 identifies the subclauses that address the MECHANICAL HAZARDS.

Table 19 – MECHANICAL HAZARDS covered by this clause

MECHANICAL HAZARD	Covered by subclause
Crushing HAZARD	9.2, 9.4 and 9.8
Shearing HAZARD	9.2 and 9.8
Cutting or severing HAZARD	9.2, 9.3 and 9.8
Entanglement HAZARD	9.2
Trapping HAZARD	9.2
Stabbing or puncturing HAZARD	9.2, 9.3 and 9.8
Friction or abrasion HAZARD	9.2 and 9.3
Expelled parts HAZARD	9.5
High pressure fluid ejection HAZARD	9.7
Falling HAZARD	9.8
Instability HAZARD	9.4
Impact HAZARD	9.2 and 9.8
Moving and positioning of PATIENT	9.2 and 9.4
Vibration and noise	9.6

9.2 * MECHANICAL HAZARDS associated with moving parts

9.2.1 * General

ME EQUIPMENT with moving parts shall be designed, built and laid out so that, when PROPERLY INSTALLED and used as indicated in the ACCOMPANYING DOCUMENTS or under reasonably foreseeable misuse, the RISKS associated with those moving parts are reduced to an acceptable level.

The RISK from contact with the moving parts shall be reduced to an acceptable level by use of ~~protective~~ RISK CONTROL measures, bearing in mind the ease of access, the ME EQUIPMENT'S function, the shape of the parts, the energy and speed of the motion and the benefits to the PATIENT.

The RESIDUAL RISK associated with moving parts is considered acceptable if exposure is needed for the ME EQUIPMENT to perform its intended function~~. If after all reasonable protective measures have been implemented HAZARDS persist, warnings shall be marked on the ME EQUIPMENT or given in the instructions for use~~, and RISK CONTROL measures have been implemented (e.g. warnings).

NOTE 1 Requirements for parts subject to wear are found in 15.2.

NOTE 2 See ISO 14971:2007, subclauses 6.2 and 6.5.

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9.2.2 TRAPPING ZONE

9.2.2.1 General

Where feasible, ME EQUIPMENT with a TRAPPING ZONE shall comply with the requirements of one or more of the following:

– gaps as specified in 9.2.2.2; or

– safe distances as specified in 9.2.2.3; or

– GUARDS and ~~protective~~ other RISK CONTROL measures as specified in 9.2.2.4; or

– continuous activation as specified in 9.2.2.5.

If implementation of the above ~~protective~~ RISK CONTROL measures would be inconsistent with the INTENDED USE of the ME EQUIPMENT or the ME SYSTEM, control of the relevant motion shall comply with 9.2.2.6.

9.2.2.2 Gaps

A TRAPPING ZONE is considered not to present a MECHANICAL HAZARD if the gaps of the TRAPPING ZONE comply with the dimensions specified in Table 20.

NOTE In general the values for adults should be used. However, in the case of devices specifically designed for use with children, the dimensions given for children should be applied.

9.2.2.3 Safe distances

A TRAPPING ZONE is considered not to present a MECHANICAL HAZARD if the distances separating the OPERATOR, PATIENT and other persons from the TRAPPING ZONES exceed the values specified in ~~ISO 13852~~ ISO:13857:2008. The distances are measured from the expected positions of the OPERATOR, PATIENT and other persons near the ME EQUIPMENT in NORMAL USE or under reasonably foreseeable misuse.

9.2.2.4 * GUARDS and ~~protective~~ other RISK CONTROL measures

9.2.2.4.1 Access to TRAPPING ZONES

A TRAPPING ZONE is considered not to present a MECHANICAL HAZARD if GUARDS ~~and protective~~ or other RISK CONTROL measures (e.g. electro-mechanical):

– are of robust construction;

– are not easy to bypass or render non-operational;

– do not introduce any additional unacceptable RISK.

NOTE RISK CONTROL measures (e.g. electro-mechanical) addressed by this subclause are intended to include collision detection or collision avoidance systems, such as those employing light barrier(s) and similar feedback control(s).

Compliance is checked by the applicable tests of 15.3 for ENCLOSURES.

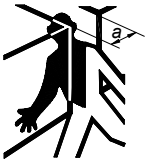
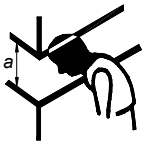
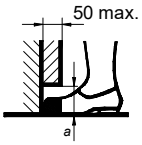
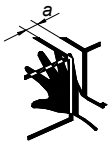
9.2.2.4.2 FIXED GUARDS

FIXED GUARDS shall be securely held in place by systems that cannot be dismantled without the use of a TOOL.

Compliance is checked by inspection.

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Table 20 – Acceptable gaps [a]

Part of body	Adult gap *a* mm	Children gap *a* mm	Illustration
Body	>500	>500	
Head	>300 or <120	>300 or <60	
Leg	>180	>180	
Foot	>120 or <35	>120 or <25	
Toes	>50	>50	
Arm	>120	>120	
Hand, wrist, fist	>100	>100	
Finger	> 25 or < 8	> 25 or < 4	
[a] The values in this table are taken from ~~ISO 13852:1996~~ ISO13857:2008.			

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9.2.2.4.3 Movable GUARDS

Movable GUARDS that can be opened without the use of a TOOL:

– shall remain attached to the ME EQUIPMENT when the GUARD is open;

– shall be associated with an interlock device that prevents the relevant moving parts from starting to move while the TRAPPING ZONE is accessible and stops movement when the GUARD is opened;

– shall be so designed that the absence or failure of one of their components prevents starting, and stops moving parts.

Compliance is checked by inspection of the ME EQUIPMENT and by conducting any applicable tests ~~and inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE~~.

9.2.2.4.4 ~~Protective~~ Other RISK CONTROL measures

Protective measures shall be designed and incorporated into the control system so that:

– moving parts cannot start to move while they are in the reach of persons;

~~– once the ME EQUIPMENT has started to move, the TRAPPING ZONE cannot be reached, or, if the TRAPPING ZONE is reached, system movement must stop. In the later case, no HAZARD or damage shall result;~~

~~– if in a SINGLE FAULT CONDITION of the protective measure, an unacceptable RISK could arise, one or more emergency stopping device(s) in the ME EQUIPMENT shall be provided (see 9.2.4).~~

~~*Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE.*~~

Other RISK CONTROL measures (e.g. electro-mechanical) shall be designed and incorporated into the control system so that:

– once the ME EQUIPMENT has started to move, if the TRAPPING ZONE is reached, system movement shall stop; and

– if the RISK CONTROL measure is defeated in a SINGLE FAULT CONDITION, a second RISK CONTROL measure shall be provided, such as one or more emergency stopping device(s) (see 9.2.4), or the ME EQUIPMENT shall otherwise be SINGLE FAULT SAFE (see 4.7).

Compliance is checked by the following as necessary:

– *inspection of the ME EQUIPMENT;*

– *examination of the construction and circuits;*

– *conducting any applicable tests including, if necessary, tests under SINGLE FAULT CONDITION.*

9.2.2.5 * Continuous activation

Where it is impractical to make the TRAPPING ZONE inaccessible, continuous activation may be used as a RISK CONTROL measure.

A TRAPPING ZONE is not considered to present a MECHANICAL HAZARD if:

a) the movement is in the OPERATOR'S field of view;

Compliance is checked by inspection.

b) movement of the ME EQUIPMENT or its parts is possible only by the continuous activation of the control by the OPERATOR as long as the response of the OPERATOR to deactivate the device can be relied on to prevent HARM;

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NOTE Manually operated movements are also considered to comply with this clause, as long as mass and velocity allow adequate control of positioning without causing an unacceptable RISK.

Compliance is checked by inspection.

~~c) in a SINGLE FAULT CONDITION of the continuous activation system an unacceptable RISK could arise, one or more emergency stopping device(s) are provided in the ME EQUIPMENT (see 9.2.4).~~

~~*Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE.*~~

c) the continuous activation system is defeated in a SINGLE FAULT CONDITION, then a second RISK CONTROL measure shall be provided, such as one or more emergency stopping device(s) (see 9.2.4), or the ME EQUIPMENT shall otherwise be SINGLE FAULT SAFE (see 4.7).

Compliance is checked by the following as necessary:

– *inspection of the ME EQUIPMENT;*
– *examination of the construction and circuits;*
– *conducting any applicable tests including, if necessary, tests under SINGLE FAULT CONDITION.*

9.2.2.6 * Speed of movement(s)

The speed of movement(s) that position parts of the ME EQUIPMENT or PATIENT, where contact with the ME EQUIPMENT could result in ~~a HAZARDOUS SITUATION~~ an unacceptable RISK, shall be limited so that the OPERATOR will have adequate control of ~~positioning without resulting in an unacceptable RISK~~ the movement.

The overtravel (stopping distance) of such movement, occurring after operation of a control to stop the movement, shall not result in an unacceptable RISK.

~~*Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE.*~~

Compliance is checked by the following as necessary:

– *inspection of the overtravel (stopping distance) calculations and evaluation;*
– *any functional tests.*

NOTE The overtravel (stopping distance) calculations and evaluation are part of the RISK MANAGEMENT FILE.

9.2.3 * Other MECHANICAL HAZARDS associated with moving parts

9.2.3.1 Unintended movement

Controls shall be so positioned, recessed, or protected by other means so that they cannot be accidentally actuated, ~~resulting in unacceptable RISK, unless ergonomic considerations for the intended PATIENT dictate otherwise (e.g. PATIENT with special needs)~~ unless for the intended PATIENT, the USABILITY ENGINEERING PROCESS concludes otherwise (e.g. PATIENT with special needs) or activation does not result in an unacceptable RISK.

Compliance is checked by inspection of ME EQUIPMENT, and, if the control is part of the PRIMARY OPERATING FUNCTIONS, inspection of the USABILITY ENGINEERING FILE.

9.2.3.2 Overtravel end stops

~~The RISK due to overtravel (past range limits) of ME EQUIPMENT parts shall be reduced to an acceptable level.~~ Overtravel past range limits of ME EQUIPMENT parts shall be prevented. End stops or other stopping means shall be provided to act as the ultimate travel limiting measure ~~in both NORMAL CONDITION and SINGLE FAULT CONDITION~~.

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Such means shall have the mechanical strength to withstand the intended loading in NORMAL USE and reasonably foreseeable misuse.

Compliance is checked by inspection of the ME EQUIPMENT~~, the RISK MANAGEMENT FILE, specifications of materials used and the processing specifications for these materials.~~ and the following test:

The ME EQUIPMENT is

– *loaded with the SAFE WORKING LOAD,*

– *unloaded, or*

– *loaded to any intermediate level that is likely to provide the most severe test result.*

The moving part is to be driven against each end stop or other mechanical means for the number of cycles, operating speed and test conditions as specified in Table 33. The end stops or other mechanical means required shall be capable of performing their intended function upon completion of the test.

Table 33 – Test conditions for overtravel end stop test

Construction	Number of cycles	Test condition
1. Motor driven: No range limit system provided [a]	6 000	Run at maximum speed
2. Motor driven: Non-independent range limit system or systems provided [a, b]	50	Defeat all switches simultaneously, and run at maximum speed
3. Motor driven: Two or more independent range limit systems [a, b]	1	Defeat all switches simultaneously, and run at maximum speed
4. Manually driven or manually driven, power assisted	50	Run at any speed, including reasonably foreseeable misuse

[a] A range limit system consists of all components required to stop motion, for example, it may consist of (1) a limit switch, (2) sensing circuits, and (3) related mechanical actuating mechanism.

[b] To qualify as an independent range limit system, each system shall, in addition to the criteria in footnote [a], comply with both of the following:

1. the system is capable of de-energizing the motor(s) directly; that is, the switch or motor controller circuit interrupts the motor's rotor or stator current, or both, and
2. the system provides a means by which a malfunction of one range limit system is made obvious to the OPERATOR. This may be an audible, visual or otherwise discernible indicator.

9.2.4 * Emergency stopping devices

Where it is considered necessary to have one or more emergency stopping device(s), the emergency stopping device shall comply with all the following requirements.

a) The emergency stopping device shall reduce the RISK to an acceptable level.

b) The proximity and response of the OPERATOR to actuate the emergency stopping device can be relied on to prevent HARM.

c) The emergency stopping device actuator shall be readily accessible to the OPERATOR.

d) Emergency stopping device(s) shall not be part of the normal operation of the ME EQUIPMENT.

e) Operation of an emergency switching or stopping means shall neither introduce a further MECHANICAL HAZARD nor interfere with the complete operation necessary to remove the original HAZARD.

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f) Emergency stopping device(s) shall be able to break the full load of the relevant circuit, taking into account possible stalled motor currents and the like.

g) Means for stopping of movements shall operate as a result of one single action.

h) The emergency stopping device shall have an actuator coloured red designed to be distinctive and easily identifiable from that of other controls.

i) An actuator that interrupts/opens mechanical movements shall be marked on, or immediately adjacent to, the face of the actuator with symbol IEC 60417-5638 (~~DB:~~2002-10) (see Table D.1, symbol 18) or the word "STOP".

NOTE If the actuator is a switch that interrupts all power, compliance with the above marking requirement is not required.

j) The emergency stopping device, once actuated, shall maintain the ME EQUIPMENT in the disabled condition until a deliberate action, different from that used to actuate it, is performed.

k) The emergency stopping device shall be shown to be suitable for its application.

Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE, and by functional tests.

9.2.5 * Release of PATIENT

Means shall be provided to permit the release of the PATIENT quickly and safely in the event of breakdown of the ME EQUIPMENT or failure of the power supply (see 11.8), activation of a ~~protective~~ RISK CONTROL measure or emergency stopping. Special attention shall be given to the following.

– Uncontrolled or unintended movement of the ME EQUIPMENT that could result in an unacceptable RISK shall be prevented.

– Situations where the PATIENT is subjected to unacceptable RISKS due to the proximity of moving parts, removal of normal exit routes, or other HAZARDS, shall be prevented.

– When, after removal of counterbalanced parts, other parts of the ME EQUIPMENT can move in a hazardous way, measures shall be provided to reduce the RISK to an acceptable level.

Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE, and by functional tests.

9.3 * MECHANICAL HAZARD associated with surfaces, corners and edges

Rough surfaces, sharp corners and edges of ME EQUIPMENT that could ~~result in an unacceptable RISK~~ cause injury or damage shall be avoided or covered.

In particular, attention shall be paid to flange or frame edges and the removal of burrs.

Compliance is checked by inspection of the ME EQUIPMENT ~~and the RISK MANAGEMENT FILE~~.

NOTE 1 If inspection is insufficient to determine sharpness of edges or burrs, the rationale for 9.3 provides a reference to an optional functional test.

NOTE 2 A sharp edge MECHANICAL HAZARD could cut wire insulation which could lead to an electrical HAZARD. This requirement is intended to cover all these HAZARDS.

9.4 * Instability HAZARDS

9.4.1 General

ME EQUIPMENT and its parts, other than FIXED ME EQUIPMENT ~~and HAND-HELD ME EQUIPMENT~~, intended to be placed on a surface such as a floor or a table in NORMAL USE shall not

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overbalance (tip over) or move unexpectedly~~, to the degree that it could present an unacceptable RISK to the PATIENT, OPERATOR or other person~~.

NOTE ~~The meaning of transport in this subclause is moving ME EQUIPMENT from room to room during NORMAL USE.~~ HAND-HELD parts of FIXED ME EQUIPMENT are intended to be tested.

Compliance is checked by the tests in 9.4.2 to 9.4.4 (inclusive). Each test is performed separately.

9.4.2 * Instability – overbalance

9.4.2.1 Instability in transport position

ME EQUIPMENT or its parts shall not overbalance when placed in any transport position of NORMAL USE on a plane inclined at an angle of 10° from the horizontal plane.

NOTE The meaning of transport in this subclause is moving ME EQUIPMENT from room to room during NORMAL USE.

Compliance is checked by the following test:

Prior to the test the ME EQUIPMENT is prepared as indicated in the ACCOMPANYING DOCUMENTS (or, if not specified, as in 9.4.2.2). The ME EQUIPMENT or its parts is placed on a plane inclined at an angle 10° from the horizontal plane. If the ME EQUIPMENT or its parts overbalances, it constitutes a failure.

9.4.2.2 Instability excluding transport position

ME EQUIPMENT or its parts shall not overbalance when placed in any position of NORMAL USE, excluding any transport positions, on a plane inclined at an angle of 5° from the horizontal plane.

If the ME EQUIPMENT or its parts overbalances when placed in any position of NORMAL USE, excluding any transport positions, on a plane inclined at an angle of 10° from the horizontal plane, it shall carry a warning notice stating that transport should only be undertaken in a certain condition that shall be clearly described in the instructions for use or marked on the ME EQUIPMENT with an indication of the RESIDUAL RISK if the ME EQUIPMENT or its parts overbalances.

NOTE For warning notice requirements, see 7.9.2.2.

Compliance is checked by the following test:

Prior to conducting the test, the ME EQUIPMENT is prepared as follows:

a) *ME EQUIPMENT is provided with all specified connection leads, the POWER SUPPLY CORD and any interconnecting cords. It is provided with the least favourable combination of possible detachable parts, ACCESSORIES and load as specified in NORMAL USE.*

b) *ME EQUIPMENT having an APPLIANCE INLET is provided with the specified DETACHABLE POWER SUPPLY CORD.*

c) *The connection leads are laid down on the inclined plane in the position most unfavourable for stability.*

d) *If castors/wheels are present, they are temporarily immobilized, if necessary by blocking, in their most disadvantageous position.*

e) *Doors, drawers, shelves and the like are placed in the most disadvantageous position and fully loaded or unloaded whichever represents "worst case" as specified in NORMAL USE according to the ACCOMPANYING DOCUMENTS.*

f) *ME EQUIPMENT having containers for liquids is tested with these containers completely or partly filled or empty, whichever is least favourable.*

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g) *The ME EQUIPMENT is not connected to the SUPPLY MAINS.*

The test floor surface is to be hard and flat (e.g. concrete floor covered with 2 mm to 4 mm thick vinyl flooring material).

The ME EQUIPMENT or the ME EQUIPMENT parts is placed on a plane inclined at an angle of 10° from the horizontal plane, or, if a warning notice is present, compliance is checked by inspection of the warning notice and the ME EQUIPMENT or its parts is placed on a plane inclined at an angle of 5° from the horizontal plane. If the ME EQUIPMENT or its parts overbalances, it constitutes a failure.

9.4.2.3 Instability from horizontal and vertical forces

a) ~~ME EQUIPMENT having a mass of 25 kg or more, other than FIXED ME EQUIPMENT that is intended to be used on the floor, shall not overbalance due to pushing, leaning, resting etc.~~

~~Surfaces of the ME EQUIPMENT where a RISK of overbalancing the ME EQUIPMENT exists from pushing, leaning, resting etc., shall be permanently marked with a CLEARLY LEGIBLE warning of this RISK, e.g. by use of safety sign ISO 7010-P017 (see Table D.2, safety sign 5).~~

* ME EQUIPMENT or its parts having a mass of 25 kg or more other than FIXED ME EQUIPMENT that is intended to be used on the floor shall be permanently marked with a CLEARLY LEGIBLE warning of this RISK, e.g. by use of safety sign ISO 7010-P017 (see Table D.2, safety sign 5), or it shall not overbalance due to being pushed, leaned, rested upon etc.

If marking is provided because the ME EQUIPMENT overbalances, the marking shall be visible during NORMAL USE, but not on surfaces for which pushing is associated with NORMAL USE (e.g. surfaces with handles).

Compliance is checked by inspection ~~and~~ of the marking provided or the following test:

Prior to the test, the ME EQUIPMENT is prepared as described in 9.4.2.2. The ME EQUIPMENT is placed on a horizontal plane and a force equal to ~~25~~ 15 % of its weight, but not more than ~~220~~ 150 N, is applied in any direction, except a direction having an upward component. Unless otherwise marked, the force is applied at any point of the ME EQUIPMENT but not exceeding 1,5 m from the floor. The ME EQUIPMENT is prevented from sliding on the floor by a horizontal obstruction, not exceeding 20 mm height, which is fastened flat on the floor. If the application of the test force results in lateral movement of the ME EQUIPMENT, increase the height of the obstruction to the minimum extent necessary to prevent lateral movement. ~~If the ME EQUIPMENT overbalances, it constitutes a failure.~~ ME EQUIPMENT without marking shall not overbalance.

b) ~~ME EQUIPMENT, other than FIXED ME EQUIPMENT, that is intended to be used on the floor or on a table, shall not overbalance due to sitting or stepping unless a legible warning of this RISK is provided on the ME EQUIPMENT, e.g. by use of safety signs ISO 7010-P018 or ISO 7010-P019 as appropriate (see Table D.2, safety signs 6 and 7).~~

ME EQUIPMENT or its parts, other than FIXED ME EQUIPMENT, that is intended to be used on the floor or on a table shall be permanently marked with a CLEARLY LEGIBLE warning of this RISK, e.g. by use of safety signs ISO 7010-P018 or ISO 7010-P019 as appropriate (see Table D.2, safety signs 6 and 7), or it shall not overbalance due to being sat or stepped upon.

NOTE Requirements for PATIENT support surfaces are found in 9.8.3.

If marking is provided because the ME EQUIPMENT overbalances, the marking shall be visible during potential stepping or sitting misuse.

Compliance is checked by inspection ~~and~~ of the marking provided or by the following test:

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Prior to the test the ME EQUIPMENT is prepared as described in 9.4.2.2. The ME EQUIPMENT is placed on a horizontal plane and a constant downward force of 800 N is applied at the point of maximum moment to any working surface, excluding PATIENT support surfaces, offering an obvious foothold or sitting surface of a minimum 20 cm by 20 cm area, and at a height not exceeding 1 m from the floor. ~~Overbalancing constitutes a failure.~~ ME EQUIPMENT without marking shall not overbalance.

9.4.2.4 * Castors and wheels

9.4.2.4.1 General

The means used for transportation of MOBILE ME EQUIPMENT, e.g. castors or wheels, shall not result in an unacceptable RISK when the MOBILE ME EQUIPMENT is moved or parked in NORMAL USE.

9.4.2.4.2 Force for propulsion

The force required for moving MOBILE ME EQUIPMENT along a hard and flat horizontal surface shall not exceed 200 N unless the instructions for use state that more than one person is needed.

Compliance is checked by placing the ME EQUIPMENT on a hard flat horizontal floor (e.g. concrete floor covered with 2 mm to 4 mm thick vinyl flooring material) and measuring the force needed to propel the ME EQUIPMENT at a speed of 0,4 m/s ± 0,1 m/s. The force is applied at a height of 1 m above the floor or at the highest point on the ME EQUIPMENT if its height is less than 1 m.

9.4.2.4.3 * Movement over a threshold

MOBILE ME EQUIPMENT exceeding 45 kg shall be able to pass over a ~~20~~ 10 mm threshold. Passing over a ~~20~~ 10 mm threshold shall not result in ~~an unacceptable RISK~~ overbalancing.

Compliance is checked by the following test:

The ME EQUIPMENT is configured in transport position with any SAFE WORKING LOAD in place as indicated in the ACCOMPANYING DOCUMENTS. The ME EQUIPMENT is moved as in NORMAL USE 10 times in forward direction over (up and down) a solid vertical plane obstruction ~~with a rectangular cross-section, 20 mm high and 80 mm wide~~ that is affixed flat on the floor. The obstruction shall have a rectangular cross section of 10 mm ± 0,5 mm high and at least 80 mm wide with a radius of 2 mm ± 0,1 mm at the top edges. The method of passing over the obstruction has to be applied in accordance with the instructions in the ACCOMPANYING DOCUMENTS, or if no instructions are given, by the following test.

All wheels and castors are to impact the obstruction at a speed of ~~0,4~~ 0,8 m/s ± 0,1 m/s for manual MOBILE ME EQUIPMENT, or, for motor driven MOBILE ME EQUIPMENT, the maximum speed capable of being maintained. Manual MOBILE ME EQUIPMENT is propelled by a force acting at its handle.

It is unacceptable for ME EQUIPMENT to be unable to go over (up) the obstruction (due to small wheel diameter, for example). Overbalancing ~~or any unacceptable RISK~~ constitutes a failure. BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained.

~~Unacceptable RISK is determined by inspection of the ME EQUIPMENT, its parts, and the RISK MANAGEMENT FILE.~~

NOTE Examples of damage that can ~~result in unacceptable RISK~~ affect BASIC SAFETY include the reduction of CREEPAGE DISTANCES and AIR CLEARANCES below those specified in 8.9, access to parts which exceed limits in 8.4, or access to moving parts which could cause HARM.

Assessment criteria that can be useful in determining if this test has resulted in ~~an unacceptable RISK~~ a loss of BASIC SAFETY include:

– those in Clause ~~9~~ 8 and 11.6;

– the dielectric strength test as specified in 8.8.3 to evaluate the integrity of solid ~~SUPPLEMENTARY or REINFORCED INSULATION~~ insulation providing a MEANS OF PROTECTION; and

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– measurement of CREEPAGE DISTANCES or AIR CLEARANCES to compare the values with the minimum distances specified in 8.9. Small chips that do not adversely affect the protection against electric shock or moisture can normally be ignored.

9.4.3 * Instability from unwanted lateral movement (including sliding)

9.4.3.1 Instability in transport position

a) Brakes of power-driven MOBILE ME EQUIPMENT shall be designed so that they are normally activated and can only be released by continuous actuation of a control.

Compliance is checked by inspection.

b) MOBILE ME EQUIPMENt shall be fitted with means (such as locking devices) intended to prevent any unwanted movement of the ME EQUIPMENT or its parts in the transport position.

Compliance is checked by inspection.

c) ~~MOBILE ME EQUIPMENT that is intended to be used on the floor shall not result in an unacceptable RISK due to unwanted lateral movement.~~
* MOBILE ME EQUIPMENT shall be provided with wheel locks or with a braking system to prevent unwanted movement on an incline of 10° when in its transport position.

Compliance is checked by the following test:

Prior to the test, the ME EQUIPMENT is prepared as described in 9.4.2.2. The MOBILE ME EQUIPMENT is placed in its transport position (or in the worst case NORMAL USE position) with the SAFE WORKING LOAD in place, and the locking device (e.g. brakes) activated, on a hard flat surface inclined at 10° from the horizontal plane. If castors are incorporated, they are positioned in their worst-case position. Following the initial elastic movement, initial creepage, and initial pivoting of castors, any further movement of the MOBILE ME EQUIPMENT greater than 50 mm (in relation to the inclined plane) constitutes a failure. ~~The RISK due to any initial movement is assessed, taking into account the NORMAL USE of the ME EQUIPMENT.~~

9.4.3.2 Instability excluding transport position

a) MOBILE ME EQUIPMENT shall be provided with wheel locks or with a braking system ~~appropriate to the intended modes of use and sufficient to ensure that unintended movement is prevented on an incline of 5°~~ to prevent unwanted movement on an incline of 5° when in any position excluding transport position.

Compliance is checked by the following test:

Prior to the test, the ME EQUIPMENT is prepared as described in 9.4.2.2. The MOBILE ME EQUIPMENT with the SAFE WORKING LOAD in place is positioned on a hard flat surface inclined at an angle of 5° from the horizontal plane with wheels locks on or braking system activated. Following the initial elastic movement, initial creepage, and initial pivoting of castors, any further movement of the ME EQUIPMENT greater than 50 mm (in relation to the inclined surface) constitutes a failure. ~~The RISK due to any initial movement is assessed taking into account the NORMAL USE of the ME EQUIPMENT.~~

b) ~~TRANSPORTABLE or STATIONARY ME EQUIPMENT that is intended to be used on the floor shall not result in an unacceptable RISK due to unwanted lateral movement.~~ MOBILE ME EQUIPMENT shall be provided with wheel locks or with a braking system to prevent unwanted movement from lateral forces.

Compliance is checked by the following test:

Prior to the test, the ME EQUIPMENT is prepared as described in 9.4.2.2. The ME EQUIPMENT is placed on a horizontal plane with the SAFE WORKING LOAD in place, and the locking device (e.g. brakes) activated. If castors are incorporated, they are positioned in their

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worst-case position. A force equal to ~~25~~ 15 % of the weight of the unit, but not more than ~~220~~ 150 N, is applied in any direction, except a direction having an upwards component, at the highest point of the ME EQUIPMENT that does not lead to overbalancing but not exceeding 1,5 m from the floor. Following the initial elastic movement, initial creepage, and initial pivoting of castors, any further movement of the ME EQUIPMENT greater than 50 mm (in relation to the horizontal plane) constitutes a failure. ~~The RISK due to any initial movement is assessed, taking into account the NORMAL USE of the ME EQUIPMENT.~~

9.4.4 Grips and other handling devices

a) ME EQUIPMENT other than PORTABLE ME EQUIPMENT or its part with a mass of more than 20 kg that needs to be lifted in NORMAL USE or transport shall either be provided with suitable handling devices (for example handles, lifting eyes, etc.) or the ACCOMPANYING DOCUMENTS shall indicate the points where it can be lifted safely, unless the method of handling is obvious and no ~~HAZARDS~~ unacceptable RISK can develop when this is done. If the means for lifting are handles, they shall be suitably placed to enable the ME EQUIPMENT or its part to be carried by two or more persons.

Compliance is checked by weighing (if necessary) and by inspection of the ME EQUIPMENT or its part or the ACCOMPANYING DOCUMENTS.

b) ME EQUIPMENT specified by the MANUFACTURER as PORTABLE ME EQUIPMENT with a mass of more than 20 kg shall have one or more carrying-handles suitably placed to enable the ME EQUIPMENT to be carried by two or more persons.

Compliance is checked by carrying.

c) Carrying handles or grips furnished on PORTABLE ME EQUIPMENT shall withstand loading as described in the following test:

The handles and their means of attachment are subjected to a force equal to four times the weight of the ME EQUIPMENT in any direction of NORMAL USE and transport.

If more than one handle is furnished on PORTABLE ME EQUIPMENT, the force is distributed between the handles. The distribution of forces is determined by measuring the percentage of the ME EQUIPMENT weight sustained by each handle with the ME EQUIPMENT in the normal carrying position. If the ME EQUIPMENT is furnished with more than one handle but is so designed that it can readily be carried by only one handle, then each handle is to be capable of sustaining the total force.

The force is applied uniformly over a 7 cm length of the handle at the centre, starting at zero and gradually increasing so that the test value will be attained in 5 s to 10 s and maintained for a period of 1 min.

Handles that break loose from the ME EQUIPMENT or exhibit any permanent distortion, cracking or other evidence of breakdown constitutes a failure.

9.5 * Expelled parts HAZARD

9.5.1 Protective means

Where expelled parts could result in an unacceptable RISK, the ME EQUIPMENT shall be provided with a means for protecting against such RISK.

Compliance is checked by assessment of the suitability of the protective means and by inspection of the RISK MANAGEMENT FILE.

9.5.2 Cathode ray tubes

Any cathode ray tube shall comply with the applicable requirements of IEC 60065:2001, Clause 18; or IEC 61965.

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Compliance is checked by inspection of a certificate of compliance or by the relevant tests of IEC 60065:2001, Clause 18.

9.6 Acoustic energy (including infra- and ultrasound) and vibration

9.6.1 * General

ME EQUIPMENT shall be designed so that human exposure to acoustic energy and vibration shall not result in an unacceptable RISK.

Compliance is checked by the tests in 9.6.2 and 9.6.3, and, if necessary, by inspection of the RISK MANAGEMENT FILE (taking into account the audibility of auditory alarm signals and PATIENT sensitivity) ~~*and the tests indicated in 9.6.2 and 9.6.3*~~*.*

9.6.2 * Acoustic energy

9.6.2.1 Audible acoustic energy

In NORMAL USE, the PATIENT, OPERATOR and other persons shall not be exposed to acoustic energy from ME EQUIPMENT, except sound from auditory ALARM SIGNALS, exceeding the levels specified below.

– 80 dBA for a cumulative exposure of 24 h over a 24 h period; an offset of 3 dBA is to be added to this value when halving the cumulative exposure time over a 24 h period (e.g. 83 dBA for 12 h over a 24 h period);

– 140 ~~dB un-weighted~~ dBC (peak) sound pressure level for impulsive or impact acoustic energy (noise).

NOTE 1 Interpolation or extrapolation is allowed for exposure times in accordance with the following formula, 80 - 10* $\log_{10}(h/24)$, in dBA, where *h* is cumulative exposure time over a 24 h period.

NOTE 2 Since PATIENTS might have a higher sensitivity to acoustic energy (noise), a lower level could be more appropriate. Consideration should also be given to perception of auditory ALARM SIGNALS. The World Health Organization has recommended a maximum impulse or impact acoustic energy (noise) level for children of 120 dB.

NOTE 3 If the A-weighted sound pressure level exceeds 80 ~~dB(A)~~ dBA, noise protection measure should be considered.

Compliance is checked by measuring the maximum A-weighted sound pressure level at the minimum distances of PATIENT, OPERATOR and other persons from the source of acoustic energy (*noise) in NORMAL USE and if necessary, calculating the A-weighted sound pressure level produced by the ME EQUIPMENT in accordance with ISO 3746, ISO 9614-1 or IEC 61672-1. The following conditions apply.*

a) The ME EQUIPMENT is operated under worst-case NORMAL CONDITION.

b) Any protective means provided or called for in ACCOMPANYING DOCUMENTS are to be in place during sound measurement.

c) Sound level meters used in the measurement conform to IEC 61672-1 and IEC 61672-2.

d) The test room is semi-reverberant with a hard reflecting floor. The distance between any wall or other object and the surface of the ME EQUIPMENT is not less than 3 m.

e) When sound measurements in a test room are not feasible (e.g. for a large PERMANENTLY INSTALLED ME EQUIPMENT), measurements may be done in situ.

9.6.2.2 Infrasound and ultrasound energy

When applicable, the MANUFACTURER shall address the RISKS associated with infrasound or ultrasound in the RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

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9.6.3 * Hand-transmitted vibration

Except for vibrations directly required to carry out the INTENDED USE of the ME EQUIPMENT, means shall be provided to protect the PATIENT, OPERATOR and other persons if in NORMAL USE the hand-transmitted frequency-weighted r.m.s. acceleration generated by the ME EQUIPMENT exceeds the value below:

– 2,5 m/s^2 for a cumulative time of 8 h during a 24 h period.

– Allowable accelerations for different times are inversely proportional to the square root of the time (e.g. the allowable acceleration for 2 h would be 5,0 m/s^2).

NOTE Interpolation or extrapolation is allowed for allowable acceleration in accordance with the following formula, 2,5 x $\sqrt{(8 / t)}$, in m/s^2, where t is the cumulative time over a 24 h period.

Compliance is checked by measurements at points of equipment in hand contact with PATIENT, OPERATOR or other persons. Measurements are made in accordance with ISO 5349-1.

9.7 * Pressure vessels and parts subject to pneumatic and hydraulic pressure

9.7.1 General

The requirements of this subclause apply to vessels and parts of ME EQUIPMENT subject to pressure, the rupture of which could result in an unacceptable RISK.

The parts of a pneumatic or hydraulic system that are used as a support system shall additionally comply with the requirements in 9.8.

9.7.2 Pneumatic and hydraulic parts

Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES shall be so designed that:

– no unacceptable RISK results from loss of pressure or loss of vacuum;

– no unacceptable RISK results from a fluid jet caused by leakage or a component failure;

– elements of the ME EQUIPMENT or an ACCESSORY, and especially pipes and hoses, that can lead to an unacceptable RISK shall be protected against harmful external effects;

– reservoirs and similar vessels (e.g. hydro-pneumatic accumulators) that can lead to an unacceptable RISK are automatically depressurized when the ME EQUIPMENT is isolated from its power supply (e.g. pulling out the pneumatic plug at the connector mounted on the facility wall). If this is not possible, means shall be provided for the isolation (e.g. cutting off from the peripheral circuit), or local depressurizing of reservoirs and similar vessels, and pressure indication;

– all elements that can remain under pressure after isolation of the ME EQUIPMENT or an ACCESSORY from its power supply and that could result in an unacceptable RISK shall be provided with clearly identified exhaust devices, and a warning label drawing attention to the necessity of depressurizing these elements before any setting or maintenance activity on the ME EQUIPMENT or ACCESSORIES.

Compliance is checked by inspection and examination of RISK MANAGEMENT FILE.

9.7.3 Maximum pressure

The maximum pressure to which a part of ME EQUIPMENT can be subjected in NORMAL CONDITION and SINGLE FAULT CONDITION shall be considered to be whichever is the highest of the following:

a) the RATED maximum supply pressure from an external source;

b) the pressure setting of a pressure-relief device provided as part of the assembly;

c) the maximum pressure that can be developed by a source of pressure that is part of the assembly, unless the pressure is limited by a pressure-relief device.

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9.7.4 Pressure rating of ME EQUIPMENT parts

The maximum pressure to which a part of ME EQUIPMENT can be subjected in NORMAL CONDITION and SINGLE FAULT CONDITION shall not exceed the MAXIMUM PERMISSIBLE WORKING PRESSURE for the part, except as allowed for pressure relief devices in 9.7.7.

Compliance is checked by inspection of the MANUFACTURER'S data for the component, inspection of the ME EQUIPMENT~~, inspection of the RISK MANAGEMENT FILE~~, and where necessary, by functional test.

9.7.5 * Pressure vessels

A pressure vessel shall withstand a HYDRAULIC TEST PRESSURE if both the following conditions are met:

– the pressure is greater than 50 kPa; and

– the product of pressure and volume is greater than 200 kPa · l.

Compliance is checked by the following tests:

The HYDRAULIC TEST PRESSURE is the MAXIMUM PERMISSIBLE WORKING PRESSURE multiplied by a factor obtained from Figure 32.

The pressure is raised gradually to the specified test value and is held at that value for 1 min. A sample that bursts or suffers from permanent (plastic) deformation or leaks constitutes a failure. Leakage at a gasket during this test is not considered to constitute failure unless it occurs at a pressure below 40 % of the required test value, or below the MAXIMUM PERMISSIBLE WORKING PRESSURE, whichever is greater.

No leakage is allowed for pressure vessels intended for toxic, flammable or otherwise hazardous substances. For other pressure vessels, no leakage is allowed that will otherwise result in an unacceptable RISK (e.g. high pressure fluid jet).

Where unmarked pressure vessels and pipes (e.g. those with no national certification) cannot be hydraulically tested, integrity is verified by other suitable tests, e.g. pneumatic using suitable media, at the same test pressure as for the hydraulic test.

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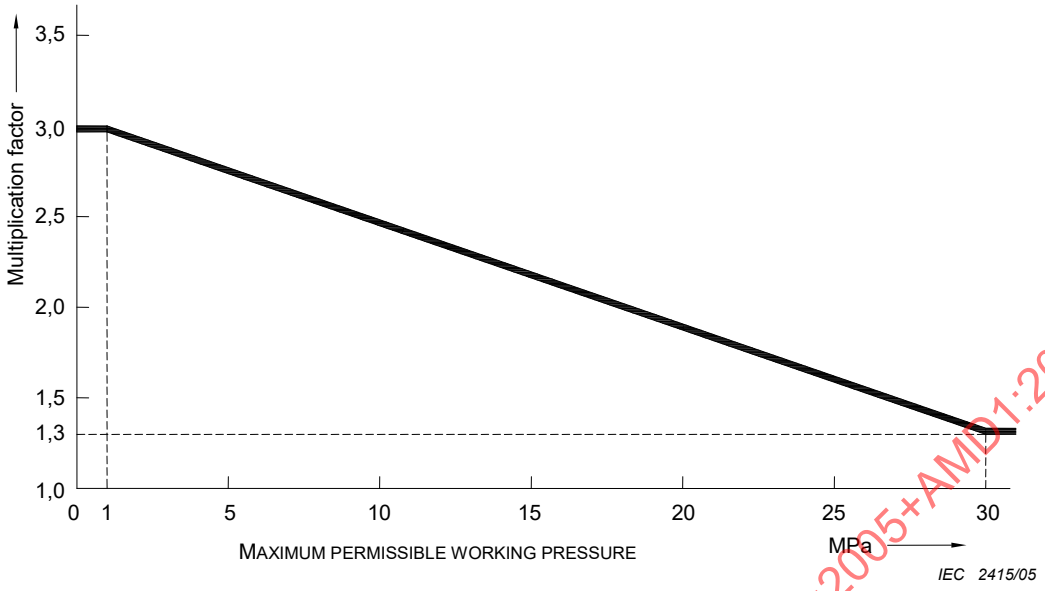


Figure 32 – Ratio between HYDRAULIC TEST PRESSURE and MAXIMUM PERMISSIBLE WORKING PRESSURE
(see 9.7.5)

9.7.6 Pressure-control device

In ME EQUIPMENT for which 9.7.7 requires a pressure-relief device, any pressure-control device responsible for regulating the pressure shall be capable of performing under RATED load for 100 000 cycles of operation and shall prevent the pressure from exceeding 90 % of the setting of the pressure-relief device under any condition of NORMAL USE.

Compliance is checked by inspection of the MANUFACTURER'S data for the component, inspection of the ME EQUIPMENT, ~~inspection of the RISK MANAGEMENT FILE~~, and where necessary, by functional test.

9.7.7 Pressure-relief device

ME EQUIPMENT shall incorporate pressure-relief device(s) where the MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded.

A pressure-relief device shall comply with all of the following requirements:

a) it shall be connected as close as reasonably practical to the pressure vessel or parts of the system that it is intended to protect;

b) it shall be so installed that it is readily accessible for inspection, maintenance and repair;

c) it shall not be capable of being adjusted or rendered inoperative without the use of a TOOL;

d) it shall have its discharge opening so located and directed that the released material is not directed towards any person;

e) it shall have its discharge opening so located and directed that operation of the device will not deposit material on parts that could result in an unacceptable RISK;

f) it shall be of adequate discharge capacity to ensure that the pressure will not exceed the MAXIMUM PERMISSIBLE WORKING PRESSURE of the system to which it is connected by more than 10 % in the event of a failure in the control of the supply pressure;

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g) there shall be no shut-off valve between a pressure-relief device and the parts that it is intended to protect;

h) the minimum number of cycles of operation shall be 100 000, except for one-time use devices such as bursting disks.

Compliance is checked by inspection of the MANUFACTURER'S data for the component, inspection of the ME EQUIPMENT, inspection of the RISK MANAGEMENT FILE, and where necessary, by functional test.

9.7.8 RATED maximum supply pressure

See 7.2.18.

9.8 * MECHANICAL HAZARDS associated with support systems

9.8.1 General

Where ME EQUIPMENT parts are designed to support loads or to provide actuating forces, the following requirements shall be applied if a mechanical fault could constitute an unacceptable RISK.

– The construction of the support, suspension or actuation system shall be designed based upon Table 21 and the TOTAL LOAD.

– Means of attachment of ACCESSORIES shall be designed such that any possibility of incorrect attachment that could result in an unacceptable RISK is avoided.

– The RISK ANALYSIS of support systems shall consider MECHANICAL HAZARDS arising from static, dynamic, vibration, impact and pressure loading, foundation and other movements, temperature, environmental, manufacture and service conditions.

– All likely failure effects shall be considered in the RISK ANALYSIS. These include excessive deflection, plastic deformation, ductile or brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep, material deterioration and residual stresses resulting from the manufacturing PROCESSES, e.g. machining, assembling, welding, heat treatment or surface coating.

– The ACCOMPANYING DOCUMENTS shall contain instructions on attachment of structures to a floor, wall, ceiling, etc. making adequate allowances for quality of the materials used to make the connection and shall list the required materials. Additionally there shall be advice on checking the adequacy of the surface of the structure to which the parts will be attached.

9.8.2 * TENSILE SAFETY FACTOR

Support systems shall maintain structural integrity during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. TENSILE SAFETY FACTORS shall not be less than those shown in Table 21 unless an alternative method demonstrates structural integrity throughout the EXPECTED SERVICE LIFE of the ME EQUIPMENT, or the support is a foot rest. The requirements for foot rests are in 9.8.3.2 a).

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Table 21 – Determination of TENSILE SAFETY FACTOR

Situation			Minimum TENSILE SAFETY FACTOR [a]	
No.	**System Part**	**Elongation**	**A [b]**	**B [c]**
1	Support system parts not impaired by wear	Metallic material [d] having a specific elongation at break equal to or greater than 5 %	2,5	4
2	Support system parts not impaired by wear	Metallic material [d] having a specific elongation at break of less than 5 %	4	6
3	Support system parts impaired by wear [e] and no MECHANICAL PROTECTIVE DEVICE	Metallic material [d] having a specific elongation at break equal to or greater than 5 %	5	8
4	Support system parts impaired by wear [e] and no MECHANICAL PROTECTIVE DEVICE	Metallic material [d] having a specific elongation at break of less than 5 %	8	12
5	Support system parts impaired by wear [e] and with MECHANICAL PROTECTIVE DEVICE (or primary system of multiple support systems)	Metallic material [d] having a specific elongation at break equal to or greater than 5 %	2,5	4
6	Support system parts impaired by wear [e] and with MECHANICAL PROTECTIVE DEVICE (or primary system of multiple support systems)	Metallic material [d] having a specific elongation at break of less than 5 %	4	6
7	MECHANICAL PROTECTIVE DEVICE (or back-up system of multiple support system)		2,5	4

[a] The TENSILE SAFETY FACTORS are intended to take account of conditions defined in 15.3.7 (i.e. environmental effects, impairing effects of wear, corrosion, material fatigue or ageing).

[b] Case A = The material TENSILE STRENGTH and all external forces to be expected are quantifiable and known accurately.

[c] Case B = Other than case A; specifically, the material TENSILE STRENGTH and all external forces to be expected are known approximately, but not with sufficient accuracy to justify the TENSILE SAFETY FACTOR for case A.

[d] For non-metallic materials, particular standards can prescribe adequate TENSILE SAFETY FACTORS (see rationale in Annex A, Subclause 9.8).

[e] Components considered impaired by wear include: chains, cables (wire rope), belts, jack screw nuts, springs, pneumatic or hydraulic hoses, gaskets or rings of pneumatic or hydraulic pistons.

Compliance with 9.8.1 and 9.8.2 is checked by inspection of the ME EQUIPMENT, the RISK MANAGEMENT FILE, the specifications of materials used and the processing specifications for these materials.

~~*When test results are part of relevant information, testing consists of gradually applying a test load to the support assembly under test equal to the TOTAL LOAD times the required TENSILE SAFETY FACTOR.*~~ *If testing is needed to demonstrate compliance with 9.8.1 or 9.8.2, a test load equal to the TOTAL LOAD times the required TENSILE SAFETY FACTOR is gradually applied to the support assembly under test. The support assembly under test is to be in equilibrium after 1 min, or otherwise not result in an unacceptable RISK.*

NOTE 1 It might be necessary to support assemblies that are connected to the assembly under test but do not require such a high safety factor, e.g. assembly under test requires TENSILE SAFETY FACTOR = 8 and assembly supporting it is designed with a TENSILE SAFETY FACTOR = 4. Use of additional support should be explained in the test report.

NOTE 2 The 1 min time period might need to be longer for materials which might have creep type problems, such as plastics or other non-metallic materials.

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9.8.3 * Strength of PATIENT or OPERATOR support or suspension systems

9.8.3.1 General

ME EQUIPMENT parts serving for support or immobilization of PATIENTS shall be designed and manufactured so ~~as to minimize the~~ there is no unacceptable RISK of physical injuries ~~and~~ or of accidental loosening of fixings.

The SAFE WORKING LOAD of ME EQUIPMENT or its parts serving for support or suspension of PATIENTS or OPERATORS shall be the sum of the mass of the PATIENTS or the mass of the OPERATORS plus the mass of ACCESSORIES intended by MANUFACTURERS to be supported or suspended by the ME EQUIPMENT or ME EQUIPMENT parts.

Unless otherwise stated by the MANUFACTURER, supporting and suspending parts for adult human PATIENTS or OPERATORS shall be designed for a PATIENT or OPERATOR having a minimum mass of 135 kg and ACCESSORIES having a minimum mass of 15 kg.

Where a MANUFACTURER specifies particular applications (e.g. paediatric use), the maximum mass of the PATIENT included in the SAFE WORKING LOAD of the ME EQUIPMENT or its parts serving for support or suspension of PATIENTS may be adapted. When the maximum allowable value of the mass of the PATIENT is less than 135 kg, that value shall be marked on the ME EQUIPMENT and described in ACCOMPANYING DOCUMENTS. When the maximum allowable value of the mass of the PATIENT is more than 135 kg, that value shall be described in ACCOMPANYING DOCUMENTS.

~~*Compliance is checked by inspection of markings, ACCOMPANYING DOCUMENTS, and the RISK MANAGEMENT FILE.*~~

Compliance is checked by inspection of the ME EQUIPMENT (including markings), the ACCOMPANYING DOCUMENTS, the MANUFACTURER'S data for the component, the RISK MANAGEMENT FILE, and, where necessary, functional test.

9.8.3.2 * Static forces due to loading from persons

In analyzing loading forces and torques on support assemblies, the part of the SAFE WORKING LOAD representing the mass of the PATIENTS or OPERATORS is distributed on the support/suspension surface in a manner representing the human body (see the example in Figure A.19).

NOTE 1 The position of the human body varies depending on the configuration of the support/suspension system and therefore the load acting on different sections will vary and should be taken into account.

In analyzing loading forces and torques on support assemblies, the part of the SAFE WORKING LOAD representing the mass of ACCESSORIES shall be deployed as in NORMAL USE or, if not defined, at the worst case position permitted by the configuration or ACCESSORIES attachment on the support/suspension parts.

a) For a foot rest that is intended to temporarily support a standing PATIENT or OPERATOR, the whole mass of the PATIENT or OPERATOR is distributed over an area of 0,1 m^2.

   Compliance is checked by inspection of the ME EQUIPMENT~~, the RISK MANAGEMENT FILE~~, the specifications of materials used and the processing specifications for these materials, and the following test:

   Prior to performing these tests, the PATIENT support/suspension system is positioned horizontally in its most disadvantageous position in NORMAL USE.

   A mass equal to two times 135 kg or two times the intended person load, whichever is greater is applied to the foot rest over an area of 0,1 m^2 for 1 min. After the test, a foot rest and its fixings that shows any damage or permanent deflection ~~that could result in an unacceptable RISK~~ from normal greater than 5° constitutes a failure. BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained.

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NOTE 2 Examples of damage that can affect BASIC SAFETY include the reduction of CREEPAGE DISTANCES and AIR CLEARANCES below those specified in 8.9, access to parts that exceed limits in 8.4, or access to moving parts that could cause HARM.

Assessment criteria that can be useful in determining if this test has resulted in a loss of BASIC SAFETY include:

– those in Clause 8 and 11.6;
– the dielectric strength test as specified in 8.8.3 to evaluate the integrity of solid insulation providing a MEANS OF PROTECTION; and
– measurement of CREEPAGE DISTANCES or AIR CLEARANCES to compare the values with the minimum distances specified in 8.9. Small chips that do not adversely affect the protection against electric shock or moisture can normally be ignored.

b) For an area of support/suspension where a PATIENT or OPERATOR can sit, deflection of a support surface from PATIENT or OPERATOR loading shall not result in an unacceptable RISK.

Compliance is checked by inspection of the ME EQUIPMENT~~, the RISK MANAGEMENT FILE~~, the specifications of materials used and the processing specifications for these materials, and the following test:

Prior to performing these tests, the PATIENT support/suspension system is positioned horizontally in its most disadvantageous position in NORMAL USE.

A mass of 60 % of the part of the SAFE WORKING LOAD representing the PATIENT or OPERATOR, as defined in the instructions for use, or ~~at~~ a minimum 80 kg, is placed on the support/suspension system with the centre of the load 60 mm from the outer edge of the support/suspension system for ~~a time of~~ at least one minute. Any permanent deflection of the support/suspension system ~~that could result in an unacceptable RISK~~ from normal greater than 5° constitutes a failure. BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained.

NOTE 3 Examples of damage that can affect BASIC SAFETY include the reduction of CREEPAGE DISTANCES and AIR CLEARANCES below those specified in 8.9, access to parts that exceed limits in 8.4, or access to moving parts that could cause HARM.

Assessment criteria that can be useful in determining if this test has resulted in a loss of BASIC SAFETY include:

– those in Clause 8 and 11.6;
– the dielectric strength test as specified in 8.8.3 to evaluate the integrity of solid insulation providing a MEANS OF PROTECTION; and
– measurement of CREEPAGE DISTANCES or AIR CLEARANCES to compare the values with the minimum distances specified in 8.9. Small chips that do not adversely affect the protection against electric shock or moisture can normally be ignored.

9.8.3.3 * Dynamic forces due to loading from persons

Where dynamic forces (due to sitting down, standing up, PATIENT handling PROCESS or the like) can be exerted on ME equipment parts intended to support or suspend a PATIENT or OPERATOR in NORMAL USE, ~~they shall not result in an unacceptable RISK~~ the ME EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.

Compliance is checked by the following test:

Prior to performing this test, the PATIENT support/suspension system is positioned horizontally in its most disadvantageous position in NORMAL USE.

~~*For the area of support/suspension where a PATIENT or OPERATOR can sit, a mass (as defined in Figure 33) equivalent to the SAFE WORKING LOAD representing the PATIENT or OPERATOR as defined in the instructions for use is dropped from a distance of 150 mm above the seat area. Any loss of function or structural damage that could result in an unacceptable RISK constitutes a failure.*~~

For the area of support/suspension where a PATIENT or OPERATOR can sit, the top reservoir of the body upper-carriage module described in Figure 33 is loaded with the appropriate mass to obtain the SAFE WORKING LOAD representing the PATIENT or OPERATOR as defined in the ACCOMPANYING DOCUMENTS. The *body upper-carriage module with appropriate mass is*

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dropped from a distance of 150 mm above the seat area. BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained.

NOTE Examples of damage that can affect BASIC SAFETY include the reduction of CREEPAGE DISTANCES and AIR CLEARANCES below those specified in 8.9, access to parts that exceed limits in 8.4, or access to moving parts which could cause HARM.

Assessment criteria that can be useful in determining if this test has resulted in a loss of BASIC SAFETY include:

– those in Clause 8 and 11.6;

– the dielectric strength test as specified in 8.8.3 to evaluate the integrity of solid providing a MEANS OF PROTECTION; and

– measurement of CREEPAGE DISTANCES or AIR CLEARANCES to compare the values with the minimum distances specified in 8.9. Small chips that do not adversely affect the protection against electric shock or moisture can normally be ignored.

9.8.4 * Systems with MECHANICAL PROTECTIVE DEVICES

9.8.4.1 General

a) A MECHANICAL PROTECTIVE DEVICE shall be provided when a support system or any of its parts impaired by wear have a TENSILE SAFETY FACTOR greater than or equal to the values specified in rows 5 and 6 but less than those in rows 3 and 4 of Table 21.

b) The MECHANICAL PROTECTIVE DEVICE shall:

– be designed on the basis of TOTAL LOAD, which shall include the effects of the SAFE WORKING LOAD when applicable;

– have TENSILE SAFETY FACTORS for all parts not less than those in row 7 of Table 21;

– activate before travel (movement) produces an unacceptable RISK;

– take into account 9.2.5 and 9.8.4.3.

~~*Compliance is checked by inspection of the ME EQUIPMENT, the RISK MANAGEMENT FILE, the specifications of materials used and the processing specifications for these materials.*~~

Compliance is checked by the following as necessary:

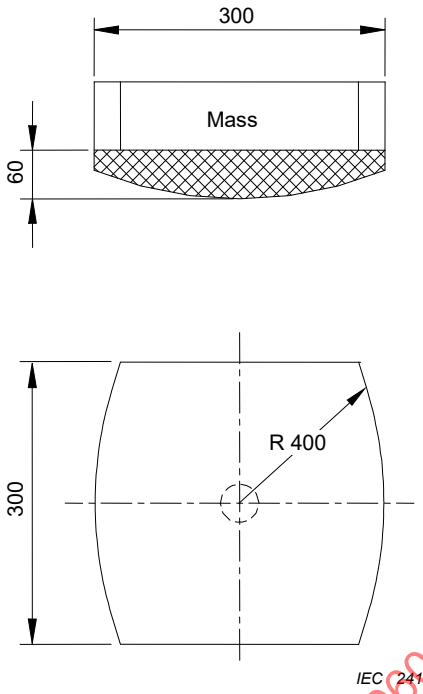
– *inspection of the overtravel (stopping distance from the time of engagement of the MECHANICAL PROTECTIVE DEVICE to the time of no further movement) calculations and evaluation;*

– *any functional tests.*

NOTE The overtravel (stopping distance from the time of engagement of the MECHANICAL PROTECTIVE DEVICE to the time of no further movement) calculations and evaluation are part of the RISK MANAGEMENT FILE.

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Dimensions in millimetres



NOTE ~~The upper carriage of the human body test mass apparatus~~ The top reservoir of the body upper-carriage module is formed of wood, metal or a similar material. The reservoir is intended to retain the appropriate human body mass, typically with high density material (e.g. lead). The bottom portion is foam. The resiliency or spring factor of the foam (ILD or IFD ratings) is not specified, as with a large mass being dropped, the foam properties are likely inconsequential. The foam is cylindrical, rather than spherical.

Figure 33 – ~~Human body test mass (see 9.8.3.3)~~ Body upper-carriage module

9.8.4.2 Use after activation of a MECHANICAL PROTECTIVE DEVICE

If ME EQUIPMENT can still be used after failure of the suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE such as a secondary cable (wire rope), it shall become obvious to the OPERATOR that the MECHANICAL PROTECTIVE DEVICE has been activated.

The MECHANICAL PROTECTIVE DEVICE shall require the use of a TOOL to be reset or replaced.

Compliance is checked by inspection of the ME EQUIPMENT.

9.8.4.3 MECHANICAL PROTECTIVE DEVICE intended for single activation

If a MECHANICAL PROTECTIVE DEVICE is intended to function only once, the following requirements shall be fulfilled:

– Further use of the ME EQUIPMENT shall be impossible until the MECHANICAL PROTECTIVE DEVICE has been replaced.

– The ACCOMPANYING DOCUMENTS shall instruct that once the MECHANICAL PROTECTIVE DEVICE has been activated, SERVICE PERSONNEL are to be called, and the MECHANICAL PROTECTIVE DEVICE must be replaced before the ME EQUIPMENT can be used again.

– The ME EQUIPMENT shall be permanently marked with safety sign ISO 7010-W001 (see Table D.2, safety sign 2).

– The marking shall be adjacent to the MECHANICAL PROTECTIVE DEVICE or so located that its relation to the MECHANICAL PROTECTIVE DEVICE is obvious to the person performing service or repair.

NOTE See also 15.3.7.

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Compliance is checked as follows:

– *by inspection of the ME EQUIPMENT, the ACCOMPANYING DOCUMENTS~~, the RISK MANAGEMENT FILE,~~ and the specifications of materials used and the processing specifications for these materials;*

– *a chain, cable (wire rope), band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, is defeated (to test the MECHANICAL PROTECTIVE DEVICE) by any convenient means, thereby causing the maximum normal load to fall from the most adverse position permitted by the construction of the ME EQUIPMENT. If the system supports a PATIENT or OPERATOR, the load is to include the SAFE WORKING LOAD defined in 9.8.3.1.*

Any evidence of damage to a MECHANICAL PROTECTIVE DEVICE that would affect its ability to perform its intended function constitutes a failure.

9.8.5 Systems without MECHANICAL PROTECTIVE DEVICES

A MECHANICAL PROTECTIVE DEVICE is not required if:

– the support system parts are not impaired by wear and have TENSILE SAFETY FACTORS greater than or equal to the values specified in rows 1 and 2 of Table 21; or

– the support system parts are impaired by wear but have TENSILE SAFETY FACTORS greater than or equal to the values specified in rows 3 and 4 of Table 21.

Compliance is checked by inspection of the ME EQUIPMENT, the design documentation and the RISK MANAGEMENT FILE.

10 * Protection against unwanted and excessive radiation HAZARDS

10.1 X-Radiation

10.1.1 * ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation

For ME EQUIPMENT not intended to produce X-radiation for diagnostic or therapeutic purposes, but which might produce ionizing radiation, the ~~dose rate~~ AIR KERMA rate shall not exceed ~~36 pA/kg (5 µSv/h) (0,5 mR/h)~~ 5 µGy/h at a distance of 5 cm from a surface of the ME EQUIPMENT taking account of the background radiation.

If the INTENDED USE of the ME EQUIPMENT requires a permanent proximity to a PATIENT, the resulting annual exposure should be made acceptable taking into account the irradiated body part and national regulations and/or international recommendations.

NOTE 1 The dose-rate value appears in ICRP 60 [39].

NOTE 2 In the member countries of CENELEC, the amount of ionizing radiation is regulated by European Council Directive 96/29/Euratom of 13 May 1996. This Directive requires that at any point 10 cm from the surface of the equipment, the dose-rate shall not exceed 1 µSv/h (0,1 mR/h) taking account of the background level.

Compliance is checked by following test:

The amount of radiation is determined by means of a radiation monitor of the ionizing chamber type with an effective area of 10 cm² or by measuring equipment of other types giving equivalent results.

The ME EQUIPMENT is operated at the most unfavourable RATED MAINS VOLTAGE and with any controls adjusted so as to give maximum radiation whilst maintaining the ME EQUIPMENT in NORMAL USE.

Internal preset controls not intended to be adjusted during the EXPECTED SERVICE LIFE of the ME EQUIPMENT are not considered.

Measurements are made at a distance of 5 cm from any surface to which OPERATORS other than SERVICE PERSONNEL:

– *can gain access without the use of a TOOL;*

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– *is deliberately provided with the means of access; or*

– *is instructed to enter regardless of whether or not a* TOOL *is needed to gain access.*

Any measurement exceeding ~~36 pA/kg (5 µSv/h) (0,5 mR/h)~~ 5 µGy/h adjusted for the level of background radiation constitutes a failure.

NOTE 3 This test PROCEDURE is equivalent to that in Annex H of IEC 60950-1:~~2001~~2005.

10.1.2 ME EQUIPMENT intended to produce diagnostic or therapeutic X-radiation

~~The MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISK from unintended X-radiation from ME EQUIPMENT designed to produce X-radiation for diagnostic and therapeutic purposes. See IEC 60601-1-3 and also see 1.3.~~

~~*Compliance is checked by inspection of the RISK MANAGEMENT FILE.*~~

Unintended X-radiation from ME EQUIPMENT designed to produce diagnostic or therapeutic X-radiation shall be reduced as far as possible by application of applicable particular and collateral standards, or in the absence of these standards by application of the RISK MANAGEMENT PROCESS.

For intended X-radiation, also see 12.4.5.2 and 12.4.5.3.

Compliance is checked by application of applicable particular and collateral standards or inspection of the RISK MANAGEMENT FILE.

10.2 Alpha, beta, gamma, neutron and other particle radiation

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with alpha, beta, gamma, neutron and other particle radiation.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

10.3 Microwave radiation

~~When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with microwave radiation.~~

~~*Compliance is checked by inspection of the RISK MANAGEMENT FILE.*~~

The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz shall not exceed 10 W/m^2 at any point 50 mm away from a surface of the ME EQUIPMENT under reference test conditions. This requirement does not apply to parts of the apparatus where microwave radiation is propagated intentionally, for example, at waveguide output ports.

NOTE This requirement is equivalent to that in subclause 12.4 of IEC 61010-1:2001.

Compliance is checked by review of MANUFACTURER'S calculations and, if necessary, the following test:

The ME EQUIPMENT is operated at the most unfavourable RATED MAINS VOLTAGE and with any control adjusted so as to give maximum microwave radiation whilst maintaining the ME EQUIPMENT in NORMAL USE.

Internal pre-set controls not intended to be adjusted during the expected SERVICE LIFE of the ME EQUIPMENT are not considered.

Measurements are made at a distance of 50 mm from any surface to which OPERATORS other than SERVICE PERSONNEL:

– *can gain access without the use of a TOOL;*

– *are deliberately provided with the means of access; or*

– *are instructed to enter regardless of whether or not a TOOL is needed to gain access.*

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Any measurement exceeding 10 W/m² under reference test conditions constitutes a failure.

10.4 * Lasers ~~and light emitting diodes (LEDs)~~

~~The relevant requirements of IEC 60825-1:1993 apply. If laser light barriers or similar products are used within equipment, they shall comply with the requirements of IEC 60825-1:1993.~~

For lasers that produce or amplify electromagnetic radiation in the wavelength range from 180 nm to 1 mm, the relevant requirements of IEC 60825-1:2007 shall apply. If laser light barriers or similar products are used within equipment, they shall comply with the requirements of IEC 60825-1:2007.

NOTE For laser equipment that is intended for use on humans or animals for surgical, therapeutic, medical diagnostic, cosmetic, or veterinary applications and classified as a Class 3b or Class 4 laser product as defined in IEC 60825-1, see also IEC 60601-2-22 [59].

Compliance is checked by following the relevant PROCEDURES of IEC 60825-1:~~1993~~2007.

10.5 Other visible electromagnetic radiation

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with visible electromagnetic radiation, other than that produced by lasers and light emitting diodes (see 10.4).

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

10.6 Infrared radiation

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with infrared radiation, other than that produced by lasers and light emitting diodes (see 10.4).

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

10.7 Ultraviolet radiation

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with ultraviolet radiation, other than that produced by lasers and light emitting diodes (see 10.4).

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

11 Protection against excessive temperatures and other HAZARDS

11.1 * Excessive temperatures in ME EQUIPMENT

11.1.1 * Maximum temperature during NORMAL USE

When ME EQUIPMENT is operated in worst-case NORMAL USE including the maximum ambient operating temperature specified in the technical description (see 7.9.3.1):

– ME EQUIPMENT parts shall not reach temperatures exceeding the values given in Table 22 and Table 23;

– the ME EQUIPMENT shall not cause the surfaces of the test corner to exceed 90 °C; and

– THERMAL CUT-OUTS shall not operate in NORMAL CONDITION.

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Table 22 – Allowable maximum temperatures of parts

Parts	Maximum Temperature °C
Insulation, including winding insulation [a]	
- of Class A Material	105
- of Class E Material	120
- of Class B Material	130
- of Class F Material	155
- of Class H Material	180
Parts with T marking	T [b]
Other components and materials	[c]
Parts in contact with flammable liquid with flash-point of T °C	T-25
Wood	90

[a] The classification of insulating materials is in accordance with IEC 60085. Any incompatibility of the materials of an insulating system that could reduce the maximum temperature limit of the system below the limits of the individual materials shall be considered.

[b] T marking refers to the marked maximum operating temperature.

[c] For each material and component, account shall be taken of the temperature ratings for each material or component to determine the appropriate maximum temperature. Each component shall be used in accordance with its temperature rating. Where doubt exists, the ball pressure test of 8.8.4.1 should be performed.

Table 23 – Allowable maximum temperatures for ME EQUIPMENT parts that are likely to be touched

ME EQUIPMENT and its parts		Maximum temperature [a] °C		
		Metal and liquids	Glass, porcelain, vitreous material	Moulded material, plastic, rubber, wood
External surfaces of ME EQUIPMENT that are likely to be touched for a time "*t*"	*t* < 1 s	74	80	86
	1 s ≤ *t* < 10 s	56	66	71
	10 s ≤ *t* < 1 min	51	56	60
	1 min ≤ *t*	48	48	48

[a] These temperature limit values are applicable for touching the healthy skin of adults. They are not applicable when large areas of the skin (10 % of total body surface or more) can be in contact with a hot surface. This also applies in the case of skin contact with over 10 % of the head surface. Where this is the case, appropriate limits shall be determined and documented in the RISK MANAGEMENT FILE.

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Table 24 – Allowable maximum temperatures for skin contact with ME EQUIPMENT APPLIED PARTS

APPLIED PARTS of ME EQUIPMENT		Maximum temperature [a] [b] °C		
		Metal and liquids	Glass, porcelain, vitreous material	Moulded material, plastic, rubber, wood
APPLIED PART having contact with the PATIENT for a time "*t*"	*t* < 1 min	51	56	60
	1 min ≤ *t* < 10 min	48	48	48
	10 min ≤ *t*	43	43	43

[a] These temperature limit values are applicable for the healthy skin of adults. They are not applicable when large areas of the skin (10 % of total body surface or more) can be in contact with a hot surface. They are not applicable in the case of skin contact with over 10 % of the head surface. Where this is the case, appropriate limits shall be determined and documented in the RISK MANAGEMENT FILE.

[b] Where it is necessary for APPLIED PARTS to exceed the temperature limits of Table 24 in order to provide clinical benefit, the RISK MANAGEMENT FILE shall contain documentation showing that the resulting benefit exceeds any associated increase in RISK.

11.1.2 * Temperature of APPLIED PARTS

11.1.2.1 APPLIED PARTS intended to supply heat to a PATIENT

The temperature (hot or cold surfaces) or (where appropriate) the clinical effects shall be determined and documented in the RISK MANAGEMENT FILE. The temperatures and clinical effects shall be disclosed in the instructions for use.

11.1.2.2 * APPLIED PARTS not intended to supply heat to a PATIENT

~~The limits of Table 24 shall apply. If the surface temperature of an APPLIED PART exceeds 41 °C, the maximum temperature shall be disclosed in the instructions for use and the clinical effects with respect to characteristics such as body surface, maturity of PATIENTS, medications being taken or surface pressure shall be determined and documented in the RISK MANAGEMENT FILE. Where 41°C is not exceeded, no justification is required.~~

~~Surfaces of APPLIED PARTS that are cooled below ambient temperatures can also result in HAZARD and shall be evaluated as part of the RISK MANAGEMENT PROCESS.~~

The limits of Table 24 shall apply in both NORMAL CONDITION and SINGLE FAULT CONDITION. If the surface temperature of an APPLIED PART exceeds 41 °C:

– the maximum temperature shall be disclosed in the instructions for use;

– the conditions for safe contact, e.g. duration or condition of the PATIENT, shall be disclosed; and

– the clinical effects with respect to characteristics such as body surface, maturity of PATIENTS, medications being taken or surface pressure shall be determined and documented in the RISK MANAGEMENT FILE.

Where 41°C is not exceeded, no justification is required.

If analyses documented in the RISK MANAGEMENT FILE demonstrate that APPLIED PART temperatures cannot be affected by operation of the ME EQUIPMENT including in SINGLE FAULT CONDITIONS, measurement of APPLIED PART temperature according to 11.1.3 is not required.

Surfaces of APPLIED PARTS that are cooled below ambient temperatures can also result in an unacceptable RISK and shall be evaluated as part of the RISK MANAGEMENT PROCESS.

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11.1.3 * Measurements

Where engineering judgement by the MANUFACTURER indicates that temperature limits cannot be exceeded, no measurement is required. Where such judgements indicate that the test corner will not impact the measurements, it may be omitted. However, the rationale for such judgement shall be documented in the RISK MANAGEMENT FILE. If the test corner is used, its surfaces shall not exceed 90 °C.

For ME EQUIPMENT parts that are likely to be touched and for APPLIED PARTS, the probability of occurrence of contact and of the duration of contact is determined and documented in the RISK MANAGEMENT FILE.

Compliance with the requirements of 11.1.1 and 11.1.2 is checked by inspection of the RISK MANAGEMENT FILE and the instructions for use, operation of ME EQUIPMENT and temperature measurements as follows:

a) Positioning

1) ME EQUIPMENT is tested in the position(s) of NORMAL USE.

2) ME EQUIPMENT is placed in a test corner. The test corner consists of two walls at right angles, a floor and, if necessary, a ceiling, all of dull black painted plywood of 20 mm thickness. The linear dimensions of the test corner are at least 115 % of the linear dimensions of the ME EQUIPMENT under test.

The ME EQUIPMENT is positioned in the test corner as follows:

- *ME EQUIPMENT normally used on a floor or a table is placed as near to the walls as is likely to occur in NORMAL USE.*
- *ME EQUIPMENT normally affixed to a wall is mounted on one of the walls, as near to the other wall and to the floor or ceiling as is likely to occur in NORMAL USE.*
- *ME EQUIPMENT normally affixed to a ceiling is mounted on the ceiling as near to the walls as is likely to occur in NORMAL USE.*

3) HAND-HELD ME EQUIPMENT is suspended in its normal position, in still air.

4) ME EQUIPMENT intended for installation in a cabinet or wall is built in as required by the technical description (see 7.9.3.1), using dull black painted plywood walls, 10 mm thick when representing cabinet walls if the technical description so specify and 20 mm thick when representing building walls.

b) Supply

- *ME EQUIPMENT having heating elements is operated as in NORMAL USE, with all heating elements energized unless prevented by switching interlocks, the supply voltage being equal to 110 % of the maximum RATED voltage.*
- *Motor operated ME EQUIPMENT is operated under normal load and normal DUTY CYCLE and the least favourable voltage between 90 % of the minimum RATED voltage and 110 % of the maximum RATED voltage.*
- *Combined heating and motor operated and other ME EQUIPMENT is tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.*
- *When modules are tested separately, the configuration for testing simulates the worst case conditions of NORMAL USE that might affect the test result.*

c) Thermal stabilization

- *For ME EQUIPMENT intended for non-CONTINUOUS OPERATION:*

  After operating in standby/quiescent mode until THERMAL STABILITY is reached, the ME EQUIPMENT is operated in NORMAL USE over consecutive cycles until THERMAL STABILITY is again achieved, or for 7 h, whichever is shorter. The "on" and "off" periods for each cycle are the RATED "on" and "off" periods;

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– *For ME EQUIPMENT for CONTINUOUS OPERATION:*

The ME EQUIPMENT is operated until THERMAL STABILITY is reached.

d) Temperature measurement

– *Resistance method (for windings):*

The value of the temperature rise of a copper winding is calculated from the formula:

$$\Delta T = \frac{R_2 - R_1}{R_1}(234{,}5 + T_1) - (T_2 - T_1)$$

where:

ΔT *is the temperature rise in* °C;

R_1 *is the resistance at the beginning of the test in* Ω;

R_2 *is the resistance at the end of the test in* Ω;

T_1 *is the room temperature at the beginning of the test in* °C;

T_2 *is the room temperature at the end of the test in* °C.

At the beginning of the test, windings are to be at room temperature.

NOTE When the resistance method is used, it is recommended that the resistance of windings at the end of the test be determined by taking measurements as soon as possible after switching off, and then at short intervals so that a curve of resistance against time can be plotted for ascertaining the value at the instant of switching off.

– *Thermocouple and other methods (for all measurements):*

Measurement is made by devices or sensors so chosen and positioned that they have a negligible effect on the temperature of the part under test.

When thermocouples are used to determine the temperature of windings, the temperature limits of Table 22 are to be reduced by 10 °C.

The temperature of electrical insulation, other than that of windings, is determined on the surface of the insulation at places where failure could cause a short circuit, bridging of a MEANS OF PROTECTION, bridging of insulation or reduction of CREEPAGE DISTANCES or AIR CLEARANCES below the values specified for the insulation type in 8.9.

The point of separation of cores of a multicore cord and where insulated wires enter lampholders are examples of places where temperatures might be measured.

e) Test criteria

During the test THERMAL CUT-OUTS are not de-activated.

The maximum temperature of a part is determined by measuring the temperature rise of the part under test and adding it to the maximum allowed ambient temperature specified in the technical description (see 7.9.3.1). Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE.

11.1.4 GUARDS

GUARDS intended to prevent contact with hot or cold accessible surfaces of ME EQUIPMENT shall be removable only with the aid of a TOOL.

Compliance is checked by inspection.

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11.2 * Fire prevention

11.2.1 * Strength and rigidity required to prevent fire in ME EQUIPMENT

ENCLOSURES shall have the strength and rigidity necessary to avoid a fire that could occur as a result of a total or partial collapse caused by reasonably foreseeable misuse.

Compliance is checked by the mechanical strength tests for ENCLOSURES (see 15.3).

11.2.2 * ME EQUIPMENT and ME SYSTEMS used in conjunction with OXYGEN RICH ENVIRONMENTS

11.2.2.1 RISK of fire in an OXYGEN RICH ENVIRONMENT

In ME EQUIPMENT and ME SYSTEMS, the RISK of fire in an OXYGEN RICH ENVIRONMENT shall be reduced as far as possible under NORMAL CONDITION or SINGLE FAULT CONDITIONS (as identified in 11.2.3). An unacceptable RISK of fire is considered to exist in an OXYGEN RICH ENVIRONMENT when a source of ignition is in contact with ignitable material and there is no means that would limit the spread of a fire.

NOTE 1 For oxygen concentrations up to 25 % at one atmosphere or partial pressures up to 27,5 kPa for higher atmospheric pressures, the requirements in 13.1.1 are considered to be sufficient.

a) * A source of ignition is considered to exist in an OXYGEN RICH ENVIRONMENT when any of the following conditions exist in NORMAL CONDITION and SINGLE FAULT CONDITIONS (including voltage and current):

   1) the temperature of the material is raised to its ignition temperature;

   2) temperatures could affect solder or solder joints causing loosening, short circuiting or other failures that could result in sparking or raising the temperature of the material to its ignition temperature;

   3) parts affecting safety crack or change their outer shape exposing temperatures exceeding 300 °C or sparks (see 4) and 5) below) due to overheating;

   4) temperatures of parts or components could exceed 300 °C;

   5) sparks provide adequate energy for ignition by exceeding the limits of Figure 35 to Figure 37 (inclusive).

   Items 4) and 5) address the worst case where the atmosphere is 100 % oxygen, the contact material (for item 5) is solder and the fuel is cotton. Available fuels and oxygen concentrations should be taken into consideration when applying these specific requirements. Where deviations from these worst case limits are made (based on lower oxygen concentrations or less flammable fuels) they shall be justified and documented in the RISK MANAGEMENT FILE.

   As an alternative to 11.2.2.1 a) 5), the following test may be used to determine whether a source of ignition exists.

   First, the place(s) within the ME EQUIPMENT where sparking might cause ignition are identified. Then the material(s) of the parts between which sparks can occur is identified. Samples of the same material are then used to construct the contact pins for the test apparatus (see Figure 34).

   Other parameters for the test are: oxygen concentration, fuel, electrical parameters (current, voltage, capacitance, inductance or resistance). These parameters are chosen such that they represent the worst case for the ME EQUIPMENT.

   NOTE 2 For ME EQUIPMENT that includes a circuit not addressed in Figure 35 to Figure 37 (inclusive), either the test voltage or current may be set at three times the worst case values with the other parameter set at the worst case value for determining whether ignition can occur.

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Two contact pins made of the material to be considered are placed in opposition (see Figure 34). One pin has a diameter of 1 mm, the other of 3 mm. The electrical source is connected to the pins as shown in Figure 35 to Figure 37. A piece of cotton is placed close to the contact surfaces of the two pins. The contacts are constantly flushed by oxygen with a speed of less than 0,5 m/s via a tube. The cathode is moved to the anode to close the contacts and pulled back to open them again. A minimum of 300 trials has to be performed before it can be decided that the sparks do not ignite. If the sparks get smaller because of bad surfaces of the electrodes, the electrodes are cleaned with a file. If the cotton gets black because it became oxidized then it is replaced. In Figure 36 and Figure 37, the resistance used to control current flowing into the inductor and the time constant for charging the capacitor is chosen such that it has minimal impact on the energy of the spark. This is tested by visual inspection without the capacitor in place or with the inductor shorted.

The situation with the highest voltage or current respectively and no ignition defines the upper limit. A safe upper limit is given by dividing the upper limit of voltage or current respectively with the safety margin factor of three.

NOTE 3 The safety margin factor is considered to cover the uncertainty of sparking experiments and the variability of the underlying parameters like pressure, quality of cotton or of the contact materials.

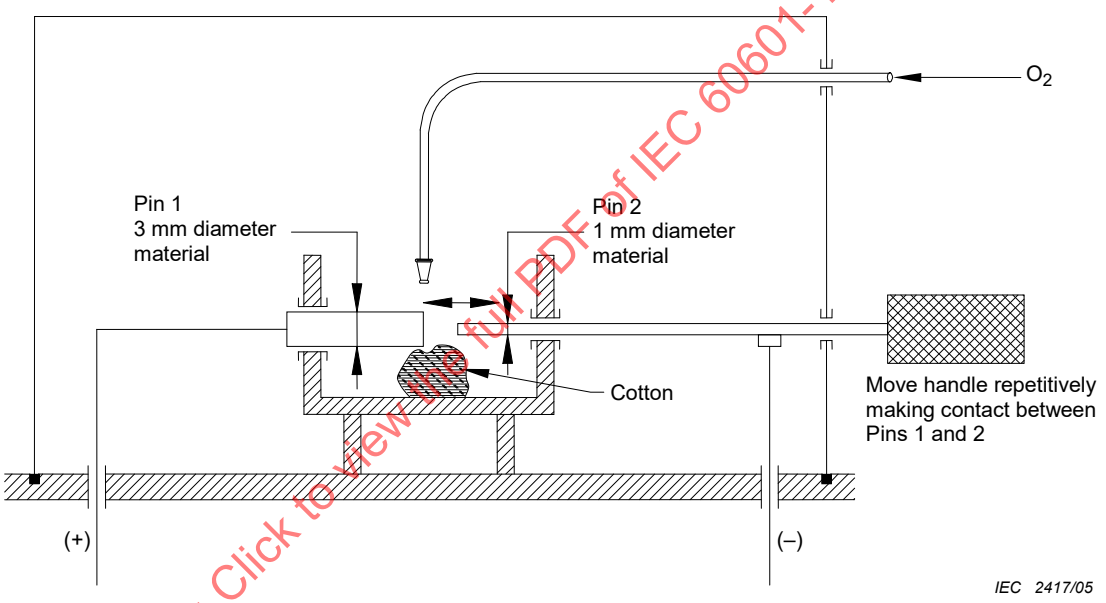


Figure 34 – Spark ignition test apparatus
(see 11.2.2.1)

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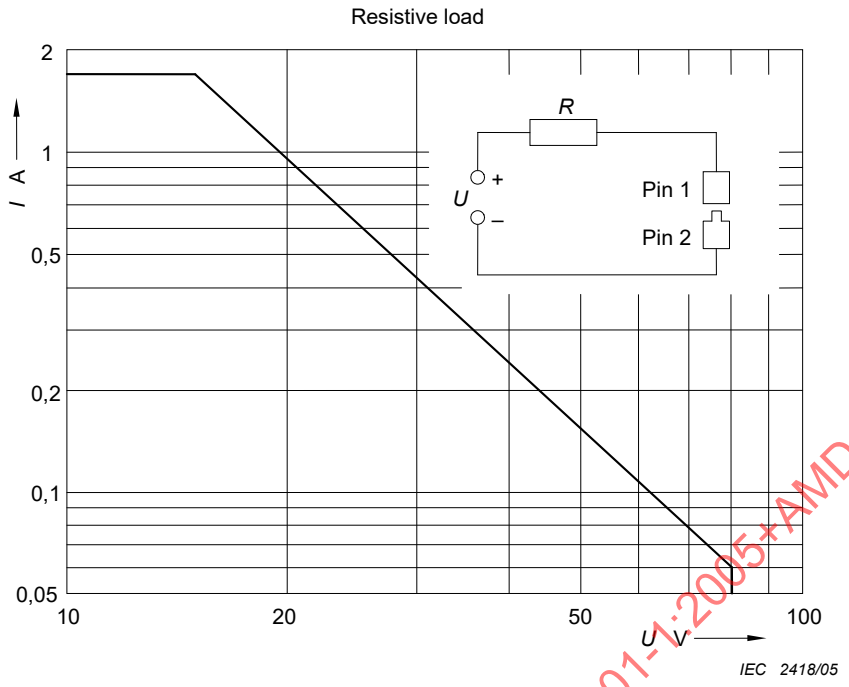


Figure 35 – Maximum allowable current *I* as a function of the maximum allowable voltage *U* measured in a purely resistive circuit in an OXYGEN RICH ENVIRONMENT
(see 11.2.2.1)

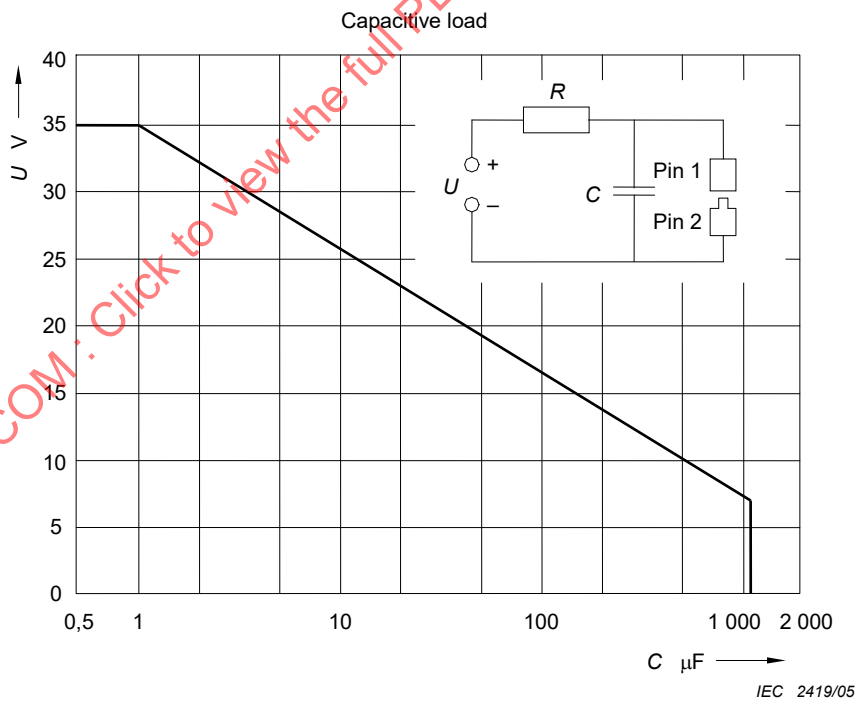


Figure 36 – Maximum allowable voltage *U* as a function of the capacitance *C* measured in a capacitive circuit used in an OXYGEN RICH ENVIRONMENT
(see 11.2.2.1)

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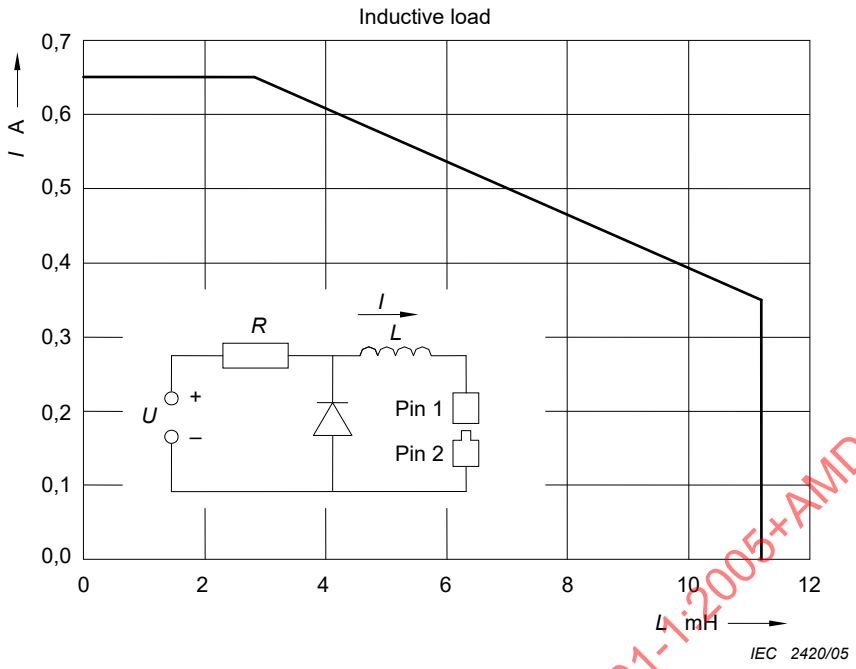


Figure 37 – Maximum allowable current *I* as a function of the inductance *L* measured in an inductive circuit in an OXYGEN RICH ENVIRONMENT
(see 11.2.2.1)

b) The following configurations, alone or in combination as appropriate (as determined by the application of the RISK MANAGEMENT PROCESS), are considered to provide an acceptable RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT.

1) Electrical components in a compartment with an OXYGEN RICH ENVIRONMENT shall have power supplies with limited energy levels. Those energy levels shall be less than those which are considered to be sufficient for ignition (see 11.2.2.1 a)).

Compliance is checked by inspection of the design and measurement or calculation of power, energy and temperature values in NORMAL CONDITION and SINGLE FAULT CONDITION (as identified in 11.2.3).

or

2) * Compartments that contain parts or components that can be a source of ignition (as defined in 11.2.2.1 a)) only under SINGLE FAULT CONDITION (as identified in 11.2.3) and that can be penetrated by oxygen (e.g. because of an undetected leak) shall be ventilated such that the oxygen concentration will not exceed 25 %.

Compliance is checked by the following test:

The oxygen concentration is measured for such a period that the highest possible concentration of oxygen occurs. The least favourable control settings are selected. The leaking conditions of oxygen are selected such that they provide the minimum leak that could be detected by the OPERATOR (e.g. because of a failure of the function of the device). If the concentration of oxygen exceeds 25 % in the presence of parts or components that could be a source of ignition including at the moment energy is applied, it constitutes a failure.

or

3) * A compartment that contains parts or components that can be a source of ignition (as defined in 11.2.2.1 a)) only under SINGLE FAULT CONDITION (as identified in 11.2.3) IS separated from another compartment that contains an OXYGEN RICH ENVIRONMENT by

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sealing all joints and any holes for cables, shafts or for other purpose. The effect of possible leaks and failures under SINGLE FAULT CONDITION (as identified in 11.2.3) that could cause ignition shall be evaluated using a RISK ASSESSMENT to determine the appropriate maintenance intervals.

Compliance is checked by visual inspection and by inspection of the documentation provided by the MANUFACTURER including the RISK MANAGEMENT FILE.

or

4) Electrical components in a compartment containing an OXYGEN RICH ENVIRONMENT that can become a source of ignition (as defined in 11.2.2.1 a)) only under SINGLE FAULT CONDITIONS (as identified in 11.2.3) shall be enclosed in such a way that should ignition occur within the ENCLOSURE, the fire would self-extinguish rapidly and no hazardous amount of toxic gases would reach the PATIENT.

Compliance shall be checked by starting a fire in the ENCLOSURE. If it is not evident that toxic gases cannot reach the PATIENT, the gas that could reach the PATIENT is analyzed.

11.2.2.2 * External exhaust outlets for OXYGEN RICH ENVIRONMENT

External exhaust outlets of an OXYGEN RICH ENVIRONMENT shall not be located so that RISK of ignition occurs because of any electrical component (which could cause a spark in NORMAL USE or SINGLE FAULT CONDITION as identified in 11.2.3) mounted on the outside of the ME EQUIPMENT or an ME SYSTEM. RISK of ignition is considered to be sufficiently low if oxygen concentration in the immediate surroundings of the electrical component does not exceed 25 % under the least favourable conditions of operation.

Compliance is checked by inspection.

11.2.2.3 Electrical connections in OXYGEN RICH ENVIRONMENTS

Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE shall not produce sparks because of loosening or breaking unless they are limited in power and energy to the values identified in 11.2.2.1 a) 5).

Prevention of loosening or breaking is accomplished by the following or equivalent methods.

– Screw-attachments shall be protected against loosening during use by methods such as varnishing, the use of spring washers or application of adequate torques.

– Soldered, crimped and pin-and-socket connections of cables that exit the ENCLOSURE shall include additional mechanical fixing.

Compliance is checked by visual inspection.

11.2.3 SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS in conjunction with ME EQUIPMENT and ME SYSTEMS

– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2).

– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3).

– Failure of a component that creates a source of ignition (as defined in 11.2.2.1 a)).

– Failure of insulation (whether solid material or spacing) providing the equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION (as described in 8.8 and 8.9) that could create a source of ignition (as defined in 11.2.2.1 a)).

– Failure of a pneumatic component that results in leakage of oxygen-enriched gas.

11.3 * Constructional requirements for fire ENCLOSURES of ME EQUIPMENT

This subclause provides an alternative means of compliance with selected HAZARDOUS SITUATIONS and fault conditions as identified in 13.1.2. In doing so, the following constructional

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requirements shall be met or specifically analyzed in the RISK MANAGEMENT FILE and if not met, specific justification shall also be given.

a) Insulated wire within the fire ENCLOSURE shall have a flammability classification equivalent FV-1, or better, according to the appropriate parts of the IEC 60695 series. Connectors, printed circuit boards and insulating material on which components are mounted shall have a flammability classification FV-2, or better, according to IEC 60695-11-10.

Compliance is checked by inspection of data on materials, or by performing the FV tests specified in IEC 60695-11-10 on three samples of the relevant parts being tested. The samples can be any of the following:

1) *complete parts; or*
2) *sections of a part, including the area with the least wall thickness and any ventilation openings.*

Components certified in accordance with IEC 60695-11-10 need not be tested.

b) The fire ENCLOSURE shall meet the following requirements:

1) The bottom shall have no openings or, to the extent specified in Figure 39, shall be constructed with baffles as specified in Figure 38, or be made of metal, perforated as specified in Table 25, or be a metal screen with a mesh not exceeding 2 mm × 2 mm centre to centre and a wire diameter of at least 0,45 mm.

2) The sides shall have no openings within the area that is included within the inclined line C in Figure 39.

3) The ENCLOSURE, and any baffle or flame barrier, shall be made of metal (except magnesium) or of non-metallic materials, except for constructions according to Table 25 and constructions with a mesh, having a flammability classification of FV-2 (or better) for TRANSPORTABLE ME EQUIPMENT and FV-1 (or better) for FIXED ME EQUIPMENT or STATIONARY ME EQUIPMENT in accordance with IEC 60695-11-10.

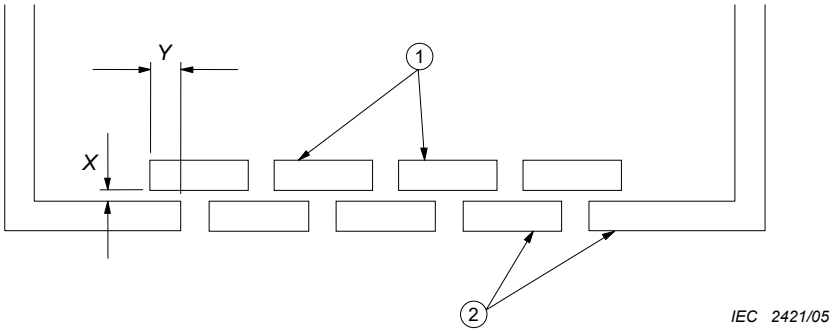
The ENCLOSURE, and any baffle or flame barrier, shall have adequate rigidity.

Conformity is checked by inspection. In case of doubt, the flammability classification of requirement b) 3) is checked as in a).

Table 25 – Acceptable perforation of the bottom of an ENCLOSURE

Minimum thickness mm	Maximum diameter of holes mm	Minimum spacing of holes centre to centre mm
0,66	1,14	1,70 (233 holes/645 mm^2)
0,66	1,19	2,36
0,76	1.15	1,70
0,76	1,19	2,36
0,81	1,91	3,18 (72 holes/645 mm^2)
0,89	1,90	3,18
0,91	1,60	2,77
0,91	1,98	3,18
1,00	1,60	2,77
1,00	2,00	3,00

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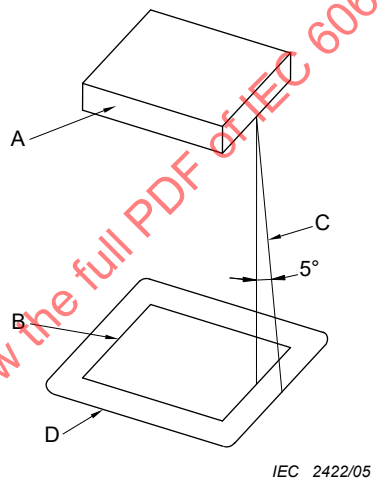


Y = twice X but never less than 25 mm

1 Baffle plates (may be below the bottom of the ENCLOSURE)

2 Bottom of the ENCLOSURE

Figure 38 – Baffle
(see 11.3)



Key

A Part or component of the ME EQUIPMENT that is considered to be a source of fire. This consists of an entire component or part of the ME EQUIPMENT if it is not otherwise shielded, or the unshielded portion of a component that is partially shielded by its casing.

B Projection of the outline of A on the horizontal plane.

C Inclined line that traces out the minimum area of the bottom and sides to be constructed as specified in 11.3 b) 1*)* and 11.3 b) 2). This line projects at a 5° angle from the vertical at every point around the perimeter of A and is oriented so as to trace out the maximum area.

D Minimum area of the bottom to be constructed as specified in 11.3 b) 1).

Figure 39 – Area of the bottom of an ENCLOSURE as specified in 11.3 b) 1)
(see 11.3)

11.4 * ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics

ME EQUIPMENT, ME SYSTEMS or their parts described in the ACCOMPANYING DOCUEMNTS for use with flammable anaesthetics (CATEGORY AP) or flammable anaesthetics with oxidants (CATEGORY APG) shall meet the applicable requirements of Annex G.

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11.5 * ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents

The MANUFACTURER'S RISK MANAGEMENT PROCESS shall address the possibility of fire and associated mitigations.

Compliance is determined by inspection of the RISK MANAGEMENT FILE.

11.6 Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT

11.6.1 General

The construction of ME EQUIPMENT and ME SYSTEMS shall ensure a sufficient degree of protection against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization as well as compatibility with substances used with the ME EQUIPMENT.

11.6.2 * Overflow in ME EQUIPMENT

If ME EQUIPMENT incorporates a reservoir or liquid storage chamber that is liable to be overfilled or to overflow in NORMAL USE, liquid overflowing from the reservoir or chamber shall not wet any MEANS OF PROTECTION that is liable to be adversely affected by such a liquid, nor ~~shall an unacceptable RISK be created~~ result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE.

If the maximum fill level is indicated by marking on the ME EQUIPMENT and a warning or safety notice is given, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow shall develop if the reservoir or liquid storage chamber is filled to its maximum capacity and the TRANSPORTABLE ME EQUIPMENT is tilted through an angle of 10°, or for MOBILE ME EQUIPMENT exceeding 45 kg, if it is moved over a threshold as described in 9.4.2.4.3.

~~Unless restricted by a marking or by the instructions for use~~ If no warning or safety notice is given regarding the maximum fill level, no HAZARDOUS SITUATION (as specified ~~herein~~ in 13.1) or unacceptable RISK due to overflow shall develop if the reservoir or liquid storage chamber is filled to 15 % above the maximum capacity and the TRANSPORTABLE ME EQUIPMENT is tilted through an angle of ~~15°~~ 10°, or in MOBILE ME EQUIPMENT exceeding 45 kg, if it is moved over a threshold as described in 9.4.2.4.3.

~~*Compliance is checked by filling the liquid reservoir completely and subsequently adding a further quantity equal to 15 % of the capacity of the reservoir, which is poured in steadily over a period of 1 min.*~~

Compliance is checked by the following:

If warnings or safety notices regarding overfilling are marked on the TRANSPORTABLE ME EQUIPMENT, the liquid reservoir is filled to the indicated maximum level.

If there is no warning or safety notice regarding overfilling marked on the TRANSPORTABLE ME EQUIPMENT, the liquid reservoir is filled completely and subsequently a further quantity equal to 15 % of the capacity of the reservoir is added poured in steadily over a period of 1 min.

TRANSPORTABLE ME EQUIPMENT is subsequently tilted through an angle of ~~15°~~ 10° in the least favourable direction(s) (if necessary with refilling) starting from the position of NORMAL USE.

MOBILE ME EQUIPMENT exceeding 45 kg is moved over a threshold as described in 9.4.2.4.3.

After these PROCEDURES, the ME EQUIPMENT is to pass the appropriate dielectric strength and LEAKAGE CURRENT tests and is to show no signs of wetting of uninsulated electrical parts or electrical insulation of parts that could result in ~~a HAZARDOUS SITUATION~~ the loss of BASIC

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SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION (based on a visual inspection).

11.6.3 * Spillage on ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT and ME SYSTEMS requiring the handling of liquids in NORMAL USE, including ME EQUIPMENT or ME SYSTEMS used in an environment where the PROCESS has determined that spillage on the ME EQUIPMENT is likely to occur, shall be so constructed that spillage does not wet parts that ~~could result in a HAZARDOUS SITUATION~~ are likely to result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE .

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by the following test:

The ME EQUIPMENT is positioned according to 5.4 a). A quantity of liquid is poured steadily on a point on the top of the ME EQUIPMENT. The type of liquid, volume, duration of the spill, and location (point) are determined through ~~application of the RISK MANAGEMENT PROCESS~~ RISK ANALYSIS . ~~All test conditions are identified through inspection of the RISK MANAGEMENT FILE.~~ Test conditions that simulate the worst case for spillage shall be documented in the RISK MANAGEMENT FILE.

After these PROCEDURES, the ME EQUIPMENT is to pass the appropriate dielectric strength and LEAKAGE CURRENT tests and is to show no signs of wetting of uninsulated electrical parts or electrical insulation of parts that could result in ~~a HAZARDOUS SITUATION~~ the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION (based on a visual inspection).

11.6.4 * Leakage

See 13.2.6.

11.6.5 * Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

ENCLOSURES of ME EQUIPMENT and ME SYSTEMS designed to give a specified degree of protection against harmful ingress of water or particulate matter shall provide this protection in accordance with the classification of IEC 60529. See also 7.2.9.

Compliance is checked by the tests of IEC 60529 with the ME EQUIPMENT placed in the least favourable position of NORMAL USE and by inspection.

After these PROCEDURES, the ME EQUIPMENT is to show no signs of bridging of insulation (or electrical components) that ~~could result in a HAZARDOUS SITUATION~~ is likely to result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION (based on a visual inspection) followed by the appropriate dielectric strength and LEAKAGE CURRENT tests.

11.6.6 Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT, ME SYSTEMS and their parts, including APPLIED PARTS and ACCESSORIES, shall be capable of withstanding, without damage or deterioration of safety provisions, the cleaning or disinfection PROCESSES specified in the instructions for use. See also 7.9.2.12.

The MANUFACTURER shall evaluate the effects of multiple cleanings/disinfections as indicated in the instructions for use during the EXPECTED SERVICE LIFE of the ME EQUIPMENT, ME SYSTEM, their parts and ACCESSORIES and assure that ~~no unacceptable RISK will occur. The results of the evaluation shall be documented in the RISK MANAGEMENT FILE~~ these PROCESSES do not result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE.

Where compliance with this standard could be ~~affected~~ effected by cleaning or disinfecting the ME EQUIPMENT, ME SYSTEM and their parts and ACCESSORIES, they are cleaned or disinfected once in accordance with the methods specified including any cooling or drying period. After these PROCEDURES, the ME EQUIPMENT, ME EQUIPMENT parts or ACCESSORIES are to show no signs of deterioration that could result in an unacceptable RISK (visual inspection) followed by

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the appropriate dielectric strength and LEAKAGE CURRENT tests. The RISK MANAGEMENT FILE is inspected to verify that the MANUFACTURER has evaluated the affects of multiple cleanings.

11.6.7 Sterilization of ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized shall be assessed and documented according to ~~ISO 11134, ISO 11135 or ISO 11137~~ ISO 11135-1, ISO 11137-1 or ISO 17665-1 as appropriate. See also 7.9.2.12.

After these PROCEDURES, the ME EQUIPMENT, ME SYSTEM and their parts or ACCESSORIES are to show no signs of deterioration that could result in an unacceptable RISK (visual inspection) followed by the appropriate dielectric strength and LEAKAGE CURRENT tests and by inspection of the RISK MANAGEMENT FILE.

11.6.8 * Compatibility with substances used with the ME EQUIPMENT

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with compatibility with substances used with the ME EQUIPMENT. Such RISKS may be addressed through the application of appropriate ISO or IEC standards (giving the presumption of acceptable RISK according to 4.2) such as ISO 15001 [70] for components that contain oxygen at pressures greater than 50 kPa or through the MANUFACTURER'S own testing and RISK CONTROL measures.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

11.7 Biocompatibility of ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT, ME SYSTEM and their parts or ACCESSORIES intended to come into direct or indirect contact with biological tissues, cells or body fluids shall be assessed and documented according to the guidance and principles given in the ISO 10993 series of standards.

Compliance is checked by inspection of the information provided by the MANUFACTURER.

11.8 * Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

ME EQUIPMENT shall be so designed that an interruption and restoration of the power supply shall not result in ~~a HAZARDOUS SITUATION other than interruption of its intended function~~ the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE .

NOTE This can require testing at several durations and ME EQUIPMENT states.

Compliance is checked by interruption and restoration of relevant power supplies.

12 * Accuracy of controls and instruments and protection against hazardous outputs

12.1 Accuracy of controls and instruments

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with accuracy of controls and instruments.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

12.2 USABILITY of ME EQUIPMENT

~~The MANUFACTURER shall address in a USABILITY ENGINEERING PROCESS the RISK of poor USABILITY, including those associated with identification, marking and documents (see 7.1.1 and 16.2). See IEC 60601-1-6 and also see 1.3.~~

~~*Compliance is checked by inspection of the results of the USABILITY ENGINEERING PROCESS.*~~

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The MANUFACTURER shall address the RISK(S) of poor USABILITY, including those associated with identification, marking and documents, through a USABILITY ENGINEERING PROCESS complying with IEC 60601-1-6.

Compliance is checked as specified in IEC 60601-1-6.

12.3 ALARM SYSTEMS

~~When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the need for alarm systems as a means of RISK CONTROL and address any RISKS associated with the operation or failure of the alarm system. See IEC 60601-1-8 and also see 1.3.~~

~~*Compliance is checked by inspection of the RISK MANAGEMENT FILE.*~~

If the MANUFACTURER has implemented an ALARM SYSTEM, this ALARM SYSTEM shall comply with IEC 60601-1-8.

Compliance is checked as specified in IEC 60601-1-8.

12.4 Protection against hazardous output

12.4.1 * Intentional exceeding of safety limits

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with hazardous output arising from the intentional exceeding of safety limits.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

12.4.2 Indication ~~of parameters~~ relevant to safety

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the need ~~for the indication of parameters that are associated with~~ to indicate any hazardous output.

EXAMPLE 1 Prior to the delivery of energy or substances to a PATIENT the energy, rate or volume ~~should be~~ is indicated quantitively.

EXAMPLE 2 During activation of an X-ray output, a flashing yellow light is displayed.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

12.4.3 * Accidental selection of excessive output values

Where ME EQUIPMENT is a multi-purpose unit designed for providing both low-intensity and high-intensity outputs for different treatments, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with accidental selection of excessive output values.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

12.4.4 Incorrect output

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with incorrect output.

EXAMPLE The RISKS associated with incorrect delivery of energy or substances to a PATIENT can be addressed by providing an alarm to alert the OPERATOR to any significant departure from the set level of delivery.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

12.4.5 Diagnostic or therapeutic radiation

12.4.5.1 Limits

For ME EQUIPMENT designed to produce radiation for diagnostic or therapeutic purposes, adequate provisions shall be made to protect PATIENTS, OPERATORS, other persons and

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sensitive devices in the vicinity, from unwanted or excessive radiation emitted by the ME EQUIPMENT.

NOTE Radiation from ME EQUIPMENT intended for application to PATIENTS for diagnostic or therapeutic purpose under medical supervision could exceed limits normally acceptable for the population as a whole.

As appropriate, particular standards shall specify requirements, limits and compliance tests to ensure radiation safety.

12.4.5.2 Diagnostic X-ray equipment

~~When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with diagnostic X-rays. See IEC 60601-1-3 and also see 1.3.~~

~~*Compliance is checked by inspection of the RISK MANAGEMENT FILE.*~~

ME EQUIPMENT and ME SYSTEMS designed to produce X-radiation for diagnostic imaging purposes shall comply with IEC 60601-1-3.

Compliance is checked as specified in IEC 60601-1-3.

12.4.5.3 Radiotherapy equipment

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with radiotherapy.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

12.4.5.4 Other ME EQUIPMENT producing diagnostic or therapeutic radiation

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with ME EQUIPMENT producing diagnostic or therapeutic radiation other than for diagnostic X-rays and radiotherapy (see 12.4.5.2 and 12.4.5.3).

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

12.4.6 Diagnostic or therapeutic acoustic pressure

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with diagnostic or therapeutic acoustic pressure.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

13 * HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

13.1 Specific HAZARDOUS SITUATIONS

13.1.1 * General

When applying the SINGLE FAULT CONDITIONS as described in 4.7 and listed in 13.2, one at a time, none of the HAZARDOUS SITUATIONS in 13.1.2 to 13.1.4 (inclusive) shall occur in the ME EQUIPMENT.

The failure of any one component at a time, which could result in a HAZARDOUS SITUATION, is described in 4.7.

13.1.2 * Emissions, deformation of ENCLOSURE or exceeding maximum temperature

The following HAZARDOUS SITUATIONS shall not occur:

– emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities;

– deformation of ENCLOSURES to such an extent that compliance with 15.3.1 is impaired;

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– temperatures of APPLIED PARTS exceeding the allowed values identified in Table 24 when measured as described in 11.1.3;

– temperatures of ME EQUIPMENT parts that are not APPLIED PARTS but are likely to be touched, exceeding the allowable values in Table 23 when measured and adjusted as described in 11.1.3;

– exceeding the allowable values for "other components and materials" identified in Table 22 times 1,5 minus 12,5 °C. Limits for windings are found in Table 26, Table 27 and Table 31. In all other cases, the allowable values of Table 22 apply.

Temperatures shall be measured using the method described in 11.1.3.

The SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2 and 13.2.2, with regard to the emission of flames, molten metal or ignitable substances, shall not be applied to parts and components where:

– The construction ~~or~~ of the supply circuit limits the power dissipation in SINGLE FAULT CONDITION to less than 15 W or the energy dissipation to less than 900 J.

Compliance is checked by drawing 15 W from the supply circuit for 1 min. If, after 1 min. the supply circuit can not supply 15 W, the circuit shall be considered to limit power dissipation to less than 15 W. The related design documentation is also reviewed.

or

– Secondary circuits meet all of the following conditions:

- mounted on material with a flammability classification of FV1 in accordance with IEC 60695-11-10 or better;
- they are energized at a voltage of 60 V d.c. or 42,2 V peak or less in NORMAL and SINGLE FAULT CONDITION;
- they are limited to 100 VA or are limited to 6 000 J in SINGLE FAULT CONDITION;
- they employ wire insulation of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide.

Compliance is checked by evaluation of the design documentation.

or

– The component is a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS as described in 4.9.

Compliance is checked by evaluation of the design documentation.

or

– They are completely contained within a fire ENCLOSURE.

Compliance is checked by inspection and evaluation of the design documentation to assure that the ENCLOSURE is constructed in accordance with 11.3.

NOTE The tests according to this subclause should be performed in the sequence indicated in Annex B.

After the tests of this clause, THERMAL CUT-OUTS and OVER-CURRENT RELEASES are inspected to determine that their setting has not changed (by heating, vibration or other causes) sufficiently to affect their safety function.

13.1.3 Exceeding LEAKAGE CURRENT or voltage limits

The following HAZARDOUS SITUATIONS shall not occur:

– exceeding the limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION as indicated in 8.7.3;

– exceeding the voltage limits for the ACCESSIBLE PARTS including APPLIED PARTS indicated in 8.4.2.

13.1.4 Specific MECHANICAL HAZARDS

For specific MECHANICAL HAZARDS, see 9.1 to 9.8 (inclusive).

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13.2 SINGLE FAULT CONDITIONS

13.2.1 General

During the application of the SINGLE FAULT CONDITIONS listed in 13.2.2 to 13.2.13 (inclusive), the NORMAL CONDITIONS identified in 8.1 a) shall also be applied in the least favourable combination.

13.2.2 Electrical SINGLE FAULT CONDITION

Requirements and tests relating to this SINGLE FAULT CONDITION are found in 8.1.

13.2.3 Overheating of transformers in ME EQUIPMENT

Requirements and tests relating to this SINGLE FAULT CONDITION are found in 15.5.

13.2.4 Failure of THERMOSTATS

Requirements and tests relating to this SINGLE FAULT CONDITION are found in 13.2.13 and 15.4.2 for overloading situations.

THERMOSTATS are short circuited or interrupted, whichever is less favourable.

13.2.5 Failure of temperature limiting devices

Requirements and tests relating to this SINGLE FAULT CONDITION are found in 13.2.13 and 15.4.2 for overloading situations.

THERMOSTATS are short circuited or interrupted, whichever is less favourable.

13.2.6 Leakage of liquid

ME EQUIPMENT shall be so constructed that liquid that might escape in a SINGLE FAULT CONDITION does not result in an unacceptable RISK.

Since only small amounts of liquid will escape when they leak, sealed rechargeable batteries are exempted from this requirement.

A RISK MANAGEMENT PROCESS shall be used to determine the appropriate test conditions for the ME EQUIPMENT.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

13.2.7 Impairment of cooling that could result in a ~~HAZARD~~ HAZARDOUS SITUATION

ME EQUIPMENT shall be so designed that it remains SINGLE FAULT SAFE during the failure of cooling systems to operate as intended.

Impairments of cooling that can occur are simulated, for example:

– *single ventilation fans are locked consecutively;*
– *ventilation through openings in top and sides is impaired by covering of openings in the top of the ENCLOSURE or positioning of ME EQUIPMENT against walls;*
– *blocking of filters is simulated;*
– *the flow of a cooling agent is interrupted.*

Temperatures that exceed the limits set in 13.1.2 constitute a failure.

Compliance is checked utilizing the test methods of 11.1, which are applied as far as possible.

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13.2.8 Locking of moving parts

ME EQUIPMENT shall be so designed that it remains SINGLE FAULT SAFE when moving parts become jammed.

Moving parts are locked if ME EQUIPMENT:

– *has moving ACCESSIBLE PARTS including APPLIED PARTS liable to be jammed, or*

– *is liable to be operated while unattended (this includes ME EQUIPMENT that is automatically or remotely controlled), or*

– *has one or more motors with a locked rotor torque smaller than the full load torque.*

If ME EQUIPMENT has more than one moving part as described above, only one part at a time is locked. If a SINGLE FAULT CONDITION can lock multiple motors, then all motors are locked simultaneously. For further test criteria see 13.2.10.

13.2.9 * Interruption and short circuiting of motor capacitors

ME EQUIPMENT shall be so designed that it remains SINGLE FAULT SAFE during the short circuit and open circuit of motor capacitors.

Compliance is checked by performing the following test:

Motors with a capacitor in the circuit of an auxiliary winding are operated according to 13.2.10 with a locked rotor, with the capacitor short circuited or open circuited in turn. Capacitor voltages are measured with one side disconnected (open circuit). A measured voltage that exceeds the RATED value constitutes a failure.

The test with a short-circuited capacitor is not performed if the motor is provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT is not intended for unattended use (including automatic or remote control).

For additional test criteria, see 13.2.10.

13.2.10 * Additional test criteria for motor operated ME EQUIPMENT

For every test in the SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, taking into account the exemptions stated in 13.1.2, motor-operated ME EQUIPMENT is operated starting from COLD CONDITION, at RATED voltage or at the upper limit of the RATED voltage range for the following periods of time:

a) *30 s for:*

– *HAND-HELD ME EQUIPMENT;*

– *ME EQUIPMENT that has to be kept switched on by hand;*

– *ME EQUIPMENT that has to be kept under physical load by hand;*

b) *5 min for other ME EQUIPMENT intended only for attended use (attended use excludes automated or remotely controlled ME EQUIPMENT that could operate when the OPERATOR is not present);*

c) *for the maximum period of a timer, if such a device terminates the operation, for ME EQUIPMENT not listed under a) or b);*

d) *as long as necessary to establish THERMAL STABILITY for all the remaining ME EQUIPMENT.*

Temperatures of windings are determined at the end of the specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices and the like.

Temperatures are measured as specified in 11.1.3 d).

Temperatures that exceed the limits of Table 26 constitute a failure.

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13.2.11 Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS

Requirements and tests relating to these SINGLE FAULT CONDITIONS are found in 11.2.2.

13.2.12 Failure of parts that might result in a MECHANICAL HAZARD

Requirements and tests relating to these SINGLE FAULT CONDITIONS are found in Clause 9 and 15.3.

Table 26 – * Temperature limits of motor windings

Temperature in °C

Type of ME EQUIPMENT	Insulation class				
	Class A	Class B	Class E	Class F	Class H
ME EQUIPMENT provided with a timer and not intended for unattended use and ME EQUIPMENT to be operated for 30 s or 5 min	200	225	215	240	260
Other ME EQUIPMENT					
– if impedance-protected, maximum value	150	175	165	190	210
– if protected by protection devices that operate during the first hour, maximum value	200	225	215	240	260
– after the first hour, maximum value	175	200	190	215	235
– after the first hour, arithmetic average	150	175	165	190	210
NOTE The temperature limits in this table were derived from IEC 61010-1:2001 [22].					

13.2.13 * Overload

13.2.13.1 * General overload test conditions

After the tests of 13.2.13.2 to 13.2.13.4 (inclusive), the ME EQUIPMENT, when cooled down to ~~approximately room temperature~~ within 3 °C of the temperature in the test environment, shall remain safe.

Compliance is determined by inspection of the ME EQUIPMENT or the appropriate tests (such as dielectric strength of motor insulation according to 8.8.3).

For insulation of thermoplastic materials that is relied upon as a MEANS OF PROTECTION (see 8.8), the ball-pressure test specified in 8.8.4.1 a) is performed at a temperature 25 °C higher than the temperature of the insulation measured during the tests of 13.2.13.2 to 13.2.13.4 (inclusive).

13.2.13.2 ME EQUIPMENT with heating elements

a) ME EQUIPMENT having heating elements is checked for compliance as follows:

1) for thermostatically controlled ME EQUIPMENT having heating elements that is intended for built-in or for unattended operation or that has a capacitor not protected by a fuse or the like connected in parallel with the contacts of the THERMOSTAT: by the tests of 13.2.13.2 b) and 13.2.13.2 c);

2) for ME EQUIPMENT having heating elements RATED for non-CONTINUOUS OPERATION: by the tests of 13.2.13.2 b) and 13.2.13.2 c);

3) for other ME EQUIPMENT having heating elements: by the test of 13.2.13.2 b).

If more than one of the tests is applicable to the same ME EQUIPMENT, these tests are performed consecutively.

If, in any of the tests, a non-SELF-RESETTING THERMAL CUT-OUT operates, a heating element or an intentionally weak part ruptures, or if the current is otherwise interrupted before

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THERMAL STABILITY is established without the possibility of automatic restoration, the heating period is ended. However, if the interruption is due to the rupture of a heating element or of an intentionally weak part, the test is repeated on a second sample. Open circuiting of a heating element or of an intentionally weak part in the second sample does not in itself entail a failure to comply. However, if either sample fails to comply with the conditions specified in 13.1.2, it constitutes a failure.

b) *ME EQUIPMENT having heating elements is tested under the conditions specified in 11.1, but without adequate heat discharge, the supply voltage being 90 % or 110 % of the RATED supply voltage, whichever is the least favourable.*

If a non-SELF-RESETTING THERMAL CUT-OUT operates, or if the current is otherwise interrupted without the possibility of automatic restoration before THERMAL STABILITY is established, the operating period is ended. If interruption of the current does not occur, ME EQUIPMENT is switched off as soon as THERMAL STABILITY is established and is allowed to cool to approximately room temperature.

For ME EQUIPMENT RATED for non-CONTINUOUS OPERATION, the duration of the test is equal to the RATED operating time.

c) *Heating parts of ME EQUIPMENT are tested with the ME EQUIPMENT operated in NORMAL CONDITION, at a supply voltage 110 % of the RATED supply voltage and as specified in 11.1. The following test conditions are met.*

1) *Any control that serves to limit the temperature in NORMAL CONDITION, except a THERMAL CUT-OUT, is disabled.*

2) *If the ME EQUIPMENT is provided with more than one control, they are disabled in turn.*

3) *The ME EQUIPMENT is operated at the RATED DUTY CYCLE until THERMAL STABILITY is achieved, irrespective of the RATED operating time.*

13.2.13.3 ME EQUIPMENT with motors

a) *ME EQUIPMENT having motors is checked for compliance as follows:*

1) *For the motor part of the ME EQUIPMENT, compliance is checked by the tests of 13.2.8 to 13.2.10 (inclusive), 13.2.13.3 b), 13.2.13.3 c) and 13.2.13.4, as applicable. For motors located in circuits with a voltage not exceeding 42,4 V peak a.c. or 60 V d.c. and where difficulty is experienced in obtaining accurate temperature measurements due to the small size or design of the motor, it is permitted to use the following test instead of temperature measurement in order to determine compliance with 13.2.9 and 13.2.10.*

The motor is covered with a single layer of cheesecloth with the following characteristics:

– *bleached cotton material;*
– *26–28 m^2 per kg mass; and*
– *13 threads per cm in one direction and 11 threads per cm in the other.*

Ignition of the cheesecloth during the test or at its conclusion constitutes a failure.

2) *For ME EQUIPMENT that also contains heating parts, the tests are performed at the prescribed voltage, with the motor part and the heating part operated simultaneously so as to produce the least favourable condition.*

3) *If more than one of the tests is applicable for the same ME EQUIPMENT, these tests are performed consecutively.*

b) *Motors are checked for running overload protection if they are:*

1) *intended to be remotely controlled or automatically controlled (by a single control device without redundant protection), or*

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2) *likely to be subjected to* CONTINUOUS OPERATION *whilst unattended.*

Compliance is determined by operating the ME EQUIPMENT *under normal load conditions at* RATED *voltage or at the maximum of the* RATED *voltage range, until* THERMAL STABILITY *is achieved (see 11.1.3).*

The load is then increased so that the current is increased in appropriate steps, the supply voltage being maintained at its original value.

When THERMAL STABILITY *is established, the load is again increased. The load is thus progressively increased in appropriate steps until the overload protection operates, or until no further temperature rise is noted.*

The motor winding temperature is determined during each steady period. If the maximum value recorded exceeds the value in Table 27, it constitutes a failure.

Table 27 – Maximum motor winding steady-state temperature

Insulation class	Maximum temperature °C
A	140
B	165
E	155
F	180
H	200

If the load cannot be changed in appropriate steps in ME EQUIPMENT*, the motor is removed from the* ME EQUIPMENT *in order to perform the test.*

The running overload test for motors located in circuits with a voltage not exceeding 42,4 V peak a.c. or 60 V d.c. is performed only if a possibility of an overload occurring is determined by inspection or by review of the design. The test need not be performed, for example, where electronic drive circuits maintain a substantially constant drive current.

c) *ME* EQUIPMENT *with three-phase motors is operated with normal load, connected to a three-phase (*SUPPLY MAINS*) with one phase disconnected. Periods of operation are according to 13.2.10.*

13.2.13.4 * ME EQUIPMENT RATED for non-CONTINUOUS OPERATION

ME EQUIPMENT *RATED for non-*CONTINUOUS OPERATION *other than:*

– *HAND-HELD ME EQUIPMENT*;

– *ME* EQUIPMENT *that has to be kept switched on manually;*

– *ME* EQUIPMENT *that has to be kept under physical load by hand;*

– *ME* EQUIPMENT *with a timer and a back-up timer system*

is operated under normal load and at RATED *voltage or at the upper limit of the* RATED *voltage range until the peak temperature does not increase by more than 5 °C in one hour, or until any protective device operates.*

Motor winding temperatures are determined when THERMAL STABILITY *is established or immediately before the operation of the protective device. Motor winding temperatures that exceed the values specified in 13.2.10 constitute a failure.*

If in NORMAL USE *a load-reducing device in the* ME EQUIPMENT *operates, the test is continued with the* ME EQUIPMENT *running idle.*

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14 * PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

14.1 * General

~~The requirements of this clause shall apply to PEMS unless:~~

~~– the PESS provides no BASIC SAFETY or ESSENTIAL PERFORMANCE; or~~

~~– the application of ISO 14971 demonstrates that the failure of the PESS does not lead to an unacceptable RISK.~~

The requirements in 14.2 to 14.12 (inclusive) shall apply to PEMS unless:

– none of the PROGRAMMABLE ELECTRONIC SUBSYSTEM (PESS) provides functionality necessary for BASIC SAFETY or ESSENTIAL PERFORMANCE; or

– the application of RISK MANAGEMENT as described in 4.2 demonstrates that the failure of any PESS does not lead to an unacceptable RISK.

The requirements in 14.13 are applicable to any PEMS intended to be incorporated into an IT-NETWORK whether or not the requirements in 14.2 to 14.12 apply.

NOTE 1 This clause requires that a PROCESS be followed throughout the PEMS DEVELOPMENT LIFE-CYCLE and that a RECORD of that PROCESS be produced. The concepts of RISK MANAGEMENT and a PEMS DEVELOPMENT LIFE-CYCLE are the basis of such a PROCESS. However, because a RISK MANAGEMENT PROCESS is already required by this standard, this clause will define the minimum elements of the PEMS DEVELOPMENT LIFE-CYCLE and only the additional elements for the PEMS that needs to be considered as part of the RISK MANAGEMENT PROCESS (see 4.2).

NOTE 2 If a RISK CONTROL measure is implemented within the PEES, it is necessary to apply Clause 14 to demonstrate that the failure of the PEES does not lead to an unacceptable RISK.

NOTE ~~2~~ 3 It is recognized that the MANUFACTURER might not be able to follow all the PROCESSES identified in Clause 14 for each constituent component of the PEMS, such as ~~off-the-shelf (OTS)~~ software of unknown provenance (SOUP), subsystems of non-medical origin, and legacy devices. In this case, the MANUFACTURER should take special account of the need for additional RISK CONTROL measures. SOUP is defined in IEC 62304:2006 as a "software item that is already developed and generally available and that has not been developed for the purpose of being incorporated into the medical device (also known as 'off-the-shelf software') or software previously developed for which adequate RECORDS of the development PROCESSES are not available".

~~*Compliance is determined by application of the requirements in 14.2 to 14.13 (inclusive), by inspection of the RISK MANAGEMENT FILE, and assessment of PROCESSES cited in this clause.*~~

Compliance is determined by inspection of all documentation required, and when necessary, assessment of the requirements in 14.2 to 14.13 (inclusive).

NOTE ~~3~~ 4 This assessment could be performed by internal audit.

When the requirements in 14.2 to 14.13 apply, the requirements in subclause 4.3, Clause 5, Clause 7, Clause 8 and Clause 9 of IEC 62304:2006 shall also apply to the development or modification of software for each PESS.

Compliance is determined by inspection and assessment as required by subclause 1.4 of IEC 62304:2006.

NOTE 5 The software development PROCESS required for compliance with this standard does not include the post-production monitoring and maintenance required by Clause 6 of IEC 62304:2006.

14.2 * Documentation

~~In addition to the RECORDS and documents required by ISO 14971, the documents produced from application of Clause 14 shall be maintained and shall form part of the RISK MANAGEMENT FILE.~~

~~NOTE See Figure H.3 as guidance.~~

The documents required by Clause 14 shall be reviewed, approved, issued and changed in accordance with a formal document control PROCEDURE.

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14.3 * RISK MANAGEMENT plan

The RISK MANAGEMENT plan required by ~~3.5 of ISO 14971~~ 4.2.2 shall also include a reference to the PEMS VALIDATION plan (see 14.11).

14.4 * PEMS DEVELOPMENT LIFE-CYCLE

A PEMS DEVELOPMENT LIFE-CYCLE shall be documented.

NOTE ~~1~~ Clause H.2 explains PEMS DEVELOPMENT LIFE-CYCLE in more detail.

~~NOTE 2 IEC 62304 [26] defines general requirements for additional PROCESSES and activities specific to software development.~~

The PEMS DEVELOPMENT LIFE-CYCLE shall include a set of defined milestones.

At each milestone, the activities to be completed and the VERIFICATION methods to be applied to those activities shall be defined.

Each activity shall be defined including its inputs and outputs.

Each milestone shall identify the RISK MANAGEMENT activities that must be completed before that milestone.

The PEMS DEVELOPMENT LIFE-CYCLE shall be tailored for a specific development by making plans which detail activities, milestones and schedules.

The PEMS DEVELOPMENT LIFE-CYCLE shall include documentation requirements.

14.5 * Problem resolution

Where appropriate, a documented system for problem resolution within and between all phases and activities of the PEMS DEVELOPMENT LIFE-CYCLE shall be developed and maintained.

Depending on the type of product, the problem resolution system may:

– be documented as a part of the PEMS DEVELOPMENT LIFE-CYCLE;

– allow the reporting of potential or existing problems affecting BASIC SAFETY or ESSENTIAL PERFORMANCE;

– include an assessment of each problem for associated RISKS;

– identify the criteria that must be met for the issue to be closed;

– identify the action to be taken to resolve each problem.

14.6 RISK MANAGEMENT PROCESS

14.6.1 * Identification of known and foreseeable HAZARDS

When compiling the list of known or foreseeable HAZARDS, the MANUFACTURER shall consider those HAZARDS associated with software and hardware aspects of the PEMS including those associated with ~~NETWORK/DATA COUPLING~~ the incorporation of the PEMS into an IT-NETWORK, components of third-party origin and legacy subsystems.

NOTE In addition to the material given in Annex ~~D~~ E of ISO 14971:2007, the list of possible causes for HAZARDS associated with PEMS ~~should~~ can include:

~~– failure of the NETWORK/DATA COUPLING to provide the characteristics necessary for the PEMS to achieve its BASIC SAFETY or ESSENTIAL PERFORMANCE;~~

– undesired feedback [physical and data] (possibilities include: unsolicited input, out of range or inconsistent input, and input originating from electromagnetic interference);

– unavailable data;

– lack of integrity of data;

– incorrect data;

– incorrect timing of data.

– unintended interactions within and among PESS;

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– unknown aspects or quality of third-party software;

– unknown aspects or quality of third-party PESS;

– lack of data security, including its effects on data privacy, and particularly vulnerability to tampering, unintended interaction with other programs and viruses.

– failure of the IT-NETWORK to provide the characteristics necessary for the PEMS to achieve its BASIC SAFETY or ESSENTIAL PERFORMANCE. See Annex H.7.2 for examples.

14.6.2 * RISK CONTROL

The following requirements for PEMS supplement ~~Subclause 6.1 of ISO 14971~~ 4.2.2.

Suitably validated tools and PROCEDURES shall be selected and identified to implement each RISK CONTROL measure. These tools and PROCEDURES shall be appropriate to assure that each RISK CONTROL measure satisfactorily reduces the identified RISK(S).

14.7 * Requirement specification

For the PEMS and each of its subsystems (e.g. for a PESS) there shall be a documented requirement specification.

NOTE Example structures of a PEMS are given in H.1.

The requirement specification for a system or subsystem shall include and distinguish any ESSENTIAL PERFORMANCE and any RISK CONTROL measures implemented by that system or subsystem.

14.8 * Architecture

For the PEMS and each of its subsystems, an architecture shall be specified that shall satisfy the requirement specification.

Where appropriate, to reduce the RISK to an acceptable level, the architecture specification shall make use of:

a) COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS;

b) fail-safe functions;

c) redundancy;

d) diversity;

e) * partitioning of functionality;

f) defensive design, e.g. limits on potentially hazardous effects by restricting the available output power or by introducing means to limit the travel of actuators.

The architecture specification shall take into consideration:

g) * allocation of RISK CONTROL measures to subsystems and components of the PEMS;

NOTE Subsystems and components include sensors, actuators, PESS and interfaces.

h) failure modes of components and their effects;

i) common cause failures;

j) systematic failures;

k) test interval duration and diagnostic coverage;

l) maintainability;

m) protection from reasonably foreseeable misuse;

n) the ~~NETWORK/DATA COUPLING~~ IT-NETWORK specification, if applicable.

14.9 * Design and implementation

Where appropriate, the design shall be decomposed into subsystems, each having both a design and test specification.

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Descriptive data regarding the design environment shall be ~~included in the RISK MANAGEMENT FILE~~ documented.

NOTE See ~~H.3~~ H.4 a) for examples of design environment elements.

14.10 * VERIFICATION

VERIFICATION is required for all functions that implement BASIC SAFETY, ESSENTIAL PERFORMANCE or RISK CONTROL measures.

A VERIFICATION plan shall be produced to show how these functions shall be verified. The plan shall include:

– at which milestone(s) VERIFICATION is to be performed for each function;

– the selection and documentation of VERIFICATION strategies, activities, techniques, and the appropriate level of independence of the personnel performing the VERIFICATION;

– the selection and utilization of VERIFICATION tools;

– coverage criteria for VERIFICATION.

NOTE Examples of methods and techniques are:

– walkthroughs;

– inspections;

– static analysis;

– dynamic analysis;

– white box testing;

– black box testing;

– statistical testing.

The VERIFICATION shall be performed according to the VERIFICATION plan. The results of the VERIFICATION activities shall be documented.

14.11 * PEMS VALIDATION

A PEMS VALIDATION plan shall include the validation of BASIC SAFETY and ESSENTIAL PERFORMANCE~~, and shall require checks for unintended functioning of the PEMS~~.

Methods used for PEMS VALIDATION shall be documented.

The PEMS VALIDATION shall be performed according to the PEMS VALIDATION plan. The results of PEMS VALIDATION activities shall be documented.

The person having the overall responsibility for the PEMS VALIDATION shall be independent of the design team. The MANUFACTURER shall document the rationale for the level of independence.

No member of a design team shall be responsible for the PEMS VALIDATION of their own design.

All professional relationships of the members of the PEMS VALIDATION team with members of the design team shall be documented in the RISK MANAGEMENT FILE.

~~A reference to the methods and results of the PEMS VALIDATION shall be included in the RISK MANAGEMENT FILE.~~

14.12 * Modification

If any or all of a design results from a modification of an earlier design then either all of this clause applies as if it were a new design or the continued validity of any previous design documentation shall be assessed under a documented modification/change PROCEDURE.

When software is modified, the requirements in subclause 4.3, Clause 5, Clause 7, Clause 8 and Clause 9 of IEC 62304:2006 shall also apply to the modification.

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14.13 ~~* Connection of PEMS by NETWORK/DATA COUPLING to other equipment~~ * PEMS intended to be incorporated into an IT-NETWORK

~~If the PEMS is intended to be connected by NETWORK/DATA COUPLING to other equipment that is outside the control of the PEMS MANUFACTURER, the technical description shall:~~

~~a) specify the characteristics of the NETWORK/DATA COUPLING necessary for the PEMS to achieve its INTENDED USE;~~

~~b) list the HAZARDOUS SITUATIONS resulting from a failure of the NETWORK/DATA COUPLING to provide the specified characteristics;~~

~~c) instruct the RESPONSIBLE ORGANIZATION that:~~

- ~~connection of the PEMS to a NETWORK/DATA COUPLING that includes other equipment could result in previously unidentified RISKS to PATIENTS, OPERATORS or third parties;~~
- ~~the RESPONSIBLE ORGANIZATION should identify, analyze, evaluate and control these RISKS;~~
- ~~subsequent changes to the NETWORK/DATA COUPLING could introduce new RISKS and require additional analysis; and~~
- ~~changes to the NETWORK/DATA COUPLING include:~~
  - ~~changes in NETWORK/DATA COUPLING configuration;~~
  - ~~connection of additional items to the NETWORK/DATA COUPLING;~~
  - ~~disconnecting items from the NETWORK/DATA COUPLING;~~
  - ~~update of equipment connected to the NETWORK/DATA COUPLING;~~
  - ~~upgrade of equipment connected to the NETWORK/DATA COUPLING.~~

If the PEMS is intended to be incorporated into an IT-NETWORK that is not validated by the PEMS MANUFACTURER, the MANUFACTURER shall make available instructions for implementing such connection including the following:

a) the purpose of the PEMS's connection to an IT-NETWORK;

b) the required characteristics of the IT-NETWORK incorporating the PEMS;

c) the required configuration of the IT-NETWORK incorporating the PEMS;

d) the technical specifications of the network connection of the PEMS including security specifications;

e) the intended information flow between the PEMS, the IT-NETWORK and other devices on the IT-NETWORK, and the intended routing through the IT-NETWORK; and

NOTE 1 This can include aspects of effectiveness and data and system security as related to BASIC SAFETY and ESSENTIAL PERFORMANCE (see also Clause H.6 and IEC 80001-1:2010).

f) a list of the HAZARDOUS SITUATIONS resulting from a failure of the IT-NETWORK to provide the characteristics required to meet the purpose of the PEMS connection to the IT-NETWORK.

NOTE 2 Connecting a PEMS to another piece of equipment for the purpose of transferring data creates a two-node IT-NETWORK. For example, connecting a PEMS to a printer creates an IT-NETWORK. If the MANUFACTURER has validated the PEMS with the printer, the resulting network would be considered within the control of the MANUFACTURER.

Compliance is checked by inspection of the instructions.

In the ACCOMPANYING DOCUMENTS, the MANUFACTURER shall instruct the RESPONSIBLE ORGANIZATION that:

– connection of the PEMS to an IT-NETWORK that includes other equipment could result in previously unidentified RISKS to PATIENTS, OPERATORS or third parties;

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– the RESPONSIBLE ORGANIZATION should identify, analyze, evaluate and control these RISKS;

NOTE 3 IEC 80001-1:2010 provides guidance for the RESPONSIBLE ORGANIZATION to address these RISKS.

– subsequent changes to the IT-NETWORK could introduce new RISKS and require additional analysis; and

– changes to the IT-NETWORK include:

- changes in the IT-network configuration;
- connection of additional items to the IT-NETWORK;
- disconnecting items from the IT-NETWORK;
- update of equipment connected to the IT-NETWORK; and
- upgrade of equipment connected to the IT-NETWORK.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

15 Construction of ME EQUIPMENT

15.1 * Arrangements of controls and indicators of ME EQUIPMENT

When applicable, the MANUFACTURER shall address ~~in the RISK MANAGEMENT PROCESS~~ the RISKS associated with the arrangement of controls and indicators of ME EQUIPMENT in the USABILITY ENGINEERING PROCESS. See 12.2.

Compliance is checked ~~by inspection of the RISK MANAGEMENT FILE~~ as specified in IEC 60601-1-6.

15.2 * Serviceability

Parts of ME EQUIPMENT subject to mechanical wear, electrical and environmental degradation or ageing that could result in an unacceptable RISK if allowed to continue unchecked for too long a period shall be accessible for inspection, replacement and maintenance.

Parts of ME EQUIPMENT that are likely to be replaced or adjusted shall be so located and secured as to permit inspection, servicing, replacement and adjustment without damage to, or interference with, adjacent parts or wiring.

Compliance is checked by inspection of the parts mentioned above in this subclause and of their location.

15.3 Mechanical strength

15.3.1 General

ME EQUIPMENT or its parts shall have adequate mechanical strength and shall not result in ~~an unacceptable RISK~~ loss of BASIC SAFETY or ESSENTIAL PERFORMANCE due to moulding stress or when subjected to mechanical stress caused by pushing, impact, dropping, and rough handling.

Compliance is checked by application of the tests in Table 28. The tests are not applied to handles, levers, knobs, the face of cathode ray tubes (see 9.5.2), or to transparent or translucent covers of indicating or measuring devices unless with the handle, lever, knob, or cover removed there is an unacceptable RISK of electric shock.

NOTE Examples of damage that can ~~result in unacceptable RISK~~ affect BASIC SAFETY include the reduction of CREEPAGE DISTANCES and AIR CLEARANCES below those specified in 8.9, access to parts which exceed limits in 8.4, or access to moving parts which could cause HARM.

Assessment criteria that can be useful in determining if ~~the tests in Table 28 have~~ this test has resulted in ~~an unacceptable RISK~~ loss of BASIC SAFETY include:

– those in Clause 8 and 11.6;

– the dielectric strength test as specified in 8.8.3 to evaluate the integrity of solid ~~SUPPLEMENTARY or REINFORCED INSULATION~~ INSULATION providing a MEANS OF PROTECTION; and

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– measurement of CREEPAGE DISTANCES or AIR CLEARANCES to compare the values with the minimum distances specified in 8.9. Small chips that do not adversely affect the protection against electric shock or moisture can normally be ignored.

Table 28 – Mechanical strength test applicability

ME EQUIPMENT type	Test
HAND-HELD	Push (15.3.2)
	Drop (15.3.4.1)
	Moulding stress relief (15.3.6)
BODY-WORN	Push (15.3.2)
	Impact (15.3.3)
	Drop (15.3.4.1)
	Moulding stress relief (15.3.6)
PORTABLE	Push (15.3.2)
	Impact (15.3.3)
	Drop (15.3.4.2)
	Moulding stress relief (15.3.6)
MOBILE	Push (15.3.2)
	Impact (15.3.3)
	Rough handling (15.3.5)
	Moulding stress relief (15.3.6)
FIXED or STATIONARY	Push (15.3.2)
	Impact (15.3.3)
	Moulding stress relief (15.3.6)

15.3.2 * Push test

ENCLOSURES of ME EQUIPMENT shall have sufficient rigidity to protect against unacceptable RISK.

Compliance is checked by the following test.

External parts of an ENCLOSURE are subject to a steady force of 250 N ± 10 N for a period of 5 s, applied by means of a suitable test tool providing contact over a circular plane surface 30 mm in diameter. However, this test is not applied to the bottom of an ENCLOSURE of ME EQUIPMENT having a mass of more than 18 kg.

After the test, any damage sustained that results in an unacceptable RISK~~, as determined by inspection of the RISK MANAGEMENT FILE,~~ constitutes a failure.

NOTE See the compliance criteria in 15.3.1.

15.3.3 * Impact test

ENCLOSURES of ME EQUIPMENT shall have sufficient resistance to impact to protect against unacceptable RISK.

Compliance is checked by the following test.

Except for HAND-HELD ME EQUIPMENT and ME EQUIPMENT parts that are HAND-HELD, ENCLOSURES and other external insulating parts, the deterioration of which could result in unacceptable RISK, are tested as indicated below.

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A sample consisting of the complete ENCLOSURE, or a portion thereof representing the largest unreinforced area, is supported in its normal position. A solid smooth steel ball, approximately 50 mm in diameter and with a mass of 500 g ± 25 g, is permitted to fall freely from a 1,3 m height once onto each relevant part of the test sample.

To test vertical surfaces, the steel ball is suspended by a cord and allowed to swing like a pendulum in order to apply a horizontal impact, dropping though a vertical distance of 1,3 m once against each relevant part of the test sample.

The test is not applied to flat panel displays, to the platen glass of ME EQUIPMENT (for example film scanners), or to cathode ray tubes (see 9.5.2).

After the test, any damage sustained that results in an unacceptable RISK~~, as determined by inspection of the RISK MANAGEMENT FILE,~~ constitutes a failure.

NOTE See the compliance criteria in 15.3.1.

15.3.4 * Drop test

15.3.4.1 HAND-HELD ME EQUIPMENT

HAND-HELD ME EQUIPMENT, ACCESSORIES and ME EQUIPMENT parts ~~that are HAND-HELD~~ shall not result in an unacceptable RISK as a result of a free fall.

Compliance is checked by the following test.

The sample to be tested, with any SAFE WORKING LOAD in place, is allowed to fall freely once from each of three different starting orientations encountered during NORMAL USE from the height at which the ME EQUIPMENT, ACCESSORY or ME EQUIPMENT part is used (as specified in the ACCOMPANYING DOCUMENTS), or from a height of 1 m, whichever is greater, onto a 50 mm ± 5 mm thick hardwood board (hardwood > 600 kg/m³) lying flat on a concrete or a similar rigid base.

After the test, the HAND-HELD ME EQUIPMENT ~~and~~, ACCESSORY or ME EQUIPMENT part~~s that are HAND-HELD~~ shall not result in an unacceptable RISK.

15.3.4.2 * PORTABLE ME EQUIPMENT

PORTABLE ME EQUIPMENT, ACCESSORIES and ME EQUIPMENT parts ~~that are PORTABLE~~ shall withstand the stress caused by a free fall from the height indicated in Table 29 onto a hard surface.

Compliance is checked by the following test.

The sample to be tested, with the SAFE WORKING LOAD in place, is lifted to a height as indicated in Table 29 above a 50 mm ± 5 mm thick hardwood board (for example, > 600 kg/m3) that lies flat on a concrete floor or a similar rigid base. The dimensions of the board are at least those of the sample tested. The sample is dropped three times from each orientation in which it can be placed during NORMAL USE.

Table 29 – Drop height

Mass (*m*) of PORTABLE ME EQUIPMENT or its parts kg	**Drop height** cm
$m \leq 10$	5
$10 < m \leq 50$	3
$m > 50$	2

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After the test, any damage sustained that results in a unacceptable RISK~~, as determined by inspection of the RISK MANAGEMENT FILE and inspection of the ME EQUIPMENT or the ME EQUIPMENT parts that are PORTABLE,~~ constitutes a failure.

NOTE See the compliance criteria in 15.3.1.

15.3.5 * Rough handling test

MOBILE ME EQUIPMENT and ME EQUIPMENT parts that are MOBILE shall withstand the stress caused by rough handling and movement and shall not result in an unacceptable RISK.

Compliance is checked by the following tests.

The sample is tested in transport position with any SAFE WORKING LOAD in place and in the most adverse condition permitted in NORMAL USE. During the test, suitable precautions shall be taken to prevent over-balance caused by the rough handling stress/shock.

a) Ascending step shock

The sample is pushed three times in its normal direction of travel at a speed of ~~0,4~~ 0,8 m/s ± 0,1 m/s, or, for motor-driven MOBILE ME EQUIPMENT, at the maximum speed capable of being maintained, against ~~an ascending hardwood step obstruction with vertical~~ a solid hardwood plane obstruction with a face of 40 mm that is rigidly attached to an otherwise flat floor. The direction of movement is perpendicular to the face of the obstacle. The sample need not go over the 40 mm obstruction.

b) Descending step shock

The sample is pushed three times in its normal direction of travel at a speed of ~~0,4~~ 0,8 m/s ± 0,1 m/s, or, for motor-driven MOBILE ME EQUIPMENT, at the maximum speed capable of being maintained, in order to fall over a vertical step having a height of 40 mm affixed flat on a rigid base (e.g. concrete). The direction of movement is perpendicular to the face of the descending step.

During performance of the descending step shock test, if a part other than the castor comes in contact with the obstruction before the castor touches the ground, the ME EQUIPMENT continues to be pushed until it has fully descended.

c) Door frame shock

The sample is moved three times in its normal direction of travel at a speed of ~~0,4~~ 0,8 m/s ± 0,1 m/s, or, for motor driven MOBILE ME EQUIPMENT, the maximum speed capable of being maintained, against a hardwood vertical obstacle having a width and thickness of 40 mm affixed to a vertical rigid support (e.g. concrete). The height of the vertical obstacle must be higher than the ME EQUIPMENT contact point(s). The direction of movement is perpendicular to the face of the obstacle.

After each test, any damage sustained that results in an unacceptable RISK~~, as determined by inspection of the RISK MANAGEMENT FILE and inspection of the ME EQUIPMENT or the ME EQUIPMENT parts that are MOBILE,~~ constitutes a failure.

NOTE 1 See compliance criteria in 15.3.1.

NOTE 2 Instability of ME EQUIPMENT, when the ME EQUIPMENT remains undamaged from the rough handling shock/stress, is evaluated in accordance with 9.4.

15.3.6 * Mould stress relief test

ENCLOSURES of moulded or formed thermoplastic materials shall be so constructed that any shrinkage or distortion of the material due to release of internal stresses caused by the moulding or forming operation does not result in an unacceptable RISK.

Compliance is checked by inspection of the construction and available data were appropriate or by the following test.

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One sample consisting of the complete ME EQUIPMENT, or of the ENCLOSURE together with any supporting framework, is placed in a circulating air oven at a temperature 10 °C higher than the maximum temperature observed on the ENCLOSURE during the test of 11.1.3, but not less than 70 °C, for a period of 7 h, then permitted to cool to room temperature.

NOTE Relative humidity need not be maintained at a specific value during this conditioning.

For large ME EQUIPMENT where it is not practical to condition a complete ENCLOSURE, it is permitted to use a portion of the ENCLOSURE representative of the complete assembly with regard to thickness and shape, including any mechanical support members.

Any damage that results in an unacceptable RISK constitutes a failure.

15.3.7 * Environmental influences

The selection and treatment of materials used in the construction of ME EQUIPMENT shall take account of the INTENDED USE, the EXPECTED SERVICE LIFE and the conditions for transport and storage.

The ME EQUIPMENT shall be so designed and constructed that during its EXPECTED SERVICE LIFE any corrosion, ageing, mechanical wear, or degradation of biological materials due to the influence of bacteria, plants, animals and the like, shall not reduce its mechanical properties in a way that results in an unacceptable RISK. See also 15.2.

Compliance is checked by inspection:

– *of the ME EQUIPMENT, of the ACCOMPANYING DOCUMENTS and of the MANUFACTURER'S specifications of materials used and of the processing specifications for these materials;*

– *of the MANUFACTURER'S relevant tests or calculations.*

15.4 ME EQUIPMENT components and general assembly

15.4.1 Construction of connectors

Design and construction of electrical, hydraulic, pneumatic and gas connection terminals and connectors of ME EQUIPMENT shall be such that incorrect connection of accessible connectors, removable without the use of a TOOL, shall be prevented where an unacceptable RISK would otherwise exist. In particular:

a) Plugs for connection of PATIENT leads or PATIENT cables shall be so designed that they cannot be connected to ~~other~~ outlets on the same ME EQUIPMENT intended for other functions, unless it can be proven that no unacceptable RISK can result.

Compliance is checked by inspection of PATIENT leads, PATIENT cables, connectors and outlets and, if interchange of the leads, cables, connectors or outlets is possible, by inspection of the RISK MANAGEMENT FILE.

b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE shall not be interchangeable. See also ISO 407 [27].

Compliance is checked by inspection of ~~the RISK MANAGEMENT FILE~~ all medical gas connectors.

15.4.2 Temperature and overload control devices

15.4.2.1 Application

a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting shall not be used in ME EQUIPMENT if their use could ~~result in~~ lead to a HAZARDOUS SITUATION described in 13.1 by such resetting.

Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE.

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b) THERMAL CUT-OUTS with a safety function that have to be reset by a soldering operation that can affect the operating value shall not be fitted in ME EQUIPMENT.

Compliance is checked by inspection of the design documentation ~~and the RISK MANAGEMENT FILE~~.

c) In ME EQUIPMENT, where a failure of a THERMOSTAT could ~~constitute~~ lead to a ~~HAZARD~~ HAZARDOUS SITUATION described in 13.1, an independent non-SELF-RESETTING THERMAL CUT-OUT shall additionally be provided. The temperature of operation of the additional device shall be outside that attainable at the extreme setting of the normal control device (THERMOSTAT) but shall be within the safe temperature limit for ~~its~~ the intended function of the ME EQUIPMENT .

Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE.

d) Loss of function of the ME EQUIPMENT caused by operation of a THERMAL CUT-OUT or OVER-CURRENT RELEASE shall not result in ~~a~~ the loss of ESSENTIAL PERFORMANCE or any of the HAZARDOUS SITUATIONS described in 13.1.

Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE.

e) Capacitors or other spark-suppression devices of ME EQUIPMENT shall not be connected between the contacts of THERMAL CUT-OUTS.

Compliance is checked by inspection.

f) The use of a THERMAL CUT-OUT or OVER-CURRENT RELEASE in the design shall not affect the safety of the ME EQUIPMENT.

Compliance is checked by inspection and, if applicable, by the following tests.

Verify compliance of positive temperature coefficient devices (PTC's) with IEC 60730-1: ~~1999~~2010, clauses 15, 17, J.15 and J.17 as applicable.

THERMAL CUT-OUTS and OVER-CURRENT RELEASES are tested by operating the ME EQUIPMENT under the conditions described in Clause 13.

SELF-RESETTING THERMAL CUT-OUTS and self-resetting OVER-CURRENT RELEASES including circuits that perform equivalent functions (other than PTC's) are caused to operate 200 times unless approved to the appropriate IEC component standard.

Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES are caused to operate 10 times, if they are not approved to the appropriate IEC component standard (see 4.5) or the MANUFACTURER has not provided adequate data to demonstrate the reliability of the component to perform its safety-related function.

Thermal protection devices can be tested separately from ME EQUIPMENT where engineering judgement indicates that doing so would not impact the test results.

g) ME EQUIPMENT that incorporates a fluid filled container having heating facilities shall be provided with a protection device to safeguard against overheating in the event of the heater being switched on with the container empty. An unacceptable RISK shall not occur from overheating.

Compliance is checked by operating the relevant ME EQUIPMENT with an empty container until the protection device activates.

h) ME EQUIPMENT that incorporates tubular heating elements shall have protection against overheating in both leads where a conductive connection to earth could result in overheating.

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Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE.

15.4.2.2 Temperature settings

Where means are provided for varying the temperature setting of THERMOSTATS in ME EQUIPMENT, the temperature setting shall be clearly indicated.

Compliance is checked by inspection.

15.4.3 * Batteries

15.4.3.1 Housing

In ME EQUIPMENT, housings containing batteries from which gases ~~that are likely to result in a HAZARD~~ can escape during charging or discharging shall be ventilated ~~to minimize the RISK of accumulation and ignition~~ so that there is no unacceptable RISK from the accumulation of gases and possible ignition is prevented.

Battery compartments of ME EQUIPMENT shall be designed to prevent accidental short circuiting of the battery where such short circuits could result in ~~a~~ the HAZARDOUS SITUATIONS described in 13.1.

Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE.

15.4.3.2 Connection

If a HAZARDOUS SITUATION might develop by the incorrect connection or replacement of a battery, ME EQUIPMENT shall be fitted with a means of preventing incorrect polarity of connection. See also 7.3.3 and 8.2.2.

Compliance is checked by inspection.

15.4.3.3 Protection against overcharging

Where overcharging of any battery of ME EQUIPMENT could result in an unacceptable RISK, the design shall prevent overcharging.

Compliance is checked by inspection of the design documentation.

15.4.3.4 Lithium batteries

~~Lithium batteries used in ME EQUIPMENT that could become a HAZARD shall comply with the requirements of IEC 60086-4. See also 7.3.3.~~

Primary lithium batteries shall comply with the requirements of IEC 60086-4. Secondary lithium batteries shall comply with the requirements of IEC 62133. See also 7.3.3.

NOTE Batteries includes both single cells and assemblies of cells, i.e. battery packages.

Compliance is checked by inspection of the battery design documentation or by performance of the tests identified in IEC 60086-4 for primary lithium batteries and IEC 62133 for secondary lithium batteries.

15.4.3.5 * Excessive current and voltage protection

An INTERNAL ELECTRICAL POWER SOURCE in ME EQUIPMENT shall be provided with an appropriately RATED device for protection against fire caused by excessive currents if the cross-sectional area and layout of the internal wiring or the rating of connected components can give rise to a fire in case of a short circuit. Protective devices shall have adequate breaking capacity to interrupt the maximum fault current (including short-circuit current) which can flow. Justification for omission of fuses or OVER-CURRENT RELEASES shall be ~~included in the RISK MANAGEMENT FILE~~ documented.

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The short circuit test between the positive pole and the negative pole of an INTERNAL ELECTRICAL POWER SOURCE in the area between the INTERNAL ELECTRICAL POWER SOURCE output contacts and the subsequent protection device may be omitted if two MEANS OF OPERATOR PROTECTION are provided. Alternatively, a short-circuit test shall not result in any of the HAZARDOUS SITUATIONS in 13.1.2.

Compliance is checked by inspection for the presence of protective means, and if necessary, by inspection of the design documentation ~~and the RISK MANAGEMENT FILE~~. Alternatively, conduct the short-circuit test and none of the HAZARDOUS SITUATIONS in 13.1.2 shall occur.

15.4.4 * Indicators

Unless it is otherwise apparent to the OPERATOR from the normal operating position, indicator lights shall be provided to indicate that ME EQUIPMENT is ready for NORMAL USE. The marking of 7.4.1 is not sufficient for this purpose.

If equipped with a stand-by state or a warm-up state whose duration exceeds 15 s, the ME EQUIPMENT shall be provided with an additional indicator light unless it is otherwise apparent to the OPERATOR from the normal operating position.

Indicator lights shall be provided on ME EQUIPMENT incorporating non-luminous heaters to indicate that the heaters are operational, if a HAZARDOUS SITUATION could exist unless it is otherwise apparent to the OPERATOR from the normal operating position.

NOTE This does not apply to heated stylus-pens for recording purposes.

Indicator lights shall be provided on ME EQUIPMENT to indicate that an output exists where an accidental or prolonged operation of the output circuit could constitute a HAZARDOUS SITUATION.

Colours of indicator lights are described in 7.8.1.

In ME EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE, the charging mode shall be visibly indicated to the OPERATOR.

Compliance is checked by inspection of the presence and function of indicating means visible from the position of NORMAL USE.

15.4.5 Pre-set controls

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with pre-set controls.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

15.4.6 Actuating parts of controls of ME EQUIPMENT

15.4.6.1 Fixing, prevention of maladjustment

a) All actuating parts of ME EQUIPMENT shall be so secured that they cannot be pulled off or work loose during NORMAL USE.

b) Controls~~, the adjustment of which can result in a HAZARDOUS SITUATION for the PATIENT or OPERATOR while ME EQUIPMENT is in use,~~ shall be so secured that the indication of any scale always corresponds with the position of the control.

~~The indication in this case refers to "on" or "off" position, scale markings or other indications of position.~~

c) Incorrect connection of the indicating device to the relevant component shall be prevented by an adequate construction, if it can be separated without the use of a TOOL.

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Compliance is checked by inspection and tests. For rotating controls, the torques as shown in Table 30 are applied between the control knob and the shaft for not less than 2 s in each direction alternately. The test is repeated 10 times.

A knob that rotates with respect to the shaft constitutes a failure.

If an axial pull is required in NORMAL USE, compliance is checked by applying for 1 min an axial force of 60 N for electrical components and 100 N for other components.

Table 30 – Test torques for rotating controls

Gripping diameter (*d*) of control knob mm [a]	**Torque** Nm
$10 \leq d < 23$	1,0
$23 \leq d < 31$	2,0
$31 \leq d < 41$	3,0
$41 \leq d < 56$	4,0
$56 \leq d \leq 70$	5,0
$d > 70$	6,0
[a] The gripping diameter (*d*) is the maximum width of a control knob regardless of its shape (e.g. control knob with pointer).	

15.4.6.2 Limitation of movement

Stops of adequate mechanical strength shall be provided on rotating or movable parts of controls of ME EQUIPMENT, where necessary to prevent an unexpected change from maximum to minimum, or vice-versa, of the controlled parameter ~~where this could produce a HAZARDOUS SITUATION~~.

Compliance is checked by inspection and manual tests. For rotating controls, the torques as shown in Table 30 are applied for not less than 2 s in each direction alternately. The test is repeated 10 times.

If an axial pull is likely to be applied to the rotating or movable parts of controls of ME EQUIPMENT in NORMAL USE~~, no unacceptable RISK shall develop~~ there shall be no unexpected change of the controlled parameter.

Compliance is checked by applying for 1 min an axial force of 60 N for electrical components and 100 N for other components.

15.4.7 Cord-connected HAND-HELD and foot-operated control devices (see also 8.10.4)

15.4.7.1 Mechanical strength

a) HAND-HELD control devices of ME EQUIPMENT shall comply with 15.3.4.1.

b) Foot-operated control devices of ME EQUIPMENT shall be able to support the weight of an adult human being.

Compliance is checked by application to the foot-operated control device, in its position of NORMAL USE, of an actuating force of 1 350 N for 1 min. The force is applied over an area of 30 mm diameter. There shall be no damage to the device resulting in an unacceptable RISK.

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15.4.7.2 Accidental operation of ME EQUIPMENT

HAND-HELD and foot-operated control devices shall not result in an unacceptable RISK by changing their control setting when accidentally placed in an abnormal position.

Compliance is checked by turning the control device in all possible abnormal positions and placing it on a flat surface. Any inadvertent change of control setting resulting in an unacceptable RISK constitutes a failure.

15.4.7.3 * Entry of liquids

a) Foot-operated control devices of ME EQUIPMENT shall be at least IPX1 according to IEC 60529.

Compliance is checked by the tests of IEC 60529.

b) In ME EQUIPMENT, ENCLOSURES of foot operated control devices used in areas such as emergency rooms or operating theatres where liquids are likely to be present at floor level and that contain electrical circuits shall be classified at least IPX6 according to IEC 60529 ~~if they are intended for NORMAL USE in areas where liquids are likely to be found (such as emergency rooms and operating theatres). The probability of occurrence shall be estimated as part of the RISK MANAGEMENT PROCESS~~.

Compliance is determined by inspection of the ACCOMPANYING DOCUMENTS, the design documentation~~, the RISK MANAGEMENT FILE~~ and by performing the appropriate tests of IEC 60529.

15.4.8 Internal wiring of ME EQUIPMENT

Aluminium wires of less than 16 mm^2 cross-section shall not be used in ME EQUIPMENT.

Compliance is checked by inspection.

15.4.9 Oil containers

a) Oil containers in PORTABLE ME EQUIPMENT shall be adequately sealed to prevent loss of oil in any position. The container design shall allow for the expansion of the oil.

b) Oil containers in MOBILE ME EQUIPMENT shall be sealed to prevent the loss of oil during transport but may be fitted with a pressure-release device that can operate during NORMAL USE.

c) Partially sealed oil-filled ME EQUIPMENT or its parts shall be provided with means for checking the oil level so that leakage can be detected (see 7.9.3.1).

Compliance is checked by inspection of the ME EQUIPMENT, the technical description, and by manual test.

15.5 * MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5

15.5.1 Overheating

15.5.1.1 * Transformers

Transformers of ME EQUIPMENT shall be protected against overheating in the event of short circuit or overload of any output winding.

Compliance is checked by the tests of 15.5.1.2 and 15.5.1.3 as appropriate under the following conditions.

Each winding is tested, in turn, with the following parameters at the most adverse value:

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– *primary voltage maintained between 90 % to 110 % of RATED voltage*

– *RATED input frequency*

– *loads on other windings between no load and their NORMAL USE load*

Short circuit or resistive load, as appropriate, is applied at the ends of the windings or at the first point that can be short circuited under SINGLE FAULT CONDITION.

Components intended to prevent overheating of the transformer during short circuit and overload conditions are included as part of the tests of 15.5.1.2 and 15.5.1.3 provided that ~~it is unlikely that a short circuit or overload condition could arise for which they would not provide protection. Failure of such circuits to provide protection are considered unlikely to occur where insulation (including spacing) is equal to at least one MEANS OF OPERATOR PROTECTION as defined in Clause 8 and COMPONENTS WITH HIGH INTEGRITY CHARACTERISTICS are used.~~:

– *the component is one with high-integrity characteristics, and*

– *two MEANS OF OPERATOR PROTECTION are provided between the output contacts of the transformer up to the COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS.*

During the tests, no winding are to open, no HAZARDOUS SITUATION occurs, and the maximum temperatures of windings are not to exceed the values in Table 31. After the short circuit and overload tests, the transformer is to pass the dielectric strength test (as described in 8.8.3) between primary and secondary windings, between the primary windings and the frame and between the secondary windings and the frame. The tests are performed under the conditions specified in 11.1, either in the ME EQUIPMENT or under simulated conditions on the bench.

Table 31 – Maximum allowable temperatures of transformer windings under overload and short-circuit conditions at 25 °C (± 5 °C) ambient temperature

Parts	Maximum temperature °C
Windings and core laminations in contact therewith, if the winding insulation is:	
– of Class A material	150
– of Class B material	175
– of Class E material	165
– of Class F material	190
– of Class H material	210

15.5.1.2 Short-circuit test

The output winding under test is short circuited. The test is continued until the protective device operates or THERMAL STABILITY is achieved. For transformers not tested according to the 5X frequency and 5X voltage test of 15.5.2 a) or the 2X frequency and 2X voltage test of 15.5.2 b), the short circuit is applied directly across the output windings.

15.5.1.3 Overload test

Windings with more than one protective device could require multiple overload tests in order to fully evaluate worst-case NORMAL USE loading and fusing.

The overload test may be applied after rectification.

If the short-circuit test is completed without operation of a protective device (such as a current limiting circuit), the overload test is not required.

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a) This test (a) is performed if the current at which the protective device operates cannot be determined based on a review of the provided protective devices and their performance data; otherwise test b) is performed.

The winding under test is loaded to its NORMAL USE load until THERMAL STABILITY is reached. The load is then progressively adjusted in appropriate steps to approach the minimum current at which the protective device operates. Each adjustment of the load is followed by a sufficient time to reach THERMAL STABILITY, and the load current and temperature are to be noted.

Following operation of a protective device, b) is performed.

b) If the protective device that operated in a) is external to the transformer, it is shunted. The winding under test is loaded based on the type of protective device as follows.

– *Fuse in accordance with IEC 60127-1:*

30 min at the appropriate test current determined from Table 32.

Table 32 – Test current for transformers

Marked value of RATED current (*I*) of protecting fuse-link A	Ratio between test current and RATED current of the fuse-link
$I \leq 4$	2,1
$4 < I \leq 10$	1,9
$10 < I \leq 25$	1,75
$I > 25$	1,6

– *Fuses not in accordance with IEC 60127-1:*

30 min at the current according to the characteristics supplied by the fuse manufacturer, specifically the 30 min clearing-time current. If no 30 min clearing-time current data is available, the test current from Table 32 is used until THERMAL STABILITY is achieved.

– *Other protective device:*

until THERMAL STABILITY at a current just below that which caused the device to operate in a).

This portion of the overload test is concluded at the specified time or when a second protective device opens.

15.5.2 * Dielectric strength

This subclause is not applicable to transformers operating at a frequency above 1 kHz, which are tested in accordance with 8.8.3.

ME EQUIPMENT transformer windings shall have adequate insulation to prevent internal short-circuits that could cause overheating where such overheating could result in a HAZARDOUS SITUATION.

The dielectric strength of the electrical insulation between turns and layers of each winding of a transformer of ME EQUIPMENT where failure of the transformer could result in a HAZARDOUS SITUATION shall be such that after the humidity preconditioning treatment (see 5.7) it passes the following tests.

a) *Transformer windings having a RATED voltage ≤ 500 V or RATED frequency ≤ 60 Hz are tested with a voltage across the winding of five times the RATED voltage or five times the upper limit of the RATED voltage range of that winding and a frequency not less than five*

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times the RATED frequency (where RATED frequency is the normal operating frequency of the transformer input voltage).

b) *Transformer windings having a RATED voltage exceeding 500 V or RATED frequency exceeding 60 Hz are tested with a voltage across that winding of twice the RATED voltage or twice the upper limit of the RATED voltage range of that winding and a frequency not less than twice the RATED frequency (where RATED frequency is the normal operating frequency of the transformer input voltage).*

In the two cases above, however, the stress on the turn and layer insulation of any winding of the transformer is to be such that the test voltage appearing at the winding with the highest RATED voltage does not exceed the test voltage specified in Table 6, for one MEANS OF PROTECTION, if the RATED voltage of such a winding is considered as the WORKING VOLTAGE. If this should occur, the test voltage on the primary winding is reduced accordingly. The test frequency can be adapted to produce in the core approximately the magnetic induction present in NORMAL USE. Where the core of the transformer is isolated from all external conductive connections (such as in most toroidal transformers), connections to the core described below may be omitted.

– *Three-phase transformers can be tested by means of a three-phase testing device or by three consecutive tests using a single-phase testing device.*

– *The value of the test voltage with respect to the core and to any screen between primary and secondary windings is in accordance with the specification of the relevant transformer. If the primary winding has an identified connection point for the neutral of the SUPPLY MAINS such a point is connected to the core (and screen if present) unless the core (and screen) are specified for connection to an unearthed part of the circuit. To simulate this, the core (and screen) are connected to a source with an appropriate voltage and frequency with respect to the identified connection point.*

  If such a connection point has not been identified, each side of the primary winding in turn is connected to the core (and screen if present) unless the core (and screen) are specified for connection to an unearthed part of the circuit.

  To simulate this, the core (and screen) are connected to a source with an appropriate voltage and frequency with respect to each side of the primary winding in turn.

– *During the test, all windings not intended for connection to the SUPPLY MAINS are left unloaded (open circuit). Windings intended to be earthed at a point or to be operated with a point nearly at earth potential are to have such a point connected to the core, unless the core is specified for connection to an unearthed part of the circuit.*

  To simulate this, the core is connected to a source with an appropriate voltage and frequency with respect to such windings.

– *Initially not more than half the prescribed voltage is applied, then, it is raised over a period of 10 s to the full value, which is then maintained for 1 min, after which the voltage is reduced gradually and switched off.*

– *Tests are not conducted at resonant frequencies.*

Compliance is checked by the following:

During the test, any flashover or breakdown of any part of the insulation constitutes a failure. There is to be no detectable deterioration of the transformer after the test.

Slight corona discharges are neglected, provided that they cease when the test voltage is temporarily dropped to a lower value, that this value is higher than the WORKING VOLTAGE and that the discharges do not provoke a drop in test voltage.

15.5.3 * Construction of transformers used to provide separation as required by 8.5

~~Transformers of ME EQUIPMENT that form MEANS OF PROTECTION as required by 8.5 shall comply with IEC 61558-1:1997, Subclause 5.12.~~

~~*Compliance is checked as specified in IEC 61558-1.*~~

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Transformers of ME EQUIPMENT that form MEANS OF PROTECTION as required by 8.5 shall comply with the following:

– Means shall be provided to prevent displacement of end turns beyond the interwinding insulation.

– If a protective earthed screen has only one turn, it shall have an insulated overlap of not less than 3 mm. The width of the screen shall be at least equal to the axial winding length of the primary winding.

– The exit of the wires from the internal windings of toroidal transformers shall be provided with double sleeving complying with the requirements for two MEANS OF PROTECTION and having a total wall thickness of at least 0,3 mm, extending at least 20 mm outside the winding.

– The insulation between primary and secondary windings shall comply with 8.8.2.

– CREEPAGE DISTANCES and AIR CLEARANCES shall comply with 8.9.4 with the following exceptions:

  • Enamelled or lacquered winding wires are considered as contributing 1 mm each to the CREEPAGE DISTANCES specified in 8.9.4 for MEANS OF PATIENT PROTECTION.

  • CREEPAGE DISTANCES are measured through the joint between two parts of an insulation barrier, except when:

    – either the two parts forming the joint are bonded by heat sealing or other similar means at the place where this is of importance;

    or

    – the joint is completely filled with adhesive at the necessary places and the adhesive bonds to the surfaces of the insulating barrier so that humidity cannot be sucked into the joint.

  • CREEPAGE DISTANCES within moulded transformers are considered not to exist if it can be shown that no gas bubbles are present and the thickness of the insulation between enamelled or lacquered primary and secondary windings is at least 1 mm for reference voltages *U* not exceeding 250 V and increased proportionally for higher reference voltages.

Compliance is checked by inspection of the transformer construction and measurement of required distances.

16 * ME SYSTEMS

16.1 * General requirements for the ME SYSTEMS

After installation or subsequent modification, an ME SYSTEM shall not result in an unacceptable RISK.

Only HAZARDS arising from combining various equipment to constitute an ME SYSTEM shall be considered.

NOTE RESPONSIBLE ORGANIZATIONS are reminded that the assembly of ME SYSTEMS and modifications during the actual service life require evaluation to the requirements of this standard.

An ME SYSTEM shall provide:

– within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with this standard; and

– outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective IEC or ISO safety standards.

Tests shall be performed:

– in NORMAL CONDITION unless otherwise specified, and

– under the operating conditions specified by the MANUFACTURER of the ME SYSTEM.

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Safety tests that have already been performed on individual equipment of the ME SYSTEM according to relevant standards shall not be repeated.

The MANUFACTURER of an ME SYSTEM that is (re)configurable by the RESPONSIBLE ORGANIZATION or OPERATOR may use RISK MANAGEMENT methods to determine which configurations constitute the highest RISKS and which measures are needed to ensure that the ME SYSTEM in any possible configuration does not present an unacceptable RISK.

Non-ME EQUIPMENT, when used in an ME SYSTEM, shall comply with IEC or ISO safety standards that are relevant to that equipment.

Equipment in which protection against electric shock relies only on BASIC INSULATION shall not be used in an ME SYSTEM.

Compliance is checked by inspection of appropriate documents or certificates.

16.2 * ACCOMPANYING DOCUMENTS of an ME SYSTEM

An ME SYSTEM, (including a modified ME SYSTEM), shall be accompanied by documents containing all the data necessary for the ME SYSTEM to be used as intended by the MANUFACTURER, and an address to which the RESPONSIBLE ORGANIZATION can refer. The ACCOMPANYING DOCUMENTS shall be regarded as a part of the ME SYSTEM.

NOTE ACCOMPANYING DOCUMENTS can be provided electronically, e.g. electronic file format or CD-ROM, for an ME SYSTEM capable of displaying or printing those documents.

These documents shall include:

a) the ACCOMPANYING DOCUMENTS for each item of ME EQUIPMENT that is provided by the MANUFACTURER (see 7.8.2);

b) the ACCOMPANYING DOCUMENTS for each item of non-ME EQUIPMENT that is provided by the MANUFACTURER;

c) the following information:

- the specification of the ME SYSTEM, including the use as intended by the MANUFACTURER and a listing of all of the items forming the ME SYSTEM;
- instructions for the installation, assembly and modification of the ME SYSTEM to ensure continued compliance with this standard;
- instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM (see 11.6.6 and 11.6.7);
- additional safety measures that should be applied, during installation of the ME SYSTEM;
- which parts of the ME SYSTEM are suitable for use within the PATIENT ENVIRONMENT;
- additional measures that should be applied during preventive maintenance;
- if a MULTIPLE SOCKET-OUTLET is present and it is a separate item, a warning that it shall not be placed on the floor;
- a warning that an additional MULTIPLE SOCKET-OUTLET or extension cord shall not be connected to the ME SYSTEM;
- a warning to connect only items that have been specified as part of the ME SYSTEM or that have been specified as being compatible with the ME SYSTEM;
- the maximum permitted load for any MULTIPLE SOCKET-OUTLET(S) used with the ME SYSTEM;
- an instruction that MULTIPLE SOCKET-OUTLETS provided with the ME SYSTEM shall only be used for supplying power to equipment that is intended to form part of the ME SYSTEM;
- an explanation of the RISKS of connecting non-ME EQUIPMENT that has been supplied as a part of the ME SYSTEM directly to the wall outlet when the non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer;

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– an explanation of the RISKS of connecting any equipment that has not been supplied as a part of the ME SYSTEM to the MULTIPLE SOCKET-OUTLET;

– the permissible environmental conditions of use of the ME SYSTEM including conditions for transport and storage; and

– instructions to the OPERATOR not to touch parts referred to in 16.4 and the PATIENT simultaneously.

d) advice to the RESPONSIBLE ORGANIZATION:

– to carry out all adjustment cleaning, sterilization and disinfection PROCEDURES specified therein; and

– that the assembly of ME SYSTEMS and modifications during the actual service life require evaluation to the requirements of this standard.

Compliance is checked by inspection.

16.3 * Power supply

If ME EQUIPMENT is intended to receive its power from other equipment in an ME SYSTEM, the instructions for use shall specify the other equipment sufficiently to ensure compliance with the requirements of this standard (see 4.10.1, 5.5 f) and 7.9.2.3). See also Figure F.5.

If an ME SYSTEM:

– is intended to receive its power from an isolated power supply (IPS) or an uninterruptible power supply (UPS), and

– the ME SYSTEM can draw large transient currents when being switching on or off or when operating,

the MANUFACTURER shall restrict such transient currents to the allowed level according to the specification of the IPS or the UPS from which the ME SYSTEM is intended to be supplied.

If an IPS or UPS is not specified, the actual transient current level shall be disclosed in the technical description and any installation instructions.

Compliance is checked by inspection.

16.4 ENCLOSURES

Parts of non-ME EQUIPMENT in the PATIENT ENVIRONMENT that can be contacted by the OPERATOR during routine maintenance, calibration, etc. after removal of covers, connectors, etc., without the use of a TOOL shall operate at a voltage not exceeding the voltage specified in 8.4.2 c) supplied from a source that is separated from the SUPPLY MAINS by two MEANS OF OPERATOR PROTECTION (see 8.5.1).

Compliance is checked by inspection.

16.5 * SEPARATION DEVICES

When FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of equipment of an ME SYSTEM or other systems can cause the allowable values of LEAKAGE CURRENT to be exceeded, then safety measures incorporating a SEPARATION DEVICE shall be applied.

The SEPARATION DEVICE shall have the dielectric strength, CREEPAGE DISTANCES and AIR CLEARANCES required for one MEANS OF OPERATOR PROTECTION appropriate for the highest voltage occurring across the SEPARATION DEVICE during a fault condition.

The WORKING VOLTAGE shall be the highest voltage across the SEPARATION DEVICE during a fault condition, but not less than the MAXIMUM MAINS VOLTAGE.

NOTE 1 For CLASS I equipment, potential differences can occur between the protective earth of the ME EQUIPMENT and the protective earth of other parts of the ME SYSTEM in the absence of a common protective earth.

NOTE 2 Situations that can require a SEPARATION DEVICE include FUNCTIONAL CONNECTIONS to an emergency calling system or a data processing system.

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Compliance is checked by the tests in 8.8 and 8.9.

16.6 * LEAKAGE CURRENTS

16.6.1 TOUCH CURRENT

In NORMAL CONDITION, the TOUCH CURRENT from or between parts of the ME SYSTEM within the PATIENT ENVIRONMENT shall not exceed 100 μA.

In the event of the interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR, the TOUCH CURRENT from or between parts of an ME SYSTEM within the PATIENT ENVIRONMENT shall not exceed 500 μA.

NOTE For the purposes of this clause, the LEAKAGE CURRENT from accessible outer surfaces of equipment is also considered to be TOUCH CURRENT.

16.6.2 EARTH LEAKAGE CURRENT of MULTIPLE SOCKET-OUTLET

If the ME SYSTEM or part of the ME SYSTEM is supplied from a MULTIPLE SOCKET-OUTLET, then the current in the PROTECTIVE EARTH CONDUCTOR of the MULTIPLE SOCKET-OUTLET shall not exceed 5 mA.

16.6.3 * PATIENT LEAKAGE CURRENT

The PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of an ME SYSTEM in NORMAL CONDITION shall not exceed the values specified for ME EQUIPMENT, as given in Table 3 and Table 4 (see also 8.7.3 and 16.1).

The total PATIENT LEAKAGE CURRENT may be measured at installation.

Compliance with the requirements of 16.6.1, 16.6.2 and 16.6.3 is checked by inspection and measurement using a measuring device as specified in 8.7.4.4.

16.6.4 Measurements

16.6.4.1 General conditions for ME SYSTEMS

a) *The TOUCH CURRENT, the PATIENT LEAKAGE CURRENT, the total PATIENT LEAKAGE CURRENT and the total EARTH LEAKAGE CURRENT ~~of any MULTIPLE SOCKET-OUTLET~~ are measured after the ME SYSTEM has been brought up to operating temperature as follows:*

The ME SYSTEM is operated:

- *For ME SYSTEMS intended for non-CONTINUOUS OPERATION;*

  After operating in standby/quiescent mode until THERMAL STABILITY is reached, the ME SYSTEM is operated in NORMAL USE over consecutive cycles until THERMAL STABILITY is again achieved, or for seven hours, whichever is shorter. The "on" and "off" periods for each cycle are the RATED "on" and "off" periods;

- *For ME SYSTEMS intended for CONTINUOUS OPERATION;*

  The ME SYSTEM is operated until THERMAL STABILITY is reached.

b) *The ME SYSTEM is connected to a supply with a voltage equal to the highest RATED MAINS VOLTAGE. When the characteristics of an ME SYSTEM can only be measured properly after it has been installed at the site of the RESPONSIBLE ORGANIZATION, prior to its clinical use, the ME SYSTEM is connected to the local SUPPLY MAINS.*

NOTE Where examination of the circuit arrangement and the arrangement of components and material of the ME SYSTEM shows no possibility of any HAZARD, the number of tests could be reduced.

16.6.4.2 Connection of the ME SYSTEM to the measuring supply circuit

a) The ME SYSTEM is tested after being assembled according to its ACCOMPANYING DOCUMENTS.

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b) Measuring arrangement

If an isolating transformer is not used for LEAKAGE CURRENT measurements (e.g. when measuring LEAKAGE CURRENT for very high input power ME SYSTEMS), the reference earth of the measuring circuits is connected to the protective earth of the SUPPLY MAINS.

NOTE 1 It is recommended to position the measuring circuit as far as possible away from unscreened power supply leads and (unless specified otherwise in the following subclauses) to avoid placing the ME SYSTEM on or near a large earthed metal surface.

NOTE 2 However, APPLIED PARTS, including PATIENT cables (when present), should be placed on an insulating surface with a dielectric constant of approximately 1 (for example, expanded polystyrene) and approximately 200 mm above an earthed metal surface.

16.7 * Protection against MECHANICAL HAZARDS

If a MECHANICAL HAZARD exists, the ME SYSTEM shall comply with the applicable requirements of Clause 9.

Compliance is checked by inspection or applicable tests.

16.8 Interruption of the power supply to parts of an ME SYSTEM

An ME SYSTEM shall be so designed that an interruption and restoration of the power to the ME SYSTEM as a whole, or any part of the ME SYSTEM, shall not result in ~~a HAZARDOUS SITUATION other than interruption of its intended function~~ the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE.

Compliance is checked by interruption and restoration of relevant power connections one at a time and all connections simultaneously.

16.9 ME SYSTEM connections and wiring

16.9.1 Connection terminals and connectors

Design and construction of electrical, hydraulic, pneumatic and gas connection terminals and connectors shall be such that incorrect connection of accessible connectors, removable without the use of a TOOL, shall be prevented ~~where a HAZARDOUS SITUATION could otherwise exist.~~ unless it can be proven that no unacceptable RISK can result. In particular:

~~– Connectors shall comply with 15.4.1.~~

– Plugs for connection of PATIENT leads or PATIENT cables shall be so designed that they cannot be connected to other outlets of the same ME SYSTEM that are likely to be located in the PATIENT ENVIRONMENT unless it can be proved that no ~~HAZARDOUS SITUATION~~ unacceptable RISK can result.

Compliance is checked by inspection ~~and, if possible, by interchanging connectors~~ of PATIENT leads, PATIENT cables, connectors and outlets and, if interchange of the leads, cables, connectors or outlets is possible, by inspection of the RISK MANAGEMENT FILE.

– Medical gas connections on the ME SYSTEM for different gases to be operated in NORMAL USE shall not be interchangeable. See also ISO 407 [27].

Compliance is checked by inspection of all medical gas connections.

16.9.2 MAINS PARTS, components and layout

16.9.2.1 * MULTIPLE SOCKET-OUTLET

a) A MULTIPLE SOCKET-OUTLET shall:

– only allow connection by using a TOOL (see Figure I.1), or

– be of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or

– be supplied via a separating transformer (see 16.9.2.1 d) and Annex I).

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Compliance is checked by inspection.

b) A MULTIPLE SOCKET-OUTLET:

- shall be marked with safety sign ISO 7010-W001 (see Table D.2, safety sign 2) such that it is visible in NORMAL USE; and:
  - shall be marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or
  - shall be marked to indicate which equipment or equipment parts may be safely attached.
- may be a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT.

NOTE Each outlet does not have to be marked.

Compliance is checked by inspection.

c) The MULTIPLE SOCKET-OUTLET shall comply with IEC 60884-1 and the following requirements.

- CREEPAGE DISTANCES and AIR CLEARANCES shall comply with 8.9.
- It shall be of CLASS I construction and the PROTECTIVE EARTH CONDUCTOR shall be connected to the earthing contacts in the socket-outlets.
- * PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS shall comply with 8.6~~, except that the total impedance of the protective earth path for an ME SYSTEM may be up to 400 mΩ, or higher if the conditions of 8.6.4 b) are satisfied~~.
- ENCLOSURES shall comply with 8.4.2 d).
- MAINS TERMINAL DEVICES and wiring shall comply with 8.11.4, if applicable.
- RATINGS of components shall not conflict with the conditions of use (see 4.8).
- Design and construction of electrical connection terminals and connectors of MULTIPLE SOCKET-OUTLETS shall prevent the incorrect connection of accessible connectors that are removable without the use of a TOOL.
- Requirements for the POWER SUPPLY CORD as described in 8.11.3 shall be fulfilled.

d) * If the MULTIPLE SOCKET-OUTLET is combined with a separating transformer, the following additional requirements apply.

- The separating transformer shall comply with ~~the requirements of IEC 61558-2-1,~~ this standard. Alternatively the separating transformer may comply with the requirements of IEC 61558-2-1, except that the requirements of maximum RATED output power of 1 kVA and degree of protection IPX4 do not apply.

  NOTE 1 As a separating transformer is not a MAINS SUPPLY TRANSFORMER, it does not require more than BASIC INSULATION.

  NOTE 2 Limitation of output power is not explained in IEC 61558-2-1 and the RATED output power is defined by the fuse in the installation and by the allowable power supply cable used. However, the characteristics of the separating transformer need to be carefully selected, taking into account the variations in the load current of the ME SYSTEM to ensure that the voltage supplied to the various items of the ME SYSTEM remains within the limits specified for the equipment.

  ~~NOTE 3 IEC 61558-2-1 should be used with the general standard IEC 61558-1.~~
- The separating transformer assembly shall be of CLASS I construction.
- The degree of protection against ingress of water as given in IEC 60529 shall be specified.
- The separating transformer assembly shall be marked according to the requirements of 7.2 and 7.3.
- The MULTIPLE SOCKET-OUTLET shall be permanently connected to the separating transformer or the socket-outlet of the separating transformer assembly shall be of a type that cannot accept MAINS PLUGS of any of the kinds identified in IEC/TR 60083 (see Figure I.1 and Figure I.2).

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Compliance is checked by inspection and as described in the relevant subclauses of this standard.

16.9.2.2 * PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS

For each part of an ME SYSTEM that shares a MAINS CONNECTION, the impedance and current carrying capability of the total protective earth path of an ME SYSTEM when tested as a unit shall comply with 8.6.4. The impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED shall not exceed 200 mΩ.

PROTECTIVE EARTH CONNECTIONS shall be made so that the removal of any single item of equipment in the ME SYSTEM will not interrupt the protective earthing of any other part of the ME SYSTEM, without at the same time disconnecting the electrical supply to that part.

Additional PROTECTIVE EARTH CONDUCTORS shall only be detachable by use of a TOOL.

Compliance is checked by inspection.

16.9.2.3 Protection of conductors

Conductors that connect different items of equipment within an ME SYSTEM shall be protected against mechanical damage.

Compliance is checked by inspection.

17 * Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

The MANUFACTURER shall address In the RISK MANAGEMENT PROCESS the RISKS associated with:

– the electromagnetic phenomena existing at the locations where the ME EQUIPMENT or ME SYSTEM is intended to be used as indicated in the ACCOMPANYING DOCUMENTS; and

– the introduction by the ME EQUIPMENT or ME SYSTEM of electromagnetic phenomena into the environment that might degrade the performance of other devices, electrical equipment and systems.

See IEC 60601-1-2 and also see 1.3.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

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Annex A
(informative)

General guidance and rationale

A.1 General guidance

The requirements for ME EQUIPMENT and ME SYSTEMS differ from those for other kinds of electrical equipment because of the particular relationship of ME EQUIPMENT or ME SYSTEM to the PATIENT, the OPERATOR and the surroundings. The following aspects play an important role in this relationship:

a) the inability of the PATIENT or OPERATOR to detect the presence of certain HAZARDS, such as ionizing and non-ionizing radiation;

b) absence of normal reactions of the PATIENT who can be ill, unconscious, anaesthetized, immobilized, etc.;

c) absence of normal protection to currents provided by the PATIENT'S skin, if this is penetrated or treated to obtain a low skin-resistance;

d) support or replacement of vital body functions, which depends on the reliability of ME EQUIPMENT or ME SYSTEM;

e) the simultaneous connection to the PATIENT of more than one piece of ME EQUIPMENT;

f) combination of high-power ME EQUIPMENT and sensitive low-signal ME EQUIPMENT often in ad hoc combinations;

g) the application of electrical circuits directly to the human body, either through contacts to the skin or through the insertion of probes into internal organs;

h) conditions, particularly in operating theatres, that can present a combination of humidity, moisture or HAZARDS of fire or explosion ~~HAZARDS~~ caused by air, oxygen or nitrous oxide.

When ME EQUIPMENT is combined with another electrical equipment to form an ME SYSTEM, additional requirements apply. These are given in Clause 16. In some instances, reference to other parts of this standard is made. If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause could be applicable to ME SYSTEMS as well as to ME EQUIPMENT.

A.2 Safety of ME EQUIPMENT and ME SYSTEMS

BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS, as described in IEC/TR 60513 [12], are part of the total safety situation, comprising safety of ME EQUIPMENT, safety of the installation to which the ME EQUIPMENT or ME SYSTEM is connected and safety of application.

BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS are required for NORMAL USE and for reasonably foreseeable misuse and in NORMAL CONDITION and SINGLE FAULT CONDITIONS. Reliability of functioning is regarded as a safety aspect for life-supporting ME EQUIPMENT and where interruption of an examination or treatment is considered as a ~~HAZARD~~ HAZARDOUS SITUATION for the PATIENT.

Adequate construction, lay-out and ACCOMPANYING DOCUMENTS that serve to prevent use errors are regarded as safety aspects.

Safety precautions are considered acceptable if they provide adequate protection without an undesirable restriction of normal function.

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Generally, it is presumed that ME EQUIPMENT and ME SYSTEMS are operated under the jurisdiction of qualified or licensed persons and that the OPERATOR has the skill required for a particular medical application and acts according to the instructions for use.

The total safety of ME EQUIPMENT can consist of:

– inherent safety by design;
– protective measures incorporated into the ME EQUIPMENT or additional protective measures, such as the use of shields or protective clothing; and
– information for safety, such as restrictions in the instructions for use concerning transport, mounting or positioning, connection, putting into service, operation and the position of the OPERATOR and his/her assistants in relation to the ME EQUIPMENT during use.

A.3 Guidance to the third edition

In this edition, a number of clauses and subclauses from the second edition have been deleted, e.g. when the clause or subclause was indicated as “Not used.” However, those clauses or subclauses from the second edition that stated “No general requirement” have been retained so that particular or collateral standards can refer to them. The statement, “No general requirement”, has been replaced with a reference to the RISK MANAGEMENT PROCESS because the “general requirement” is that, in the absence of a particular or collateral standard, these issues are dealt with through the application of RISK MANAGEMENT.

While preparing the third edition, basic safety standards and ISO/IEC guides have been taken into consideration to the extent possible consistent with the particular relationship of ME EQUIPMENT or ME SYSTEM to the PATIENT, the OPERATOR and the surroundings.

The format of the third edition has been aligned with the basic requirements of Part 2 of the ISO/IEC Directives. All the sections except Section 1 of the second edition have been converted into major clauses. This change was implemented because sections are no longer allowed under the drafting rules and the new numbering system will allow future changes to modify a clause without affecting the number of other parts of the standard.

The normative references have been moved from Appendix L of the second edition to Clause 2. Informative references are listed in the Bibliography.

The definitions in Clause 3 have been rearranged into a single alphabetical listing as organizing the definitions by category was becoming increasingly difficult and the result less intuitive. The index has been expanded to identify each page where a term is used in the body of the standard. A number of new defined terms have been introduced in support of new or expanded requirements.

A general requirement for a RISK MANAGEMENT PROCESS has been introduced in 4.2.

Clause 8 has been extensively restructured to bring together in one clause the requirements relating to electrical safety. The requirements in Clause 8 have been reviewed against the safety requirements for information technology (IT) equipment in IEC 60950-1 and harmonized where appropriate given the particular relationship of ME EQUIPMENT to the PATIENT, the OPERATOR and the surroundings.

Clause 9 on protection against MECHANICAL HAZARDS has been substantially revised to deal with a wide range of the HAZARDS that ME EQUIPMENT could pose to the OPERATOR or PATIENT. Requirements relating to the mechanical strength of the ME EQUIPMENT when subjected to the stresses caused by pushing, impact, dropping, and rough handling are in 15.3.

The standard now deals with USABILITY in 12.2 as opposed to “user or human errors.”

Section six of the second edition on protection against the HAZARDS of ignition of flammable anaesthetic mixtures has been moved to a normative annex. While this annex was originally intended to be informative because the use of such anaesthetics is rare, comments from

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National Committees indicated that some MANUFACTURERS might still want to offer ME EQUIPMENT for such applications.

The surface temperature limit in 11.1.2.2 for APPLIED PARTS that are in contact with the PATIENT for 10 min or more has been increased from 41 °C to 43 °C. However, the MANUFACTURER is to disclose in the ACCOMPANYING DOCUMENTS if the surface temperature of an APPLIED PART exceeds 41 °C.

The requirements of IEC 60601-1-4 [14] for PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS, as referred to in 52.1 of the second edition, have been incorporated into the body of this standard in a new Clause 14.

The requirements of IEC 60601-1-1 [13] for ME SYSTEMS have been incorporated into the body of this standard in a new Clause 16.

A.4 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclause in this standard, with clause and subclause numbers parallel to those in the body of the document.

Subclause 1.1 – Scope

The scope of this standard is established by the reference to the definitions of ME EQUIPMENT and ME SYSTEMS. This is to clearly define the scope of this standard as compared with requirements for other types of electrical equipment.

Laboratory equipment within the scope of IEC 61010-1 [22] is not covered by this standard except when a MANUFACTURER incorporates such laboratory equipment into an ME SYSTEM.

This standard does not apply to active implantable medical devices covered by the ISO 14708-1 [31] except where the ISO 14708-1 requires compliance with IEC 60601-1.

This standard does not apply to any other electrical equipment unless it falls under the definition of ME EQUIPMENT or ME SYSTEMS.

Subclause 1.3 – Collateral standards

Collateral standards are a vehicle developed by Technical Committee 62 as a way of extending the general standard. Collateral standards fall into two categories:

– standards that address additional BASIC SAFETY and ESSENTIAL PERFORMANCE requirements that are common to a subgroup of ME EQUIPMENT. For example, Subcommittee 62B developed IEC 60601-1-3 to provide general requirements for protection against ionizing radiation in medical diagnostic X-ray equipment in order that the dose equivalent to the PATIENT, the OPERATOR and other staff can be kept as low as reasonably achievable; or

– standards that address additional BASIC SAFETY or ESSENTIAL PERFORMANCE requirements that deal with characteristic of ME EQUIPMENT or ME SYSTEMS that are not fully covered by the general standard. At the time of publication, three collateral standards in this category have been published by Subcommittee 62A: EMC (IEC 60601-1-2), Usability (IEC 60601-1-6) and Alarm systems (IEC 60601-1-8).

The editions of IEC 60601-1-2, IEC 60601-1-3, IEC 60601-1-6 and IEC 60601-1-8 existing at the time of publication of this third edition of the general standard were all developed in relation to the second edition of the general standard (IEC 60601-1:1988). It is intended that revised editions of these collateral standards, relating specifically to this third edition, will be developed and published as soon as possible. As stated in 1.3, these will become normative at the date of their publication and shall apply together with this standard.

Until such new editions of these collateral standards are published, users of this standard should apply the existing editions as far as possible when they are relevant to the ME EQUIPMENT or ME SYSTEM concerned. However some requirements of these collateral standards might not be compatible with this standard.

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The requirements from two of the collateral standards developed for the second edition of IEC 60601-1 have been incorporated into the body of this standard. They are:

– IEC 60601-1-1:2000, *Medical electrical equipment – General requirements for safety – Collateral standard: Safety requirements for medical electrical systems*

– IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral standard: Programmable electrical medical systems* and its Amendment 1 (1999)[21)].

While both standards will remain active until all the particular standards based on the second edition of IEC 60601-1 have been aligned with this standard, they are not applicable when applying this standard.

Additional collateral standards can be published from time to time as needs are identified. While those standards will not be mentioned in this standard, they still establish general requirements that need to be considered when applicable. Readers are encouraged to consult the registers of currently valid International Standards maintained by their national standards body to see what applicable collateral standards have been published.

Subclause 1.4 – Particular standards

A particular standard can specify:

– clauses or subclauses of this standard that apply without amendment;

– clauses or subclauses (or parts of them) of this standard that do not apply;

– clauses or subclauses (or parts of them) of this standard that are replaced by clauses or subclauses in the particular standard; or

– additional clauses or subclauses.

A particular standard can contain:

a) requirements that result in an increase of BASIC SAFETY or ESSENTIAL PERFORMANCE;

b) requirements that can be less stringent than the requirements in this standard, if the latter cannot be maintained because of, for example, the power output of ME EQUIPMENT;

c) requirements concerning performance, reliability, interfaces, etc.;

d) accuracy of working data; or

e) extension and limitation of environmental conditions.

Clause 2 – Normative references

This clause provides a list of the documents cited in other normative parts of this standard in such a way as to make them indispensable for the application of the document. However, conformance with the documents in this list is required only to the extent that they are referenced in a normative requirement in this standard. For example, if a reference is made to a specific clause, subclause, table or figure, then the user of this standard is only required to conform to the requirements in that clause, subclause, table or figure in order to satisfy the requirement in this standard.

Undated references are made only to a complete document or to a major part thereof and only if it is accepted that it will be possible to use all future changes of the referenced document for the purposes of this standard. For example, an undated reference is made to IEC 60529 because it is intended that the MANUFACTURER will always use the latest edition of that standard when assigning IP Codes to ENCLOSURES.

Undated references are understood to include all amendments to and revisions of the referenced document.

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21) There exists a consolidated edition 1.1 (2000) including IEC 60601-1-4 (1996) and its Amendment 1 (1999).

Dated references are made when the requirements of a particular edition are to be used to satisfy a requirement of this standard. Subsequent amendments to, or revisions of, dated references will need to be incorporated by amendment of this standard. ~~For example, a dated reference is made to IEC 60825-1 because relevant parts of that standard are applied to light emitting diodes (LEDs) and IEC/TC 76 was in the early stages of developing a third edition of IEC 60825-1 and was considering removing the requirements for LEDs.~~

References to specific clauses, subclauses, tables and figures of another document are always dated.

Clause 3 – Terminology and definitions

This clause contains definitions for terms that are necessary for the understanding of the requirements in this standard. Many of these terms are inherited from the second edition. However, a number of terms have been added during the course of developing new or modified requirements. Where possible, existing definitions in other standards have been copied or adapted.

Except when used to support other defined terms, a definition is only provided if the term is used more than once in the text of the standard.

Defined terms are printed in SMALL CAPITALS to assist the reader in identifying them in the body of the standard. When normal case is used, the words have their normal English meaning. The committee made an effort to avoid using the same word both as a defined term and in its normal English meaning. At times this has not been possible. For example, the word “procedure” is used as a defined term in Start-up PROCEDURE, specifically meaning a “specific way to perform an activity” of starting up the ME EQUIPMENT or ME SYSTEM. It is also used in the definition of PATIENT according to its general English meaning, i.e. “Living being (person or animal) undergoing a medical, surgical or dental procedure.”

Subclause 3.8 – APPLIED PART

Parts that contact PATIENTS can present greater HAZARDS than other parts of the ENCLOSURE, and these APPLIED PARTS are therefore subject to more stringent requirements, for example, for temperature limits and (according to classification B/BF/CF) for LEAKAGE CURRENT.

NOTE Some other ACCESSIBLE PARTS of the ENCLOSURES of ME EQUIPMENT are subject to tests that are more demanding than those for ENCLOSURES of other kinds of equipment, because the PATIENT can touch them, or the OPERATOR can touch them and the PATIENT simultaneously.

In order to determine which requirements apply, it is necessary to distinguish between APPLIED PARTS and parts that are simply considered as the ENCLOSURE.

Thus, typically:

– an infrared therapy lamp does not have an APPLIED PART because it does not need to be brought into direct contact with the PATIENT;

– the only part of an X-ray table that is an APPLIED PART is the top on which the PATIENT lies;

– likewise, in an MRI scanner, the only APPLIED PART is the table supporting the PATIENT.

However, a part that unintentionally comes into contact with an unconscious, anaesthetized or incapacitated PATIENT can present the same RISKS as an APPLIED PART that necessarily has to contact the PATIENT. On the other hand, a part that an active PATIENT can reach out and touch might present no more RISK to that PATIENT than it presents to an OPERATOR.

The definition in the first and second editions of this standard failed to address this problem. The second amendment to the second edition extended the definition to include parts that can be brought into contact with the PATIENT, but the new definition continued to cause difficulties.

In this edition, subclause 4.6 requires the RISK MANAGEMENT PROCESS to identify which parts, other than APPLIED PARTS, are subject to the same requirements as APPLIED PARTS. These can include parts of non-ME EQUIPMENT in an ME SYSTEM.

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Particular standards should specifically identify the APPLIED PART(S) in particular types of ME EQUIPMENT.

In order to assess which parts are APPLIED PARTS and what are the PATIENT CONNECTIONS, the following PROCESS is employed in the order shown.

a) Determine whether the ME EQUIPMENT has an APPLIED PART, and if it has, identify the extent of the APPLIED PART (these decisions being based on non-electrical considerations).

b) If there is no APPLIED PART, there are no PATIENT CONNECTION(S).

c) If there is an APPLIED PART, there can be one or more PATIENT CONNECTION(S). Even if the APPLIED PART has no accessible conductive parts, foil applied in accordance with 8.7.4.7 is regarded as one PATIENT CONNECTION.

d) Where a conductive part of the APPLIED PART is not in direct contact with the PATIENT, but is not separated and current can flow through such a part to or from the PATIENT, it is to be treated as an individual PATIENT CONNECTION.

NOTE Relevant separation requirements are those that relate to MEANS OF PATIENT PROTECTION.

An APPLIED PART can include one or more functions. Each function can include one or more PATIENT CONNECTIONS. A PATIENT CONNECTION can be an electrode that is intended to carry current; or the electrical connection can be incidental to the purpose, for example with an intra-vascular fluid line or a PATIENT support.

See also the rationale for 3.78.

Figure A.1 to Figure A.7 (inclusive) provide examples of the way in which APPLIED PARTS and PATIENT CONNECTIONS are identified in order to apply the requirements for PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT in various ME EQUIPMENT and ME SYSTEMS.

Figure A.1 and Figure A.2 shows an ECG monitor that includes the ECG monitor, the PATIENT cable, PATIENT leads and the ECG electrodes. In Figure A.1 and Figure A.2:

– The APPLIED PART includes the electrodes and those parts of the PATIENT leads or PATIENT cable that need to physically contact the PATIENT in NORMAL USE.
– Application of RISK MANAGEMENT might identify other parts of the PATIENT lead or PATIENT cable that have to be treated as APPLIED PARTS because of the probability they will come in contact with the PATIENT.
– The PATIENT CONNECTIONS consist of the ECG electrodes, which are all part of the same function of the APPLIED PART.

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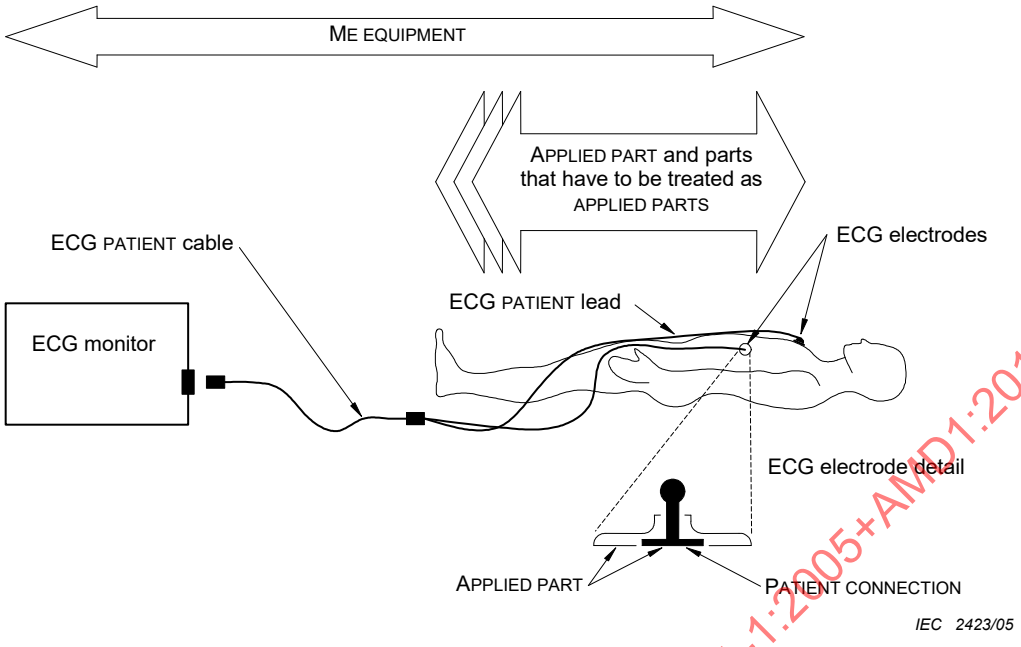


Figure A.1 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in an ECG monitor

Figure A.2 shows the required F-TYPE APPLIED PART insulation. The parts within the dotted line are the PATIENT circuit.

In Figure A.2, the required APPLIED PART insulation is:

– one MEANS OF PATIENT PROTECTION between earth and parts within the dotted line based on the MAINS VOLTAGE;

– two MEANS OF PATIENT PROTECTION between earth and parts within the dotted line based on the voltage carried by these parts; and

– two MEANS OF PATIENT PROTECTION between live parts (including mains) and the parts within the dotted line.

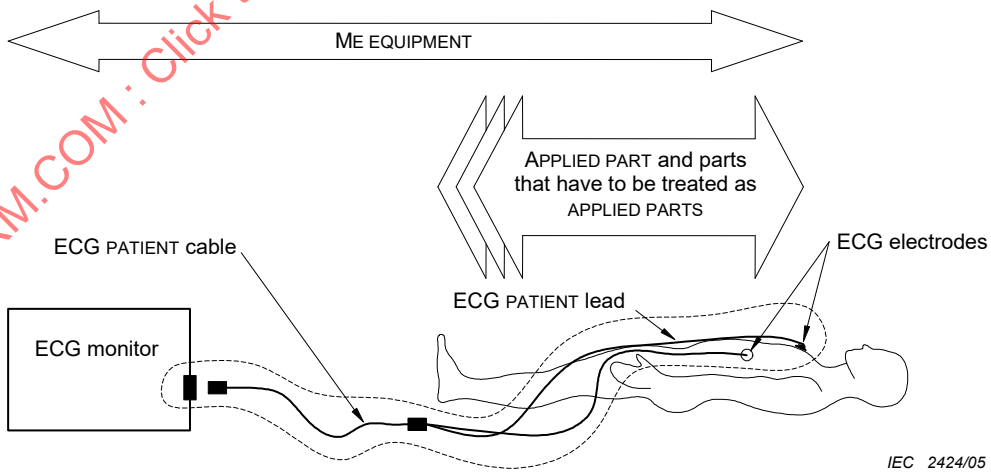


Figure A.2 – Example of the insulation of an F-TYPE APPLIED PART with the insulation incorporated in the ME EQUIPMENT

Figure A.3 shows an F-TYPE APPLIED PART with the insulation incorporated in a transducer. The parts within the dotted line are the PATIENT circuit. There are parts outside the dotted line that

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are subject to the requirements for APPLIED PARTS as determined through the RISK MANAGEMENT PROCESS.

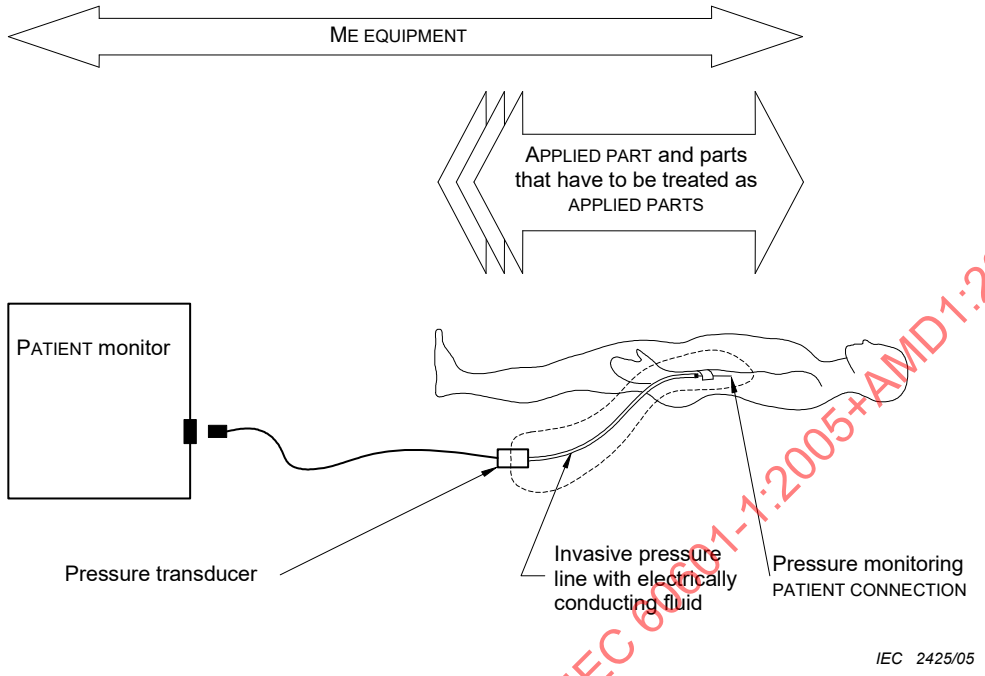


Figure A.3 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a PATIENT monitor with invasive pressure monitoring facility

Figure A.4 shows a PATIENT monitor with ECG and invasive pressure monitoring facilities. In this example:

– The ME EQUIPMENT includes the ECG monitor; the ECG PATIENT cable, the PATIENT leads and ~~its~~ their electrodes; and the pressure transducer and its fluid filled line.

– The APPLIED PART(s) include the ECG electrodes and those parts of the PATIENT cable and PATIENT leads that need to physically contact the PATIENT in NORMAL USE; and the fluid filled pressure monitoring line.

– Application of RISK MANAGEMENT might identify other parts of the ECG PATIENT cable, the PATIENT leads or the pressure transducer that have to be treated as APPLIED PARTS because of the probability they will come in contact with the PATIENT.

– The ECG PATIENT CONNECTIONS consist of the ECG electrodes.

– The pressure monitoring PATIENT CONNECTION consists of the electrically conducting fluid in the pressure line. For the measurement of PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT, an electrode is placed in the electrically conducting fluid and treated as a single PATIENT CONNECTION.

– If the PATIENT CONNECTIONS associated with the ECG function are not electrically separated from the PATIENT CONNECTION associated with the pressure monitoring function, these are treated as two functions of the same APPLIED PART.

– If the PATIENT CONNECTIONS associated with the ECG function are electrically separated from the PATIENT CONNECTION associated with the pressure monitoring function, these are treated as separate APPLIED PARTS.

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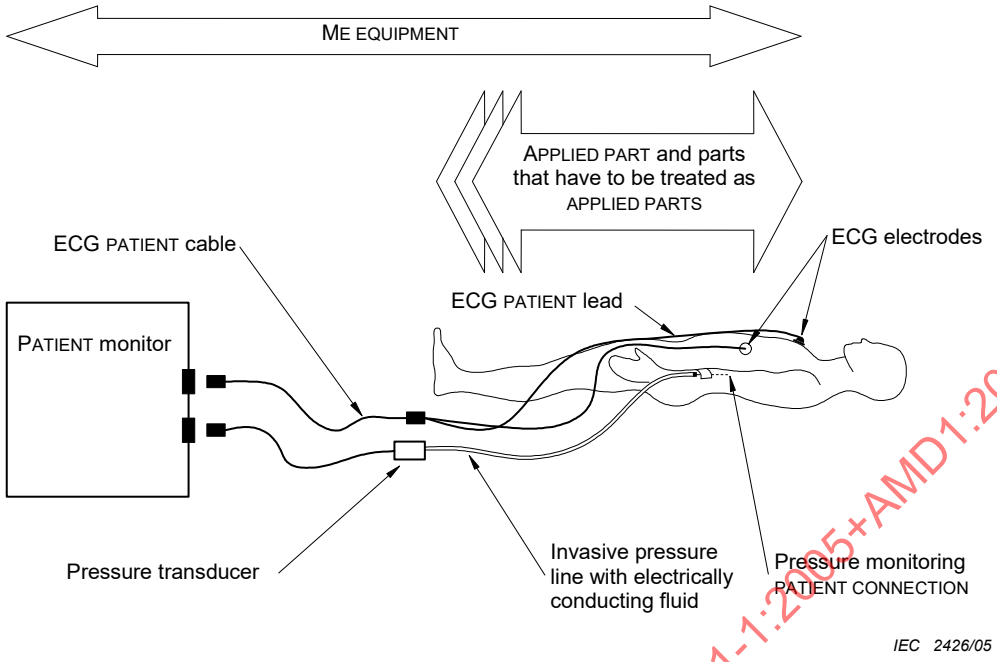


Figure A.4 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a multifunction PATIENT monitor with invasive pressure monitoring facilities

Figure A.5 shows an X-ray ME SYSTEM in which:

– The ME SYSTEM includes the X-ray ~~tube~~ source assembly, the X-ray table and the wall stand, which are all items of ME EQUIPMENT. Other parts of the ME SYSTEM such as the X-ray generator and OPERATOR console are not shown.

– The APPLIED PART(s) include the top of the table and the front of the wall stand, as these parts need to physically contact the PATIENT in NORMAL USE.

– The application of RISK MANAGEMENT might identify some parts of the tube assembly and some other parts of the table and the wall stand ~~have~~ as having to be treated as APPLIED PARTS because of the probability they will come in contact with the PATIENT.

– The PATIENT CONNECTIONS consist of the conductive parts of these APPLIED PARTS that electrically contact the PATIENT.

– The MANUFACTURER can specify that the table and the wall stand are different functions of the same APPLIED PART.

– Alternatively, the MANUFACTURER can specify that the table and the wall stand are different APPLIED PARTS.

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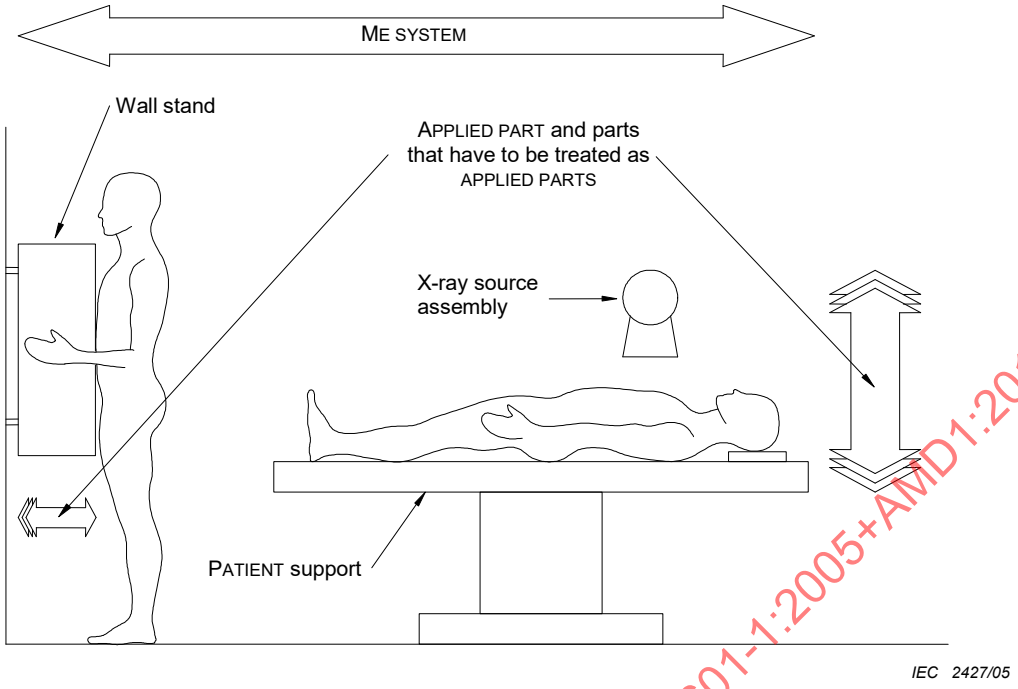


Figure A.5 – Identification of APPLIED PARTS and PATIENT CONNECTIONS in an X-ray ME SYSTEM

Figure A.6 shows a transcutaneous electronic nerve stimulator (TENS) that is intended to be worn on the PATIENT's belt and connected to electrodes applied to the PATIENT's upper arm. In this case:

– The ME EQUIPMENT includes the TENS stimulator, the electrode cable and the electrodes.

– The APPLIED PART includes the electrodes and those parts of the electrode leads that physically need to contact the PATIENT in NORMAL USE.

– The application of RISK MANAGEMENT might identify that the case of the stimulator and its belt clip also have to be treated as APPLIED PARTS because of the probability they will come in contact with the PATIENT.

– The PATIENT CONNECTIONS consist of the electrodes, which are all part of the same function of this APPLIED PART.

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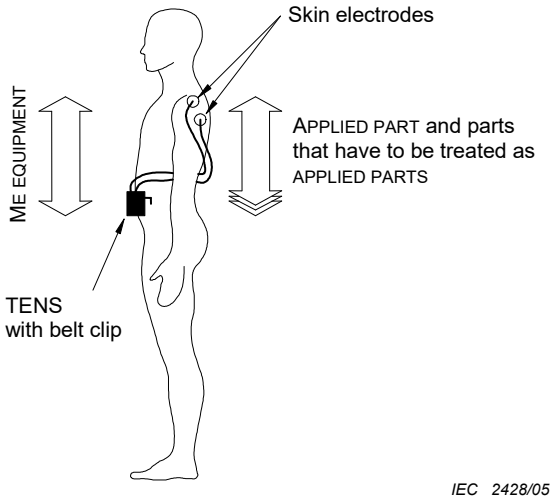


Figure A.6 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a transcutaneous electronic nerve stimulator (TENS) intended to be worn on the PATIENT'S belt and connected to electrodes applied to the PATIENT'S upper arm

Figure A.7 shows an ECG processing ME EQUIPMENT / ME SYSTEM in which:

– The ME SYSTEM includes the ECG module, PATIENT cable, PATIENT leads and electrodes, and the personal computer and any of its ACCESSORIES (not shown).

– The MANUFACTURER can choose to specify one of the following situations:

  • The ECG module and its PATIENT cable, PATIENT leads and electrodes are an item of ME EQUIPMENT; and the personal computer is not an item of ME EQUIPMENT. This would be an ME SYSTEM.

  • The ECG module and its PATIENT cable, PATIENT leads and electrodes are one item of ME EQUIPMENT; and the personal computer is a separate item of ME EQUIPMENT. This would also be an ME SYSTEM.

  • The ECG module and its PATIENT cable, PATIENT leads and electrodes together with the personal computer is a single item of ME EQUIPMENT and not an ME SYSTEM.

– The APPLIED PART includes the electrodes and those parts of the PATIENT cable or, PATIENT leads that need to physically contact the PATIENT in NORMAL USE.

– Application of RISK MANAGEMENT might identify other parts of the PATIENT cable or, PATIENT leads have to be treated as APPLIED PARTS because of the probability they will come in contact with the PATIENT.

– The PATIENT CONNECTIONS consist of the ECG electrodes, which are all part of the same function of the APPLIED PART.

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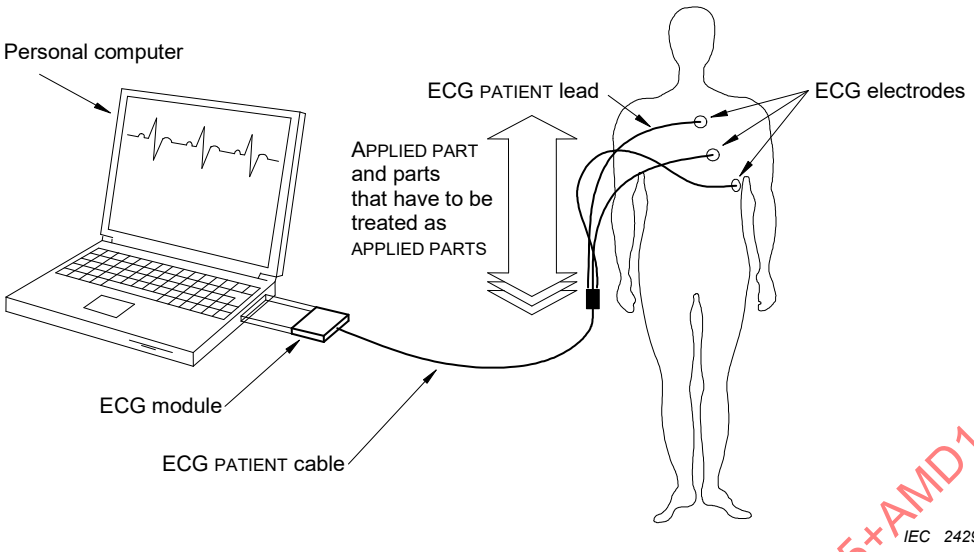


Figure A.7 – Identification of ME EQUIPMENT or ME SYSTEM, APPLIED PARTS and PATIENT CONNECTIONS in a personal computer with an ECG module

Subclause 4.6 would likely not apply to ACCESSIBLE PARTS of ME EQUIPMENT which are positioned according their INTENDED USE in such a way that the PATIENT could touch them only by a deliberate movement. This is based on the assumption that a PATIENT could react to a negative stimulus. Further, such PATIENTS are likely to have contact with non-ME EQUIPMENT such as bedside lights, personal computers, radios, etc.

Subclause 3.9 – BASIC INSULATION

This definition does not include insulation used exclusively for functional purposes.

Subclause 3.10 – BASIC SAFETY

BASIC SAFETY relates to a device not ~~harming the PATIENT~~ resulting in HARM incidental to its operation.

BASIC SAFETY is often a passive form of protection (such as radiation shielding or electrical grounding).

ESSENTIAL PERFORMANCE generally relates to ME EQUIPMENT or ME SYSTERMS operating as intended without creating a HAZARD. A failure of ESSENTIAL PERFORMANCE can be either a lack of performance (such as life supporting performance) or incorrect performance (such as delivering an incorrect dose to the PATIENT).

In general, BASIC SAFETY relates to product properties that are not device specific and ESSENTIAL PERFORMANCE relates to a class of products (such as a defibrillators being able to deliver the correct electrical shock).

While the terms BASIC SAFETY and ESSENTIAL PERFORMANCE are generally considered to be mutually exclusive, there are some HAZARDS that may relate to both BASIC SAFETY and ESSENTIAL PERFORMANCE concurrently.

Subclause 3.15 – CLEARLY LEGIBLE

Vision or visual acuity can be tested by reading a Snellen eye chart at a distance of 6 m. Near vision can be tested using a Jaeger test card. By examining a large number of people, doctors have decided what a “normal” human being should be able to see at various distances. That is the description of normal vision.

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Subclause 3.17 – COMPONENT WITH HIGH-INTEGRITY CHARACTERISITCS

The concept of high-integrity refers only to specific characteristics of the component. These characteristics are relied upon to ensure safety of the product. Such a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS should be identified in the ACCOMPANYING DOCUMENTS by the MANUFACTURER (e.g. for maintenance). See also the rationale for 4.9.

Subclause 3.18 – CONTINUOUS OPERATION

While the terms CONTINUOUS OPERATION or non-CONTINUOUS OPERATION are used with regard to the ME EQUIPMENT, parts of the ME EQUIPMENT can be RATED differently. For example, an electrosurgical generator might be RATED for CONTINUOUS OPERATION while the APPLIED PART is RATED for non-CONTINUOUS OPERATION.

Subclause 3.20 – DEFIBRILLATION-PROOF APPLIED PART

A DEFIBRILLATION-PROOF APPLIED PART is protected only against discharges of defibrillators complying with IEC 60601-2-4 [15]. Higher voltage defibrillators could damage DEFIBRILLATION-PROOF APPLIED PARTS.

Subclause 3.21 – DETACHABLE POWER SUPPLY CORD

Cord sets are covered by IEC 60320-1.

Subclause 3.22 – DIRECT CARDIAC APPLICATION

A distinction is made between use of APPLIED PARTS that might come in direct contact with the PATIENT'S heart and all other circumstances of contact with the PATIENT. Ventricular fibrillation can be caused by a much smaller current flowing through a small contact area where a wire or catheter makes direct contact with the heart than a current flowing through any other point of contact on or in the PATIENT'S body.

Subclause 3.23 – DOUBLE INSULATION

BASIC INSULATION and SUPPLEMENTARY INSULATION can, if required, be tested separately. Where multiple layers of insulation cannot be tested separately, the insulation system is considered as REINFORCED INSULATION.

Subclause 3.24 – DUTY CYCLE

The terms "on time" and "off time" are considered to include "bursts" of operation and deactivation as well as CONTINUOUS OPERATION.

Subclause 3.26 – ENCLOSURE

The ENCLOSURE of ME EQUIPMENT or ME EQUIPMENT parts includes all ACCESSIBLE PARTS, knobs, grips, cables, connectors and the like. This includes any ACCESSIBLE PARTS of external connections between other separate parts.

Subclause 3.27 – ESSENTIAL PERFORAMNCE

It has long been recognized that ME EQUIPMENT or an ME SYSTEM that does not perform properly could result in unacceptable RISK for PATIENTS, OPERATORS, or others. ~~All features or functions that must perform properly to prevent HARM to the PATIENT, OPERATOR or others are important, but not every feature or function of ME EQUIPMENT is ESSENTIAL PERFORMANCE. When a failure to perform would result in unacceptable RISK for the PATIENT, OPERATOR or others, then those features or functions are, for the purposes of this standard, seen as ESSENTIAL PERFORMANCE.~~ Hence the concept of "safety" has been broadened from the BASIC SAFETY considerations in the first and second editions of this standard to include ESSENTIAL PERFORMANCE matters.

~~Assessment of this RISK is made on the assumption that the performance aspect in question has been lost or degraded, and takes account of the probability that HARM would then occur~~

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~~(which in some instances could be 100 %) and the SEVERITY of that HARM. Application of the RISK MANAGEMENT PROCESS then ensures that the probability of loss of the performance aspect is low enough to make the RESIDUAL RISK acceptable.~~

~~A problem with ESSENTIAL PERFORMANCE exists when the feature or function in question is either absent or its characteristics are degraded to a point that the ME EQUIPMENT or ME SYSTEM is no longer suitable for its INTENDED USE.~~

In order to achieve its INTENDED USE, the ME EQUIPMENT or ME SYSTEM needs to perform within certain limits. These limits are usually specified by the MANUFACTURER but could be specified by this standard, a collateral standard or a particular standard in the IEC 60601 family.

Examples of ESSENTIAL PERFORMANCE are:

– ~~accuracy of a life-supporting function or~~ correct administration of a drug by a syringe pump where inaccuracy/incorrect administration would cause an unacceptable RISK to the PATIENT;

– the ability of an electrocardiograph/monitor to recover from the effects of the discharge of a defibrillator where the failure to recover could lead to an incorrect response by the medical staff that would present an unacceptable RISK to the PATIENT;

– correct operation of an ALARM SYSTEM in an intensive care or operating room monitoring system where an incorrect/missing ALARM SIGNAL could lead to an incorrect response by the medical staff that would present an unacceptable RISK to the PATIENT; or

– correct output of diagnostic information from ME EQUIPMENT that is likely to be relied upon to determine treatment, where incorrect information could lead to an inappropriate treatment that would present an unacceptable RISK to the PATIENT.

~~ESSENTIAL PERFORMANCE is identified without taking into account the probability of occurrence of factors that could result in a loss of functionality. These factors are taken into account in the RISK MANAGEMENT PROCESS.~~

For purposes of this standard, performance related to BASIC SAFETY aspects of the ME EQUIPMENT, such as the performance of BASIC INSULATION, is not considered to be ESSENTIAL PERFORMANCE.

Particular and collateral standards in the IEC 60601 family are expected to identify specific ESSENTIAL PERFORMANCE.

Subclause 3.33 – FUNCTIONAL CONNECTION

The defined term FUNCTIONAL CONNECTION is used to facilitate the definition of an ME SYSTEM. The FUNCTIONAL CONNECTION is a coupling between items of an ME SYSTEM, including the possibility of supplying power.

The phrase "or otherwise" could include mechanical, optical or wireless connections for example.

Subclause 3.35 – FUNCTIONAL EARTH TERMINAL

In ME EQUIPMENT, functional earth connections can be made by means of a FUNCTIONAL EARTH TERMINAL that is accessible to the OPERATOR. Alternatively this standard also allows a functional earth connection for CLASS II ME EQUIPMENT via a green and yellow conductor in a POWER SUPPLY CORD. In this case the parts to which this conductor is connected cannot be ACCESSIBLE PARTS (see 8.6.9), and have to be insulated from ACCESSIBLE PARTS.

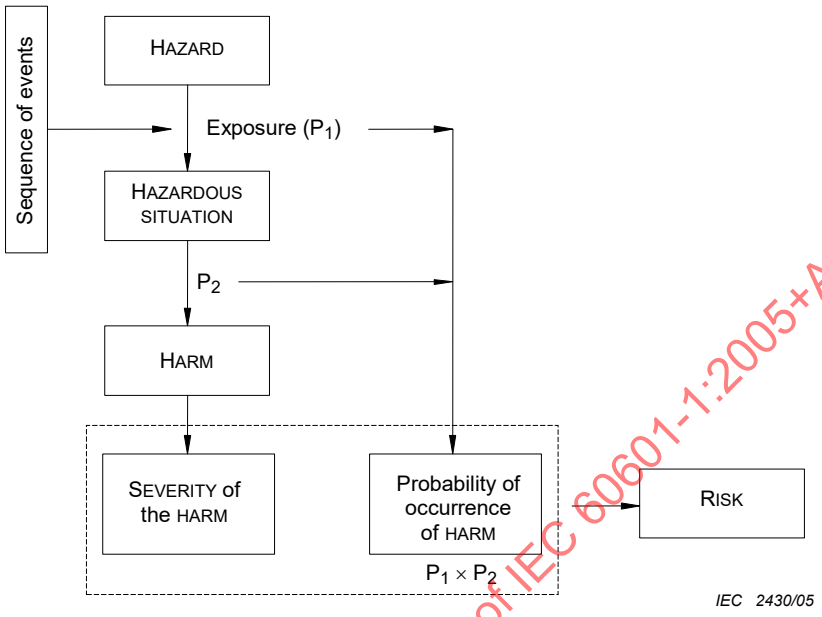
Subclause 3.38 – HARM

The definition of HARM is based on the definition in ISO 14971 modified to include animals. This change was made since the scope of the IEC 60601-1 includes the safety of animals.

Subclause 3.40 – HAZARDOUS SITUATION

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As used in this standard, a HAZARD cannot result in HARM until such time as a sequence of events or other circumstances (including NORMAL USE) lead to a HAZARDOUS SITUATION. As a result of the RISK MANAGEMENT PROCESS, the related RISK acceptability can be assessed by estimating both SEVERITY and probability of occurrence of the HARM that could result from this HAZARDOUS SITUATION (see Figure A.8 adapted from the draft text of the 2nd edition of the ISO 14971).



NOTE P_1 is the probability of a HAZARDOUS SITUATION occurring.
P_2 is the probability of a HAZARDOUS SITUATION leading to a HARM.

Figure A.8 – Pictorial representation of the relationship of HAZARD, sequence of events, HAZARDOUS SITUATION and HARM

Subclause 3.44 – ~~INTENDED USE~~

~~ISO 14971:2000 defined the compound term INTENDED USE/INTENDED PURPOSE because, at the time that version was being developed, there was no consensus on which term to use. The European Medical Device Directive uses "intended purpose," whereas the United States regulations use "intended use." Both terms have essentially the same definition. After some year of experience with applying ISO 14971, it has generally been accepted that the combined term is unwieldy and a consensus has emerged to use the shorter term "intended use." The second edition of ISO 14971 (in preparation) is expected to use "intended use" as the preferred term with "intended purpose" being an "admitted term." To avoid being out of step with the future edition of ISO 14971, this standard has adopted the shorter defined term INTENDED USE. The definition itself is identical to that in ISO 14971:2000 and to the definition that is expected to be in the second edition of ISO 14971.~~

Subclause 3.49 – MAINS PART

A definition of MAINS PART is needed to identify the parts to which certain requirements apply. The definition given in the first and second editions of this standard depended on another defined term, "conductive connection." During the development of this edition, a difficulty with the definition of "conductive connection" became apparent and the requirements were revised so the defined term was no longer needed. This necessitated a new definition of MAINS PART focussing on the MEANS OF PROTECTION that separate the MAINS PART from other parts.

Subclause 3.50 – MAINS PLUG

A definition of MAINS PLUG is needed to identify the plug to which certain requirements apply. The words "mains plug" without a definition would also cover other connectors within ME EQUIPMENT that carry MAINS VOLTAGE.

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Subclause 3.56 – MAXIMUM MAINS VOLTAGE

Several requirements and tests of this standard relate to the possibility that an unintended voltage originating from an external source becomes connected to the PATIENT or to certain parts of the ME EQUIPMENT. The actual magnitude of such a voltage is unknown but it is assumed to be related to the voltage of the SUPPLY MAINS in the location where the ME EQUIPMENT is used. See also the rationale for 8.5.3.

In the early stages of preparing this edition, a defined term "reference supply voltage" was introduced to avoid repetition of extensive wording. During the review of the National Committees' comments on an early draft, it became apparent that there was some confusion between the defined term "reference supply voltage" and the undefined term "reference voltage" which was used in relation to the requirements for dielectric strength, CREEPAGE DISTANCES and AIR CLEARANCES.

In order to clarify the requirements, the term "reference supply voltage" has been replaced by MAXIMUM MAINS VOLTAGE and "reference voltage" has been replaced by the defined terms WORKING VOLTAGE and PEAK WORKING VOLTAGE.

Subclause 3.57 – MAXIMUM PERMISSIBLE WORKING PRESSURE

The MAXIMUM PERMISSIBLE WORKING PRESSURE is decided by a competent person, taking into account the original design specification, the manufacturer's rating, the current condition of the vessel and the circumstances of use.

In some countries, the figure could be reduced from time to time.

Subclause 3.58 – MEANS OF PROTECTION

One guiding principle in the development of the third edition of this standard was to make it less prescriptive than the second edition, especially Clauses 17 and 20 of the second edition. The concept of MEANS OF PROTECTION was conceived as a generic one that could cover a number of things such as PROTECTIVE EARTH CONNECTIONS, BASIC INSULATION, SUPPLEMENTARY INSULATION, impedances, etc; and that might also be expanded to include other things which serve in the same capacity but have not yet been envisaged or are not yet practical. This concept, with the general requirement for ME EQUIPMENT to have two MEANS OF PROTECTION, fitted in well with the single fault philosophy, which all agreed was to be retained in the third edition. It enables a consistent approach to carry through a design effort without getting bogged down in the wordy prescriptive subclauses.

The concept also fitted in well when it was decided to differentiate protection of PATIENTS from protection of OPERATORS.

Some National Committee comments during the development of this edition suggested that the concept could be extended to apply to protection against HAZARDS other than electric shock. However it was decided that such a change would not be justified by the benefits.

Subclause 3.59 – MEANS OF PATIENT PROTECTION

See the rationale for 8.5.1.

Subclause 3.60 – MEANS OF OPERATOR PROTECTION

See the rationale for 8.5.1.

Subclause 3.63 – MEDICAL ELECTRICAL EQUIPMENT

The present definition of ME EQUIPMENT excludes multiple connections to the same particular SUPPLY MAINS, but does not exclude different connectors to different particular SUPPLY MAINS. However, connection to more than one of different SUPPLY MAINS at the same time should be avoided. While it might be possible to design equipment with provision to be connected simultaneously to two different SUPPLY MAINS in an electrically safe manner, the particular ~~HAZARDS~~ HAZARDOUS SITUATIONS that might arise have not been identified in this standard.

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This standard applies several terms to describe ME EQUIPMENT, ACCESSORIES and ME EQUIPMENT parts. They are FIXED (3.30), STATIONARY (3.118), TRANSPORTABLE (3.130), MOBILE (3.65), PORTABLE (3.85), HAND-HELD (3.37) and BODY-WORN (3.144). To help in understanding the relationship of these terms, the chart in Figure A.20 was developed.

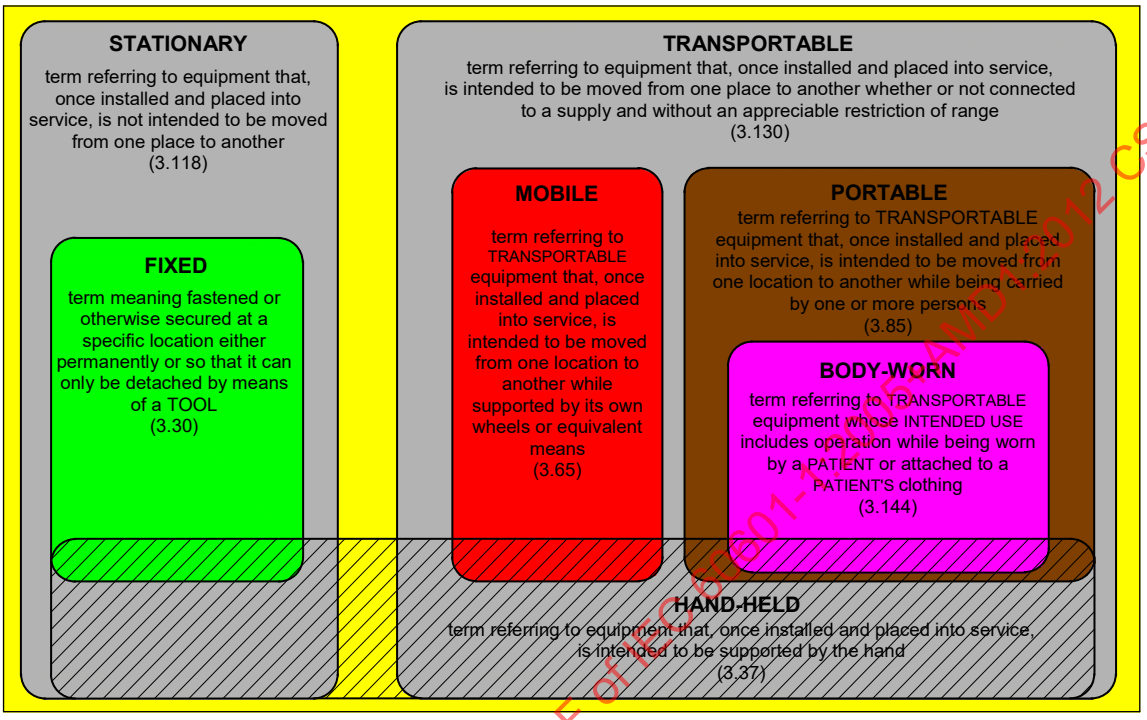


Figure A.20 – Relationship of the terms used to describe equipment, ACCESSORIES or equipment parts

Subclause 3.64 – MEDICAL ELECTRICAL SYSTEM

It is common practice for MANUFACTURERS, RESPONSIBLE ORGANISATIONS and OPERATORS to connect ME EQUIPMENT and other medical or non-medical equipment to MULTIPLE SOCKET-OUTLETS. The inclusion of such arrangements within the definition of ME SYSTEM brings them within the scope of this standard and thus allows appropriate requirements to be specified for BASIC SAFETY and ESSENTIAL PERFORMANCE.

To minimize the impairment of the safety level of this standard, the connection of a MULTIPLE SOCKET-OUTLET to the SUPPLY MAINS is subject to certain conditions. Subclause 16.9.2.1 requires that MULTIPLE SOCKET-OUTLETS are constructed to comply with the requirements from this standard applying to ME EQUIPMENT.

Subclause 3.66 – MODEL OR TYPE REFERENCE

The MODEL OR TYPE REFERENCE is intended to establish the relationship of the ME EQUIPMENT to commercial and technical publications, to ACCOMPANYING DOCUMENTS and between separable parts of ME EQUIPMENT. It is also important for identifying of ME EQUIPMENT or ACCESSORIES in case of a safety alert or other required field action.

Subclause 3.67 – MULTIPLE SOCKET-OUTLET

The definition is derived from IEC 60884-1.

In the second edition of IEC 60601-1-1 [13], there were definitions for multiple portable socket-outlet and auxiliary mains socket-outlet. In this edition, these definitions have been merged.

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A single socket-outlet forming part of an equipment is also considered a MULTIPLE SOCKET-OUTLET.

MULTIPLE SOCKET-OUTLETS are sometimes necessary and offer advantages and disadvantages, which have to be investigated in order to establish a balance. MULTIPLE SOCKET-OUTLETS might be necessary for the following reasons:

– to minimize the number of POWER SUPPLY CORDS lying on the floor;
– to allow all the equipment necessary for proper treatment or diagnosis to be used despite an insufficient number of FIXED mains socket-outlets;
– to improve mobility by having all equipment on one trolley;
– to reduce potential differences within the protective earth wiring to below those that occur in some FIXED installations.

The use of MULTIPLE SOCKET-OUTLETS should be avoided as far as possible for the following reasons:

– combined EARTH LEAKAGE CURRENTS could result in:
  • excessive EARTH LEAKAGE CURRENT in NORMAL CONDITION,
  • excessive TOUCH CURRENT in the SINGLE FAULT CONDITION of the broken PROTECTIVE EARTH CONDUCTOR of the MULTIPLE SOCKET-OUTLET supply cable;
– availability of the SUPPLY MAINS depends on the reliability of a single FIXED mains socket-outlet;
– a complete interruption of electrical supply is possible and might require a long set-up time to reactivate the complete ME SYSTEM;
– only one PROTECTIVE EARTH CONNECTION to the electrical installation is provided; this is less reliable than when each part of the ME SYSTEM is directly earthed;
– the protective earth resistance is increased.

The optimum solution includes installing an adequate number of FIXED mains socket-outlets according to appropriate installation rules.

Subclause 3.68 – NETWORK/DATA COUPLING

The definition of NETWORK/DATA COUPLING has been written so as not to be restricted to any particular technology, such as electronic transmission along wires. The definition allows for wireless electromagnetic transmission, infra-red, optical, etc., as well as any future technology.

Subclause 3.73 – OPERATOR

The OPERATOR is defined as the person who handles the equipment, which could be ME EQUIPMENT or any item of equipment in the context of an ME SYSTEM. This person could be:

– a health care professional using the equipment with a PATIENT,
– either a PATIENT or a layperson assisting a PATIENT in a home-care environment,
– a person who is using the equipment to compensate or alleviate the effects of disease, injury or disability, or
– the person that installs, assembles, maintains or repairs the equipment.

People who install, assemble, maintain or repair the equipment are also referred to in this standard as SERVICE PERSONNEL.

Many requirements in this standard are constructed so that SERVICE PERSONNEL experience the same RESIDUAL RISK as the person who uses the equipment for its INTENDED USE. However, SERVICE PERSONNEL, who are often engineers or engineering technicians, are expected to have certain competencies and to take account of the technical description. Other OPERATORS are expected to have different competencies and to follow the instructions for use. Therefore, this standard presumes in certain circumstances that the safety of SERVICE PERSONNEL depends partly on their knowledge and training to take appropriate precautions when gaining

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access to hazardous parts. The other OPERATORS are presumed to be competent to use the ME EQUIPMENT or ME SYSTEM but are not necessarily competent to avoid RISKS that can arise during servicing.

Subclause 3.75 – OXYGEN RICH ENVIRONMENT

At a 25 % oxygen concentration, the increase in the burning rate of a paper strip is only moderate (30 %) (per NFPA 99 [42]). In NFPA 99, 23,5 % is defined to be oxygen-enriched atmosphere that requires protective measures, but it allows this value also for oxygen chambers at pressures of more than 200 kPa. NASA allows concentrations of 25,9 % in its space shuttles (NFPA 53 [41]). UL 2601-1 [44] uses 25 % as threshold value. A sample of epoxy circuit board material burns incompletely at 20,9 % and 25,9 % (burning length of 3 cm and 8,3 cm) but completely at 30 % according to Rimanosky, E.M. et al., ASTM STP 1267 [36].

When first considering the relationship between flame rate and the amount of oxygen, it would seem reasonable that the flame rate would be proportional to the total locally available amount of oxygen, which is given by the partial pressure. However, experience shows that this is only true to a degree. Figures C-1.2.2(a) and (b) in NFPA 53:1999 and Figure A.3.3.14.4 in NFPA 99:2002 show that for paper strips the increase of flame rate with oxygen concentration at a set absolute pressure is stronger than the increase of flame rate with absolute pressure at a set concentration. For the borderline "complete combustion" to "incomplete combustion" the oxygen concentration seems to come to the same number (14 %) at high pressures, independent of the absolute (and partial) pressure. Therefore, to be on the safe side, two numbers are given in the definition. The concentration limit makes sure that for smaller ambient pressures than one atmosphere the danger does not increase. The partial pressure limit makes sure that for higher pressures (e.g. in oxygen chambers) the situation is safe.

Subclause 3.77 – PATIENT AUXILIARY CURRENT

PATIENT AUXILIARY CURRENT is a current that is necessary for:

– the ME EQUIPMENT to perform its function, e.g. electrical impedance imaging, monitoring of respiration by impedance changes;

– monitoring the correct operation of the ME EQUIPMENT, e.g. contact impedance of electrodes with the PATIENT;

– the functioning of the ME EQUIPMENT;

or that is incidental to the functioning of the ME EQUIPMENT. An example is the bias current of an amplifier for physiological signals.

PATIENT AUXILIARY CURRENT could have a function, but not a physiological function, or it could have no function.

Subclause 3.78 – PATIENT CONNECTION

One of the HAZARDS associated with the application of PATIENT CONNECTIONS is the fact that LEAKAGE CURRENT can flow through the PATIENT via the PATIENT CONNECTIONS. Particular limits are placed on the magnitude of these currents, both in the NORMAL CONDITION and in various fault conditions.

NOTE The current that flows through the PATIENT between various PATIENT CONNECTIONS is known as PATIENT AUXILIARY CURRENT. The LEAKAGE CURRENT that flows through the PATIENT to earth is known as PATIENT LEAKAGE CURRENT.

The definition of PATIENT CONNECTION is intended to ensure the identification of each individual part of the APPLIED PART between which current could flow as PATIENT AUXILIARY CURRENT, and from which PATIENT LEAKAGE CURRENT could flow into an earthed PATIENT.

In some cases it will be necessary to carry out PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT measurements to determine which parts of the APPLIED PARTS are individual PATIENT CONNECTIONS.

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PATIENT CONNECTIONS are not always accessible to touch. Any conductive parts of the APPLIED PART that come into electrical contact with the PATIENT, or which are prevented from doing so only by insulation or air gaps that do not comply with the relevant dielectric strength tests or AIR CLEARANCE and CREEPAGE DISTANCE requirements specified in this standard, are PATIENT CONNECTIONS. See also the rationale for 3.8.

Examples include the following.

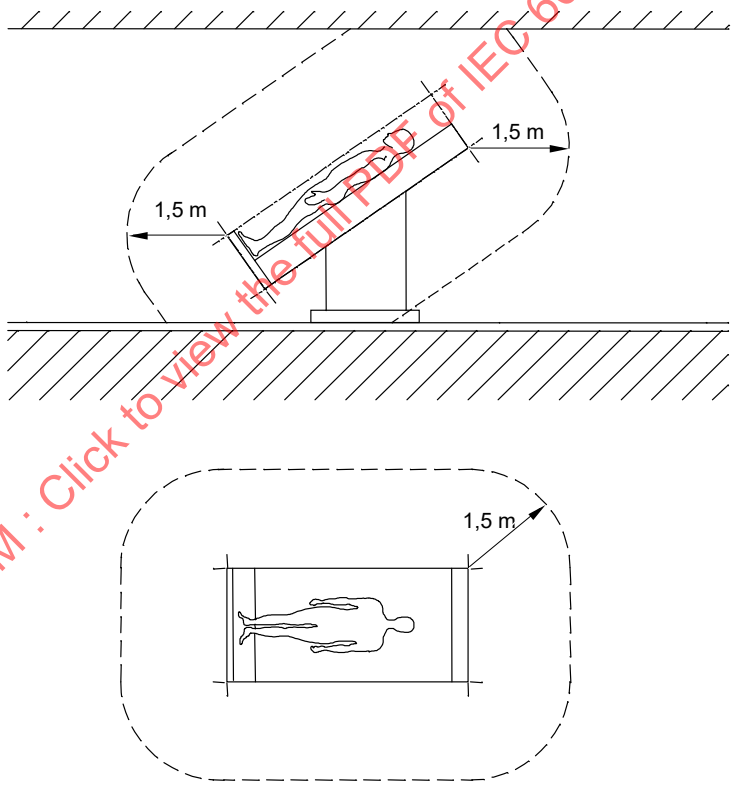
– A table top supporting a PATIENT is an APPLIED PART. Sheets do not provide adequate insulation and the conductive parts of the table top would therefore be classified as PATIENT CONNECTIONS.

– The administration set or needle of an infusion controller is an APPLIED PART. Conductive parts of the controller separated from the (potentially conducting) fluid column by inadequate insulation would be PATIENT CONNECTIONS.

Where an APPLIED PART has a surface of insulating material, 8.7.4.7 d) specifies that it is tested using foil or saline solution. This is then considered as a PATIENT CONNECTION.

Subclause 3.79 – PATIENT ENVIRONMENT

It is difficult for this standard to define dimensions for the volume in which diagnosis, monitoring or treatment occurs. The dimensions for the PATIENT ENVIRONMENT given in Figure A.9 have been justified in practice.



IEC 2431/05

NOTE The dimensions in the figure show minimum extent of the PATIENT ENVIRONMENT in a free surrounding.

Figure A.9 – Example of PATIENT ENVIRONMENT

Subclause 3.81 – PEAK WORKING VOLTAGE

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This definition was taken from IEC 60950-1:~~2001~~2005, subclause ~~1.2.9.7~~ 1.2.9.8. Use of this term along with the defined term WORKING VOLTAGE should make the INSULATION CO-ORDINATION requirements incorporated from IEC 60950-1 easier to understand for those already familiar with that standard. See also the rationale for 3.56.

Subclause 3.99 – REINFORCED INSULATION

The term "insulation system" does not imply that the insulation has to be one homogeneous piece. It could comprise several layers that cannot be tested separately as SUPPLEMENTARY or BASIC INSULATION.

Subclause 3.110 – SECONDARY CIRCUIT

This definition is based on the definition of the same term in IEC 60950-1:~~2001~~2005, subclause ~~1.2.8.4~~ 1.2.8.5 and identifies circuits that are subject to lower transient overvoltages than the MAINS PART and therefore have lower values for dielectric strength test voltages and AIR CLEARANCES.

Subclause 3.112 – SEPARATION DEVICE

Assembly of equipment into an ME SYSTEM could involve connections that transfer power or signals. In both cases, the same separation requirements are needed.

Subclause 3.115 – SIGNAL INPUT/OUTPUT PART

If a SIGNAL INPUT/OUTPUT PART carries electrical signals, or if it carries non-electrical signals but nevertheless introduces a conductive connection to the other equipment (e.g. through an optical fibre cable with a metal sheath), appropriate separation from other circuits can be necessary to satisfy the requirements of this standard. Alternatively a SIGNAL INPUT/OUTPUT PART could have no conductive connections, in which case it will automatically satisfy the requirements for electrical BASIC SAFETY.

Subclause 3.120 – SUPPLY MAINS

An external d.c. power source (e.g. in an ambulance) is considered as a SUPPLY MAINS. ME EQUIPMENT specified for connection to such a power source has to satisfy all requirements for mains powered ME EQUIPMENT. In the past, some ME EQUIPMENT specified for such a power source has had a direct connection between the ENCLOSURE and one side of the supply, presumed to be at earth potential. In the event of interruption of the connection to this side of the supply, the ENCLOSURE of such ME EQUIPMENT assumes the supply potential and would therefore exceed the specified limit for TOUCH CURRENT. The first and second editions of this standard were intended to exclude such an arrangement, but this was not always understood by users of the standard. This rationale has been added to clarify the requirement.

Subclause 3.132 – TYPE B APPLIED PART

TYPE B APPLIED PARTS provide the lowest degree of PATIENT protection of all the types of APPLIED PART and are not suitable for DIRECT CARDIAC APPLICATION.

The PATIENT CONNECTION(S) of a TYPE B APPLIED PART could be:

– PROTECTIVELY EARTHED;
– connected to earth but not PROTECTIVELY EARTHED; or
– floating, but not isolated from earth to the degree that would be required for a TYPE BF APPLIED PART.

Subclause 3.133 – TYPE BF APPLIED PART

TYPE BF APPLIED PARTS provide a degree of PATIENT protection higher than provided by TYPE B APPLIED PARTS. This is achieved by isolating the PATIENT CONNECTIONS from earthed parts and other ACCESSIBLE PARTS of the ME EQUIPMENT, thus limiting the magnitude of current that would flow through the PATIENT in the event that an unintended voltage originating from an external

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source is connected to the PATIENT, and thereby applied between the PATIENT CONNECTIONS and earth. However, TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

Subclause 3.134 – TYPE CF APPLIED PART

TYPE CF APPLIED PARTS provide the highest degree of PATIENT protection. This is achieved by increased isolation of the PATIENT CONNECTION from earthed parts and other ACCESSIBLE PARTS of the ME EQUIPMENT, further limiting the magnitude of possible current flow through the PATIENT. TYPE CF APPLIED PARTS are suitable for DIRECT CARDIAC APPLICATION insofar as PATIENT LEAKAGE CURRENT is concerned, though they could be unsuitable in other respects, such as sterility or biocompatibility.

Subclause 3.139 – WORKING VOLTAGE

This definition is taken from IEC 60950-1:~~2001~~2005, subclause 1.2.9.6. Use of this term along with the defined term PEAK WORKING VOLTAGE should make the INSULATION CO-ORDINATION requirements incorporated from IEC 60950-1 easier to understand for those already familiar with that standard. See also the rationale for 3.56.

Subclause 4.1 –Conditions for application to ME EQUIPMENT or ME SYSTEMS

The condition for application of RISK MANAGEMENT to ME EQUIPMENT and ME SYSTEMS includes ~~reasonable~~ reasonably foreseeable misuse. The MANUFACTURER identifies foreseeable misuse as part of the RISK ANAYLSIS (see ~~ISO 14971:2000, subclause~~ 4.2). This identification could include the results of a USABILITY ENGINEERING PROCESS.

Subclause 4.2 –RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

A change introduced in the third edition of this standard is that, in specifying minimum BASIC SAFETY and ESSENTIAL PERFORMANCE requirements, provision is made for assessing the adequacy of the design PROCESS where this provides an appropriate alternative to the application of laboratory testing with specific pass/fail criteria, (e.g. in assessing the safety of new technologies). Application of this principle leads to the introduction of a general requirement to carry out elements of a RISK MANAGEMENT PROCESS as part of demonstrating compliance with this standard.

The MANUFACTURER is responsible for ensuring that the design and construction of the ME EQUIPMENT renders it suitable for its INTENDED ~~PURPOSE~~ USE and that any RISKS that are associated with its use are acceptable when weighed against the benefits. ISO 14971 specifies a PROCEDURE for the MANUFACTURER to identify HAZARDS associated with the ME EQUIPMENT or ME SYSTEM and its ACCESSORIES, to estimate and evaluate the RISKS associated with those HAZARDS~~,~~ and to control those RISKS~~, and to monitor the effectiveness of that control~~.

The scope of this standard is confined to type examination of ME EQUIPMENT and ME SYSTEMS; it does not extend to lifecycle monitoring. For this reason, the monitoring of production and post-production information and the planning thereof, as required by ISO 14971:2007, is excluded from the RISK MANAGEMENT PROCESS described in this standard. The requirement in ISO 14971:2007 for periodic review of the suitability of the RISK MANAGEMENT PROCESS is also excluded.

Compliance with the clauses of this standard that contains specific, verifiable requirements is presumed to reduce the associated RISK(S) to an acceptable level.

The MANUFACTURER of ME SYSTEMS should make this determination on a system level. The MANUFACTURER should assess RISKS resulting from the fact that individual system components have been integrated into one system. This assessment should include all aspects of the information exchanged between the system components. Even when these components are non-ME ELECTRICAL components, the potential RISK related to the integration of these components into the ME SYSTEM need to be considered. Further requirements for the integration of non-medical equipment into an ME SYSTEM are described in Clause 16. It gives

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the requirements for an ME SYSTEM and how RISKS associated with non-ME EQUIPMENT are addressed.

It should be noted that compliance with ISO 14971 does not require that the MANUFACTURER have a formal quality system in place.

This RISK MANAGEMENT PROCESS results in a set of RECORDS and other documents: the RISK MANAGEMENT FILE. Compliance of the RISK MANAGEMENT PROCESS is checked by inspection of the RISK MANAGEMENT FILE.

In all cases, the MANUFACTURER is to be considered the expert on the device being developed and on the HAZARDS associated with its use.

Where compliance tests are by inspection or review of the RISK MANAGEMENT FILE, only the relevant parts of the RISK MANAGEMENT FILE need to be reviewed, e.g. MANUFACTURER'S calculations or test results, or the determination of RISK acceptability.

Some requirements of this standard use the term unacceptable RISK, other requirements use the term HAZARDOUS SITUATION. All unacceptable RISKS result from a HAZARDOUS SITUATION, not all HAZARDOUS SITUATIONS result in an unacceptable RISK.

In deciding which ~~term~~ phrase to use in a requirement the following rule has been used.

~~– Unacceptable RISK is used when the MANUFACTURER has to, or is permitted to, make a judgment about the acceptability of the RISK. This judgement needs to be supported by an appropriate rationale such as experience, historical data, etc.~~

~~– HAZARDOUS SITUATION is used when the possibility of HARM determines whether certain requirements apply. In these cases the only determination a MANUFACTURER has to make is whether or not a HAZARDOUS SITUATION exists; this determination is made regardless of the RISK resulting from that HAZARDOUS SITUATION.~~

~~– The term HAZARD is used when the HAZARD is not necessarily exposed.~~

– The phrase “no unacceptable RISK” is used when the MANUFACTURER has to, or is permitted to, make a judgement about the acceptability of the RISK. This judgement is to be supported by an appropriate rationale such as experience, historical data, etc.

– The phrase “no HAZARDOUS SITUATION” is used when the MANUFACTURER has to demonstrate (e.g. by technical drawing or technical description) that there is no exposure to a HAZARD or no possibility of HARM can develop. In these cases the only determination a MANUFACTURER has to make is whether or not a HAZARDOUS SITUATION exists; this determination is made regardless of the acceptability of the RISK that could develop from that HAZARDOUS SITUATION.

– The phrase “no HAZARD” is never used.

The following provides guidance on how to use several elements of the RISK MANAGEMENT PROCESS as defined in ISO 14971 within the context of IEC 60601-1.

– **INTENDED USE:** The INTENDED USE is determined at the highest level of the ME EQUIPMENT or ME SYSTEM and should be used in identifying HAZARDS or HAZARDOUS SITUATIONS related to the use of the ME EQUIPMENT or ME SYSTEM. The INTENDED USE is not (or very rarely) used in the evaluation of specific components. Further, the INTENDED USE is the primary input when determining what aspects of the clinical functions of the ME EQUIPMENT or ME SYSTEM constitute ESSENTIAL PERFORMANCE as required by 4.3.

– **HAZARD identification:** This standard and ISO 14971 require identification of all HAZARDS and HAZARDOUS SITUATIONS associated with the ME EQUIPMENT or ME SYSTEM, regardless of whether they are identified in an international safety standard or not (see 4.2.2, Note 1, and 4.2.3.2). This holds for NORMAL USE, reasonably foreseeable misuse and SINGLE FAULT CONDITIONS. However, when HAZARDS or HAZARDOUS SITUATIONS identified in this standard cannot occur for the specific ME EQUIPMENT or ME SYSTEM, the HAZARD identification would be performed only to document that the corresponding requirements of this standard do not apply. In this case, further RISK ASSESSMENT or VERIFICATION of compliance is not

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required. When a requirement does apply, no HAZARD identification is necessary (because the standard has already done so). For example, no HAZARD of electric shock arises in ME EQUIPMENT having no voltages capable of producing LEAKAGE CURRENTS that exceed the applicable limits as specified in 8.4.2 c).

– **RISK EVALUATION:** RISK is evaluated at two points in the RISK MANAGEMENT PROCESS—before and then again after implementation of RISK CONTROL measures. Evaluation before implementation of RISK CONTROL measures is applicable to the requirements of this standard only in order to demonstrate that the associated RISK is acceptable without applying a requirement. However, when this standard requires that RISKS related to a specific requirement remain acceptable or that no unacceptable RISK occurs in relation to a specific requirement, compliance is checked by inspection of the RISK MANAGEMENT FILE for the HAZARDS or HAZARDOUS SITUATIONS related to this requirement and for OBJECTIVE EVIDENCE (e.g. by MANUFACTURER'S calculations, analyses or test results) that the corresponding RISKS are judged to be acceptable based on the MANUFACTURER'S criteria for acceptability of RISK. The effectiveness of the RISK CONTROL measures is evaluated in accordance with subclause 6.3 of ISO 14971:2007.

– **RISK reduction:** When a requirement of this standard requires implementation of specific RISK CONTROL measures to assure that the associated RISK is acceptable, compliance is checked by either of the following:

  - by assuring that the specific measures have been implemented, in which case no RISK MANAGEMENT and no evaluation of RESIDUAL RISK are required because the RISKS are assumed to be reduced to an acceptable level by the presence of the specific measures (meeting the objective requirements of this standard), or
  - by inspection of the RISK MANAGEMENT FILE for the HAZARDS or HAZARDOUS SITUATIONS identified in the requirement in absence of the measures specified by the requirement and for OBJECTIVE EVIDENCE (e.g. by MANUFACTURER'S calculations, analyses or test results) that the corresponding RISKS are judged to be acceptable.

  Subclauses 7.2.2 for detachable components and 7.2.17 for protective packaging are examples where special markings are required unless no unacceptable RISKS occur. So, either the markings must be provided or the RISKS in absence of those markings must be evaluated and judged acceptable. Another example is 15.4.1 a), for the design and construction of connector plugs.

– **RISK/benefit analysis:** A RISK/benefit analysis according to subclause 6.5 of ISO 14971:2007 is only required when the RESIDUAL RISK associated with a specific HAZARD or HAZARDOUS SITUATION remains unacceptable using the criteria for RISK acceptability recorded in the RISK MANAGEMENT plan and further RISK CONTROL is not practicable. Such RISK/benefit analyses are not required when the RESIDUAL RISKS are judged acceptable or when the ME EQUIPMENT or ME SYSTEM complies with specific requirements of this standard. Subclause 11.1.2 is one of the few examples where a RISK/benefit analysis is required when temperature limits are exceeded to achieve a clinical purpose (see Table 24, footnote [b]).

Subclause 4.3 – ESSENTIAL PERFORMANCE

~~The concept of "safety" has been broadened from the BASIC SAFETY considerations in the first and second editions of this standard to include ESSENTIAL PERFORMANCE matters, (e.g. the accuracy of physiological monitoring equipment). Application of this principle leads to the change of the title from "Safety of medical electrical equipment, Part 1: General requirements for safety" in the second edition, to "Medical electrical equipment, Part 1: General requirements for basic safety and essential performance".~~

~~For an explanation of ESSENTIAL PERFORMANCE, see the rationale for 3.27.~~

During the initial RISK ANALYSIS, the MANUFACTURER identifies the performance of the clinical fuction(s) of the ME EQUIPMENT or ME SYSTEM that is necessary for achieving the INTENDED USE. The MANUFACTURER also identifies other qualitative and quantitative characteristics that could affect the safety of the ME EQUIPMENT or ME SYSTEM.

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The performance limits specified by the MANUFACTURER could be anywhere within the full range of intended performance in NORMAL CONDITION and SINGLE FAULT CONDITION, to no performance.

The MANUFACTURER then determines if the loss or failure to perform within specified limits would result in a RISK to the PATIENT. The estimate is often made with the assumption that the performance aspect in question has been lost or degraded beyond the specified limits (i.e. P_1 in Figure A.8 is 100 %). The MANUFACTURER takes into account the probability of a HAZARDOUS SITUATION leading to HARM (P_2 in Figure A.8) as well as the SEVERITY of that HARM. In some instances P_2 could also be 100 %, in which case the RISK estimate is based entirely on the SEVERITY of the HARM. When considering the RISK associated with a level of degraded performance, which might include full loss, the analysis should include expected measures as prescribed in the ACCOMPANYING DOCUMENTS, which might return some or all performance after a delay including service to the ME EQUIPMENT or ME SYSTEM, or a return of some or all of the PATIENT'S medical care with back-up medical care measures.

The MANUFACTURER then evaluates the RISK using their established RISK acceptance criteria. If the RISK is unacceptable, then the identified performance is ESSENTIAL PERFORMANCE because RISK reduction is required to achieve an acceptable level of RESIDUAL RISK.

Once the ESSENTIAL PERFORMANCE is identified, the MANUFACTURER puts in place RISK CONTROL measures that are appropriate to reduce the RISK to an acceptable level. When conducting the RISK CONTROL option analysis, the MANUFACTURER is to follow the priority order listed in ISO 14971, namely:

a) inherent safety by design;

b) protective measures;

c) information for safety.

The RISK CONTROL measures selected need to be reasonably practicable and consistent with the generally accepted technology. For example, it might be possible to build a critical care ventilator that will continue to function in the presence of a single component failure, but, given the generally accepted technology, this is not practicable. Therefore, the MANUFACTURER might rely on a protective measure, such as an ALARM SYSTEM, to alert the OPERATOR of the failure so the OPERATOR can take appropriate and timely action to prevent the onset of HARM. The ALARM SIGNAL coupled with required OPERATOR training might be adequate RISK CONTROL measures to reduce the RISK arising from the loss or degradation of the identified performance to an appropriate level, i.e. the RESIDUAL RISK is acceptable. These RISK CONTROL measures can be integral with the consideration of ESSENTIAL PERFORMANCE.

Of course, the RISK CONTROL measure has to be sufficiently independent such that the condition that causes the loss or degradation of the identified performance does not compromise the effectiveness of the RISK CONTROL measure. This is consistent with the two MEANS OF PROTECTION philosophy employed in the IEC 60601 series. For example, an ALARM SYSTEM intended to alert the OPERATOR that the SUPPLY MAINS has been interrupted could not depend on the SUPPLY MAINS as the sole source of its power. A back-up battery could be used to power the ALARM SYSTEM if the SUPPLY MAINS is interrupted.

In RISK CONTROL, timing is everything. If there is insufficient time from the onset of the event (interruption of the SUPPLY MAINS) for the OPERATOR to register that an ALARM CONDITION has occurred and take appropriate action to prevent the onset of HARM, then the ALARM SYSTEM alone would not be an effective RISK CONTROL measure. A back-up power source to keep the ME EQUIPMENT operating for a period of time sufficient for the OPERATOR to take the necessary corrective action could also be required.

As with all aspects of the RISK MANAGEMENT PROCESS, the identification of ESSENTIAL PERFORMANCE can be iterative. The MANUFACTURER might have to revisit the process of determining what the ESSENTIAL PERFORMANCE is during the lifecycle of the ME EQUIPMENT or ME SYSTEM.

See also the rationale for 3.27.

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Subclause 4.4– EXPECTED SERVICE LIFE

The EXPECTED SERVICE LIFE is the time period during which the ME EQUIPMENT or ME SYSTEM is expected to remain suitable for its INTENDED USE. It is also the period when all RISK CONTROL measures need to remain effective to ensure that RISKS remain acceptable.

The EXPECTED SERVICE LIFE needs to be determined by the MANUFACTURER, as part of the RISK MANAGEMENT PROCESS, as a precondition for assessing compliance with many requirements of this standard, such as 4.5, 4.7, 7.1.3, 8.6.3, 9.8.2 and 11.6.6.

In the ACCOMPANYING DOCUMENTS, the MANUFACTURER should provide information to allow the RESPONSIBLE ORGANIZATION to assess when the ME EQUIPMENT is approaching the end of its life. Such information should include the EXPECTED SERVICE LIFE as determined by the MANUFACTURER (e.g. in terms of years of service or number of uses) but could also include tests to be performed as part of preventive maintenance, or other criteria to allow the RESPONSIBLE ORGANIZATION to make an appropriate determination. The need for such information and the appropriate way to present it should be addressed as part of the RISK MANAGEMENT PROCESS.

In defining the EXPECTED SERVICE LIFE, the MANUFACTURER should assume that the RESPONSIBLE ORGANIZATION will follow the MANUFACTURER'S instructions for routine maintenance. See 7.9.2.13.

Subclause 4.5 – ~~Equivalent safety for ME EQUIPMENT or ME SYSTEMS~~ Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS

This subclause allows alternative means of achieving ~~equivalent safety to be used~~ safety to those means specified in this standard. This is important as it permits a MANUFACTURER to use innovative solutions that ~~might be safer or~~ are safe and can have other benefits, e.g. lower cost or ~~performance~~ better manufacturability.

Because it is often difficult to ascertain a sense of RISK acceptability for an individual RISK CONTROL measure or test method, the MANUFACTURER is permitted to use scientific data, clinical opinion, or comparative studies on a case-by-case basis to establish that the RESIDUAL RISK from applying an alternative remains acceptable.

Documentation in the RISK MANAGEMENT FILE should show that the RESIDUAL RISK achieved using the alternative means ~~is~~ remains acceptable ~~because it is equal to or less than the RESIDUAL RISK achieved by applying the requirements of this standard~~ and is comparable to this standard. Comparative studies should take into account scientific studies referenced in this standard and applicable to the alternative means.

~~If the RESIDUAL RISK is greater than the RESIDUAL RISK achieved by applying the requirements of this standard, the ME EQUIPMENT or ME SYSTEM cannot be regarded as complying with this standard, even if the RESIDUAL RISK is fully justified by other considerations such as the clinical benefit to the PATIENT.~~

Subclause 4.6 – ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

A part that unintentionally comes into contact with an unconscious, anaesthetized or incapacitated PATIENT can present the same RISKS as an APPLIED PART that necessarily has to contact the PATIENT. On the other hand, a part that an active PATIENT could reach out and touch might present no more RISK to that PATIENT than it presents to an OPERATOR.

The definition of APPLIED PART in the first and second editions of this standard failed to address this problem. The second amendment to the second edition extended the definition to include parts that can be brought into contact with the PATIENT, but the new definition continued to cause difficulties.

Since this standard now requires a RISK MANAGEMENT PROCESS to be followed, it is appropriate to use this PROCESS to establish whether such parts should be subject to the requirements for APPLIED PARTS or not.

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The exclusion of marking requirements reflects the majority view of the National Committees that responded to an enquiry on the subject during the development of this edition. It would be confusing to OPERATORS if parts that are not intended to be APPLIED PARTS were marked like APPLIED PARTS.

Parts identified as needing to be subject to the requirements for APPLIED PARTS (except for marking) will typically contact PATIENTS less frequently than APPLIED PARTS, so the benefits of electrical separation from earth would be less. However in some cases, these parts might need to satisfy the requirements for TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS in order to provide an appropriate level of safety.

Subclause 4.7 – SINGLE FAULT CONDTION for ME EQUIPMENT

The requirement that ME EQUIPMENT is SINGLE FAULT SAFE effectively puts a lower limit on the probability of occurrence of HARM from a HAZARD. If this probability is achieved then the RISK of the HAZARD is acceptable. In all cases where this discussion refers to the SEVERITY or probability of a particular HAZARD, it is intended to refer to the probability or SEVERITY of the HARM resulting from that HAZARD.

SINGLE FAULT SAFE is a concept that flows from the single fault philosophy described in IEC/TR 60513 [12]. SINGLE FAULT SAFE is a characteristic of ME EQUIPMENT that assures BASIC SAFETY during its EXPECTED SERVICE LIFE. For a high SEVERITY HARM, application of a RISK MANAGEMENT PROCESS can conclude that the single fault concept does not achieve an acceptable RISK.

The probability of simultaneous occurrence of two single faults is considered small enough to be negligible, provided that:

a) a single fault causes operation of a protective device (e.g. a fuse, OVER-CURRENT RELEASE, safety catch, etc.) that prevents occurrence of a HAZARD, or

b) a single fault is discovered by an unmistakable and clearly discernible signal that becomes obvious to the OPERATOR, or

c) a single fault is discovered and remedied by periodic inspection and maintenance that is prescribed in the instructions for use. There is a finite probability that a second fault can arise before the next scheduled inspection and maintenance cycle. As with case a) above, for the probability of this double fault condition to be negligible, the probability of each fault has to be low. This means that the frequency of inspection and maintenance has to be high compared to the expected probability of occurrence of the fault. The longer the time that one SINGLE FAULT CONDITION remains present before being detected and rectified, the greater the probability that a second fault will arise. Therefore, the MANUFACTURER might need to explicitly consider the detection time in relation to the occurrence of a possible second fault as part of RISK ANALYSIS.

Non-exclusive examples of the categories a) to c) are:

– REINFORCED or DOUBLE INSULATION;

– CLASS I ME EQUIPMENT in case of a fault in BASIC INSULATION;

– abnormal indications of displays, defect in a redundant suspension cord causing excessive noise or friction;

– deterioration of a flexible PROTECTIVE EARTH CONDUCTOR that is moved in NORMAL USE.

Subclause 4.8 – Components of ME EQUIPMENT

Resistors bridging a MEANS OF PROTECTION

A resistor or group of series connected resistors (two or more), can bridge one or two MEANS OF PROTECTION (MOOP or MOPP), providing the following is observed:

– the resistor or group of resistors has a voltage rating twice the value of the WORKING VOLTAGE across the MEANS OF PROTECTION;

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– the resistor or group of resistors can withstand dielectric strength tests according to 8.8.3 and considering the expected transient voltages that the component(s) will be subjected to during NORMAL USE over the EXPECTED SERVICE LIFE;

– the resistor or group of resistors has a power rating twice that expected in NORMAL USE;

– the resistor or group of resistors have a resistance value such that TOUCH CURRENT, PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT requirements are not exceeded;

– the resistor or group of resistors have a construction that maintains the MOP separation requirements for CREEPAGE DISTANCE and AIR CLEARANCE (For a series group, separation at each component is additive making up the required separation.);

– the resistor or group of resistors are constructed such that their inductance is low;

– the resistor or group of resistors have a construction that cannot fail short-circuit; and

– when using a group of resistors they all need have the same resistance value and the voltage and power doubling requirement applies also to each component based on the expected WORKING VOLTAGE across that resistor in NORMAL USE.

Subclause 4.9 – Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISITCS in ME EQUIPMENT

The first step to determine a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS is to conduct a RISK ANALYSIS to find those characteristics that are required to maintain BASIC SAFETY or ESSENTIAL PERFORMANCE. Having done this, the appropriate component can be selected. Reference can be made to IEC component standards as part of the determination of the characteristics required.

TYPE TESTS of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS are only part of the required determination of suitability. Since a particular COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS has to function as intended or a HAZARD is likely to occur, additional considerations include as appropriate:

– continuous surveillance as part of the manufacturing PROCESS and also after assembly into the end product;

– particular characteristics of the device concerned;

– lot testing;

– calibration;

– control of manufacturing defects;

– maintenance;

– EXPECTED SERVICE LIFE of equipment;

– use of relevant component standards;

– failure mode characteristics;

– environmental conditions;

– anticipated misuse of equipment;

– interaction with other equipment.

Subclause 4.10 – Power supply

An alternating voltage is considered in practice to be sinusoidal if any instantaneous value of the waveform concerned differs from the instantaneous value of the ideal waveform at the same moment by no more than ± 5 % of the peak value of the ideal waveform.

A polyphase voltage system is considered to be symmetrical if neither the magnitude of its negative sequence components nor the magnitude of its zero sequence components exceeds 2 % of the magnitude of its positive sequence components.

A polyphase supply system is considered to be symmetrical if, when supplied from a symmetrical voltage system, the resulting current system is symmetrical. That is, the magnitude of neither the negative sequence current components nor the zero sequence

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current components exceeds 5 % of the magnitude of the positive sequence current components.

Clause 5 – General requirements for testing ME EQUIPMENT

In ME EQUIPMENT there could be many pieces of insulation, components (electrical and mechanical) and constructional features in which a failure would not produce a HAZARD to PATIENT, OPERATOR or surroundings, even though causing a deterioration in or a failure of performance of ME EQUIPMENT.

Subclause 5.1 – TYPE TESTS

The RISK MANAGEMENT PROCESS identifies the RISK CONTROL measures that are necessary to ensure that the ME EQUIPMENT is safe.

Unless otherwise specified in this standard, tests should not be repeated. This applies particularly to the dielectric strength tests, which are performed only at the MANUFACTURER'S site or in test laboratories.

In order to ensure that every individually produced item of ME EQUIPMENT conforms to this standard, the MANUFACTURER or installer should carry out such measures during manufacture or installation assembly as to ensure that each item satisfies all requirements even if it is not completely tested individually during manufacture or installation.

Such measures could take the form of:

a) production methods (to ensure good manufacturing output and constant quality) where such quality would be related to safety;

b) production tests (routine tests) performed on every produced item;

c) production tests performed on a production sample where results would justify a sufficient confidence level.

Production tests need not be identical with TYPE TESTS, but can be adapted to manufacturing conditions and possibly invoking less RISK for the quality of the insulation or other characteristics important for BASIC SAFETY and ESSENTIAL PERFORMANCE.

Production tests would, of course, be restricted to settings (possibly derived from TYPE TESTS) that would provoke the worst case situation.

Depending upon the nature of ME EQUIPMENT, production methods or tests could concern critical insulation of the MAINS PART, of the PATIENT CONNECTIONS and the insulation or the separation between these parts.

Suggested test parameters could be LEAKAGE CURRENT and dielectric strength.

When applicable, the continuity of protective earthing can be a major test parameter.

Guidance on general testing procedures that can be used with this standard is given in IEC TR 62354 [66].

This standard uses several terms to describe fault conditions that could be encountered. They are:

SINGLE FAULT CONDITION

The SINGLE FAULT CONDITION is defined in 3.116 to describe those conditions where "a single means for reducing a RISK is defective" or "a single abnormal condition is present". Possible SINGLE FAULT CONDITIONS are listed in this standard and can affect verifiable values like CREEPAGE DISTANCES, protective earth path impedances, LEAKAGE CURRENTS, etc.

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Faults not leading to a SINGLE FAULT CONDITION

Compared with SINGLE FAULT CONDITIONS, this standard does not have verifiable requirements for faults not leading to a SINGLE FAULT CONDITION. This means this standard does not give guidance how reliable it is that faults can be prevented.

Combination of simultaneous independent faults

Because there are no reliable verifiable requirements defined in this standard for the prevention of faults, all possible simultaneous faults should be considered in accordance with 4.7.

Where a SINGLE FAULT CONDITION remains undetected (e.g. bridging of one MEANS OF OPERATOR PROTECTION), further simultaneous faults should be considered in accordance with 4.7.

NOTE For additional guidance, see IEC 60513:1994.

The worst cases of simultaneous faults are those which lead to most dangerous results. The wording of the standard is used to avoid conducting all possible simultaneous fault tests, because many of them could be covered by worst case testing.

Subclause 5.2 – Number of samples

The TYPE TEST sample or samples need to be representative of the units intended for the RESPONSIBLE ORGANIZATION.

Subclause 5.7 – Humidity preconditioning treatment

According to IEC 60529, the ENCLOSURE of ME EQUIPMENT that is RATED IPX8 prevents, under stated conditions, the entry of an amount of water where its presence could result in a HAZARD.

The test condition as well as the acceptable amount and location of water are to be defined in particular standards. If no ingress of water is tolerated (sealed ENCLOSURES) the application of the humidity preconditioning treatment is inappropriate.

Parts sensitive to humidity, normally used in controlled environments and which do not influence ~~safety~~ BASIC SAFETY and ESSENTIAL PERFORMANCE, need not be subjected to this test. Examples are: high-density storage media in computer-based systems, disc and tape drives, etc.

To prevent condensation when ME EQUIPMENT is placed in the humidity cabinet, the temperature of such a cabinet should be equal to or slightly lower than the temperature of the ME EQUIPMENT when it is introduced. To avoid the need for a temperature stabilization system for the air in the room outside the cabinet, the cabinet air temperature during the treatment is adapted to that of the outside air within the limits of the range of +20 °C to +32 °C and then "stabilized" at the initial value. Although the effect of the cabinet temperature on the degree of absorption of humidity is recognized, it is felt that the reproducibility of test results is not impaired substantially and the cost-reducing effect is considerable.

Subclause 5.9 – Determination of APPLIED PARTS and ACCESSIBLE PARTS

Except in special cases, such as PATIENT supports and waterbeds, contact with ME EQUIPMENT is supposed to be made with:

– one hand, simulated for LEAKAGE CURRENT measurements by a metal foil of 10 cm x 20 cm (or less if the total ME EQUIPMENT is smaller);

– one finger, straight or bent in a natural position, simulated by a test finger provided with a stop plate;

– an edge or slit that can be pulled outwards allowing subsequent entry of a finger, simulated by a combination of test hook and test finger.

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Subclause 5.9.2.1 – Test finger

An ACCESS COVER is a part of the ENCLOSURE that can be removed in order to allow access to parts of electrical equipment for purposes of adjustment, inspection, replacement or repair. It is presumed that parts that can be removed without the use of a TOOL are intended to be replaced by any OPERATOR, not only by SERVICE PERSONNEL, even if this is not described in the instructions for use. OPERATORS other than SERVICE PERSONNEL might not be as well trained or experienced in good safety practices as SERVICE PERSONNEL. Therefore, extra safety precautions are needed to prevent accidental contact with hazardous voltages. That is why parts such as lamps, fuses, and fuseholders that can be removed without the use of a TOOL are to be removed before determining which parts inside the ACCESS COVER are to be considered ACCESSIBLE PARTS.

Fuseholders where the fuselink is held in a cap that can be removed without use of a TOOL are a special concern. If the fuselink does not come out when the cap is removed, the OPERATOR could be inclined to try to remove it by gripping the end of the fuselink with the fingers. The OPERATOR could try to insert a new fuselink into the fuseholder without first inserting it in the cap. Both cases can be considered reasonably foreseeable misuse. This should be taken intoconsideration with assessing what parts are accessible.

The reader is referred to IEC 60127-6 [7] for more information on fuseholders.

Clause 6 – Classification of ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT can have a multiple classification.

Subclause 6.2 – Protection against electric shock

The term “Class III equipment” is used in some other standards to identify equipment that is powered from a safety extra-low voltage (SELV) mains supply system. The term Class III equipment is not formally used in this standard. The BASIC SAFETY of Class III equipment is critically dependent on the installation and on other Class III equipment connected thereto. These factors are outside the control of the OPERATOR and this is considered to be unacceptable for ME EQUIPMENT. Additionally, limitation of voltage is not sufficient to ensure safety of the PATIENT. For these reasons, this standard does not recognize Class III construction.

Subclause 6.3 – Protection against harmful ingress of water or particulate matter

It should be noted that compliance with the requirements of this standard automatically allows MANUFACTURERS to rate ME EQUIPMENT as IP2X because the requirements of IEC 60529 for this rating are the same as the accessibility requirements (see 5.9).

Subclause 6.6 – Mode of operation

CONTINUOUS OPERATION and non-CONTINUOUS OPERATION cover the range of operating modes of virtually all equipment. ME EQUIPMENT that remains plugged into the SUPPLY MAINS continuously but is operated intermittently should be RATED for non-CONTINUOUS OPERATION, have the appropriate indication of on/off times in the ACCOMPANYING DOCUMENTS and markings on the ME EQUIPMENT (see 7.2.11).

Subclause 7.1.1 – USABILITY of the identification, marking and documents

For ME EQUIPMENT to be well designed, its markings and ACCOMPANYING DOCUMENTS should be clear, consistent, and help to reduce potential use error. Thus, markings and ACCOMPANYING DOCUMENTS should undergo the same rigorous evaluation as other OPERATOR-ME EQUIPMENT interface elements.

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Subclause 7.1.2 – Legibility of markings

Markings on ME EQUIPMENT are expected to be CLEARLY LEGIBLE by an OPERATOR over the range of normal illumination levels where the ME EQUIPMENT is typically operated. The levels used in this test are derived from the following recommended illumination levels for use in interior lighting design [51]:

– 100 lx to 200 lx is recommended for working spaces where visual tasks are performed only occasionally;

– 500 lx to 1000 lx is recommended for visual tasks of small size or reading medium-pencil handwriting;

– 1 000 lx to 2 000 lx is recommended for visual tasks of low contrast or very small size, e.g. reading handwriting in hard-pencil on poor-quality paper.

If markings are not legible to the OPERATOR under the expected conditions of use, there would be an unacceptable RISK.

The Minimum Angle of Resolution (MAR) is a visual acuity measurement method developed as an improvement on the long-used Snellen scale. The values are express as a logarithm of the Minimum Angle of Resolution. Log MAR can be calculated from the Snellen scale, i.e. log MAR = log(6/6) = 0 for normal vision.

The Jaeger test card is used for determining near vision. N6 corresponds to reading at a distance of 0,87 m from the face.

An ambient light level of 500 lx is recommended for conducting the visual acuity examination.

If a recommended minimum font size is to be considered, then a readable font size is a function of reading distance and the resulting visual angle of the marking image presented to the retina of the eye. Calculations of visual angle in minutes of arc are found in ANSI/AAMI HE-75:2009 [71], subclause 6.2.2.6.5, Table 6.2. Using a minimal acceptable visual angle of 12 minutes of arc, a font size of 9 would be recommended for a reading distance of one meter and a font size of 6 for a typical reading distance of 0,7 m.

Subclause 7.1.3 – Durability of markings

The rubbing test is performed with distilled water, ~~methylated spirits~~ ethanol 96 % and isopropyl alcohol.

Ethanol 96% is defined in the European Pharmacopoeia as a reagent in the following terms: C_2H_6O (MW46.07).

Isopropyl alcohol is defined in the European Pharmacopoeia as a reagent in the following terms: C_3H_8O (MW60.1).

Subclause 7.2.2 – Identification

This subclause is intended to apply to any detachable component when misidentification could ~~present a HAZARD~~ result in a HAZARDOUS SITUATION. For examples, normal consumables would probably need to be identified, but a cosmetic cover would not need to be identified.

Although a MODEL OR TYPE REFERENCE usually denotes a certain performance specification, it might not denote the exact construction, including the applied components and materials. ~~If this is required,~~ The MODEL OR TYPE REFERENCE ~~can be~~ is supplemented by a serial number or lot or batch identifier. The serial number or lot or batch identifier can be used for other purposes such as providing traceability in case the MANUFACTURER needs to take a corrective action.

~~Indication of a manufacturing series only might not be sufficient if local requirements require individual identification.~~

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It is characteristic of software that different versions can run on a PEMS. The identification of the software will often be on the user interface, although this might not be possible e.g. where the software does not have a user interface. Identification of the software could need special tools. For this reason, the requirement permits the identification to be only available to designated people.

Subclause 7.2.3 – Consult ACCOMPANYING DOCUMENTS

It is not intended in every case when the instructions for use contain warnings, that the ME EQUIPMENT be marked with ~~IEC 60878 Safety 01~~ ISO 7010-M002 (see Table D.2, safety sign 10). Too many warnings and unnecessary warnings are counterproductive. Only when the MANUFACTURER, as a RISK CONTROL measure for a specific RISK, decides to mark the ME EQUIPMENT to instruct the OPERATOR to read the instructions for use, should safety sign ~~IEC 60878 Safety 01~~ ISO 7010-M002 be used.

Subclause 7.2.4 – ACCESSORIES

RESPONSIBLE ORGANIZATIONS and OPERATORS need to be able to identify ACCESSORIES in order to know which ones can be used without impairing BASIC SAFETY or ESSENTIAL PERFORMANCE. A MODEL OR TYPE REFERENCE alone is not sufficient, because different MANUFACTURERS might use the same number. The name marked on the ACCESSORY could be that of the ME EQUIPMENT MANUFACTURER or a different name.

Subclause 7.2.10 – APPLIED PARTS

According to the second edition of this standard, the marking could be either on the APPLIED PART itself or adjacent to the connection point. Neither location is satisfactory in all cases.

Where a conductor that is not separated from PATIENT CONNECTIONS extends up to the point inside ME EQUIPMENT where an isolation barrier exists, a TYPE BF or TYPE CF marking on the APPLIED PART itself could mislead the RESPONSIBLE ORGANIZATION or the OPERATOR into believing that isolation is built into the APPLIED PART itself. If, on the other hand, the classification depends on the particular APPLIED PART in use, a single marking on the connection point would be inaccurate and multiple marking would be confusing.

For DEFIBRILLATION-PROOF APPLIED PARTS, if protection against the effect of the discharge of a cardiac defibrillator is partly in the PATIENT cable, a warning to the OPERATOR is necessary because there ~~are~~ can be non-obvious ~~HAZARDS~~ HAZARDOUS SITUATIONS if the wrong cable is used. ~~HAZARDS~~ These HAZARDOUS SITUATIONS can include decreasing the defibrillation energy delivered to the PATIENT, damage to the ME EQUIPMENT with consequent loss of ESSENTIAL PERFORMANCE, or electric shock to the OPERATOR or other persons.

Subclause 7.2.12 – Fuses

Examples of marking for fuses complying with IEC 60127-1 are:

– T 315L, 250V
– T 315mAL, 250V
– F 1,25H, 250V
– F 1,25AH, 250V

The operating speed can be marked by the letter or colour codes in IEC 60127-1, which are as follows:

– very quick acting: FF, or black
– quick acting: F, or red
– medium time lag: M, or yellow
– time lag: T, or blue
– long time lag: TT, or grey

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Subclause 7.2.21 – Mass of MOBILE ME EQUIPMENT

MOBILE ME EQUIPMENT is intended to be transported from one location to another by its own wheels or equivalent means. For safety, it is important that the OPERATOR be aware of the total mass of the ME EQUIPMENT with its SAFE WORKING LOAD installed. This is important when moving the ME EQUIPMENT, and, for heavy ME EQUIPMENT, understanding any limitations on locations where the ME EQUIPMENT can be taken. The ME EQUIPMENT can have bins, shelves or drawers that might have their own maximum loading requirements. The marking on the ME EQUIPMENT needs to be sufficiently separate and distinct from any markings on the bins, shelves or draws to avoid confusing the OPERATOR as to what the marking applies.

Subclause 7.3.2 – HIGH VOLTAGE parts

HIGH VOLTAGE parts present a significant electric shock HAZARD to SERVICE PERSONNEL and others who could be required to work inside the ME EQUIPMENT while it is energized. Because the parts are inside the ENCLOSURE, the RISK is perceived to be substantially less than that for HIGH VOTAGE TERMINAL DEVICES located on the outside of the ME EQUIPMENT. Therefore, the "dangerous voltage" symbol (IEC 60417-5036) (~~DB:~~2002-10) (see Table D.1, symbol 24) is permitted as a marking to alert SERVICE PERSONNEL and others to the potential presence of these dangerous voltages. The MANUFACTURER is permitted to use ~~a safety sign 3~~ ISO 7010-W012 (see Table D.3, safety sign 3). The RISK MANAGEMENT PROCESS could determine that the safety sign is the most appropriate choice if the personnel exposed to the HAZARD have minimal training or might otherwise be unaware that HIGH VOLTAGE is present.

Subclause 7.3.4 – Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES

See the rationale for 7.2.12.

Subclause 7.3.5 – PROTECTIVE EARTH TERMINALS

This standard does not require marking of terminals for internal PROTECTIVE EARTH CONNECTIONS, but does not preclude it.

Subclause 7.4.1 – Power switches

If a marking is used for a toggle-type switch, the symbols for "on" () and "off" () [symbols 12 and 13 from Table D.1] should be used to indicate its ON and OFF positions.

For a push-button type switch, the appropriate marking will depend on the type of switch. For a push button switch with bistable positions, the symbol () [symbol 14 from Table D.1] should be used to indicate that both the ON and OFF positions are stable.

For a push button switch with a momentary ON position, the symbol () [symbol 15 from Table D.1] should be used to indicate that mains power is applied for only as long as the push button is depressed. As soon as the button is released the switch returns to the stable OFF position.

Subclause 7.4.2 – Control devices

The different positions of switches that control the functionality of the ME EQUIPMENT or a part of the ME EQUIPMENT, but do not control mains power to the ME EQUIPMENT or a part of the ME EQUIPMENT should also be marked in such a way as to clearly indicate the state of the control function. Any appropriate means including figures, letters, indicator lights, etc. can be used. If the marking includes symbols, the symbols for "on" for part of the equipment () and "off" for part of the equipment () [symbols 16 and 17 from Table D.1] can be used to indicate its ON and OFF positions.

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A switch or switch position by means of which the ME EQUIPMENT or part of the ME EQUIPMENT is switched on in order to bring it into the "stand-by" condition can be indicated by the stand-by symbol ( ) [symbol 29 from Table D.1]. This symbol is required by IEC 60950-1 to indicate the stand-by mode of the information technology equipment covered by that standard.

Subclause 7.8 – Indicator lights and controls

For colours of indicator lights see also IEC 60073 [5].

Colour alone should not be used to convey important information. A redundant means of conveying information such as shape, location, sound or marking is recommended.

Subclause 7.9.1 – General

It is important that ME EQUIPMENT or an ME SYSTEM is not unintentionally used in an application for which it is not intended by its MANUFACTURER.

The USABILITY ENGINEERING PROCESS requires the MANUFACTURER to develop an applications specification that includes the intended environments of use. The MANUFACTURER is required to supply a summary of this specification in the ACCOMPANYING DOCUMENTS. See 12.2.

Subclause 7.9.2.1 – General

RESPONSIBLE ORGANIZATIONS and OPERATORS frequently deal with many different types of ME EQUIPMENT. Because of the complexity of modern ME EQUIPMENT, the instructions for use are an important part of the ME EQUIPMENT. Some commonality in the structure for the instructions for use could help OPERATORS to find needed material quickly and easily. However, because of the diversity of ME EQUIPMENT covered by this standard, no one format will be equally applicable to all ME EQUIPMENT. ~~Therefore, the MANUFACTURER is encouraged, but not required, to use the sequence of topics in 7.9.2.2 to 7.9.2.16 as an outline when developing the instructions for use.~~

When considering if the PATIENT can act as an OPERATOR, the MANUFACTURER needs to take into account that the level of protection provided by this standard for the OPERATOR can be different from that for the PATIENT. For example, acceptable LEAKAGE CURRENT levels and accessible voltages values are higher for the OPERATOR than they are for the PATIENT. Instead of PATIENT LEAKAGE CURRENT, TOUCH CURRENT could be applied. Additionally the OPERATOR can have access to voltages up to 42,4 V peak a.c. or 60 V d.c.

Other conditions to consider include:

– Is the ME EQUIPMENT to be used under medical supervision or guidance?
– What is the health condition of the PATIENT?
– What treatment is being provided to the PATIENT?
– Are there special USABILITY considerations (see IEC 60601-1-6)?
– Is the ME EQUIPMENT to be used in the professional healthcare environment, the home healthcare environment (see IEC 60601-1-11 [55]) or the emergency medical service environment (see IEC 60601-1-12 [58])?
– Does the PATIENT have access to the instructions for use?
– Is adequate training of the PATIENT as an OPERATOR available?

The problem of languages used in markings and in ACCOMPANYING DOCUMENTS cannot be solved by IEC. Even a requirement that identifications and ACCOMPANYING DOCUMENTS have to be in the national languages cannot be upheld world-wide.

Subclause 7.9.2.2 – Warning and safety notices

For CLASS I ME EQUIPMENT, where operation from either a SUPPLY MAINS or an INTERNAL ELECTRICAL POWER SOURCE is specified, the instructions for use should state that the INTERNAL

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ELECTRICAL POWER SOURCE is to be used if the integrity of the PROTECTIVE EARTH CONDUCTOR or the protective earthing system in the installation is in doubt.

Subclause 7.9.2.6 – Installation

The instructions for use can contain a statement saying that the MANUFACTURER, assembler, installer or importer considers himself responsible for the effect on BASIC SAFETY, reliability and performance of the ME EQUIPMENT or ME SYSTEM only if:

– appropriately trained personnel carry out assembly operations, extensions, readjustments, modifications or repairs;

– the electrical installation of the relevant room complies with the appropriate requirements; and

– the ME EQUIPMENT or ME SYSTEM is used in accordance with the instructions for use.

Subclause 7.9.2.7 – Isolation from the SUPPLY MAINS

A plug and socket provide suitable means for isolation from the SUPPLY MAINS to satisfy 8.11.1 a), but they would not be suitable if they were not readily accessible when needed.

Subclause 7.9.2.19 – Unique version identifier

MANUFACTURERS frequently issue multiple revisions of the instructions for use. RESPONSIBLE ORGANIZATIONS and OPERATORS need to be able to determine if the instructions for use they have are current. This is particularly important when dealing with PEMS software that can be updated in the environment of use. Providing a date of issuance is a widely accepted method for identifying versions of a document. The MANUFACTURER decides what level of detail is appropriate with month and year being common for printed material. However, greater granularity might be required, particularly for material distributed electronically. The MANUFACTURER could include a revision number when appropriate.

Subclause 7.9.3.1 – General

According to the INTENDED USE of ME EQUIPMENT, the MANUFACTURER should specify the permissible environmental conditions for which a HAZARD is not induced. Environmental conditions such as the following are expected to be considered:

– the effect of humidity;

– the effect of temperature;

– the effect of atmospheric pressure;

– the effect of shock and vibration;

– the effect of ultra-violet radiation.

– the effect of the temperature of the water for water cooled ME EQUIPMENT;

– the effect of pollution.

Accuracy and precision are not possible to define in this standard. These concepts have to be addressed in particular standards.

The values listed below were used in the second edition of IEC 60601-1 to describe the range of environmental conditions over which ME EQUIPMENT was required to be safe.

a) an ambient temperature range of + 10 °C to + 40 °C;

b) a relative humidity range of 30 % to 75 %;

c) an atmospheric pressure range of 70,0 kPa to 106,0 kPa;

d) a temperature of the water at the inlet of water-cooled ME EQUIPMENT not higher than 25 °C.

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These environmental conditions were based on the conditions in buildings without air-conditioning in climates where the ambient temperature occasionally reaches + 40 °C.

In the second edition of IEC 60601-1, the ME EQUIPMENT had to be safe when operated under the above conditions but it only needed to be fully operable under conditions specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

This edition specifies particular environmental conditions for some requirements and tests. Where this is not the case, ME EQUIPMENT has to remain safe and operate correctly over the range of environmental conditions specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

Attention is drawn to the fact that there was always a problem to apply a 40 °C environmental condition to a ME EQUIPMENT in cases where the APPLIED PART needed to operate at temperatures close to the 41 °C limit.

The second edition of IEC 60601-1 specified the following range of environmental conditions for transport and storage of ME EQUIPMENT unless otherwise specified by the MANUFACTURER:

– an ambient temperature range of - 40 °C to + 70 °C;
– a relative humidity range of 10 % to 100 %, including condensation;
– an atmospheric pressure range of 50 kPa to 106 kPa.

Amendment 2 to the second edition replaced the above list with a requirement that the MANUFACTURER state the permissible transport and storage conditions. However, in the absence of other information, the above list can serve as a useful starting point in determining the permissible limits.

Information on environmental parameters and a limited number of their severities within the range of conditions met by electrotechnical products when being transported, stored, installed and used can be found in the IEC 60721 series [18].

For PERMANENTLY INSTALLED high power ME EQUIPMENT, it might be necessary to control the voltage drop in the customer installation to prevent input voltage getting below the minimum normal voltage due to local conditions. Control can be done by specifying the required apparent impedance of the SUPPLY MAINS.

Subclause 7.9.3.4 – Mains isolation

SERVICE PERSONNEL need to know how to isolate the ME EQUIPMENT from the SUPPLY MAINS. This is not always obvious, particularly if there is a switch in the MAINS PART that does not meet the requirements of 8.11.

Clause 8 – Protection against electrical HAZARDS from ME EQUIPMENT

The fundamental principle for protection against electric shock is that the voltage or current between any accessible surface and any other accessible surface or earth is low enough not to ~~present a HAZARD~~ result in a HAZARDOUS SITUATION, in all relevant circumstances including NORMAL CONDITION and SINGLE FAULT CONDITION.

Requirements for achieving protection have been formulated in various ways in IEC basic safety standards, in previous editions of this standard, and in other IEC product standards.

In order for the fundamental principle to be satisfied:

a) parts that are “live” (as defined in the second edition of this standard) or “hazardous live” (as defined in some other standards, such as IEC 61140 [23] and IEC 61010-1 [22]) have to be inaccessible (but see below regarding problems in identifying what is “live”) and

b) ACCESSIBLE PARTS including APPLIED PARTS have to be not “live” / “hazardous live.”

NOTE The term “live” was defined in the second edition of this standard as, “State of a part which, when connection is made to that part, can cause a current exceeding the allowable LEAKAGE CURRENT (specified in Sub-

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clause 19.3) for the part concerned to flow from that part to earth or from that part to an ACCESSIBLE PART of the same EQUIPMENT.

These two requirements are in principle equivalent but some standards state both of them.

These requirements in turn imply that:

c) ACCESSIBLE PARTS including APPLIED PARTS have to be separated from certain internal live parts: in general two separate MEANS OF PROTECTION are necessary, one to provide separation in NORMAL CONDITION and a second to maintain BASIC SAFETY in SINGLE FAULT CONDITION, and

d) LEAKAGE CURRENTS (and possibly also voltages and energies) have to be below acceptable limits.

Most standards include explicit requirements covering each of these aspects of providing protection. For example the first and second editions of this standard dealt with a) in Clause 16, with b) and d) in Clause 19 and with c) in Clauses 17, 18 and 20.

Requirement a) has typically been formulated as a requirement for the provision of ENCLOSURES or barriers to prevent contact with internal hazardous live parts. However it can alternatively be formulated in terms of the determination of which parts are accessible. Anyway the adequacy of ENCLOSURES or barriers is determined by use of the relevant test fingers and probes.

Application of the above approach to ME EQUIPMENT has presented some difficulties. The limits for voltage and current depend on how, if at all, the part(s) concerned can be connected to a PATIENT, e.g. directly to the heart, directly to other parts of the body, or indirectly via the OPERATOR. This has led to difficulties in identifying which parts are “live” parts.

The definition of “live” in the second edition of this standard refers to the allowable LEAKAGE CURRENT. The definition is therefore difficult to apply to internal parts for which no particular LEAKAGE CURRENT limits are specified.

Certain parts could be regarded as “live” (within the definition of the second edition of this standard) for some purposes and at the same time as not “live” for other purposes. For example an internal part that can source a current of, say, 200 μA has to be separated from all ACCESSIBLE PARTS, including PATIENT CONNECTIONS in NORMAL CONDITION.

The separation from PATIENT CONNECTIONS of TYPE CF APPLIED PARTS has to remain effective in SINGLE FAULT CONDITION, because a current of 200 μA from these is not permissible. The same part can however become connected to other ACCESSIBLE PARTS and PATIENT CONNECTIONS in SINGLE FAULT CONDITION.

Thus two MEANS OF PROTECTION (DOUBLE INSULATION or REINFORCED INSULATION) would be needed between such a part and the PATIENT CONNECTIONS of TYPE CF APPLIED PARTS, but a single MEANS OF PROTECTION (such as BASIC INSULATION alone) would be acceptable between such a part and other ACCESSIBLE PART.

Furthermore, requirements that specify the necessary separation between parts that are accessible and parts that are “live” do not easily take account of parts that are not “live” but can become “live,” such as the parts of a floating circuit that become “live” when a connection is made to another part of the same circuit.

Consider, for example, the simple situation shown in Figure A.10.

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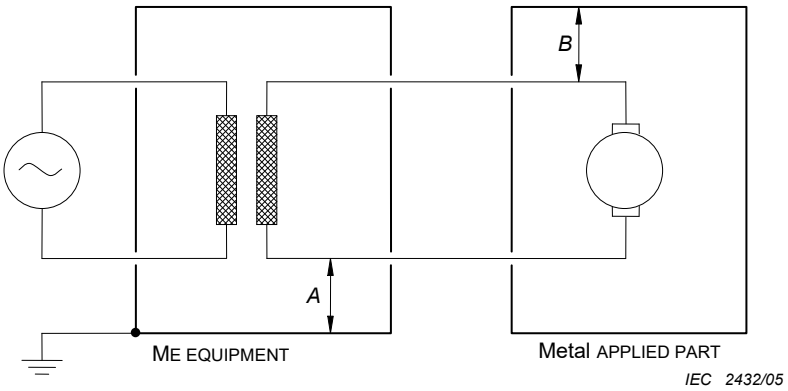


Figure A.10 – Floating circuit

The APPLIED PART has a metal ENCLOSURE that is not PROTECTIVELY EARTHED. If there is a direct connection at point A, then the other end of the SECONDARY CIRCUIT is "live," and even the first edition of this standard would have required DOUBLE INSULATION or REINFORCED INSULATION at point B.

If, instead, there is a direct connection at point B, the first edition would have required only BASIC INSULATION at point A; but this was dealt with in the second edition by adding Subclause 20.2 B-e, which requires DOUBLE INSULATION or REINFORCED INSULATION at point A.

If however there is some insulation at both points A and B, then no part of the SECONDARY CIRCUIT is "live" according to the definition in the second edition, so the second edition of this standard specifies no requirements for that insulation, which can therefore be minimal. The German National Committee of the IEC discovered this problem in 1993, unfortunately just too late for it to be dealt with in the second (and final) amendment to the second edition of this standard. The approach adopted in this edition is intended to overcome this problem.

The formulation proposed for the third edition of this standard is to specify:

1) how to determine which parts are to be regarded as ACCESSIBLE PARTS (by inspection and where necessary by the use of appropriate test probes and fingers);
2) the permissible limits for voltage/current/energy in NORMAL CONDITION and relevant SINGLE FAULT CONDITIONS; these limits depend on the possible circumstances of connection to a PATIENT or to an OPERATOR;
3) that NORMAL CONDITION includes short circuit of any insulation, AIR CLEARANCE or CREEPAGE DISTANCE or impedance which does not comply with specified requirements for the relevant WORKING VOLTAGE, and open circuit of any earth connection which does not comply with the requirements for PROTECTIVE EARTH CONNECTIONS; and
4) that SINGLE FAULT CONDITIONS include short circuit of any insulation, AIR CLEARANCE or CREEPAGE DISTANCE which does comply with specified requirements for the relevant WORKING VOLTAGE, short circuit of any relevant component, and open circuit of any earth connection which does comply with the requirements for PROTECTIVE EARTH CONNECTIONS.

This approach avoids the need to include explicit separate requirements for particular protective means, as specified in existing IEC standards. Arguably it could avoid even a general requirement for two MEANS OF PROTECTION, as presently specified, but the working group considered that such a requirement is desirable.

Where requirements from the second edition that used the defined term "live" have been retained, they have been re-phrased so as not to use this term.

Generally, protection is obtained by a combination of:

– limitation of voltage or energy, or protective earthing (see 8.4 and 8.6);
– enclosing or guarding of energized circuits (see 5.9);
– insulation of adequate quality and construction (see 8.5).

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The dielectric strength requirements are included to check the quality of the insulation material used at different places in the ME EQUIPMENT.

Subclause 8.1 – Fundamental rule of protection against electric shock

Subclause 8.1 a)

Insulation not complying with 8.8, spacing less than specified in 8.9, etc. are not MEANS OF PROTECTION, but they could influence the voltages or LEAKAGE CURRENTS appearing on ACCESSIBLE PARTS including APPLIED PARTS. Measurements might therefore need to be made with such parts intact or bypassed, whichever is the worse case.

As there are in general no integrity requirements for signal connections, interruption of a functional earth connection has to be considered as a NORMAL CONDITION.

Subclause 8.1 b)

LEAKAGE CURRENTS are not generally measured in the SINGLE FAULT CONDITION of breakdown of BASIC INSULATION in CLASS I EQUIPMENT because either the LEAKAGE CURRENTS in this case flow only during the time before a fuse or OVER-CURRENT RELEASE operates or the use of an isolated power supply limits the LEAKAGE CURRENTS to safe values. Exceptionally, LEAKAGE CURRENTS are measured during short circuiting of BASIC INSULATION in cases where there are doubts concerning the effectiveness of PROTECTIVE EARTH CONNECTIONS inside the ME EQUIPMENT (see 8.6.4 b)).

In certain instances the short-circuit condition is not necessarily the worst case. As an example, an overvoltage device, intended to prevent damage to insulation, could fail in the open-circuit condition thereby no longer rendering its safety function. This could lead to damaged insulation. It is recognized that in most cases in this subclause, the open-circuit condition is superfluous but for select components it was acknowledged that the open-circuit condition is a valid failure mode. Components of ME EQUIPMENT are also addressed in 4.8.

With regard to the presence of the MAXIMUM MAINS VOLTAGE on an unearthed ACCESSIBLE PART including APPLIED PARTS, see the rationales for 8.5.2.2 and 8.7.4.7 d).

If ME EQUIPMENT were configured as shown in Figure A.11, interruption of the connection would result in excessive TOUCH CURRENT. This situation is therefore one of the SINGLE FAULT CONDITIONS that should be investigated.

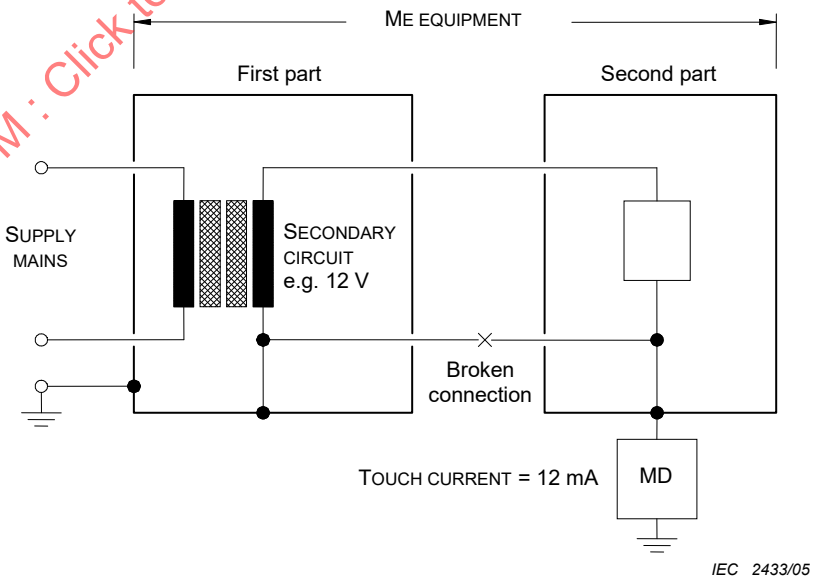


Figure A.11 – Interruption of a power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES

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Subclause 8.3 – Classification of APPLIED PARTS

Subclause 8.3 a)

ME EQUIPMENT intended for DIRECT CARDIAC APPLICATION having one or more TYPE CF APPLIED PARTS could have one or more additional TYPE B APPLIED PARTS or TYPE BF APPLIED PARTS that can be applied simultaneously (see also 7.2.10).

Similarly ME EQUIPMENT could have a mixture of TYPE B APPLIED PARTS and TYPE BF APPLIED PARTS.

Subclause 8.3 b)

Most particular standards developed for kinds of ME EQUIPMENT that have PATIENT electrodes require the APPLIED PARTS to be TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS. For similar kinds of ME EQUIPMENT for which no particular standards are available, it is better to include such a requirement in this standard than to allow such APPLIED PARTS to be TYPE B APPLIED PARTS. The TYPE B APPLIED PART classification is mainly used, in practice, for PATIENT supporting ME EQUIPMENT such as X-ray tables, not for PATIENT electrodes.

~~**Subclause 8.3 d)**~~

~~Parts identified according to 4.6 as needing to be subject to the requirements for APPLIED PARTS (except for marking) will typically contact PATIENTS less frequently than APPLIED PARTS, so the benefits of electrical separation from earth would be less. However in some cases the RISK MANAGEMENT PROCESS could identify a need for such parts to satisfy the requirements for TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS. This requirement reflects the majority view of the National Committees that responded to an inquiry on this subject during the preparation of this edition.~~

Subclause 8.4.1 – PATIENT CONNECTIONS intended to deliver current

This standard does not specify any limits for currents that are intended to produce a physiological effect in the PATIENT, but particular standards can do so. Any other currents flowing between PATIENT CONNECTIONS are subject to the specified limits for PATIENT AUXILIARY CURRENT.

Subclause 8.4.2 – ACCESSIBLE PARTS including APPLIED PARTS

Subclause 8.4.2 b)

It is presumed that TOUCH CURRENT can reach the PATIENT by chance contact through various paths, including a path via the OPERATOR. The limits for TOUCH CURRENT therefore apply to all ACCESSIBLE PARTS except PATIENT CONNECTIONS, which are covered by 8.4.2 a), and parts that satisfy the conditions specified in 8.4.2 c).

Subclause 8.4.2 c)

There is little or no justification for the difference in the second edition between the cases where there is a cover that is removable without a TOOL and where there is no cover. The limit values have been harmonized with IEC 60950-1:~~2001~~2005 because Information Technology (IT) equipment is commonly used in ME SYSTEMS, and the values in IEC 60950-1 are not much different from those in the second edition of this standard. (60 V dc is the same, and 42,4 V peak is not much different from 25 V r.m.s.).

Essentially OPERATOR protection is now based on IEC 60950-1 and, therefore, we need to incorporate the protection requirements from that standard. Previously IEC 60601-1 did not have a requirement for protection against hazardous energy but there is a definite RISK from burn, fire and flying debris. This is now addressed using the requirement from IEC 60950-1:~~2001~~2005. The limit values have been established for many years in IEC 60950 and its predecessor standards. The maximum available energy is allowed to exceed 240 VA during the first 60 s after contact with the ACCESSIBLE PART (e.g. it takes time for the current

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limit circuit in a power supply to operate and during this time the hazardous energy level can be exceeded).

Subclause 8.4.2 d)

As well as parts that are determined to be ACCESSIBLE PARTS in accordance with 5.9, electrical contact with internal parts is supposed to be made with:

– a pencil or pen, held in a hand, simulated by a guided test pin;

– a necklace or similar pendant, simulated by a metal rod suspended over openings in a top cover;

– a screwdriver for adjustment of a preset control by the OPERATOR, simulated by an inserted metal rod.

Subclause 8.4.3 – ME EQUIPMENT intended to be connected to a power source by a plug

The 45 μC limit is the same as that specified in IEC 60335-1, which is based on the limits in IEC 60479-1 [11]. It is comparable (though not exactly equivalent) to the 100 nF limit specified in the second edition of this standard. With regard to BASIC SAFETY there is no reason to specify a more stringent limit between the line and earth pins, as in the second edition.

Subclause 8.4.4 – Internal capacitive circuits

The limit has been changed from the 2 mJ specified in the second edition of this standard to the same value as specified in the previous subclause, because whatever is safe for an OPERATOR, or even a PATIENT, who touches the pins of a MAINS PLUG is also safe for someone who opens an ACCESS COVER to gain access to the inside of ME EQUIPMENT.

Subclause 8.5.1 – MEANS OF PROTECTION

Two MEANS OF PROTECTION can be provided in several ways. The following are examples:

1) PATIENT CONNECTIONS and other ACCESSIBLE PARTS are separated from parts different from earth potential by BASIC INSULATION only, but PROTECTIVELY EARTHED and have such a low internal impedance to earth that LEAKAGE CURRENTS do not exceed the allowable values in NORMAL CONDITION and SINGLE FAULT CONDITION.

2) PATIENT CONNECTIONS and other ACCESSIBLE PARTS are separated from parts different from earth potential by BASIC INSULATION and an intermediate PROTECTIVELY EARTHED metal part, which could be a fully enclosing metal screen.

3) PATIENT CONNECTIONS and other ACCESSIBLE PARTS are separated from parts different from earth potential by DOUBLE or REINFORCED INSULATION.

4) Impedances of components prevent the flow to PATIENT CONNECTIONS and other ACCESSIBLE PARTS of LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS exceeding the allowable values.

A survey of insulation paths is found in Annex J.

Previous editions of this standard also recognized the possibility of achieving separation by use of a PROTECTIVELY EARTHED intermediate circuit. However it is in general not possible for the whole of a circuit to be connected with very low impedance to the PROTECTIVE EARTH TERMINAL. Also, if one part of a circuit is earthed, other parts of the circuit are then different from earth potential, so have to be further separated from PATIENT CONNECTIONS and other ACCESSIBLE PARTS.

Air can form part or all of the BASIC INSULATION or SUPPLEMENTARY INSULATION.

In general DOUBLE INSULATION is preferable to REINFORCED INSULATION.

The first edition of this standard specified numerous pairs of parts between which separation was required, but the list was incomplete. It was expanded in the second edition but still remained incomplete, for example with regard to the situation illustrated in Figure A.10.

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Discussion in the working group at an early stage of the development of this edition established that test houses actually have to identify the various circuits inside ME EQUIPMENT and the various points at which separation could be needed. This edition therefore specifies this PROCEDURE explicitly.

The distinction between MEANS OF OPERATOR PROTECTION and MEANS OF PATIENT PROTECTION was introduced in response to concerns that the requirements of previous editions of this standard for insulation testing, CREEPAGE DISTANCES and AIR CLEARANCES were too stringent.

Many ME SYSTEMS incorporate equipment complying with IEC 60950-1. Also many kinds of ME EQUIPMENT incorporate parts, such as power supplies, that have been primarily designed for use in equipment complying with IEC 60950-1. This led some experts and National Committees to propose that the requirements of this standard be harmonized with IEC 60950-1 as far as possible.

However the test voltages and the minimum values of CREEPAGE DISTANCES and AIR CLEARANCES specified in IEC 60950-1 are derived from IEC 60664-1 and are based on assumptions about possible overvoltages in mains and other circuits, particularly the frequency of occurrence of various levels of overvoltage. According to the understanding of the working group experts who revised the corresponding requirements of this standard, compliance with the requirements of IEC 60664-1 or IEC 60950-1 leaves a RISK that transient insulation breakdown could occur with a frequency up to about once per year.

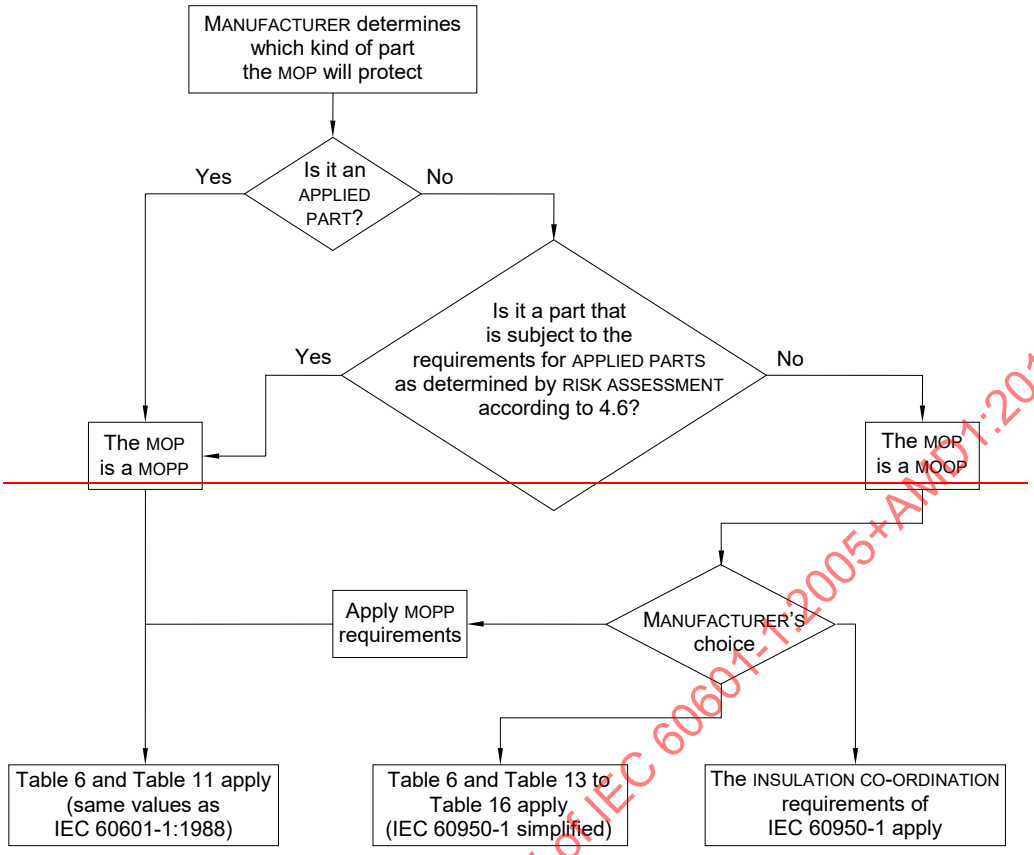
The probability of occurrence of an OPERATOR coming in contact with a relevant part and with earth at the moment when breakdown occurs is low, so the RESIDUAL RISK is acceptable for ME EQUIPMENT, just as it is for IT equipment. However the probability of occurrence of a PATIENT being in contact with an APPLIED PART and with earth is significantly higher. The working group therefore decided that a larger margin of safety should be applied where PATIENT safety is concerned. However there was no reliable basis for deciding what additional margin might be applied to the values from IEC 60664-1, so the same values that were specified in the second edition of this standard have been retained for MEANS OF PATIENT PROTECTION.

For MEANS OF OPERATOR PROTECTION this revision of the standard allows the MANUFACTURER three options (see Figure A.12). One option is to apply the requirements of IEC 60950-1 and to identify the appropriate installation category and pollution degree. Alternatively, the MANUFACTURER can apply the values in the tables, which have been derived from IEC 60950-1 on the basis of reasonable assumptions about the installation category and pollution degree. The third option is to treat the MEANS OF OPERATOR PROTECTION as if it were a MEANS OF PATIENT PROTECTION.

Y capacitors are used to reduce radio frequency interference by providing a low impedance path to earth for high frequency a.c. They are also used for bridging DOUBLE or REINFORCED INSULATION as part of the interference suppression regime. There are four types: Y1, Y2, Y3 and Y4. Y1 capacitors are designed for use with three phase mains and have a WORKING VOLTAGE of up to 500 V a.c. and a withstand voltage of 4 000 V a.c. Y2 capacitors are designed for use with single phase mains and have a WORKING VOLTAGE up to 300 V a.c. and a withstand voltage of ~~2 500~~ 1 500 V a.c. Y3 capacitors are similar to Y2 capacitors but have a WORKING VOLTAGE up to 250 V a.c. Y4 capacitors are designed for use with low voltage mainsand have a WORKING VOLTAGE up to 150 V a.c. and a withstand voltage of 1 000 V a.c. These capacitors are safety critical since they provide a leakage path to earth or across a barrier. So they must be certified and monitored by a recognised test house to IEC 60384-14, which serves to control their manufacture.

~~One Y1 capacitor can be used to provide two MOOP's but only one MOPP (PATIENTS need a higher level of protection than OPERATORS). A Y2 capacitor can be used to provide one MOOP only.~~

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MOP MEANS OF PROTECTION
MOPP MEANS OF PATIENT PROTECTION
MOOP MEANS OF OPERATOR PROTECTION

IEC 2434/05

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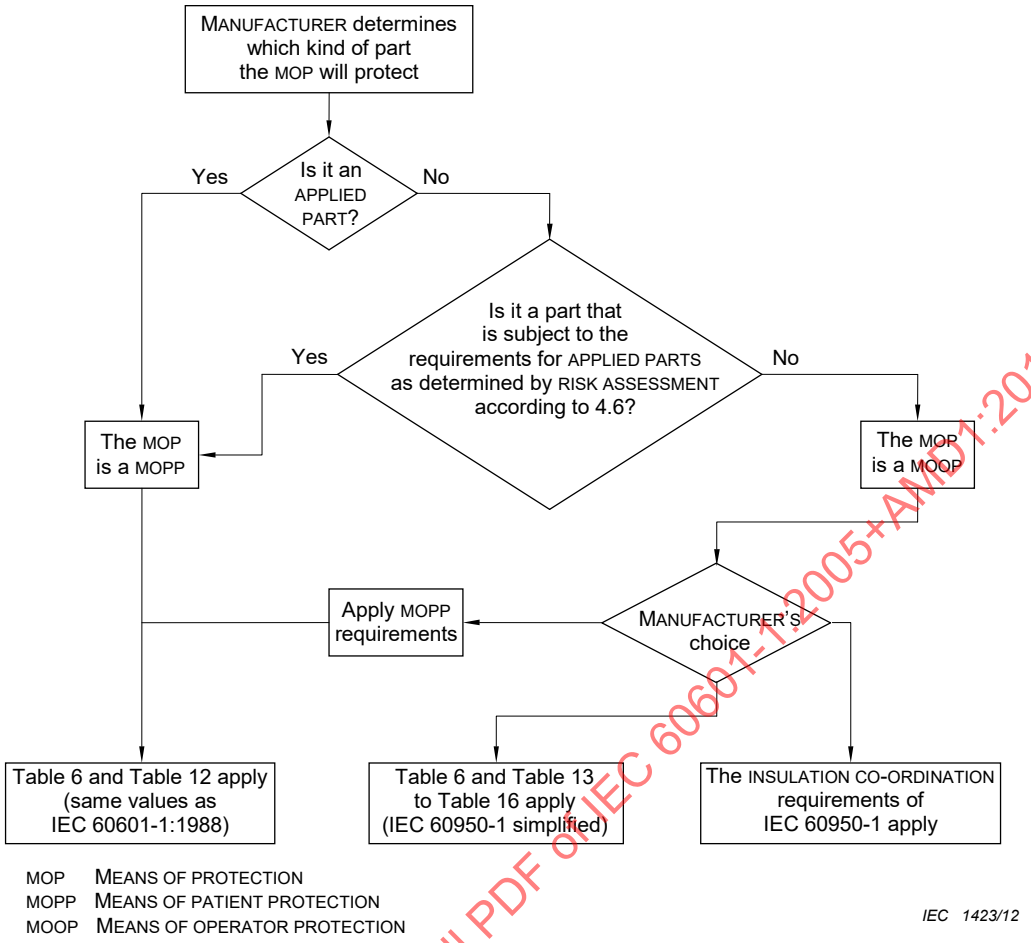


Figure A.12 – Identification of MEANS OF PATIENT PROTECTION and MEANS OF OPERATOR PROTECTION

Subclause 8.5.1.2 – MEANS OF PATIENT PROTECTION (MOPP)

When fitting Y capacitors across barriers, the dielectric strength requirement must be considered. For example, for voltages in the range of 212 V peak to 354 V peak, two MEANS OF PATIENT PROTECTION are required to be tested at 4 000 V a.c. This would then require the use of Y1 capacitors. Two Y2 capacitors in series would not withstand this voltage as they are rated at 1 500 V a.c. each. For voltages below 212 V peak, two Y2 capacitors would suffice as the dielectric strength requirement is 3 000 V a.c.

Subclause 8.5.2.1 – F-TYPE APPLIED PARTS

The essential feature of an F-TYPE APPLIED PART is its separation from other parts. This subclause specifies and quantifies the necessary degree of separation.

Multiple functions can be considered as multiple APPLIED PARTS (which have to be separated from each other by one MEANS OF PATIENT PROTECTION) or as one APPLIED PART. This is decided by the MANUFACTURER after assessing the RISK that earthing of one or more of the PATIENT CONNECTION(S) of one function could result in excessive LEAKAGE CURRENT through the PATIENT CONNECTION(S) of another function, in the condition in which an unintended voltage originating from an external source becomes connected to the PATIENT.

The 500 V r.m.s. limit for protective devices was already specified in the first edition of this standard. The original rationale is not known, but this voltage corresponds to the highest RATED voltage specified in 4.10.

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Subclause 8.5.2.2 – TYPE B APPLIED PARTS

This requirement addresses the possibility that an unintended voltage originating from an external source becomes connected to a part of the ME EQUIPMENT. In the absence of appropriate separation between such a part and PATIENT CONNECTIONS, an excessive PATIENT LEAKAGE CURRENT could result.

According to Clause 17 c) of the second edition of this standard, this requirement applied to all APPLIED PARTS, but in many cases it no longer applies:

– For F-TYPE APPLIED PARTS, the isolation required by 8.5.2.1 also covers this situation (but TYPE BF APPLIED PARTS require an additional test, as explained in the rationale to 8.7.4.7 d)).

– ~~The RISK cannot arise~~ A HAZARDOUS SITUATION cannot develop if either the ME EQUIPMENT part concerned or the PATIENT CONNECTIONS of a TYPE B APPLIED PART are PROTECTIVELY EARTHED. (Failure of the PROTECTIVE EARTH CONNECTION together with the appearance of the unintended voltage would be a double fault condition.)

– If the ME EQUIPMENT part concerned is physically contiguous with the APPLIED PART (for example a dental handpiece) the requirement does not apply if the RISK of contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low.

Subclause 8.5.2.3 – PATIENT leads or PATIENT cables

There are two sets of circumstances to guard against:

– firstly, for TYPE BF APPLIED PARTS and TYPE CF APPLIED PARTS, there should be no possibility of an accidental PATIENT-to-earth connection via any lead that can become detached from the ME EQUIPMENT; even for a TYPE B APPLIED PART an unwanted connection to earth can have an adverse effect on the operation of the ME EQUIPMENT;

– secondly, for all types of APPLIED PART, there should be no possibility of connecting the PATIENT accidentally to parts of ME EQUIPMENT or other conductive parts in the vicinity from which a current in excess of the allowable LEAKAGE CURRENT could flow.

An extreme case of the latter HAZARD would be a direct connection to the SUPPLY MAINS, resulting from insertion of the connector into a mains outlet or into the socket end of a DETACHABLE POWER SUPPLY CORD. It is essential to prevent this from occurring.

With certain combinations of PATIENT and MAINS CONNECTORS it will be possible to plug the PATIENT connector accidentally into the mains socket.

This possibility cannot reasonably be removed by dimensional requirements as to do so would make single-pole connectors excessively large. Such an incident is rendered safe by the requirement for the PATIENT connector to be protected by insulation having a CREEPAGE DISTANCE of at least 1,0 mm and a dielectric strength of at least 1 500 V. The latter on its own would not suffice as 1 500 V protection could easily be achieved by thin plastic foil that would not stand up to daily wear or to being pushed, possibly repeatedly, into a mains socket. For this reason also it can be seen that the insulation should be durable and rigid.

The wording of this requirement was modified from that in the second edition of this standard to avoid use of the phrases “conductive connection”, which was eliminated as a defined term. This change was a direct result of National Committee comments during the preparation of this edition.

According to the rationale in the second edition of this standard, the test in which the test finger is applied with a force of 10 N was intended “to check the strength of the insulating material.” This has now been supplemented by an explicit cross reference to 8.8.4.1.

In response to an enquiry, one National Committee stated that this test is “a mechanical test of the protective cover over the pin;” suggesting that the test was intended to apply specifically to one particular kind of connector design, in which the contact is surrounded by a movable sheath designed to allow contact with the correct mating connector but not with other parts.

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During the development of this edition of this standard, the question arose whether this test should be restricted to single-pole connectors, as in the second edition of this standard, or should apply to multi-pole connectors as well. Some multi-pole connectors are of similar shape to single-pole connectors and could similarly be inserted into a MAINS CONNECTOR, so the same considerations of adequacy of insulation apply equally. On the other hand, typical kinds of multi-pole connectors that are in common use cannot be inserted into a MAINS CONNECTOR, but would fail this test if they were subject to it, because the test finger can easily touch their contacts, even without the application of a 10 N force.

A further enquiry to the National Committees yielded a range of responses, with reasonable consensus on some questions but no consensus as to whether this test should apply to all connectors or should be restricted to single-pole connectors.

This test should certainly apply to a multi-pole connector that is of such shape and size that it could be inserted into a mains socket. In this case, the RISK is the same as with a single-pole connector.

Another reason for applying this test to some multi-pole connectors is that the test with the flat plate does not exhaustively assess the possibility of contact with conductive parts in the vicinity from which a current in excess of the allowable LEAKAGE CURRENT could flow. Almost any kind of connector, if detached from the ME EQUIPMENT or dropped, could possibly make contact with something besides the intended mating connector, but the RISK depends on the shape of the connector and the circumstances. In most cases the RISK is low. For example a typical "D" connector is likely to make contact with an earthed object only momentarily, whereas a straight pin could make contact for a prolonged period. However even prolonged contact with a metal object can result in a ~~HAZARD~~ HAZARDOUS SITUATION only if it occurs in combination with a fault or abnormal situation that allows an excessive current to flow through the PATIENT. The RISK is in all cases much less than the RISK if the connector can make contact with a mains socket. The requirements of this standard should be formulated in relation to the RISK. The standard should minimise RISK to the PATIENT, while allowing MANUFACTURERS a reasonable range of choice of connectors.

"Any connector" should be understood to include multiple contact connectors, several connectors and connectors in series.

The dimension of 100 mm diameter is not in the least important and merely serves to indicate the scale of the flat surface. Any sheet of conductive material larger than this would be suitable.

Subclause 8.5.3 – MAXIMUM MAINS VOLTAGE

Several requirements and tests of this standard relate to the possibility that an unintended voltage originating from an external source becomes connected to the PATIENT or to certain parts of the ME EQUIPMENT. The actual magnitude of such a voltage is unknown; but according to the second edition of this standard it was taken to be the highest RATED MAINS VOLTAGE, or for polyphase equipment the phase to neutral supply voltage. These values reflected a reasonable worst-case assumption that the actual unintended external voltage is unlikely to exceed the voltage of the SUPPLY MAINS in the location where the ME EQUIPMENT is used, and that ME EQUIPMENT is unlikely to be used in a location where the SUPPLY MAINS has a voltage higher than its highest RATED MAINS VOLTAGE. For INTERNALLY POWERED ME EQUIPMENT the value specified was (and remains) 250 V, because this is the highest commonly encountered phase-to-neutral voltage in locations where ME EQUIPMENT is used.

In early drafts of this edition, the corresponding wording only referred to a.c. SUPPLY MAINS. This mistake was pointed out during the comment period. Discussion of this comment confirmed that the requirements should not depend on whether the SUPPLY MAINS is a.c. or d.c., but revealed a further anomaly. If ME EQUIPMENT is specified for connection to an extra-low voltage (ELV) SUPPLY MAINS (for example 12 V in an ambulance) but not to any higher voltage SUPPLY MAINS, the external voltage assumed for test purposes would be only the ELV. Such ME EQUIPMENT could however be used in locations where a higher voltage SUPPLY MAINS is also installed. The wording has therefore been revised to remove this anomaly.

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If ME EQUIPMENT has a highest RATED supply voltage less than 100 V, it will necessarily be used in a special location where that supply is available, and we do not know what other supplies could also be present. Therefore the external voltage assumed for relevant tests is 250 V, as for INTERNALLY POWERED ME EQUIPMENT.

However ME EQUIPMENT having a highest RATED MAINS VOLTAGE of around 115 V is unlikely to be used in locations having higher voltage SUPPLY MAINS, so the external voltage assumed for relevant tests is equal to the highest RATED MAINS VOLTAGE, as in the second edition of this standard.

Subclause 8.5.4 – WORKING VOLTAGE

The dielectric strength test voltages specified in Table 6 are appropriate for insulation that is normally subjected to a continuous WORKING VOLTAGE and to transient overvoltages.

The WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION is the voltage to which the DOUBLE INSULATION as a whole is subjected, because either MEANS OF PROTECTION can be subjected to this voltage if the other MEANS OF PROTECTION fails.

For insulation between two isolated parts or between an isolated part and an earthed part, the WORKING VOLTAGE could in some cases be equal to the arithmetic sum of the highest voltages between any two points within both parts.

For DEFIBRILLATION-PROOF APPLIED PARTS, a test voltage deduced on the basis of a WORKING VOLTAGE equal to the defibrillation peak voltage would be far too high for insulation that in NORMAL USE is exposed only occasionally to voltage impulses, normally shorter than ~~10~~ 1 s and without additional overvoltage.

Subclause 8.5.5 – DEFIBRILLATION-PROOF APPLIED PARTS

The special test described in 8.5.5 is considered to ensure sufficient protection against exposure to defibrillation pulses, no separate dielectric strength test being necessary.

Subclause 8.5.5.1 – Defibrillation protection

One or the other of the defibrillation paddles could, by virtue of its clinical application, be connected to earth or at least referenced to earth.

When a defibrillator is used on the PATIENT, a HIGH VOLTAGE can thus be impressed either between one part of the ME EQUIPMENT and another, or between such parts collectively and earth. ACCESSIBLE PARTS should be adequately isolated from PATIENT CONNECTIONS or protected in some other way. The insulation of the PATIENT CONNECTIONS cannot be protected by voltage limiting devices relying on earthed connections.

The DEFIBRILLATION-PROOF APPLIED PART marking indicates that an APPLIED PART can safely remain attached to a PATIENT who is being defibrillated without any adverse effect on subsequent use of the ME EQUIPMENT.

The tests ensure:

a) that any ACCESSIBLE PARTS of ME EQUIPMENT, PATIENT cables, cable connectors, etc. that are not PROTECTIVELY EARTHED will not deliver a hazardous level of charge or energy due to flashover of defibrillation voltage; and

b) that the ME EQUIPMENT will continue to function (at least with regard to BASIC SAFETY and ESSENTIAL PERFORMANCE) after exposure to defibrillation voltage.

The requirement and the test PROCEDURE refer to “any necessary time” stated in the ACCOMPANYING DOCUMENTS. There is no requirement for the ACCOMPANYING DOCUMENTS to include a statement of a recovery time, but if there is no statement the ME EQUIPMENT has to recover and deliver its BASIC SAFETY and ESSENTIAL PERFORMANCE immediately.

The tests are conducted with the ME EQUIPMENT connected to the SUPPLY MAINS and in operation according to the instructions for use because the tests deal not only with the effect

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of the defibrillation energy on BASIC SAFETY but also on the ability of the ME EQUIPMENT to deliver its ESSENTIAL PERFORMANCE after the stated recovery time.

NORMAL USE includes the situation that a PATIENT is defibrillated while connected to the ME EQUIPMENT and, at the same time, the OPERATOR or another person is in contact with the ENCLOSURE. The possibility of this occurring at the same time as the SINGLE FAULT CONDITION of a defective PROTECTIVE EARTH CONNECTION is very unlikely and is therefore disregarded. However, interruption of functional earth connections is more probable, and is therefore required for these tests.

The SEVERITY of electric shock that a person receives when touching ACCESSIBLE PARTS during the discharge of a defibrillator is limited to a value (corresponding to a charge of 100 µC) which can be felt and which could be unpleasant, but which is not dangerous.

SIGNAL INPUT/OUTPUT PARTS are included, as signal lines to remote ME EQUIPMENT could otherwise carry energies that might be hazardous.

The test circuits of Figure 9 and Figure 10 of this standard are designed to simplify the test by integrating the voltage appearing across the test resistance (R_1).

The value of the inductance L in the test circuits of Figure 9 and Figure 10 is chosen to provide a shorter than normal rise time in order to test adequately the incorporated protective means.

If ME EQUIPMENT would be designed according to 8.5.2.1 and 8.5.5.1, it might have two different functions on one common APPLIED PART circuit. Consider the example in Figure A.21. In this example, the ECG and an invasive blood pressure catheter (IBP) share one common APPLIED PART circuit. In real use in the hospital, sometimes only one function (ECG) is used while the other function (IBP) is not connected. If the PATIENT needs to be defibrillated, there is a potential that a second OPERATOR would get an electric shock at unused IBP outlets during selecting of proper adjustments at the ME EQUIPMENT (e.g. at a multi-parameter patient monitor). It should be pointed out that in principle, the 5 KV could occur at every disconnected connector, which does not have adequate recessed pins. However, in practice, the probability of occurrence of HARM is much higher at the unused APPLIED PART outlets on the ME EQUIPMENT compared to any connector of adapter cables. Adapter cables will normally not be touched by the OPERATOR during defibrillation, because before defibrillation the command “stand clear” will be given. Even in the case that a disconnected adapter cable would be touched by an OPERATOR during defibrillation, it will most probably be touched at the isolated plastic parts, but not at its internal pins.

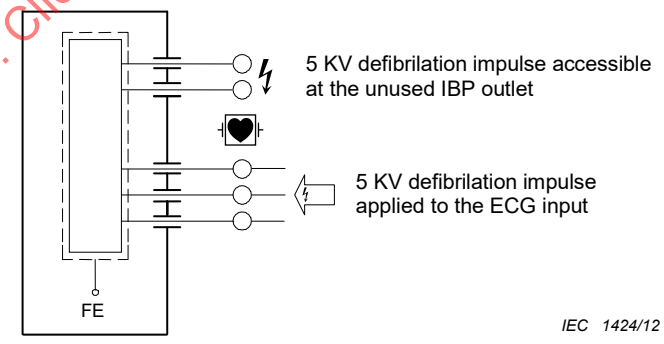


Figure A.21 – Example of ME EQUIPMENT having two different functions on one common APPLIED PART circuit

Rationale for impulse test voltage

When a defibrillation voltage is applied to the thorax of a PATIENT, via externally applied paddles (or defibrillation electrodes), the body tissue of the PATIENT in the vicinity of the paddles and between the paddles becomes a voltage dividing system.

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The voltage distribution can be gauged roughly using three-dimensional field theory but is modified by local tissue conductivity that is far from uniform.

If the electrode of another item of ME EQUIPMENT is applied to the PATIENT, roughly within the compass of the defibrillator paddles, the voltage to which such an electrode is subjected depends on its position but will generally be less than the on-load defibrillation voltage.

Unfortunately it is not possible to say how much less as the electrode in question can be placed anywhere in this area, including immediately adjacent to one of the defibrillator paddles. In the absence of a relevant particular standard, it is required that such an electrode and the ME EQUIPMENT to which it is connected is able to withstand the full defibrillation voltage. This is the no-load voltage as one of the defibrillator paddles might not be making good contact with the PATIENT.

This standard therefore specifies 5 kV d.c. as the appropriate test voltage in the absence of a relevant particular standard.

Applying Subclause 4.5, a MANUFACTURER is allowed to use alternate means to address a RISK covered by this standard if the RESIDUAL RISK after applying the alternate means is equal or less than the RESIDUAL RISK after applying the requirements of this standard. It is possible for a MANUFACTURER to determine that a lower test voltage is appropriate depending on the INTENDED USE of the ME EQUIPMENT and the location of the APPLIED PARTS on the PAIENT if it can be demonstrated that the test voltage selected is the maximum voltage that can appear on the APPLIED PART with 5 kV applied to the chest. Such parts can be classified and marked as a DEFIBRILLATION-PROOF APPLIED PARTS.

Subclause 8.6 – Protective earthing, functional earthing and potential equalization of ME EQUIPMENT

Typically, metal ACCESSIBLE PARTS of CLASS I ME EQUIPMENT are PROTECTIVELY EARTHED. However, they could be separated by other MEANS OF PROTECTION, in accordance with 8.5. Also some metal ACCESSIBLE PARTS could be earthed incidentally, neither by a PROTECTIVE EARTH CONNECTION nor for functional purposes. For example, such a part could be in contact with another part that is PROTECTIVELY EARTHED but does not itself need to be PROTECTIVELY EARTHED.

Subclause 8.6.1 – Applicability of requirements

PROTECTIVE EARTH CONNECTIONS that are only relevant to the safety of OPERATORS are allowed to comply either with the requirements of this standard or with those of IEC 60950-1, but the latter alternative is not allowed for PROTECTIVE EARTH CONNECTIONS that are relevant to the safety of both OPERATORS and PATIENTS.

Subclause 8.6.2 – PROTECTIVE EARTH TERMINAL

These requirements are intended to ensure a reliable connection between the ME EQUIPMENT and the protective earthing system of the electrical installation.

Subclause 8.6.3 – Protective earthing of moving parts

Connections to moving parts, whether made by sliding contacts, by flexible wires or by any other means, could be more susceptible than ordinary FIXED connections to deterioration during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. Therefore, they are not acceptable as PROTECTIVE EARTH CONNECTIONS unless their reliability is demonstrated.

Subclause 8.6.4 a)

PROTECTIVE EARTH CONNECTIONS can only perform their protective function if they are able to carry the fault current resulting from a failure in BASIC INSULATION.

Such a current is assumed to have sufficient amplitude to cause operation of protective devices in the electrical installation (fuses, circuit-breakers, earth leakage circuit-breakers and the like) in a reasonably short time.

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It is therefore necessary to check both the impedance and the current-carrying capability of PROTECTIVE EARTH CONNECTIONS.

The minimum time required for the test current is intended to reveal any overheating of parts of the connection due to thin wiring or a bad contact. Such a "weak spot" might not be discovered by resistance measurement alone.

PROTECTIVE EARTH CONNECTIONS can have zones of higher impedance, for example due to oxidation of materials. Use of a current source with an unlimited voltage could prevent detection of such zones because of their ability to flash through. The impedance is therefore determined first, using a limited voltage.

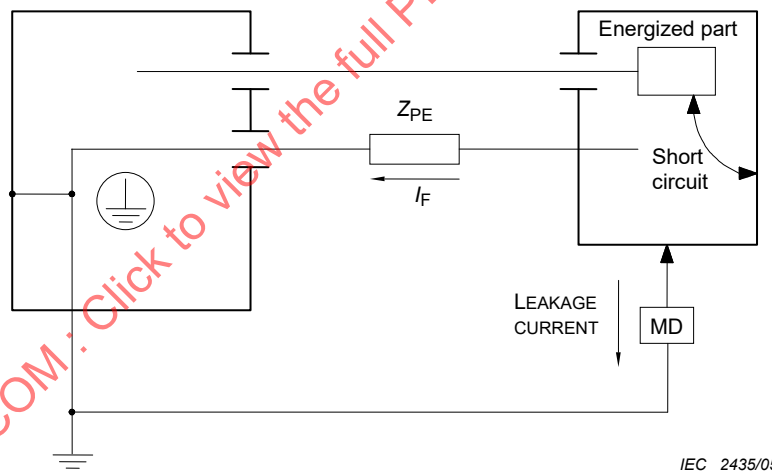
If this voltage is sufficient to drive the specified test current through the total impedance, then this one test also serves to demonstrate the current-carrying capability of the connection. Otherwise an additional test is necessary, either using a higher voltage or by assessing the cross-sectional area of the connection by inspection.

Where a long (> 3 m) DETACHABLE POWER SUPPLY CORD is supplied, specified or used, the 200 mΩ total protective earth pathway requirement still applies. Therefore, it might be necessary to use a DETACHABLE POWER SUPPLY CORD with conductors of a greater cross sectional area than the minimum required by 8.11.3.3.

Subclause 8.6.4 b)

The fault current could be limited to a relatively low value because of inherent impedance or the characteristic of the power source, for example where the power system is not connected to earth or connected to it via a high impedance (see Figure A.13).

In such cases, the cross-section of the PROTECTIVE EARTH CONNECTION can be determined primarily by mechanical considerations.



Legend

Z_{PE} = Impedance of PROTECTIVE EARTH CONNECTION in ohms (exceeding the limit specified in 8.6.4 a))

I_F = Maximum continuous prospective fault current in amperes in the PROTECTIVE EARTH CONNECTION caused by a single failure of the insulation to earth

MD Measuring device (see Figure 12)

NOTE The figure shows ME EQUIPMENT having a main ENCLOSURE and a remote part in a separate ENCLOSURE, as an example of a situation where the impedance of a PROTECTIVE EARTH CONNECTION could exceed the limit specified in 8.6.4 a): however this situation could also exist in ME EQUIPMENT having a single ENCLOSURE.

Figure A.13 – Allowable protective earth impedance where the fault current is limited

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Subclause 8.6.7 – POTENTIAL EQUALIZATION CONDUCTOR

Medically used rooms in most countries have no facilities for the use of detachable POTENTIAL EQUALIZATION CONDUCTORS. This standard therefore does not require any means to be provided for the connection of a POTENTIAL EQUALIZATION CONDUCTOR to the ME EQUIPMENT. If however the ME EQUIPMENT does have such means, for use in locations where POTENTIAL EQUALIZATION CONDUCTORS are used, the appropriate requirements have to be satisfied.

Subclause 8.6.9 – CLASS II ME EQUIPMENT

This requirement allows a CLASS II ME EQUIPMENT to have a connection to protective earth for functional reasons only. Green/yellow is required to avoid confusion in installation. The allowance does not degrade the degree of protection against electric shock.

The current flowing through the FUNCTIONAL EARTH CONDUCTOR has to be limited in the same way as current in the PROTECTIVE EARTH CONDUCTOR. To prevent the FUNCTIONAL EARTH CONDUCTOR from becoming a PROTECTIVE EARTH CONDUCTOR, the insulation between internal screens including internal wiring connected to them and ACCESSIBLE PARTS needs to provide two MEANS OF PROTECTION.

Subclause 8.7.2 – SINGLE FAULT CONDITIONS

Short circuiting of one part of DOUBLE INSULATION would be likely to increase LEAKAGE CURRENT by a factor of the order of 2. In some cases the test could be difficult to carry out and, as the allowable values for SINGLE FAULT CONDITION are five times those for NORMAL CONDITION, the test would not provide useful information.

Subclause 8.7.3 – Allowable values, Table 3 and Table 4

The value of electric current flowing in the human or animal body that can cause a certain degree of stimulation varies from individual to individual, according to the way in which the connection to the body is made and according to the frequency of the current applied and its duration.

Currents of low frequency flowing directly into or through the heart considerably increase the danger of ventricular fibrillation. For currents of medium or high frequency, the RISK of electric shock is less or negligible, but the RISK of burning remains.

The sensitivity of the human or animal body to electric currents, depending upon the degree and nature of contact with the ME EQUIPMENT, leads to a system of classification reflecting the degree and quality of protection provided by the APPLIED PARTS (classified as TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS and TYPE CF APPLIED PARTS). TYPE B APPLIED PARTS and TYPE BF APPLIED PARTS are generally suitable for applications involving external or internal contact with the PATIENT, excluding the heart. TYPE CF APPLIED PARTS are suitable for DIRECT CARDIAC APPLICATIONS with regard to LEAKAGE CURRENT.

In conjunction with this classification, the requirements for allowable LEAKAGE CURRENT have been formulated. The absence of sufficient scientific data concerning the sensitivity of the human heart for currents causing ventricular fibrillation still presents a problem.

Nevertheless, the publication of the first edition of this standard in 1977 provided engineers with data enabling them to design ME EQUIPMENT; and these requirements have proved over the years since then to ensure a very low level of RISK without being too onerous for designers.

The requirements for LEAKAGE CURRENT were formulated taking into account:

– that the possibility of ventricular fibrillation is influenced by factors other than only electrical parameters;

– that the values for allowable LEAKAGE CURRENTS in SINGLE FAULT CONDITION should be as high as is considered safe, taking into account statistical considerations, in order not to present designers with unnecessary difficulties; and

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– that values for NORMAL CONDITION are necessary to create a safe condition in all situations by providing a sufficiently high safety factor with respect to SINGLE FAULT CONDITIONS.

The measurement of LEAKAGE CURRENTS has been described in a way that enables the use of simple instruments, avoiding different interpretations of a given case and indicating possibilities for periodic checking by the RESPONSIBLE ORGANIZATION.

Allowable values of LEAKAGE and PATIENT AUXILIARY CURRENTS for a.c. and d.c. composite waveforms with frequencies up to and including 1 kHz take account of the following considerations.

~~d~~a) In general the RISK of ventricular fibrillation or pump failure increases with the value or duration, up to a few seconds, of the current passing through the heart. Some areas of the heart are more sensitive than others. That is, a current that causes ventricular fibrillation when applied to one part of the heart could have no effect when applied to another part of the heart.

~~e~~b) The RISK is highest and approximately equal for frequencies in the 10 Hz to 200 Hz range. It is lower, by a factor of nearly 5, at d.c. and by approximately 1,5 at 1 kHz. Beyond 1 kHz, the RISK decreases rapidly [45]. However lower limits are needed for d.c. to prevent tissue necrosis with long-term application.

The values in Table 3 and Table 4 apply to currents measured with the measuring device shown in Figure 12 a), which automatically allows for the reduced sensitivity at higher frequencies. SUPPLY MAINS frequencies of 50 Hz and 60 Hz are in the range of highest RISK.

~~f~~c) Although as a general rule requirements in a general standard are less restrictive than the requirements in particular standards, some of the allowable values in Table 3 and Table 4 have been set at such a value that:

– the majority of ME EQUIPMENT types can comply, and

– they can be applied to most ME EQUIPMENT types (existing or future) for which no particular standards exist.

EARTH LEAKAGE CURRENT

The EARTH LEAKAGE CURRENT flowing through the PROTECTIVE EARTH CONDUCTOR is not a HAZARD per se. The PATIENT and OPERATOR are protected by specifying appropriately low values for PATIENT LEAKAGE CURRENT and TOUCH CURRENT in NORMAL CONDITION and in relevant SINGLE FAULT CONDITIONS including interruption of the PROTECTIVE EARTH CONDUCTOR. However, an excessive EARTH LEAKAGE CURRENT could pose a possible problem for the installation's earthing system and any circuit breakers operated by current imbalance detectors.

See also IEC 60364-7-710 [10].

TOUCH CURRENT

The limits are based on the following considerations.

~~g~~d) The TOUCH CURRENT of ME EQUIPMENT is subject to the same values regardless of the type(s) of APPLIED PARTS, if any, because even ME EQUIPMENT that does not itself have a TYPE CF APPLIED PART could be used in situations where intracardiac PROCEDURES are performed.

~~h~~e) Although TOUCH CURRENT flows from parts other than PATIENT CONNECTIONS, it can reach the PATIENT by chance contact through various paths, including a path via the OPERATOR.

~~i~~f) The current density created at the heart by current entering the chest is 50 μA/mm^2 per ampere [46]. The current density at the heart for 500 μA (maximum allowable value in

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SINGLE FAULT CONDITION) entering the chest is 0,025 μA/mm², well below the level of concern.

jg) The probability of the TOUCH CURRENT flowing through the heart and causing ventricular fibrillation or pump failure.

TOUCH CURRENT could conceivably reach an intracardiac site if careless PROCEDURES are used in handling intracardiac conductors or fluid filled catheters. Such devices should always be handled with great care and always with dry rubber gloves. The following RISK ANALYSIS is based on pessimistic assumptions about the degree of care exercised.

The probability of a direct contact between an intracardiac device and an ME EQUIPMENT ENCLOSURE is considered to be very low, perhaps 1 in 100 medical procedures. The probability of an indirect contact via the medical staff is considered to be somewhat higher, say 1 in 10 medical procedures. The maximum allowable LEAKAGE CURRENT in NORMAL CONDITION is 100 μA, which itself has a probability of inducing ventricular fibrillation of 0,05. If the probability of indirect contact is 0,1 then the overall probability is 0,005. Although this probability would appear undesirably high, it should be recalled that with correct handling of the intracardiac device this probability can be reduced to that for mechanical stimulation alone, 0,001.

The probability of the TOUCH CURRENT rising to the maximum allowable level of 500 μA (SINGLE FAULT CONDITION) is considered to be 0,1 in departments with poor maintenance PROCEDURES. The probability of this current causing ventricular fibrillation is taken as 1.

The probability of accidental contact directly with the enclosure is, as above, considered as 0,01, giving an overall probability of 0,001, equal to the mechanical stimulation alone probability.

The probability of TOUCH CURRENT at the maximum allowable level of 500 μA (SINGLE FAULT CONDITION) being conducted to an intracardiac device via the medical staff is 0,01 (0,1 for the SINGLE FAULT CONDITION, 0,1 for accidental contact). Since the probability of this current causing ventricular fibrillation is 1, the overall probability is also 0,01. Again this probability is high; however it can be brought down to the mechanical stimulation alone probability of 0,001 by adequate medical procedures.

kh) The probability of the TOUCH CURRENT being perceptible to the PATIENT.

The probability of 500 μA being perceptible is 0,01 for men and 0,014 for women when using grip electrodes with intact skin [45] [48]. There is a higher perceptibility for current passing through mucous membranes or skin punctures [48]. Since distribution is normal, there will be a probability that some PATIENTS will perceive very small currents. One person is reported to have sensed 4 μA passing through a mucous membrane [48].

PATIENT LEAKAGE CURRENT

The allowable value of PATIENT LEAKAGE CURRENT for ME EQUIPMENT with TYPE CF APPLIED PARTS in NORMAL CONDITION is 10 μA, which has a probability of 0,002 for causing ventricular fibrillation or pump failure when applied through small areas to an intracardiac site.

Even with zero current, it has been observed that mechanical irritation can produce ventricular fibrillation [50]. A limit of 10 μA is readily achievable and does not significantly increase the RISK of ventricular fibrillation during intracardiac procedures.

The 50 μA maximum allowed in SINGLE FAULT CONDITION for ME EQUIPMENT with TYPE CF APPLIED PARTS is based on a value of current that has been found, under clinical conditions, to have a very low probability of causing ventricular fibrillation or interference with the pumping action of the heart.

For catheters 1,25 mm - 2 mm diameter likely to contact the myocardium, the probability of 50 μA causing ventricular fibrillation is near 0,01 (see Figure A.14 and its explanation). Small cross-section area (0,22 mm² and 0,93 mm²) catheters used in angiography have higher

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probabilities of causing ventricular fibrillation or pump failure if placed directly on sensitive areas of the heart.

The overall probability of ventricular fibrillation being caused by PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION is 0,001 (0,1 for probability of SINGLE FAULT CONDITION, 0,01 probability of 50 μA causing ventricular fibrillation) equal to the probability for mechanical stimulation alone.

The 50 μA current allowed in SINGLE FAULT CONDITION is not likely to result in a current density sufficient to stimulate neuromuscular tissues nor, if d.c., cause necrosis.

For ME EQUIPMENT with TYPE B APPLIED PARTS and TYPE BF APPLIED PARTS where the maximum allowable PATIENT LEAKAGE CURRENT under SINGLE FAULT CONDITION is 500 μA, the same rationale applies as that for TOUCH CURRENT since this current will not flow directly to the heart.

As the existence of an earth connection to a PATIENT is a NORMAL CONDITION, not only PATIENT AUXILIARY CURRENT but also PATIENT LEAKAGE CURRENT can flow for a prolonged period. A very low value of direct current is therefore necessary to avoid tissue necrosis, regardless of the classification of the APPLIED PART.

The appearance of MAINS VOLTAGE, from a low-impedance source, on the PATIENT CONNECTIONS of an F-TYPE APPLIED PART would have to be caused by a double failure of protective means in other ME EQUIPMENT, simultaneously connected to the PATIENT and complying with this standard or another IEC standard, or by a single failure of protective means in equipment not complying with a standard. As such this condition is extremely unlikely in good medical practice.

However the appearance of a lesser voltage, or of a LEAKAGE CURRENT from a source having an open-circuit voltage of the order of MAINS VOLTAGE, is possible.

Since the main safety feature of ME EQUIPMENT with an F-TYPE APPLIED PART is that the PATIENT is not earthed by the connection to the ME EQUIPMENT, the electrical separation of an F-TYPE APPLIED PART from earth is to have a minimum quality. This is assured by the requirement that, even if a hypothetical voltage of supply frequency and equal to the highest supply voltage to earth present in the location where the ME EQUIPMENT is used would appear on the PATIENT CONNECTIONS, the limit for the PATIENT LEAKAGE CURRENT would not be exceeded.

For TYPE CF APPLIED PARTS, the PATIENT LEAKAGE CURRENT will be limited to 50 μA, no worse than the previously discussed SINGLE FAULT CONDITION.

For TYPE BF APPLIED PARTS the maximum PATIENT LEAKAGE CURRENT under these conditions is 5 mA. Even this value entering the chest would produce only a current density at the heart of 0,25 μA/mm^2. This current would be very perceptible to the PATIENT, however the probability of its occurrence is very low. The RISK of harmful physiological effects is small and the MAXIMUM MAINS VOLTAGE used for this test represents a worst case, more severe than is likely to arise in practice.

Total PATIENT LEAKAGE CURRENT

The values of PATIENT LEAKAGE CURRENT in this standard are for a single function of a TYPE B APPLIED PART or TYPE BF APPLIED PART or a single PATIENT CONNECTION of a TYPE CF APPLIED PART. With multiple functions or multiple APPLIED PARTS the total PATIENT LEAKAGE CURRENT could be much higher. This total PATIENT LEAKAGE CURRENT is the vector sum of the individual PATIENT LEAKAGE CURRENTS. Therefore, it is necessary to specify limits for total PATIENT LEAKAGE CURRENT. These requirements are derived from IEC 60601-2-49:2001 [16].

This standard does not fix the number of APPLIED PARTS connected to a single PATIENT. It has been estimated that the number of APPLIED PARTS connected to a single PATIENT ranges from one to five.

Total PATIENT LEAKAGE CURRENT for TYPE CF APPLIED PARTS

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For TYPE CF APPLIED PARTS the PATIENT LEAKAGE CURRENT for the NORMAL CONDITION is 10 μA. The following is to be considered for multiple PATIENT functions:

~~l~~i) The current entering the heart is distributed over all of the PATIENT CONNECTIONS and is not applied to the same small sensitive area of the cardiac tissue.

~~m~~j) The number of PATIENT CONNECTIONS connected directly to cardiac tissue is not likely to exceed three. Accordingly, the LEAKAGE CURRENT entering a single small area of the heart is less than 50 μA and is in the vicinity of 15 μA to 20 μA for an algebraic summation of the currents. The current would be less for a vector summation. The probability of ventricular fibrillation, according to the rationale for PATIENT LEAKAGE CURRENT, is in the range of 0,003 even if all the PATIENT CONNECTIONS are very close together. This is not much different from the probability of 0,002 that is accepted for a single APPLIED PART connected directly to the heart.

~~n~~k) The LEAKAGE CURRENT from APPLIED PARTS on the surface of the body flows in a distributed manner through the body. According to the rationale for PATIENT LEAKAGE CURRENT, 5 mA entering the chest produces a current density at the heart of 0,025 μA/mm².

Therefore, 50 μA for NORMAL CONDITION for total PATIENT LEAKAGE CURRENT is considered acceptable.

For SINGLE FAULT CONDITION the LEAKAGE CURRENT for TYPE CF ~~EQUIPMENT~~ APPLIED PARTS has been increased to 0,1 mA. The rationale for PATIENT LEAKAGE CURRENT gives a probability of 0,07 of ventricular fibrillation for current directly entering the heart. The probability of a SINGLE FAULT CONDITION was given as 0,1. This was over a decade ago. Because of improvements in design, more reliable components, better materials, and the use of RISK MANAGEMENT in accordance with ISO 14971 and the consequent use of associated tools, such as HAZARD based RISK ANALYSIS, the probability of a SINGLE FAULT CONDITION should be much less. It is now felt to be in the vicinity of at least 0,02. The probability of ventricular fibrillation is 0,07 × 0,02, or 0,0014, close to that accepted for a single TYPE CF APPLIED PART.

Total PATIENT LEAKAGE CURRENT for TYPE BF APPLIED PARTS

The total PATIENT LEAKAGE CURRENT has been increased to 500 μA for NORMAL CONDITION and to 1 000 μA for SINGLE FAULT CONDITION. As explained in ~~c)~~ k) above, the current density at the heart for current of 5 000 μA is quite small. There should be no concern for either the NORMAL CONDITION or the SINGLE FAULT CONDITION.

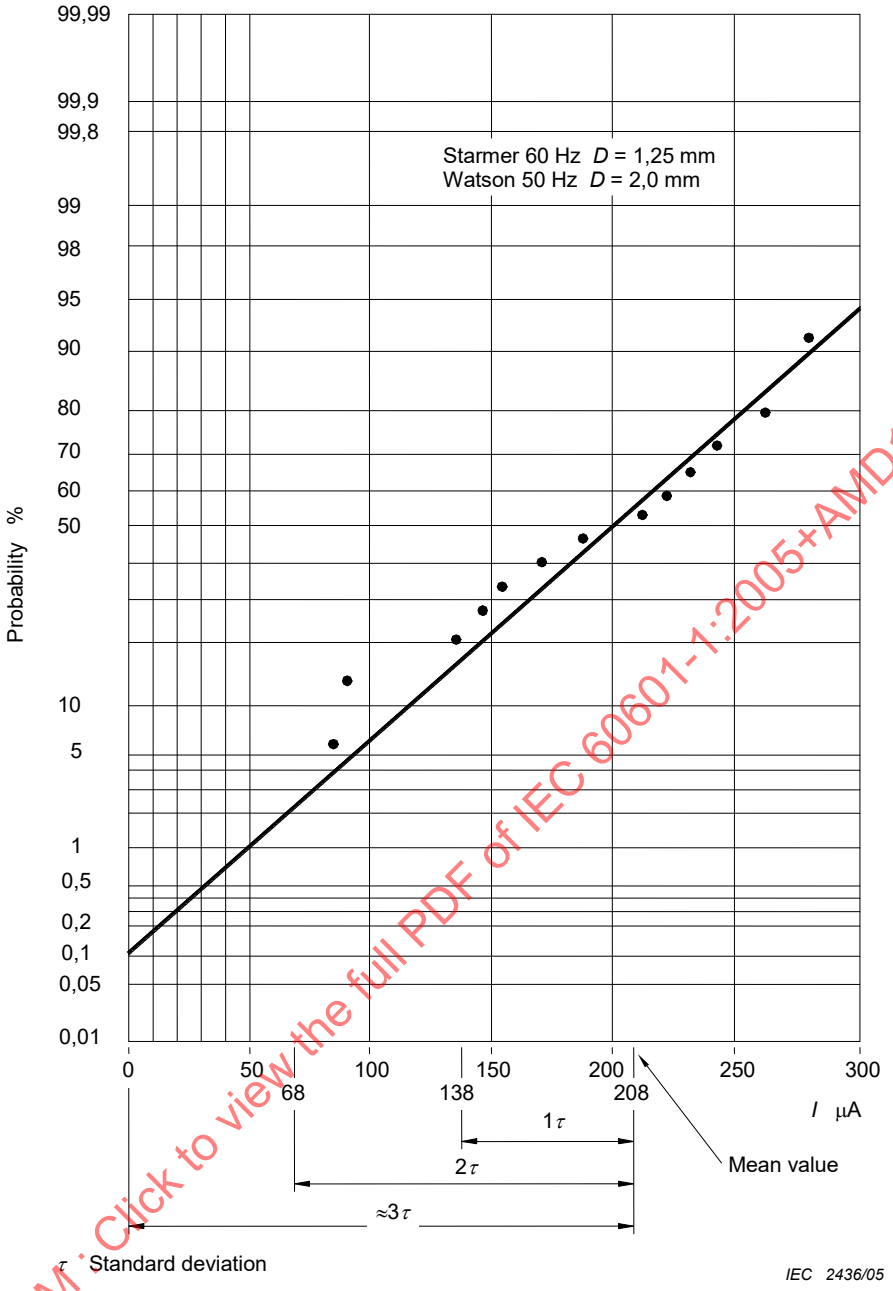
Total PATIENT LEAKAGE CURRENT caused by an external voltage on the PATIENT CONNECTION

For TYPE CF APPLIED PARTS, the limit has been increased to 100 μA. The rationale for PATIENT LEAKAGE CURRENT states that the probability of failure of protective earthing of CLASS I ME EQUIPMENT is 0,1 and that the probability of a fault in one MOP is less than 0,1. This was a decade ago. As explained earlier, these probabilities should be much lower today and are considered to be no worse than 0,02. The probability of MAINS VOLTAGE appearing on the PATIENT is 0,02 × 0,02, or 0,0004. This is below the probability of 0,001 accepted in the second edition of IEC 60601-1.

PATIENT AUXILIARY CURRENT

The allowable values for PATIENT AUXILIARY CURRENT are based on similar considerations to those for PATIENT LEAKAGE CURRENT. They apply regardless of whether the PATIENT AUXILIARY CURRENT is necessary for the functioning of the ME EQUIPMENT (e.g. impedance plethysmographs) or incidental to its functioning. Lower values are given for d.c. to prevent tissue necrosis with long-term application.

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NOTE Refer to original papers by Starmer [53] and Watson [54] for interpretation of data.

Figure A.14 – Probability of ventricular fibrillation

Explanation of Figure A.14

Articles by Starmer [53] and Watson [54] provide data on ventricular fibrillation caused by 50 Hz and 60 Hz currents applied directly to the hearts of human populations with cardiac disease. Fibrillation probability was obtained as a function of the electrode diameter and the magnitude of the current. For electrodes of 1,25 mm and 2 mm diameter and currents up to 0,3 mA, the distribution appears normal. Accordingly, it has been extrapolated to encompass the values commonly used in assessing PATIENT RISK (values noted on Figure A.14). From this extrapolation, it is seen that:

– any value of current, however small, has some probability of causing ventricular fibrillation, and

– the commonly used values have low probabilities, ranging from approximately 0,002 to 0,01.

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Since ventricular fibrillation is governed by many factors (PATIENT condition, probability of current entering a more sensitive area of the myocardium, probability of fibrillation as a function of current or current density, physiology, electric field, etc.), it is reasonable to use statistics in determining the possibility of RISK for the multiple conditions.

Heating effect of LEAKAGE CURRENTS

A current of 10 mA will produce no sensation of heating with a typical PATIENT CONNECTION with a contact area of the order of 1 cm^2, but a current a few times higher than this would produce a burn. The RISK of a burn depends on the magnitude of the current but not on its frequency, so the current has to be measured with a non-frequency-weighted device, such as a device similar to that shown in Figure 12 a) but without C_1 and R_1.

Subclause 8.7.3 f)

LEAKAGE CURRENTS can flow through a FUNCTIONAL EARTH CONDUCTOR. This can lead to an unexpected RISK if CLASS II equipment is combined with CLASS I equipment or with an earthed trolley, e.g. using an MSO. Although proper application of the 'rules' for assembling an ME SYSTEM would eliminate this RISK, the causal RISK can be mitigated by limiting the allowed LEAKAGE CURRENT in a FUNCTIONAL EARTH CONDUCTOR.

Subclause 8.7.4.2 – Measuring supply circuits

For correct results of LEAKAGE CURRENT measurements, it is essential to have a common reference point within the measuring circuit. The point also has to be electrically referenced to all parts of the circuit. Also the measured LEAKAGE CURRENT could be different according to the particular supply configuration. For example, if ME EQUIPMENT that is specified for connection to a supply having one side at earth potential is connected instead to a supply having two symmetrical phases (such as a 230 V supply in the USA) the measured LEAKAGE CURRENT will be much lower than the worst case. If the installed SUPPLY MAINS of the room where the measurements are made does not represent the worst case, a specific supply circuit has to be established. This can be done by using an isolating transformer with the appropriate point in the SECONDARY CIRCUIT connected to the reference point. Accurate and reproducible results when making LEAKAGE CURRENT measurements can also be obtained without an isolating transformer. However this would depend on the quality of the SUPPLY MAINS used for the measurements. Factors that need to be considered would include transients, interference signals and voltage differences between neutral and earth in the measuring circuit.

The earth symbols in the figures represent this common reference point, which is not connected to the protective earth of the SUPPLY MAINS. Such a separate reference point can provide additional protection for the person carrying out the measurements.

A variable-voltage transformer is necessary to provide 110 % of the RATED supply voltage to the ME EQUIPMENT. Although it would be possible to test with the MAINS VOLTAGE normally present in the test room and to multiply the measured LEAKAGE CURRENT values by the appropriate factor, this would not always produce the same result as testing with 110 % of the RATED supply voltage, particularly with ME EQUIPMENT that includes a switched-mode power supply.

The switches S_1 or $S_1 + S_2$ or $S_1 + S_2 + S_3$ in Figure F.1 to Figure F.4 (inclusive) can be omitted and the interruptions of the relevant leads can be obtained by other means.

Instead of the single or polyphase isolating transformers with adjustable output voltage(s), as shown in Figure F.1 to Figure F.5 (inclusive), a combination of an isolating transformer with set output voltage and an auto-transformer with adjustable output voltage can be used.

Subclause 8.7.4.3 – Connection to the measuring supply circuit

Although it is not unlikely that ME EQUIPMENT is used while placed on or in an earthed metal environment, such a position would be rather difficult to describe in a way that test results would become reproducible. The advice in the note in 8.7.4.3 d) 1) is therefore to be considered as a convention.

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The fact that PATIENT cables can have a significant capacitance to earth is usually important and of considerable influence on test results. A position providing reproducible results is therefore prescribed.

The isolation transformer in the measuring supply circuit provides additional protection for the person making the measurements and increases the accuracy of the LEAKAGE CURRENT measurements. However, it is not absolutely necessary to use an isolating transformer when making LEAKAGE CURRENT measurements. In some cases, such as high input power ME EQUIPMENT and ME SYSTEMS, use of an insolating transformer is not feasible. When making LEAKAGE CUURENT measurement without an isolating transformer, the MANUFACTURER needs to consider the following:

– is it possible to extrapolate the LEAKAGE CURRENTS at 110 % of the RATED supply voltage;
– the influence of currents that are driven by voltage differences between the protective earth and the mains supply neutral of ME EQUIPMENT or for ME SYSTEMS with multiple PROTECTIVE EARTH CONNECTIONS.

Measuring without an isolation transformer can produce LEAKAGE CURRENT readings that are greater than the LEAKAGE CURRENT measurement with an isolating transformer.

Subclause 8.7.4.5 – Measurement of EARTH LEAKAGE CURRENT and current in FUNCTIONAL EARTH CONNECTION

The measuring device represents a measuring method that takes into account the physiological effect of a current through the human body, including the heart, as well as the possibility of a low impedance contact between a PATIENT CONNECTION and the PATIENT. Although IEC 60990 [20] specifies some measuring devices for general use, none of these would be appropriate for measuring PATIENT LEAKAGE CURRENT. As the measuring device of the second edition is being retained for that purpose, it is most convenient to use the same device for all LEAKAGE CURRENT measurements, apart from the measurement of currents or current components with frequencies exceeding 1 kHz in relation to the 10 mA limit specified in 8.7.3 d).

Subclause 8.7.4.6 – Measurement of the TOUCH CURRENT

Where metal foil is to be applied to an ENCLOSURE made of insulating material, intimate contact can be achieved by pressing the foil against the insulating material with a pressure of approximately 5 kPa (0,5 N/cm^2).

Subclause 8.7.4.7 – Measurement of PATIENT LEAKAGE CURRENT

Subclause 8.7.4.7 b)

This test confirms that the separation between the PATIENT CONNECTIONS and other parts is adequate to limit the PATIENT LEAKAGE CURRENT to the allowed value when an external voltage is present.

If the APPLIED PART can be disconnected from the ME EQUIPMENT, it is possible that the contacts of its connector could touch an earthed object, but that situation is covered by thetests of 8.5.2.3, not by 8.7.4.7 b), which applies to the ME EQUIPMENT and the APPLIED PART together.

The 20 cm × 10 cm metal foil represents the size of a human hand. For some ME EQUIPMENT, the area of contact is greater then the size of the hand. In this case, the size of the foil can be increased.

Subclause 8.7.4.7 c)

Some of the tests specified in the second edition of this standard related to the possible presence of MAINS VOLTAGE on a SIGNAL INPUT PART or a SIGNAL OUTPUT PART (as defined in that edition, now covered by the combined term SIGNAL INPUT/OUTPUT PART). There were various exclusions, but if none of the exclusions applied this condition was regarded as a SINGLE FAULT CONDITION. The assumption made in this third edition is that, if the ACCOMPANYING DOCUMENTS place no restrictions on what other equipment is allowed to be

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connected to the SIGNAL INPUT/OUTPUT PART, the presence of the MAXIMUM MAINS VOLTAGE should be regarded as a NORMAL CONDITION.

Instead of an isolating transformer T_2 with an adjustable output voltage, a combination of an isolating transformer with a set output voltage and an auto-transformer with an adjustable output voltage can be used.

Subclause 8.7.4.7 d)

The test with an external voltage applied to unearthed metal ACCESSIBLE PARTS reflects the requirement in 8.5.2.2 for isolation between such parts and unearthed PATIENT CONNECTIONS of TYPE B APPLIED PARTS.

For TYPE BF APPLIED PARTS this test applies as well as the test of 8.7.4.7 b), even though both test the isolation between the PATIENT CONNECTIONS and other parts, because the PATIENT LEAKAGE CURRENT might not be the same in these two situations and different limit values apply.

Instead of an isolating transformer T_2 with an adjustable output voltage, a combination of an isolating transformer with a set output voltage and an auto-transformer with an adjustable output voltage can be used.

Care should be taken that the capacitance of the measuring device and its connecting leads to earth and to the body of the ME EQUIPMENT is kept as low as possible.

As explained in the rationale to 8.7.3, the presence of the MAXIMUM MAINS VOLTAGE on a PATIENT represents a worst case, this is more severe than is likely to arise in practice, and the allowable PATIENT LEAKAGE CURRENT for a TYPE BF APPLIED PART in this situation is 5 mA. It was pointed out that the application of MAINS VOLTAGE to an unearthed ACCESSIBLE PART could therefore cause a PATIENT LEAKAGE CURRENT of up to 5 mA to flow from the PATIENT CONNECTIONS of a TYPE BF APPLIED PART; whereas in the same situation a TYPE B APPLIED PART (which in general offers a lower level of safety) was allowed only 500 μA. In order to resolve this anomaly, the test of 8.7.4.7 d), with 110 % of the MAXIMUM MAINS VOLTAGE on unearthed ACCESSIBLE PARTS, also applies to TYPE BF APPLIED PARTS, and in this condition the allowable PATIENT LEAKAGE CURRENT is the general 500 μA value for SINGLE FAULT CONDITION.

There is no need to perform the test of 8.7.4.7 d) on TYPE CF APPLIED PARTS because for these the same allowable value of 50 μA would apply as in the test of 8.7.4.7 b).

Subclause 8.7.4.7 h)

The requirement represents a compromise between requiring extensive testing, which with most ME EQUIPMENT would yield no useful information, and having no specific requirement to address this RISK.

Most TYPE B APPLIED PARTS are earthed, so the measurement according to 8.7.4.7 g) (all PATIENT CONNECTIONS of a single function connected directly together) will give the same result as the measurement according to 8.7.4.7 h) (all PATIENT CONNECTIONS of all APPLIED PARTS of the same type connected together). If this is within the PATIENT LEAKAGE CURRENT limit it will certainly be within the total PATIENT LEAKAGE CURRENT limit. However it is possible to have TYPE B APPLIED PARTS that are not directly earthed, and in that case the measured values can be different.

Subclause 8.7.4.9 – ME EQUIPMENT with multiple PATIENT CONNECTIONS

This requirement was introduced in the second amendment to the second edition of this standard. It addresses a RISK that can arise, for example, with equipment for measuring physiological signals where an amplifier drives one electrode to reduce common-mode interference. If one of the sensing electrodes is disconnected from the PATIENT and picks up a large voltage at mains frequency, the amplifier could drive a large current into the PATIENT in a vain attempt to cancel the interference.

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The requirement represents a compromise between requiring extensive testing, which with most ME EQUIPMENT would yield no useful information, and having no specific requirement to address this RISK.

Subsequently IEC 60601-2-49:2001 [16] introduced a comprehensive set of tests, to be performed on all equipment within the scope of that standard. These include measurement of what is termed "PART LEAKAGE CURRENT" in that standard: this is the current flowing between the PATIENT CONNECTIONS of one function and the PATIENT CONNECTIONS of other function(s), which is covered in this edition of the general standard by the revised definition of PATIENT AUXILIARY CURRENT.

Consideration was given to incorporating these tests in this general standard, but it was decided that such specific testing should be left to particular standards. The scenarios to which they relate, such as having the PATIENT CONNECTIONS of one function in use and connected to the PATIENT while the PATIENT CONNECTIONS of another function are not in use and could make contact with earth or other objects, are likely to arise with multifunction PATIENT monitoring equipment but unlikely with most other kinds of ME EQUIPMENT.

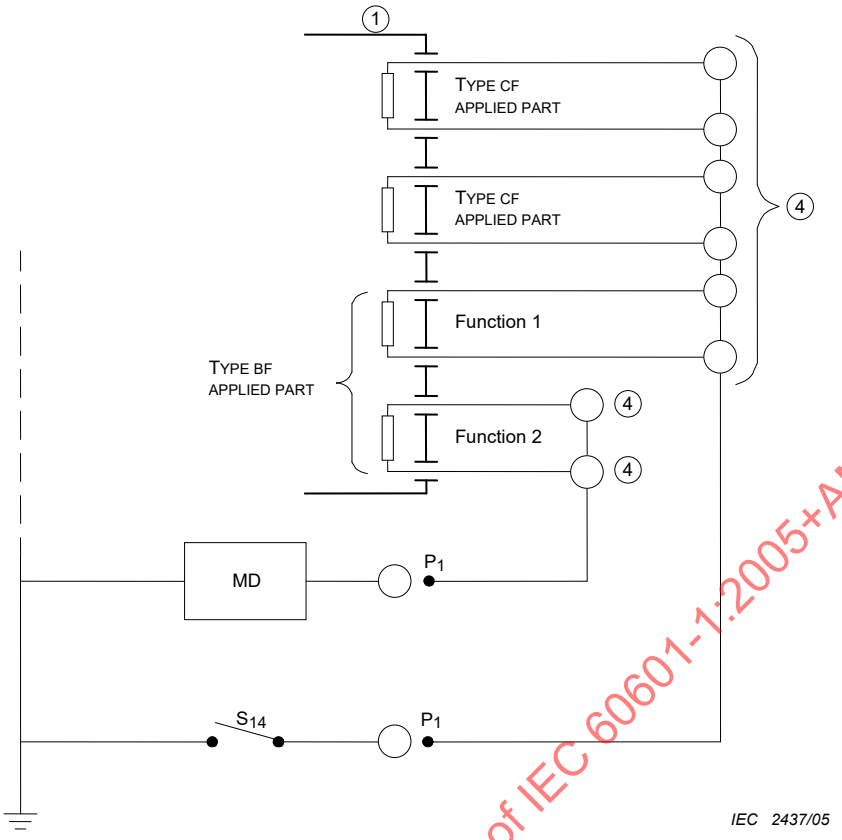
Figure A.15, based on Figure KK.101 of IEC 60601-2-49:2001 [16], shows an example of measuring the PATIENT LEAKAGE CURRENT from one function of a TYPE BF APPLIED PART while the PATIENT CONNECTIONS of another function of the same APPLIED PART and of two TYPE CF APPLIED PARTS are either floating or earthed.

Subclause 8.8.1 – General

Care should be taken that the voltage applied to a REINFORCED INSULATION does not overstress either of the MEANS OF PROTECTION in the ME EQUIPMENT. If there are multiple paths between the same points, these might need to be tested separately. There could, for example, be one path from the MAINS PART to a PATIENT CONNECTION that has BASIC INSULATION plus a PROTECTIVE EARTH CONNECTION plus PATIENT CONNECTIONS isolation as required by 8.5.2.1, and a parallel path having REINFORCED INSULATION. ME EQUIPMENT parts might need to be disconnected to allow the REINFORCED INSULATION to be tested without overstressing the separate insulation of the MAINS PART or the PATIENT CONNECTIONS.

This could be avoided, for example in the case of a transformer, by the use of a voltage divider with a tapping point connected to the core or some other suitable connecting point to ensure the correct voltage division over the actual insulations, or by the use of two test transformers, correctly phased.

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For legends, see Table 5.

Key

All measurements are made with S_{14} closed and again with S_{14} open.

Figure A.15 – Example of a measuring circuit for the PATIENT LEAKAGE CURRENT from a PATIENT CONNECTION to earth for ME EQUIPMENT with multiple PATIENT CONNECTIONS

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Subclause 8.8.2 – Distance through solid insulation or use of thin sheet material

The second edition of this standard placed no restrictions on the thickness of solid insulation, except as specified in 57.9.4 e) for transformers and for the need for all insulation covered by Clause 20 to be thick enough to pass the dielectric strength test. A very thin film of insulating material might pass that test but might not provide reliable insulation during the EXPECTED SERVICE LIFE of all production items.

Some National Committee comments during the development of this edition proposed introducing relevant requirements derived from IEC 60950-1 to address this omission. Both WG 14 (Testing) and WG 16 (Electrical hazards) recommended accepting these proposals.

These requirements have been included in IEC 60950-1 for many years without causing problems. They should not be onerous in practice for ME EQUIPMENT, and indeed most ME EQUIPMENT designed according to the previous editions of this standard would have satisfied them.

The requirements that have been introduced are intended to be technically equivalent to those of IEC 60950-1, but the editorial structure has been changed for clarity, as follows.

– IEC 60950-1 specifies a general requirement for distance through insulation, with an exception for voltages up to 71 V. This has been changed to state explicitly that the requirement applies above 71 V.

– IEC 60950-1 specifies an exception from the requirement for distance through insulation where the requirements for thin sheet material apply, as set out in another subclause, but

that subclause does not refer explicitly to the 71 V limit. This has been made explicit by stating the requirements for thin sheet material as an alternative to the thickness requirement, under the same introductory wording.

– IEC 60950-1 specifies that “Insulation in thin sheet materials is permitted . . provided that” certain conditions are satisfied. This has been changed to an explicit requirement that insulation in thin sheet materials needs to satisfy these conditions.

– IEC 60950-1 requires that insulation in thin sheet materials “is used within the equipment ENCLOSURE”. However the ENCLOSURE as defined in this standard includes all outer surfaces, including the surfaces of cables, APPLIED PARTS, etc. The requirement has therefore been rephrased.

Elsewhere in this standard the terms SUPPLEMENTARY INSULATION and REINFORCED INSULATION have mostly been replaced by references to MEANS OF PROTECTION, but they have been retained here because, as in IEC 60950-1, the requirements concerning distance through insulation and the use of thin sheet material apply to SUPPLEMENTARY INSULATION and to REINFORCED INSULATION, but not to BASIC INSULATION. Thus these requirements do not apply where BASIC INSULATION, as one MEANS OF PROTECTION, is used in conjunction with a PROTECTIVE EARTH CONNECTION as the other MEANS OF PROTECTION. Where DOUBLE INSULATION is used, these requirements apply to whichever constituent part thereof is regarded as the SUPPLEMENTARY INSULATION.

Subclause 8.8.3 – Dielectric strength

Components designed to limit the voltage might need to be removed in order to allow the full test voltage to be applied to the insulation being tested.

The purpose of this test is to check all solid insulation under the worst-case condition after having achieved operating temperature. For heating elements, the worst case is achieved with heaters remaining energized during measurement.

The test voltages specified are appropriate for solid insulation only. Spacings (CREEPAGE DISTANCES and CLEARANCES) are evaluated by 8.9. IEC 60664-1 gives details of electrical test methods for clearances using impulse voltage dielectric strength tests. These tests can be used under the IEC 60950-1 route for MOOPs, but are not specified for MOPPs. IEC 60664-1 states that the 2U + 1 000 V type of dielectric strength test “is not relevant for the testing of clearances”.

Since the dielectric strength test is applied immediately after the humidity preconditioning treatment, with the ME EQUIPMENT still in the humidity cabinet, adequate precautions for the protection of laboratory personnel could be necessary.

In Table 6, the values for OPERATOR protection are taken from IEC 60950-1 and the values for PATIENT protection are taken from the second edition of IEC 60601-1. In constructing the table, three principles were employed:

– MOPP are always at a higher value than MOOP.

– Mains circuits are effected by transient overvoltages as detailed in Table 10. In SECONDARY CIRCUITS, the transient overvoltage level is at least one level less than the mains circuits.

– The value of test voltage is primarily determined by the transient voltage on the SUPPLY MAINS which is usually orders of magnitude larger than the WORKING VOLTAGE.

In order to align with the second edition of IEC 60601-1 for the common WORKING VOLTAGE of 220 V r.m.s to 240 V r.m.s. the test voltage of 4 000 V r.m.s. was retained even though this value is more that twice the test voltage for one MOPP. However, each individual MOPP has to meet the 1 500 V r.m.s. minimum requirement.

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Subclause 8.8.3 a)

The test voltage can be provided by a transformer, by a d.c. power source or by using the transformer(s) of the ME EQUIPMENT. In the last case, to prevent overheating, the test voltage can have a frequency that is higher than the RATED frequency of the ME EQUIPMENT.

The PROCEDURE and duration of the test for WORKING VOLTAGE equal to or higher than 1 000 V a.c. or 1 500 V d.c. or peak values can be specified further by particular standards.

Subclause 8.8.4.1 – Mechanical strength and resistance to heat

Tests concerning flammability of materials will be found in IEC 60695-11-10.

Subclause 8.9 – CREEPAGE DISTANCES and AIR CLEARANCES

For ME EQUIPMENT intended to be supplied from the SUPPLY MAINS, AIR CLEARANCE and dielectric strength requirements are based on the expected overvoltage transients that could enter the equipment from the SUPPLY MAINS. According to IEC 60664-1, the magnitude of these transients is determined by the normal supply voltage and the supply arrangements. These transients are categorized according to IEC 60664-1 into four groups called overvoltage categories I to IV (also known as installation categories I to IV). Elsewhere in this standard overvoltage category II is assumed.

The design of solid insulation and AIR CLEARANCES should be co-ordinated in such a way that, if an incident overvoltage transient exceeds the limits of overvoltage category II, the solid insulation can withstand a higher voltage than the AIR CLEARANCES.

The values in Table 13 to Table 15 correspond to those of IEC 60950-1 for overvoltage category II for MAINS PARTS and overvoltage category I for SECONDARY CIRCUITS. If ME EQUIPMENT is intended to be used in locations where the SUPPLY MAINS is in overvoltage category III or IV, these values will be inadequate.

A SECONDARY CIRCUIT derived from a SUPPLY MAINS will normally be overvoltage category I if the SUPPLY MAINS is overvoltage category II; the maximum transients for various SUPPLY MAINS voltages in overvoltage category I are shown in the column headings of Table 13.

For insulation between the ENCLOSURE and the PATIENT CONNECTION of an F-TYPE APPLIED PART special rules apply:

1) In the case of an F-TYPE APPLIED PART containing no voltage difference, the insulation between the PATIENT CONNECTIONS and the ENCLOSURE will only be stressed to the MAINS VOLTAGE in the case of a fault in other equipment connected to the PATIENT.

   This condition rarely occurs; furthermore this insulation is not normally subject to the transient overvoltages found in the MAINS PART. In view of the above, the insulation necessary between the APPLIED PART and the ENCLOSURE for the case quoted, need only satisfy the requirements for BASIC INSULATION.

2) In the case of an F-TYPE APPLIED PART containing parts with voltage difference, the connection of a PATIENT CONNECTION to earth via an earthed PATIENT (NORMAL CONDITION) could subject the insulation between other parts and the ENCLOSURE to the whole of the voltage within the APPLIED PART.

   Since this voltage appears in NORMAL CONDITION, even though infrequently, the relevant insulation should satisfy the requirements for DOUBLE INSULATION or REINFORCED INSULATION. ~~In view of the low probability of this condition occurring, the CREEPAGE DISTANCES and AIR CLEARANCES given in Table 11 are considered adequate.~~

3) The value to be applied is the highest of the values found according to Items 1) and 2) above.

In the absence of a theoretical background to refer to, it was decided that the values above 1 000 V would be drawn from Table 7 of IEC 61010-1:2001 [22] for CREEPAGE DISTANCES using the column for material group IIIa-b, pollution degree 3, which correlates with the existing

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values in the second edition of IEC 60601-1 or is slightly more onerous. For AIR CLEARANCES, the values have been estimated based on the relationship between creepage and clearance for values below 1 000 V r.m.s. from Table 12. These derived values are shown in Table A.1.

Table 16 of the second edition of IEC 60601-1 was split into two tables in this standard (Tables 9 and 10). To align it with tables derived from other standards such as IEC 60950-1, the factor between the a.c. voltages and the d.c. voltages was changed from 1,2 to about 1,4. This relaxation was accepted as it is a common approach in other standards and it prevents having different CREEPAGE DISTANCES or AIR CLEARANCES in circuits where there is a d.c. voltage rectified from an a.c. voltage.

Table A.1 – Values of AIR CLEARANCE and CREEPAGE DISTANCE derived from Table 7 of IEC 61010-1:2001 and Table 12

WORKING VOLTAGE V d.c. up to and including	WORKING VOLTAGE V r.m.s up to and including	Spacing providing one MEANS OF PATIENT PROTECTION		Spacing providing two MEANS OF PATIENT PROTECTION	
		AIR CLEARANCE mm	CREEPAGE DISTANCE mm	AIR CLEARANCE mm	CREEPAGE DISTANCE mm
1 500	1 250	11,5	20	23,0	40
1 920	1 600	14,5	25	29,0	50
2 400	2 000	18,5	32	37,0	64
3 000	2 500	23,0	40	46,0	80
3 840	3 200	29,0	50	58,0	100
4 800	4 000	36,0	63	72,0	126
6 000	5 000	46,0	80	92,0	160
7 560	6 300	57,0	100	114,0	200
9 600	8 000	71,5	125	143,0	250
12 000	10 000	91,5	160	183,0	320

Table A.2 contains CREEPAGE DISTANCES for WORKING VOLTAGE above 1 000 V derived from IEC 60664-1:2007, Table 4 F.4.

Subclause 8.9.1 – Values

When using the values of CREEPAGE DISTANCE and AIR CLEARANCE, it should be noted that peak, d.c. and r.m.s. values are all used. It is important to read the tables carefully.

The tables for MOOPs use values from IEC 60950-1 representing the following basic principles, taken from IEC 60664-1:

– "The basis for the determination of a CREEPAGE DISTANCE is the long-term r.m.s. value of the voltage existing across it."

– "AIR CLEARANCES shall be dimensioned to withstand the required impulse withstand voltage". Impulse withstand voltage is the "highest peak value of withstand voltage ...."

However, the tables for MOPPs are taken from the second edition of IEC 60601-1, where both creepages and clearances were related to r.m.s. or d.c. voltages.

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Table A.2 – CREEPAGE DISTANCES to avoid failure due to tracking from IEC 60664-1

WORKING VOLTAGE V r.m.s or d.c.	Spacing for one MEANS OF OPERATOR PROTECTION						
	Pollution degree 1	Pollution degree 2			Pollution degree 3		
	Material group	Material group			Material group		
	I, II, IIIa, IIIb	I	II	IIIa or IIIb	I	II	IIIa or IIIb
1 250	Use the AIR CLEARANCE from the appropriate table	6,3	9,0	12,5	16,0	18,0	20,0
1 600		8,0	11,0	16,0	20,0	22,0	25,0
2 000		10,0	14,0	20,0	25,0	28,0	32,0
2 500		12,5	18,0	25,0	32,0	36,0	40,0
3 200		16,0	22,0	32,0	40,0	45,0	50,0
4 000		20,0	28,0	40,0	50,0	56,0	63,0
5 000		25,0	36,0	50,0	63,0	71,0	80,0
6 300		32,0	45,0	63,0	80,0	90,0	100,0
8 000		40,0	56,0	80,0	100,0	110,0	125,0
10 000		50,0	71,0	100,0	125,0	140,0	160,0

Subclause 8.9.1.6 – Interpolation

Interpolation for CREEPAGE DISTANCES but not for AIR CLEARANCES is allowed, except where the WORKING VOLTAGE is above 2 kV r.m.s. or 2,8 kV d.c. This approach is generally consistent with IEC 60950-1 and IEC 61010-1 [22].

Subclause 8.9.1.15 – CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS

From IEC 60664-1:2007, Table ~~2~~ F.2, a distance of 4 mm is adequate for pulses of 5 kV having a short duration of less than 10 ms, such voltages arising typically from the use of a defibrillator.

Subclause 8.9.2 – Application

Subclause 8.9.2 a)

Depending on the INTENDED USE of the ME EQUIPMENT, operation of the fuse or OVER-CURRENT RELEASE can be a HAZARD. The opening of a branch circuit breaker is not acceptable. Subclause 8.9.2 a) is based on the fact that there is an over-current device in the input of the ME EQUIPMENT before the part of the circuit where this subclause is applied. Before this over-current device, the spacings need to comply with the basic requirement for parts of opposite polarity within the MAINS PART.

Subclause 8.9.3 – Spaces filled by insulating compound

CREEPAGE DISTANCES are measured through the joint between two parts of an insulation barrier, except for cemented joints, i.e. those in which:

– either the two parts forming the joint are bonded by heat sealing or other similar means at the place where this is of importance;

– or the joint is completely filled with adhesive at the necessary places and the adhesive bonds to the surfaces of the insulating barrier so that humidity cannot be sucked into the joint.

In the second edition of this standard, the captions to Figures 43 to 45 referred to “uncemented joints.” Item 7 of the legends to these figures referred to 57.9.4 f), second dash, “for a description of cemented joints” but did not specify any test methods other than

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inspection. During the preparation of this edition, it was proposed to introduce relevant requirements derived from IEC 60950-1 to address the related subject of potting.

The requirements that have been introduced are closely based on those of IEC 60950-1 and cover potting, encapsulation, cemented joints, etc. The editorial structure has been somewhat revised from that of IEC 60950-1 for clarity. These requirements have been included in 8.9 rather than 8.8 because they specify circumstances that allow exemption from the requirements for CREEPAGE DISTANCES and AIR CLEARANCES, rather than additional requirements applying to solid insulation.

Subclause 8.9.4 – Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES

Narrow gaps, running in the direction of a possible creepage path and being some tenths of 1 mm wide only, should be avoided as far as possible, for dirt and moisture can deposit there.

Subclauses 8.10.1 – Fixing of components

In many cases it will be obvious that components and wiring are adequately secured (e.g. small components soldered to a printed circuit board) without the need for specific justification in the RISK MANAGEMENT FILE; but if any relevant information is included in the RISK MANAGEMENT FILE, it should be taken into account in assessing compliance with these requirements.

Subclause 8.10.2 – Fixing of wiring

It is generally accepted that wiring connections are subject to the SINGLE FAULT CONDITION. That is those having only one means of being secured that would prevent a loosened/broken wire from ~~creating a HAZARD~~ resulting in a HAZARDOUS SITUATION, such as removing a PROTECTIVE EARTH CONNECTION or bridging a MEANS OF PROTECTION, are considered not in compliance.

Examples of connection that could comply with SINGLE FAULT CONDITION are:

– double crimping of both the wire and the wire insulation;

– mechanical security of the wire and soldering;

– mechanical security of the wire and wire movement restraints such as tie wraps, wire clamps, bundling straps, etc.;

– strain relief mechanisms and mechanical security.

Subclause 8.10.4 – Cord-connected HAND-HELD parts and cord-connected foot-operated control devices

HAND-HELD switches and footswitches are in practice exposed to severe conditions. This requirement ensures that even in the worst case, where the ENCLOSURE of such a switch is completely broken, only parts at voltages within the limits specified in 8.4.2 c), which are safe to touch, can become exposed.

Subclause 8.10.5 – Mechanical protection of wiring

There is no requirement for specific justification to be given in the RISK MANAGEMENT FILE, but if any relevant information is included in the RISK MANAGEMENT FILE it should be taken into account in assessing compliance with these requirements.

Subclause 8.10.7 – Insulation of internal wiring

Conductors can be routed in separated jacketed cords of adequate rating. Where conductors of different circuit categories have to be run through common cords, wiring channels, conduits or connecting devices, adequate separation is realized by sufficient rating of the conductor insulation and by arranging for sufficient AIR CLEARANCES and CREEPAGE DISTANCES, complying with the requirements of 8.9, between conductive parts in connecting devices.

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Subclause 8.11.1 – Isolation from the SUPPLY MAINS

Subclause 8.11.1 a)

Skilled persons, such as SERVICE PERSONNEL, who need to gain access to internal, possibly hazardous, ME EQUIPMENT parts, need a means by which the ME EQUIPMENT can be isolated from the SUPPLY MAINS.

A mains isolating switch, where provided, could also serve as a functional off switch for routine use or for disabling hazardous output in an emergency. However it does not necessarily serve these purposes, nor does this standard specify any general requirement for an emergency off switch.

Subclause 8.11.1 c)

In the second edition of this standard, the requirement for minimum contact spacing of switches used to provide isolation from the SUPPLY MAINS was specified in IEC Publication 328. IEC 61058-1 superseded IEC 328 in 1990. The first edition of IEC 61058-1 required 3 mm contact spacing for full disconnection from the SUPPLY MAINS. No mention of overvoltage category was made. The third edition of IEC 61058-1 introduced the concept of overvoltage category according to IEC 60664-1. For a 230 V SUPPLY MAINS in overvoltage category II, Table 22 of IEC 61058-1:2000 allows a minimum contact spacing of 1,5 mm. While the requirements in this standard generally relate to overvoltage category II (see 8.9.1.11), it was thought prudent to stay with the 3 mm requirement associated with a 230 V SUPPLY MAINS IN overvoltage category III for all switches intended to provide isolation from the SUPPLY MAINS. Not only is this consistent with the requirement of the second edition of IEC 60601-1 but it is also harmonious with the requirements of IEC 60065 and IEC 60950-1, which both require a minimum contact separation of 3 mm for switches intended to provide isolation from the SUPPLY MAINS.

Subclause 8.11.1 h)

Such a protective device whether or not it caused the operation of an over-current protection device built into the ME EQUIPMENT, would be likely also to cause a fuse or circuit breaker in the installation to operate, thus removing the supply of power to other ME EQUIPMENT, possibly including life-support ME EQUIPMENT. Such a device might also cause undesirable thermal effects inside the ME EQUIPMENT and might anyway not be a reliable method of protecting against the relevant HAZARDS.

Subclause 8.11.1 i)

Parts that cannot be disconnected from the supply might include, for example, a circuit for room lighting or a circuit for remote control of the mains switch. Such parts could become accessible when a cover is opened, for example for the purpose of maintenance.

A spatially separated arrangement is one where parts that need to be accessible for servicing are located such that the SERVICE PERSONNEL are unlikely to come in contact with parts energized at voltages exceeding those specified in this standard while performing the required service. In this case, a warning is deemed to provide adequate safety for the SERVICE PERSONNEL.

Subclause 8.11.2 – MULTIPLE SOCKET-OUTLETS

This requirement reduces the probability that other equipment is connected that might lead to excessive LEAKAGE CURRENT.

Subclause 8.11.3.4 – APPLIANCE COUPLERS

A POWER SUPPLY CORD connected to a MAINS CONNECTOR is subject to similar stresses to a non-DETACHABLE POWER SUPPLY CORD. If it is not adequately protected from excessive bending, a ~~HAZARD~~ HAZARDOUS SITUATION could result.

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Subclause 8.11.3.5 – Cord anchorage

If a power cord were not adequately protected against strain and abrasion, there would be a high probability of damage to insulation providing MEANS OF PROTECTION and, with CLASS I ME EQUIPMENT, a high probability of breakage or disconnection of the PROTECTIVE EARTH CONDUCTOR.

Subclause 8.11.3.6 – Cord guards

If a power cord were not adequately protected against excessive bending, there would be a high probability of breakage of power-carrying conductors, giving a RISK of fire, and with CLASS I ME EQUIPMENT, a high probability of breakage of the PROTECTIVE EARTH CONDUCTOR.

The bending test described is identical to that specified in ~~3.29 of~~ IEC 60950-1:~~2001~~2005, subclause 3.2.8. The second edition of IEC 60601-1 included the wording "Guards which fail the above dimensional test shall have to pass the test described in IEC 60335-1, Amendment 6. 1988, subclause 25.10." This alternative has been retained, but the reference is now to a later edition of IEC 60335-1. Also the requirement to perform one test in all cases, and then to perform the other test if the ME EQUIPMENT fails the first test, has been changed to allow either test to be performed first, because this makes no difference to whether the ME EQUIPMENT complies.

Subclause 8.11.4.1 – General requirements for MAINS TERMINAL DEVICES

Mains terminals should ensure connections of sufficiently low resistance to avoid overheating and should minimise the RISK of disconnection. Reliable connection can be made by means of screws, nuts, soldering, clamping, crimping of conductors or equally effective methods.

Use of terminals of components other than terminal blocks as terminals intended for external conductors is allowed in special cases where the terminal arrangement is adequate (accessible and clearly marked) and complying with this standard. The wiring terminals of certain types of components are often rated for field wiring purposes. These include fuse holders, EMC filters, circuit breakers, contactors, wiring strips, motor controllers and phase detectors. Each of these can be one of the first connected components thereby putting them in a good position to accept the first wiring connections.

Subclause 8.11.4.2 – Arrangement of MAINS TERMINAL DEVICES

Subclause 8.11.4.2 a)

One naturally expects to see all the terminals for connection of external cords or POWER SUPPLY CORDS grouped together. The possibility of an incorrect connection can increase if the terminals are not grouped together.

Subclause 8.11.4.4 – Connections to mains terminals

The term "special preparation of the conductor" covers soldering of the strands, use of cord lugs, attachment of eyelets, etc., by SERVICE PERSONNEL (i.e. in the field), but not the reshaping of the conductor before its introduction into the terminal or the twisting of a stranded conductor to consolidate the end. When preparation of the conductor is performed by the MANUFACTURER and the flexible cord is provided as the only acceptable replacement part, such part is considered to comply with this requirement.

Subclause 8.11.5 – Mains fuses and OVER-CURRENT RELEASES

Provision of fuses or OVER-CURRENT RELEASES in ME EQUIPMENT reduces the RISK that a fault in the ME EQUIPMENT will cause a protective device in the installation to operate, thus removing the supply of power to other ME EQUIPMENT, possibly including life-support ME EQUIPMENT.

It is obvious that fusing in a PROTECTIVE EARTH CONNECTION would be inappropriate.

Fusing of the neutral conductor of PERMANENTLY INSTALLED ME EQUIPMENT would serve no purpose and, with 3-phase equipment, might lead to overstressing of insulation in the event

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that such a fuse were to operate while the line connections remained intact. However an OVER-CURRENT RELEASE that interrupts all poles, including the neutral, simultaneously is acceptable.

The exemption for the case where DOUBLE INSULATION or REINFORCED INSULATION is present between all parts of opposite polarity within the MAINS PART was supported by the National Committees' responses to an inquiry during the preparation of this edition. It could apply where provision of a fuse or OVER-CURRENT RELEASE would be inconvenient, for example in a small plug-in power supply.

Clause 9 – Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Requirements in Clause 9 describe HAZARDS of a mechanical nature caused by ME EQUIPMENT (HARM caused by moving parts, by rough surfaces, by sharp edges and corners, by instability, by expelled parts, by vibration and noise and by breakdown of PATIENT supports and of suspension means for ME EQUIPMENT parts). Requirements describing HAZARDS caused by damage or deterioration of ME EQUIPMENT (mechanical strength) have been collected into 15.3.

ME EQUIPMENT can become unsafe because of parts damaged or deteriorated by mechanical stresses such as blows, pressures, shocks, vibration, by ingress of solid particles, dust, fluids and moisture and aggressive gases, by thermal and dynamic stresses, by corrosion, by loosening of fastenings of a moving part or a suspended mass, and by radiation.

Effects of mechanical overloads, material failure or wear can be avoided by:

– means that interrupt or render non-hazardous the operation or the energy supply (for example, fuses, pressure-relief valves) as soon as overloading occurs; or

– means that guard against or catch flying or falling parts (caused by material failures, wear or overload) that could constitute a MECHANICAL HAZARD.

Protection against breakdown of PATIENT supports and suspensions can be provided by redundancy or the provision of safety catches.

ME EQUIPMENT parts that are intended to be held in the hand or positioned on a bed need to be sufficiently robust to withstand a fall. They can be subject to vibration and shocks, not only when transported but also when used in vehicles.

Subclause 9.2 – MECHANICAL HAZARDS associated with moving parts

OPERATORS, PATIENTS and other people need to be protected from MECHANICAL HAZARDS. This can be achieved in a number of ways, for example:

– by providing sufficient distance between people and MECHANICAL HAZARDS;

– by restricting access to areas that present MECHANICAL HAZARDS;

– by providing a barrier, whether mechanical or non-mechanical, between people and MECHANICAL HAZARDS;

– by reducing the RISK associated with MECHANICAL HAZARDS;

– by ensuring adequate OPERATOR control over the movements causing a MECHANICAL HAZARD; or

– by providing back-up systems so that an acceptable RESIDUAL RISK is achieved when the initial control system fails.

When reference is made, in this subclause, to the RISK to persons, rather than to the PATIENT or OPERATOR, it should be noted, that there can be other people, in addition to the PATIENT or OPERATOR in the vicinity of ME EQUIPMENT. Depending upon the ME EQUIPMENT, visitors, family members and other non-qualified personnel could be in the vicinity.

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Subclause 9.2.1 – General

Requirements concerning moving parts have been based on those in other standards applying to non-medical equipment and machinery, but have been modified to take account of the necessity for ME EQUIPMENT to be in contact with or very close to the PATIENT.

Due to the diversity of situations, it is not possible in this standard to dictate where the warnings to address RESIDUAL RISK should be placed. Depending on the application, and the level of RESIDUAL RISK, it could be important to place a warning on the product. It might, however, be acceptable to place the warning only in the ACCOMPANYING DOCUMENTS.

Subclause 9.2.2.4 – GUARDS and ~~protective~~ other RISK CONTROL measures

The degree of protection required for ENCLOSURES or GUARDS protecting moving parts depends upon the general design and INTENDED USE of the ME EQUIPMENT. Factors to be taken into consideration in judging the acceptability of exposed moving parts include the degree of exposure, the shape of the moving parts, the probability of occurrence of accidental contact, the speed of movement and the probability of occurrence that fingers, arms or clothing will be drawn into moving parts (for example where gears mesh, where belts travel on to a pulley or where moving parts close in a pinching or shearing action).

These factors can be considered with respect to both NORMAL USE and the setting of any adjustments, or the replacement of any ACCESSORY or attachment, possibly including the installation, because GUARDS can be provided at installation and might not be part of a single item of STATIONARY equipment.

Features of GUARDS that can be considered include:

– removable with the use of TOOLS only;
– removable for servicing and replacement;
– strength and rigidity;
– completeness;
– creation of additional HAZARDS such as pinch points, and the necessity for additional handling because of the increased need for servicing such as for cleaning.

~~Protective measures addressed by this clause are also intended to include collision detection systems, such as those employing light barriers.~~

~~Protective measures can be used in lieu of continuous activation type control. The protective measures need to provide feedback control.~~

Subclause 9.2.2.5 – Continuous activation

Motion control systems with the OPERATOR in the feedback loop need to employ continuous activation (e.g. momentary contact, dead-man switch). Such factors as speed of motion and visible feedback to the OPERATOR also need to be adequate.

In some circumstances, OPERATOR training and other qualifications are necessary in order to have adequate OPERATOR control. In such cases, it could be desirable to utilize “lock out controls” that require intentional action to allow movement. Examples of such controls include:

– a key switch with an “enable” function;
– a finger print switch with an “enable” function;
– a password card.

In other circumstances, accidental control can be a concern. In this case, controls could employ such construction techniques as:

– control with an “enable” function, before any motions are possible;
– controls with recessed actuators; this could prevent movement if a hand or leg hits actuator unintentionally.

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If the OPERATOR could have access to hazardous moving parts, controls could be designed which would prevent access to the TRAPPING ZONE by location of the OPERATOR controls. An example is a control system that needs two-hand activation.

For OPERATOR control systems without continuous activation, there can be an acceptable mitigation of RISKS, however it is necessary to evaluate the system to the other options in 9.2.2.1.

This clause deals with electronic motion control systems. For manually driven motion systems see other options in 9.2.2.1.

Subclause 9.2.2.6 – Speed of movement(s)

For some medical equipment there will be unavoidable HAZARDS due to moving parts.

Subclause 9.2.3 – Other MECHANICAL HAZARDS associated with moving parts

Subclause 9.2.2.1 deals with MECHANICAL HAZARDS caused by TRAPPING ZONES. Movement could result in other MECHANICAL HAZARDS, such as impact, puncture, etc.

Subclause 9.2.4 – Emergency stopping devices

Emergency stopping devices are designed to prevent accidental damage by preventing or stopping movements of ME EQUIPMENT parts. There could be more than one emergency stopping device on ME EQUIPMENT. ME EQUIPMENT can also include emergency off devices that are intended to disconnect all power to the installation. Emergency off devices are not subject to the requirements of this subclause unless they are also intended to provide the emergency stopping function. Emergency stopping devices could be only one part of the emergency switching function.

Subclause 9.2.5 – Release of PATIENT

This requirement takes account of the possible effect of a power interruption causing unwanted movements, and the likely need in that situation, for the removal of compression forces or the removal of PATIENTS from a hazardous position.

Subclause 9.3 – MECHANICAL HAZARD associated with surfaces, corners and edges

The RISK associated with a sharp edge depends upon the position of the sharp edge and the application of the ME EQUIPMENT. For this reason, compliance with this subclause is checked by inspection. In cases of doubt, the test for sharp edges described in UL 1439 [43], can be used as guidance.

This subclause applies for surfaces accessible during NORMAL USE. Care should be given to protecting SERVICE PERSONNEL, or other internal systems where damage could result in an unacceptable RISK (e.g. fluid systems).

Subclause 9.4 – Instability HAZARDS

In NORMAL USE, many types of ME EQUIPMENT are exposed to a variety of conditions during transport (movement from room to room during NORMAL USE). While the requirements of this standard attempt to represent those that might be encountered, the RISK MANAGEMENT PROCESS should evaluate the conditions under which the ME EQUIPMENT is intended to be used and how those conditions might impact BASIC SAFETY or ESSENTIAL PERFORMANCE.

Where failure to remain stable during the performance of these tests could cause HARM to the OPERATOR, PATIENT and other persons (e.g. from crushing or falling); or result in the ME EQUIPMENT failing to meet the applicable BASIC SAFETY requirements of this standard (such as: exposing hazardous voltages, reducing CREEPAGE DISTANCES or AIR CLEARANCES or creating breaches in fire proof ENCLOSURES which are not clearly obvious) or causing a loss of ESSENTIAL PERFORMANCE, instability should be considered to result in an unacceptable RISK.

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All ME EQUIPMENT is tested for overbalance with 5° tip, 10° tip, and push in 9.4.2.1, 9.4.2.2, 9.4.2.3 a) and b). In 9.4.3.1 a), b) and c) and 9.4.3.2 a) and b), only MOBILE ME EQUIPMENT is tested as these are requirements for wheels and their brakes.

Subclause 9.4.2 – Instability – overbalance

As an aid to understanding, Table A.3 and Figure A.16 illustrate the logic behind the stability test requirements.

Table A.3 – Instability test conditions

Transport warning	Test plane angle	
	10° plane	5° plane
Transport warning not provided	Must pass in all positions	Not applicable (represented by 10° test)
Transport warning provided	Must pass in transport position (only) ~~Must pass in all positions except transport~~	Must pass in all positions except transport

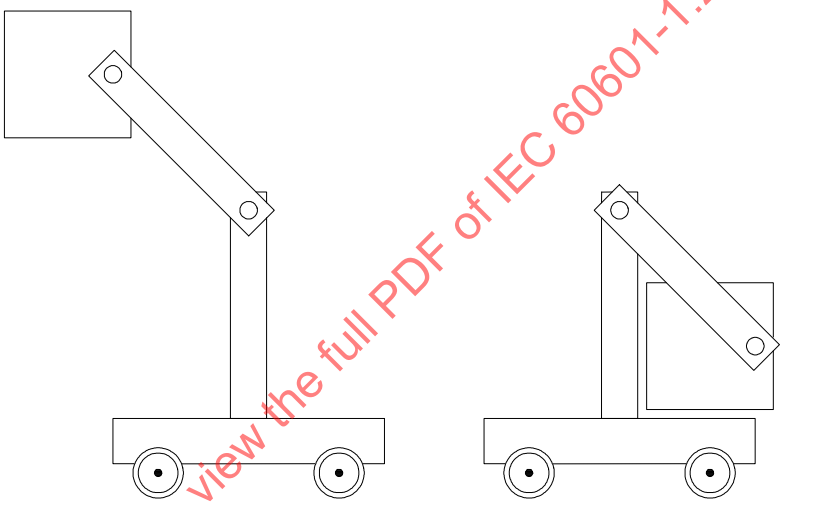


Figure A.16 – Instability test conditions

Subclause 9.4.2.3 a)

The push force of 15 % of the ME EQUIPMENT'S weight or a maximum of 150 N was selected in order to represent foreseeable misuse for typical ME EQUIPMENT, based on input from ME EQUIPMENT MANUFACTURERS. The marking option for ME EQUIPMENT that overbalances with this push force is considered something that provides medical care benefit, and with the no-pushing marking the committee presumes that the RISK would be acceptable, but the MANUFACTURER needs to make this determination based on their own analysis, which might include usability studies, including the location of the marking.

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Subclause 9.4.2.4 – Castors and wheels

Compliance with this subclause is required not only to avoid obvious unacceptable RISK but also to ensure the substantially operative movement as an ESSENTIAL PERFORMANCE. ~~For ME EQUIPMENT to be considered MOBILE, it must be able to be moved from room to room.~~ MOBILE ME EQUIPMENT is defined as equipment intended to be moved from one location to another.

Subclause 9.4.2.4.3 – Movement over a threshold

The 10 mm threshold height came from the thought that cables are represented by an 8 mm to 10 mm height. The committee felt that elevator alignment is now closer to 10 mm (e.g. 4 mm) rather than 20 mm. Normally, hospitals would not have door threshold.

The manual speed of 0,8 m/s was selected from an anticipated range of 0,4 m/s to 1,5 m/s during NORMAL USE, based on input from ME EQUIPMENT MANUFACTURERS. A speed of 0,8 m/s was felt to be the most representative of NORMAL USE and normal walking speed. There's a balance between too slow a speed such that the ME EQUIPMENT won't go over the threshold and too fast a speed causing the ME EQUIPMENT to become unstable. A single speed was selected for the test as this was felt to be necessary for reproducibility among testers.

Some MOBILE ME EQUIPMENT is provided with castors for convenience but not as means to be wheeled across thresholds or similar obstacles. When the MANUFACTURER clearly indicates this use is not intended there should be no need for the threshold test. Examples of equipment that might not require a threshold test include trolleys and treatment tables that are fitted with castors to enable them to be moved easily aside for cleaning the floor or making space.

Subclause 9.4.3 – Instability from unwanted lateral movement (including sliding)

The braking functional verification tests allow the braking system to be assessed with compliance giving the presumption of acceptable RISK. The test criteria assume that generally any initial elastic movement and subsequent movement up to 50 mm are acceptable. In accordance with 4.2, if these movements for a specific piece of ME EQUIPMENT and its INTENDED USE seem inappropriate, the RISK should be lowered with additional RISK CONTROL measures.

The braking push force of 15 % or the maximum of 150 N was selected in order to represent reasonably foreseeable misuse for typical ME EQUIPMENT based on input from ME EQUIPMENT MANUFACTURERS.

The intent of braking requirements is to provide a generic test for general ME EQUIPMENT. Thus compliance criteria are black and white. It is acknowledged that some slow unwanted movement of low weight carts (low momentum), could be considered an acceptable RISK.

It is accepted that for many carts with 4 wheels, providing 2 brakes is a reasonable RISK CONTROL measure to mitigate unwanted movement due to inadequate braking. Placing 4 brakes on many carts will not result in greater usage of the brakes, as some of the wheels will typically be pivoted out of reach.

Subclause 4.5 is always applicable and allows the MANUFACTURER to use alternative RISK CONTROL measures, or variations to test method, or test compliance criteria, with justification.

Subclause 9.4.3.1 c) – Instability in transport

The hard flat surface used in this test should reflect the worst case of INTENDED USE. Slippage of wheels against the hard flat surface is a secondary concern. If slippage is detected, it should be determined whether a more appropriate surface should be chosen for the test or the wheel material is inappropriate.

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Subclause 9.5 – Expelled parts HAZARD

Expelled parts are ME EQUIPMENT parts or fragments of ME EQUIPMENT parts, such as parts of a damaged vacuum display, a mechanical spring, a gas pressure cylinder, a rotating flywheel or an exploded lithium battery that could be expelled by collision, expansion etc.

The degree of protection against “expelled parts” depends upon the probability of occurrence of HARM and the SEVERITY of HARM. Protective measures can include an ENCLOSURE, barrier, or electronic means (e.g. redundant means to prevent lithium battery charging current).

Subclause 9.6.1 – General

Excessive noise can cause fatigue, interference with speech and acoustic signals, or even damage to hearing. Limits to prevent hearing damage are described in ISO standards.

In medically used rooms, much lower limits are needed for the comfort of PATIENTS and medical personnel. The actual effect of ME EQUIPMENT noise is strongly influenced by the acoustical properties of the room, the insulation between rooms and interaction of ME EQUIPMENT parts.

Excessive vibration will cause discomfort to the PATIENT, OPERATOR, and other persons. Prolonged exposure can cause vascular, neurological, or osteo-articular disorders. Excessive vibration can also cause damage to ME EQUIPMENT or a shift in calibration.

Most ME EQUIPMENT covered by this standard exposes the PATIENT and OPERATOR or other persons to negligible levels of noise and vibration. The RISK MANAGEMENT PROCESS should be able to clearly identify those cases where measurements are required.

Subclause 9.6.2 – Acoustic energy

These values are based on the potential for long term hearing impairment. The value usually used for regulatory purposes worldwide is currently 90 dBA with an offset of 5 dBA. However the latest research indicates a value of 85 dBA for 8 h over a 24 h period with an offset of 3 dBA when the time doubles or halves [34].

Although the criteria for judging whether a noise is considered impact noise is intentionally not provided, judgement should be used referring to the situation. Examples of impact noise include: the gradient noise of MRI equipment, and lithotripsy impulses.

Subclause 9.6.3 – Hand-transmitted vibration

Threshold values for vibration are much less clear than those for acoustic energy (noise). The value used here is from the *Directive of the European Parliament and of the Council on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (vibration)* (sixteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). It corresponds to about a 10 % incidence of blanching (indicative of neurological damage) after 8 years of regular exposure according to ISO 5349-1. It is more difficult to establish limit values for whole body vibration. Therefore this standard does not specify such limits. The end points such as back pain and other adverse health effects are not easily quantifiable, and so no agreed-upon exposure standards have been developed. Relevant information of this subject can be found in standards such as ISO 5805 [28], and ISO 8041 [29].

When a person is exposed to various levels of acceleration over a 24 h period, allowable cumulative exposure can be determined as follows. Consider first Table A.4 of allowable time of exposure over a 24 h period for each level of acceleration.

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Table A.4 – Allowable time exposure for level of acceleration

Allowable time of exposure over a 24 h period h	Acceleration m/s^2
1	7,07
2	5,00
3	4,08
4	3,54
5	3,16
6	2,89
7	2,67
8	2,50
9	2,36
12	2,04
16	1,77
24	1,44

Some examples of allowable cumulative exposure are provided below.

If a person were exposed to a 5 m/s^2 acceleration for 1 h (which represents 1/2 daily allowable exposure time for this acceleration), followed by an exposure to a 1,44 m/s^2 acceleration for 12 h (which represents 1/2 daily allowable exposure time for this acceleration), this would be an acceptable cumulative exposure over a 24 h period.

If a person were exposed to a 4,08 m/s^2 acceleration for 1 h (which represents 1/3 the allowable daily exposure time for this acceleration), followed by exposure to a 2,36 m/s^2 acceleration for 3 h (which represents 1/3 allowable daily exposure time for this acceleration), followed by exposure to a 1,44 m/s^2 acceleration for 8 h (which represents 1/3 allowable daily exposure time for this acceleration), this would be an acceptable cumulative exposure over a 24 h period.

If a person were exposed to a 5 m/s^2 acceleration for 1 h (which represents 1/2 the allowable daily exposure time for this acceleration), followed by exposure to a 4,08 m/s^2 acceleration for 1 h (which represents 1/3 allowable daily exposure time for this acceleration), followed by exposure to a 2,04 m/s^2 acceleration for 2 h (which represents 1/6 allowable daily exposure time for this acceleration), this would be an acceptable cumulative exposure over a 24 h period.

To summarize, for each acceleration determine the fractional value of allowable daily exposure by dividing the actual exposure time for a given acceleration by the allowable daily exposure time for that acceleration. The sum of the fractional values for each acceleration is not to be greater than 1.

Subclause 9.7 – Pressure vessels and parts subject to pneumatic and hydraulic pressure

The requirements of this subclause do not represent the most stringent combination of national regulations or standards.

In some countries such regulations or standards apply.

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Type of systems considered include pneumatic pressure systems, hydraulic pressure systems, steam pressure systems and combinations thereof. These systems might or might not include pressure vessels.

HAZARDS

a) Mechanical rupture or breakage (HARM: lacerations, puncture wounds)

The requirements from Clause 45 of the second edition dealing with this HAZARD, have been moved to this subclause, and remain unchanged.

Requirements have been clarified to indicate that all parts have a MAXIMUM PERMISSIBLE WORKING PRESSURE not less than the pressure in NORMAL CONDITION or SINGLE FAULT CONDITION. In principal there should be a suitable safety factor between the MAXIMUM PERMISSIBLE WORKING PRESSURE and the bursting pressure, where the bursting pressure is the pressure at which a part suffers from permanent (plastic) deformation or leakage. Industry standards for pressure parts vary, but suitable safety factors are 3 ×, 4 ×, and sometimes 5 × (ISO, ASME, SAE). As a suitable safety factor can vary depending on factors associated with the end-use application and RISK, it was considered inappropriate to specify a minimum safety factor in the definition of MAXIMUM PERMISSIBLE WORKING PRESSURE, but instead leave this to the declaration of the MANUFACTURER of such part. It is assumed that MAXIMUM PERMISSIBLE WORKING PRESSURE declarations will be based on recognized international or national standards, and therefore below bursting pressures at least in line with the multiplication factor shown in Figure 32, (3 ×, derated after 1 MPa to as low as 1,3 × after 30 MPa).

For pressure vessels exceeding both an energy limit (pressure × volume) and a maximum pressure limit, the requirement is to conduct a hydrostatic overpressure test based on the MAXIMUM PERMISSIBLE WORKING PRESSURE declaration and the multiplication factor shown in Figure 32, (3 ×, derated after 1 MPa to as low as 1,3 × after 30 MPa).

b) Mechanical loss of support (HARM: crush, puncture wounds)

Requirements have been clarified to specify that components in a pressure system, such as those in a hydraulic lift system whose integrity is relied on to reduce the RISK from loss of support need to comply with the NORMAL CONDITION TENSILE SAFETY FACTORS specified in 9.8. The TENSILE SAFETY FACTOR is typically 4 × for parts not impaired by wear, and 8 × for parts impaired by wear (Case B). Thus parts subject to pressure whose failure could result in mechanical rupture and loss in support need to have a MAXIMUM PERMISSIBLE WORKING PRESSURE based on the higher of the SINGLE FAULT CONDITION pressure and the MANUFACTURER's declaration for each system component as specified in 9.7, or the NORMAL CONDITION pressure and the TENSILE SAFETY FACTOR as specified in 9.8.

c) Leakage of toxic gas or liquid (HARM: chemical or biological cell damage)

The requirements from Clause 45 of the second edition dealing with this HAZARD have been moved to this clause, and remain unchanged.

Requirements have been clarified to indicate that all pressure system components need to have a MAXIMUM PERMISSIBLE WORKING PRESSURE based on the SINGLE FAULT CONDITION pressure and the MANUFACTURER's declaration for each system component.

d) Leakage of flammable gas or liquid (HARM: fire causing burns or property damage)

The requirements from Clause 45 of the second edition dealing with this HAZARD, have been moved to this clause, and remain unchanged.

Requirements have been clarified to indicate that all pressure system components need to have a MAXIMUM PERMISSIBLE WORKING PRESSURE based on the SINGLE FAULT CONDITION pressure and MANUFACTURER'S declaration each system component.

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Subclause 9.7.5 – Pressure vessels

The Oxford dictionary defines a pressure vessel as “a container designed to hold material at high pressures.” This is the usage intended by this standard.

It is assumed that a hydraulic test is not necessary if the pressure is less than or equal to 50 kPa or the product of the pressure and volume is less than or equal to 200 kPa · l.

The safety factors implied by Figure 32 are higher than those generally applied in testing pressure vessels. However, whereas hydraulic testing is normally used to verify that a pressure vessel is free from production faults or serious deterioration, the adequacy of the design being determined in other ways, the present hydraulic test is intended to verify the adequacy of a design where this cannot be established in other ways.

The deletion of national references in the amended text avoids subordinating the requirements of the standard to those of local regulations. The ME EQUIPMENT will sometimes have to satisfy both, or the more demanding, assuming that there are no local regulations that conflict with this standard.

A hydraulic test is specified even for pneumatic vessels, as this is safer for the tester. In achieving the test pressure with a gas, the gas will compress, resulting in more stored energy in the test vessel than would a hydraulic test method. Both methods result in the same test pressure, which is the objective of the test.

Subclause 9.8 – MECHANICAL HAZARDS associated with support systems

The term “support” is taken to include “suspension” and loads can include PATIENTS, OPERATORS and other masses.

Support systems can broadly be categorized as follows.

– A suspension system is one that contains flexing or rigid elements that are designed to suspend masses, including PATIENTS and OPERATORS during NORMAL USE.

– Flexing elements include ropes, cables, chains, belts, bands and springs. Additionally a jack screw nut is considered impaired by wear to the extent needing a higher TENSILE SAFETY FACTOR.

– An actuating system is one that contains elements such as electric, pneumatic or hydraulic actuators, motors, gearboxes, shafts, bearings, pulleys, sheaves, band wheels and guides.

– A support structure is generally a rigid device that can be static or moving and which supports ME EQUIPMENT, external loads and, where necessary, PATIENTS and OPERATORS.

Subclause 9.8.2 – TENSILE SAFETY FACTOR

TENSILE SAFETY FACTORS are applied to provide a margin of safety to the design after all reasonable allowances for operating conditions, material and manufacturing variables, etc., have been made.

In determining whether case A or B is to be used from Table 21, certainty of material strength is required in order to apply case A values. Additionally there needs to be confidence in the determination of TOTAL LOAD in order to apply case A values. TOTAL LOAD is constituted from “static force” and “dynamic force” components. The static force is normally clear. But the dynamic force/loading is sometimes uncertain. When the dynamic forces are known as well as static forces, the TENSILE SAFETY FACTOR is determined with case A. When the dynamic forces are not clear, and the static forces are known, the TENSILE SAFETY FACTOR is determined with case B.

External forces for PATIENT supports can include those generated by application of CPR, etc.

Elongation at break of 5 % is based on historical experience with metallic materials, in particular steel and cast iron. Materials with elongation at break less than 5 % are considered

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brittle and their failure is likely catastrophic, and therefore a higher safety factor is considered appropriate.

For non-metallic materials:

– Where no other experience exists, and where failure mode is likely catastrophic, this elongation factor is considered appropriate, and therefore a higher TENSILE SAFETY FACTOR is considered appropriate.

– Where experience and testing show otherwise, an elongation at break of less than 5 % can be appropriate before a higher TENSILE SAFETY FACTOR is justified.

For example, PATIENT tables of X-ray/CT/MR systems are often designed with plastic materials laminated or reinforced by carbon fibres/cloths or glass fibres/cloths, since these PATIENT tables must be optimised for low absorption of X-ray radiation (aluminium equivalence), MR compatibility (low proton signal), as well as structural stability. Although these plastic materials reinforced by carbon fibres/cloths can have elongation at break of less than 5 %, many years knowledge, acquired expertise, and post-market surveillance can provide sufficient evidence that suitable structural stability of PATIENT tables is achieved by applying a TENSILE SAFETY FACTOR from Table 21, Situation 1 (rather than Situation 2).

At end of life or periodic maintenance cycle, ME EQUIPMENT needs to maintain structural integrity. Line 1 of Table 21 is normally appropriate for end of life or the end of the periodic maintenance cycle since wear is no longer considered.

Suspension and actuating systems have TENSILE SAFETY FACTORS that are necessarily high to reduce the effects of deterioration through wear and fatigue.

Particular attention should be given to the fixing of structures to floors, ceilings, etc. that are subject to variable TENSILE SAFETY FACTORS.

A hidden defect is one that is not revealed during manufacture, service or normal operation of the ME EQUIPMENT but that could cause failure of a part that could result in a HAZARD. Examples are high internal stresses in heat-treated parts such as springs, broken strands of wire inside cables and porosity inside castings.

Figure A.17 contains an example of determining the appropriate TENSILE SAFETY FACTOR using Table 21. Figure A.18 contains an example of determining design and test loads. These examples are not intended to cover all possible cases. For a particular design, these TENSILE SAFETY FACTORS and design/test loads can vary according to the materials used, their wear characteristics, loading conditions, etc.

This subclause focuses on safety factors as the suggested approach to have confidence that the equipment will maintain structural integrity during its EXPECTED SERVICE LIFE. In some cases the specified safety factors are more than needed, and in some cases even larger factors could be considered appropriate. The compliance criteria can be satisfied by RISK MANAGEMENT rather than by the use of the safety factor route. For new materials or for structures with sophisticated monitoring of stresses, the safety factors might not be necessary.

If it is deemed that the failure mode of the part does not result in an unacceptable RISK, the TENSILE SAFETY FACTORS specified in Table 21 do not apply. For example, for proprietary components such as bearings it is acceptable to rely on the component MANUFACTURER'S data for load and life expectancy without applying a TENSILE SAFETY FACTOR.

A jack screw nut considered impaired by wear is usually intentionally constructed from a material softer than the jack screw. The intent is to have generic requirement provided for general ME EQUIPMENT.

Newer jack screw designs can have less friction than traditional designs, and, for example, can include multiple ball bearings. Such designs can be considered as less “impaired by wear” as dictated by vendor declarations and a MANUFACTURER’S RISK ASSESSMENT.

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Subclause 4.5 is always applicable and allows the MANUFACTURER to use alternative RISK CONTROL measures, or variations to a test method or test compliance criteria, with justification.

Subclause 9.8.3 – Strength of PATIENT or OPERATOR support or suspension systems

This subclause deals with forces applied on support or suspension parts of ME EQUIPMENT, intended to support or suspend the mass of a human body or part of the mass of a human body, and to ACCESSORIES used on such support or suspension parts. For adult PATIENTS or OPERATORS the 135 kg mass represent the 99 percentile of the population. For specific populations, higher mass or lower mass can be used (e.g. heavy person or paediatric application).

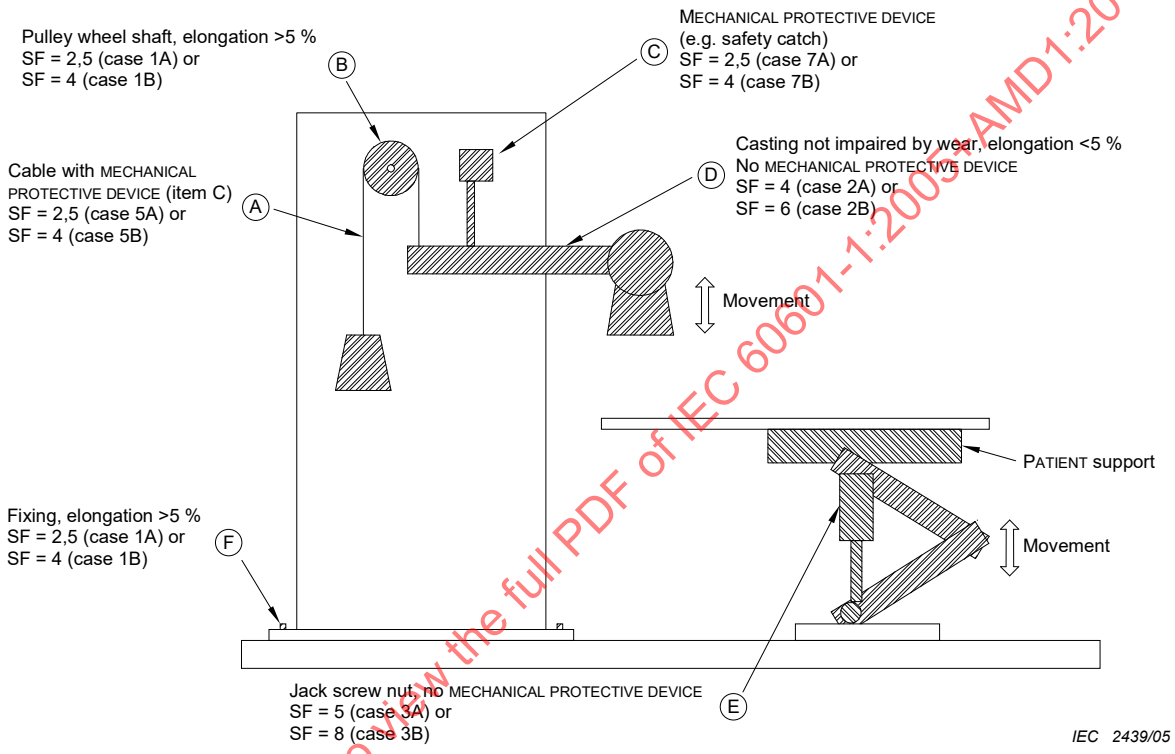
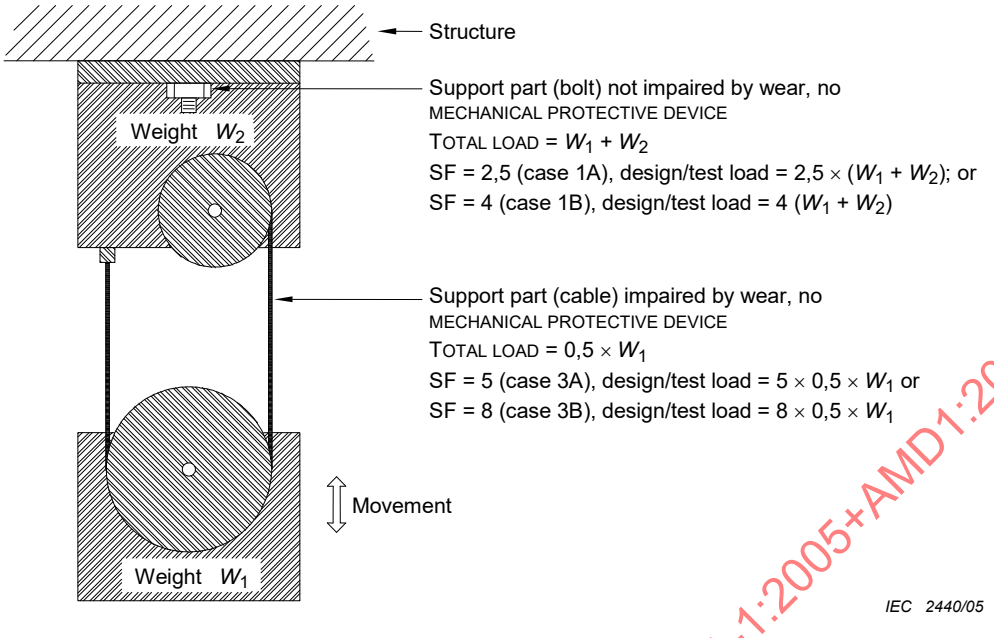


Figure A.17 – Example of determining TENSILE SAFETY FACTOR using Table 21

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NOTE TOTAL LOAD is shown based on only static forces to obtain actual total loads, dynamic forces also need to be included.

Figure A.18 – Example of determining design and test loads

Subclause 9.8.3.2 – Static forces due to loading from persons

Figure A.19 contains an example of human body mass distribution for PATIENT support surfaces.

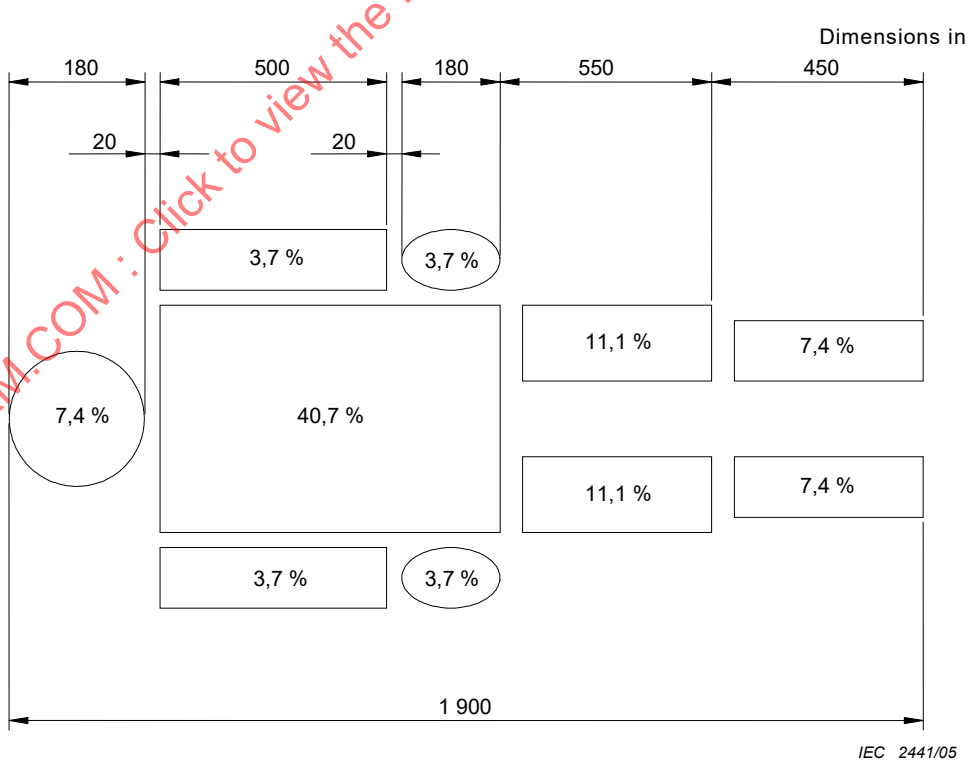


Figure A.19 – Example of human body mass distribution

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The distribution mass of a body diagram is an average distribution based on anthropometrical data. Due to the variety of population or specific categories of age, it can vary. For sedentary people not having a physical activity the mass of the upper part of the body can represent a more important percentage.

The variety of ME EQUIPMENT does not allow more precision to be given in this general standard. It is up to the particular standard to define more adequately the distribution area or the worst-case position, rather than dynamic tests.

A foot rest is tested for twice its normal load, rather than a load based on a TENSILE SAFETY FACTOR value from Table 21, as it is intended to support a PATIENT'S weight for only a short duration of time.

The test with a mass of 80 kg placed 60 mm from the outer edge is intended to simulate the centre of gravity of a PATIENT sitting or leaning on the edge of a support surface.

During the static loading tests, it's intended that any temporary elastic deflection (during the test), and permanent plastic deflection (after the test) are checked for any adverse effect on BASIC SAFETY or ESSENTIAL PERFORMANCE.

For the step loading test, the committee felt that a 5° deflection would provide a measurable quantity that would represent a reasonable limit for acceptance. The 2X loading factor is a precedent from the 2nd edition of IEC 60601-1, and seems to recognize the temporary loading that steps represent during their life.

For the sitting surface loading test, no specific linear or arc limits are specified. The intent is to evaluate any temporary elastic or permanent plastic deflections for any adverse effect on BASIC SAFETY or ESSENTIAL PERFORMANCE. The 60 % sitting loading factor was considered representative of actual sitting load, when legs are dangling off the edge of the sitting surface. Loss of function is not considered unacceptable unless associated with ESSENTIAL PERFORMANCE. The intent is damage should not result in injury to persons, or loss of RISK CONTROL measures. Surfaces that are intended to support sitting and at other times full patient loads are also evaluated for compliance with the appropriate loading factor(s) in 9.8.2.

Subclause 9.8.3.3 – Dynamic forces due to loading from persons

A general dynamic test is defined which represents common situations represented by a person sitting down or standing up.

The requirement of this subclause is intended to apply to the chairs for dental surgical procedures, X-ray tables, and many other similar types of ME EQUIPMENT. The ME EQUIPMENT should be in all operating modes and positions where dynamic loads from PATIENTS can be reasonably expected. For example, when a PATIENT table is positioned in an area of a CAT or magnet structure, the dynamic test is not applicable as the dynamic loading caused by a PATIENT is negligible.

ME EQUIPMENT should be designed to bear a repeating force, by considering appropriate TENSILE SAFETY FACTORS and the results of fatigue calculations. TENSILE SAFETY FACTORS exist to show the reliability of the equipment without real testing.

The bottom portion of the human body test mass apparatus shown in Figure 33 is foam, and should simulate contact by the relevant PATIENT part.

Subclause 9.8.4 – Systems with MECHANICAL PROTECTIVE DEVICES

The intent of a MECHANICAL PROTECTIVE DEVICE is to act to prevent HARM in the event of the failure of the primary support means that is subject to wear. The failure of the primary support means subject to wear is considered a SINGLE FAULT CONDITION if it has a TENSILE SAFETY FACTOR in accordance with Table 21, rows 5 and 6. To protect against HARM in this SINGLE FAULT CONDITION, the MECHANICAL PROTECTIVE DEVICE acts as a backup, and needs to have the TENSILE SAFETY FACTOR indicated in Table 21, Row 7. It is considered good engineering practice to construct a MECHANICAL PROTECTIVE DEVICE from non-brittle materials, and therefore Row 7 does not include an elongation column.

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To test a MECHANICAL PROTECTIVE DEVICE, the primary support means subject to wear needs to be defeated. For example if the primary support system is a cable, the cable would be cut.

Clause 10 – Protection against unwanted and excessive radiation HAZARDS

Radiation from ME EQUIPMENT can occur in all forms known in physics. BASIC SAFETY requirements are concerned with unwanted radiation. Protective measures are necessary for ME EQUIPMENT and for the environment and methods for determining levels of radiation need to be standardized.

This clause is intended to deal with stray radiation (such as scattered radiation from radiological equipment) and incidental radiation (such as X-ray emitted by CRTs). A requirement for unintended or excessive output of radiation that ME EQUIPMENT is intended to deliver to the PATIENT is covered in 12.4.5.

For ionizing radiation IEC requirements generally comply with the International Commission for Radiation Protection (ICRP) Recommendations. Their purpose is to provide data that are immediately usable by designer and RESPONSIBLE ORGANIZATION.

Their evaluation is possible only by adequate study of operating methods and duration of operation of ME EQUIPMENT and positioning of OPERATOR and assistants, because application of worst case conditions would give rise to situations that might hamper proper diagnosis or treatment.

Recent ICRP publications also instruct the OPERATOR in methods for the restriction of intentional irradiation.

Subclause 10.1.1 – ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation

Spurious X-radiation from components such as Video Display Units (VDU) is a potential source of concern for ME EQUIPMENT, many of which contain VDUs. Annex H of IEC 60950-1:2001 contains a well-accepted PROCEDURE for measuring such spurious emissions for information technology equipment. The limits in that annex are based on ICRP 60 [39]. The requirements from Annex H of IEC 60950-1:2001 were incorporated into the body of this standard because this was the only normative reference that required the use of IEC 60950-1.

Other normative references to IEC 60950-1 are alternative means of addressing items such as CREEPAGE DISTANCE and AIR CLEARANCE. A user of this standard does not have to reference 60950-1 unless they wish to use the insulation coordination methods contain in that document.

Subclause 10.3 – Microwave radiation

This subclause specifies a microwave power density limit to mitigate thermal harm to whole body tissue. The intention is that compliance might be appropriately determined with engineering judgement, in lieu of testing, when it's obvious that emissions are nowhere near the 10 W/m^2 power density limit. Knowledge about equipment transmission specifications and engineering judgement might be used to determine compliance. The safety threshold of 10 W/m^2 greatly exceeds that allowed for wireless communication uses, where SAR (W/kg) limits are applicable. For example, equipment with microprocessor clock oscillators or intentional transmission radios such as Wi-Fi™, Bluetooth®, GPS, or cellular would comply with this threshold since these meet more stringent limits for their applicable bandwidth. When this confidence does not exist, appropriate power density measurements should be conducted.

Subclause 10.4 – Lasers ~~and light emitting diodes (LEDs)~~

~~A dated reference to IEC 60825-1 was used because at the time of publication of this standard IEC/TC 76 was in the early stages of developing a third edition of IEC 60825-1 and was considering removing the requirements for LEDs from IEC 60825-1.~~

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IEC 60825-1 is applicable to safety of laser products emitting laser radiation in the wavelength range 180 nm to 1 mm. A laser product can consist of a single laser with or without a separate power supply or it can incorporate one or more lasers in a complex optical, electrical, or mechanical system.

Any laser product is exempt from all further requirements of IEC 60825-1 if classification by the manufacturer of that product according to Clauses 3, 8 and 9 of IEC 60825-1 shows that the emission level does not exceed the AEL (Accessible Emission Limit) of Class 1 under all conditions of operation, maintenance, service and failure.

In previous editions of IEC 60825-1, LEDs were included in the scope of that standard, and they can be still included in other parts of the IEC 60825 series. However, with the development of lamp safety standards, optical radiation safety of LEDs in general can be more appropriately addressed by lamp safety standards. The removal of LEDs from the scope of IEC 60825-1 does not preclude other standards from including LEDs whenever they refer to lasers. IEC 62471 [67] can be applied to determine the risk group class of an LED or product incorporating one or more LEDs.

IEC 62471 gives guidance for evaluating the photobiological safety of lamps and lamp systems including luminaires. Specifically, it specifies the exposure limits, reference measurement technique and classification scheme for the evaluation and control of photobiological hazards from all electrically powered incoherent broadband sources of optical radiation, including LEDs but excluding lasers, in the wavelength range from 200 nm through 3 000 nm. IEC 62471 was originally prepared as Standard CIE S 009:2002 by the International Commission on Illumination.

Subclause 11.1 – Excessive temperatures in ME EQUIPMENT

Temperature limits are required to prevent ~~HAZARDS~~ HAZARDOUS SITUATIONS for almost all types of ME EQUIPMENT with the purpose of preventing rapid ageing of insulation and discomfort where ME EQUIPMENT is touched or manipulated, or injuries where PATIENTS could contact ME EQUIPMENT parts.

ME EQUIPMENT parts might be inserted into body cavities, usually temporarily but sometimes permanently.

For PATIENT contact, special temperature limits have been set.

Subclause 11.1.1 – Maximum temperature during NORMAL USE

Table 22 addresses limits for parts that could affect compliance of the ME EQUIPMENT with this standard in general (e.g. electrical BASIC SAFETY).

It is not intended that the ME EQUIPMENT parts be tested in every possible configuration of NORMAL USE as long as the MANUFACTURER can determine the worst-case conditions. The "worst case" will almost always include the highest allowable ambient temperature and operation of the ME EQUIPMENT at the maximum DUTY CYCLE, but other specific aspects of the configuration of the ME EQUIPMENT (such as attachment of ACCESSORIES) should be determined by the MANUFACTURER based on a thorough understanding of the ME EQUIPMENT'S design.

Subclause 11.1.2 – Temperature of APPLIED PARTS

Table 23 and Table 24 addresses HAZARDS that could arise from human contact with higher temperatures. Human contact temperatures were based on clinical expertise, clinical literature [52] and experimentation. In addition, the values agree with those of the European Norm EN 563 [38].

Although the maximum surface temperature for an APPLIED PART was raised from 41 °C to 43 °C in response to the clinical input mentioned above, input from some clinicians pointed out that infants as well as some other (thermally) high risk groups could be more prone to HARM from heated surfaces at 43 °C.

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Ideally, particular standards for ME EQUIPMENT used for these PATIENT groups would have requirements for (where necessary) lower contact temperatures. In order to address those cases where such particular standards do not exist, the working group felt that notification of the RESPONSIBLE ORGANIZATION when temperatures exceed the second edition limit of 41 °C was adequate. However, the new 43 °C limit is to be considered an absolute maximum.

When measuring APPLIED PART temperatures, the method used should simulate the worst-case configuration when possible using real or simulated human skin. Determination of the worst-case configuration should consider aspects such as the likely body temperature and whether or not the part of the body or APPLIED PART itself is covered (such as with a blanket). Simulated human skin for these purposes could include materials such as silicon rubber.

Subclause 11.1.2.2 – APPLIED PARTS not intended to supply heat to a PATIENT

Table A.5 is provided as guidance for ME EQUIPMENT that creates low temperatures (cools) for therapeutic purposes or as part of its operation. Normative requirements have not been included in this standard because such ME EQUIPMENT is uncommon.

Table A.5 – Guidance on surface temperatures for ME EQUIPMENT that creates low temperatures (cools) for therapeutic purposes or as part of its operation

ME EQUIPMENT and its parts		Minimum Temperature [a] °C	
		Aluminium	Steel
External surface of ME EQUIPMENT and its parts that are likely to be touched for a time "*t*".[b]	$t < 1$ s	–20	–20
	1 s ≤ t < 10 s	–10	–15
	10 s ≤ t < 60 s	–2	–7

[a] The allowable minimum temperature limit values for external surfaces that are likely to be touched by the PATIENT, OPERATOR and other persons are based on freezing threshold values of a finger touching different materials (frostbite threshold).

[b] The probability of occurrence of contact and the duration of contact should be determined and documented in the RISK MANAGEMENT FILE.

Subclause 11.1.3 – Measurements

The proper use of thermocouples is recognized in other standards as a valid test technique. The temperature limits are lowered to compensate for errors that could occur in the construction and placing of the thermocouple.

During development of the requirements of 11.1.3, the working group discussed whether it would be appropriate to reduce the maximum allowable temperature for surfaces and APPLIED PARTS at higher altitudes. In response to this question, a thorough evaluation was performed by Dr. Joachim Kohl, an expert member of the group. The following summarizes the results of that evaluation (see Figure A.22).

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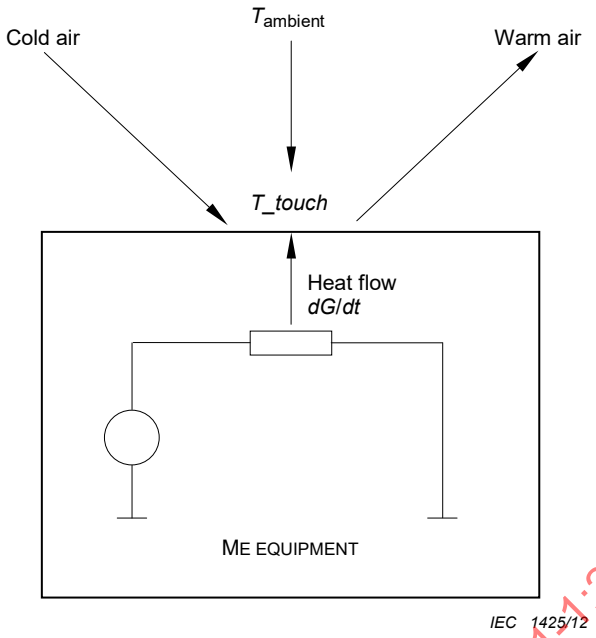


Figure A.22 – Maximum allowable temperature for surfaces and APPLIED PARTS at higher altitudes

The following variables and symbols are used in the evaluation:

T_touch	touch temperature at the surface of the ME EQUIPMENT
DeltaT	temperature difference of the touched area to ambient
R_thermal	thermal resistance of the ME EQUIPMENT area under test to ambient
Q	heat
dQ/dt	heat flow
Pambient	ambient air pressure
alpha	heat transfer coefficient = *dQ/dt* / (*DeltaT* * *area*)
L	characteristic length of the heat transfer area
area	cooling area of the device
lambda	heat conductance
eta	dynamic viscosity
rho	density of gas
Nu	Nusselt number
Re	Reynold number
Gr	Grashof number
sqrt	square root
~	proportional

Evaluation of the effects of altitude on thermal transfer:

The standard heat transfer equation is:

$$DeltaT = R_thermal * dQ/dt$$

For *R_thermal*, one can estimate:

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$$R_thermal \sim 1 / Pambient^{m}$$

with the exponent m = 0,6 … 0,8, we will assume 1.

Equations about the proportionality to 1 / *Pambient*^{m}:

Therefore,

$$R_thermal \sim 1 / alpha$$

where the proportionality factor contains geometric data.

Definition of *Nu*:

$$Nu = alpha * L / lambda$$

Results of theoretical investigations:

$$Nu \sim Re^{m}$$

The proportionality factor depends on geometry and on the kind of gas and the way of air flow, but not on temperature, pressure, density.

The exponent m is determined by geometry and the way of air flow. For free convection due to a temperature gradient *Re* is given by:

$$Re = sqrt\ (\ 0{,}4 * Gr)$$

The definition of *Gr* leads to:

$$Gr \sim (rho\ /\ eta)^{2}$$

so that:

$$Re \sim rho / eta.$$

This last relationship also holds true for forced convection.

From the general gas equation we can see:

$$rho \sim Pambient$$

Lambda and *eta* do not depend on pressure (according to standard physics textbooks). Putting it all together leads to the above stated proportionality between *R_thermal* and *Pambient*.

Subclause 11.2 – Fire prevention

Within most environments where ME EQUIPMENT is used, other sources of “fuel” for combustion are typically far more significant than that provided by the ME EQUIPMENT itself. The requirements addressing fire in this standard focus on preventing the ME EQUIPMENT from being the source of combustion. For this reason, these requirements focus on ME EQUIPMENT that contains or is used in the presence of OXYGEN RICH ENVIRONMENTS. These requirements attempt to ensure that any potential source of ignition remains isolated from the OXYGEN RICH ENVIRONMENTS under NORMAL USE and SINGLE FAULT CONDITIONS.

Where ME EQUIPMENT is not used in such environments, assuring that the limits for operating temperatures and requirements for overload protection are met should be considered adequate.

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For ME EQUIPMENT that could provide a significant source of fuel (in comparison to the normal operating environments) additional requirements should be provided by particular standards. Where no particular standard exists, such issues should be specifically addressed in applying the RISK MANAGEMENT PROCESS as required in 4.2.

Subclause 11.2.1 –Strength and rigidity required to prevent fire in ME EQUIPMENT.

At least all electrical parts that could result in a ~~HAZARD~~ HAZARDOUS SITUATION, with the exception of POWER SUPPLY CORDS and other necessary interconnecting cords, should be enclosed in material that will not support combustion.

This does not preclude the use of an outer cover of other material covering an inner cover complying with the above recommendation.

For guidance on assessing fire HAZARDS, see IEC 60695-1-10 [17].

Subclause 11.2.2 – ME EQUIPMENT and ME SYSTEMS used in conjunction with OXYGEN RICH ENVIRONMENTS

While not a flammable mixture, the presence of an OXYGEN RICH ENVIRONMENT increases the flammability of many substances. Reports of fires in OXYGEN RICH ENVIRONMENTS in ME EQUIPMENT are unusual. However, when such fires do occur in the hospital environment they can have tragic consequences.

ME EQUIPMENT intended to operate in conjunction with an OXYGEN RICH ENVIRONMENT should be designed to minimize the probability or occurrence of ignition of flammable materials.

Where appropriate, particular standards should specify the corresponding requirements.

Subclause 11.2.2.1 a)

Cotton is regarded to be the material with the lowest ignition temperature and energy in comparison with electronic circuits and it is assumed that it can be found in the interior of a device as dust.

The maximum surface temperature limit is based on the minimum hotplate ignition temperature for fire retardant cotton in 100 % oxygen that is given in NFPA 53 [41] as 310 °C. The assumption was therefore made that 300 °C was an acceptable temperature limit in ME EQUIPMENT with OXYGEN RICH ENVIRONMENTS.

The worst case conditions described in the text make it possible to provide simple numbers as limitations.

The values for sparking are taken from Kohl, H.-J. *et al.*, ASTM STP 1395 [37].

This subclause allows the use of electronic circuits in OXYGEN RICH ENVIRONMENTS only when their power supply is limited. The resistive limitation of the power input is necessary for the SINGLE FAULT CONDITION of an open solder joint that might spark. The same reason applies to the limitation of energy in capacitances and inductances. In most cases the limitation in item 4) to 300 °C is more restrictive than these. For most small components like decoupling capacitors, or where the failure of a component causes the maximum possible power to be drawn from the source, it is necessary to limit the power to about 1 W. The PROCEDURE to find the necessary value to limit the power so that the 300 °C limit is not exceeded can be as follows:

– look for the smallest component that can match to the power source in a SINGLE FAULT CONDITION;
– estimate its thermal resistance;
– calculate the power limitation = 200 °C / thermal resistance.

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Subclause 11.2.2.1 b) 2)

This item addresses the condition of an undetected oxygen leak. In accordance with the definition of SINGLE FAULT SAFE, such a leak (because it is undetected) is considered a NORMAL CONDITION (see 4.7). Similarly, only the failure of the ventilation, which is undetected, needs to be considered a NORMAL CONDITION. Where a ventilation system's design makes it unlikely that it will be completely blocked in NORMAL USE, such blockages should not be considered. The only way to find the maximum leak rate that needs to be considered is to find the minimum leak rate that can safely be detected by the RESPONSIBLE ORGANIZATION.

Subclause 11.2.2.1 b) 3)

The cause of the HAZARDOUS SITUATION is: a leak occurs and is not detected; some time later an electrical failure occurs that starts an ignition. The time interval t_c for checking the seals can be calculated as follows:

– estimate the probability per time p_e of an electrical failure that exceeds the values given in 11.2.2.1 a);

– estimate the probability per time of the oxygen leak p_o ;

– determine the accepted probability of dangerous failures per time r;

– calculate: $t_c = r / (0{,}5 \times p_e \times p_o)$.

Subclause 11.2.2.2 – External exhaust outlets for OXYGEN RICH ENVIRONMENT

Serious oxygen fires have been reported where the ignition source has been a faulty electrical connector close to an oxygen outlet.

Subclause 11.3 – Constructional requirement for fire ENCLOSURES of ME EQUIPMENT

The requirements for fire ENCLOSURES from IEC 61010-1 [22] have been included primarily as an alternate to the tests related to SINGLE FAULT CONDITIONS (associated with combustion and its consequences listed in Clause 13). By requiring flame resistance for the ENCLOSURE and materials contained within it, the probability of occurrence of fire escaping such ENCLOSURES is considered minimal. Where the fire ENCLOSURE constitutes only a part of the ME EQUIPMENT, careful analysis should be performed to assure that a reliable barrier to the propagation of fire exists.

IEC 60950-1:2005 components (i.e. power supplies, modems, network routers, etc.) are allowed to be integrated into ME EQUIPMENT when MOOP insulation has been determined to be adequate and TOUCH CURRENT limits have been satisfied.

The flame resistance requirements for wire insulation, when used inside a fire ENCLOSURE, in accordance with IEC 60950-1:2005, subclause 4.7.3.4, are:

– Minimum of FV-2 when tested in accordance with IEC 60695-11-10, or

– insulated with PVC, TFE, PTFE, FEP, polychloroprene or polyimide.

While the ME EQUIPMENT flame resistance requirement of FV-1 for wire insulation when used inside a flame enclosure is slightly more stringent than the IEC 60950-1:2005, subclause 4.7.3.4 requirement, it would seem reasonable to conclude an equivalent level of risk should IEC 60950-1 compliant wire be integrated into the ME EQUIPMENT or ME SYSTEM either:

– indirectly when IEC 60950-1 components have been integrated into the ME EQUIPMENT or ME SYSTEM, or

– directly as part of a wire selection decision for the ME EQUIPMENT or ME SYSTEM.

IEC 61010-1:2010 [22], subclause 9.3.2, requires wire insulation when used inside a fire enclosure to have a UL 2556 [72] rating of VW-1, or comply with the applicable requirements of IEC 60332-1-2 [55] or IEC 60332-2-2 [56]. These wire flame resistance requirements are considered acceptable for ME EQUIPMENT and ME SYSTEMS.

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Subclause 11.4 – ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics

While the use of flammable anaesthetics is uncommon, it was determined during the writing of this edition that some MANUFACTURERS might still want to rate their ME EQUIPMENT as CATEGORY AP or CATEGORY APG. In order to make this edition more usable (by removing the rarely used section on this topic) while maintaining the availability of the CATEGORY AP and CATEGORY APG RATINGS, the material has been moved to an annex and only this clause's brief reference to it remains in the body of the standard.

The final determination of whether ME EQUIPMENT should be RATED CATEGORY AP or CATEGORY APG should be determined by the MANUFACTURER based on the INTENDED USE. Requirements related to CATEGORY AP and CATEGORY APG are found in Annex G (see also the rationale for Annex G).

Subclause 11.5 – ME EQUIPMENT and ME SYSTEMS intended for use with flammable agents

While it was necessary to address cases where ME EQUIPMENT is used with flammable agents (such as some disinfectants) or in areas where they are commonly used and where the MANUFACTURER of the ME EQUIPMENT has given no special handling instructions or precautions, the variety of such agents, their volatility as well as many other determinant factors precludes giving specific instructions. The only reasonable solution in such cases is to assure that the MANUFACTURER evaluates and addresses the associated RISK.

A mixture of the vapour of a flammable disinfection or cleaning agent with air can be treated as a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR subject to national or local regulations.

Subclause 11.6.2 – Overflow in ME EQUIPMENT

The purpose of this test is to assess not only whether the liquid actually wets any parts in a way that would adversely affect a MEANS OF PROTECTION or result in a HAZARD; but also whether a similar amount of liquid that could overflow on another occasion and reach the same parts of the ME EQUIPMENT, but possibly not land in exactly the same way, could adversely affect a MEANS OF PROTECTION or result in a HAZARD. The results of the test should be evaluated to assure they realistically represent conditions that will be experienced when the ME EQUIPMENT is used.

Subclause 11.6.3 – Spillage on ME EQUIPMENT and ME SYSTEMS

In addition to ME EQUIPMENT that requires the use of fluids~~, many types are~~ some ME EQUIPMENT is exposed to fluid spills as part of ~~their~~ REASONABLY FORESEEABLE MISUSES. In such cases spillage is considered NORMAL USE and the associated RISKS are addressed by the requirements of this subclause. Furthermore, as described in 9.4.2, tilting of TRANSPORTABLE ME EQUIPMENT to an angle of 10º is considered NORMAL USE. In such cases (as well as for ME EQUIPMENT requiring fluids) the amount and location where spills can occur vary greatly. Only a proper evaluation of the ME EQUIPMENT being tested can determine an appropriate application of the requirement. Doing such an evaluation is the responsibility of the MANUFACTURER and the results are to be provided to those performing the test (typically in the RISK MANAGEMENT FILE). This requirement would be an appropriate area for evaluation by writers of particular standards.

In accord with the principles outlined in IEC 62366, where explicit warnings or safety notices (validated as described in IEC 62366) are given, failure to heed such warnings or safety notices is considered abuse of the ME EQUIPMENT that is beyond the responsibility of the MANUFACTURER. Therefore where such warnings or safety notices are given, the liquid reservoir is filled only to the intended fill level before being tilted to 10º. Where they are not given, the liquid reservoir is filled 15% above the intended level.

Examination of the NORMAL USE of ME EQUIPMENT should provide an adequate estimate of the amount of fluid that is likely to be spilled on it.

Spillage for equipment that does not require the use of fluids is considered to be a SINGLE FAULT CONDITION.

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Subclause 11.6.4 – Leakage

Leakage is considered to be a SINGLE FAULT CONDITION.

Subclause 11.6.5 – Ingress of water and particulate matter into ME EQUIPMENT and ME SYSTEMS

Although it is unlikely that ME EQUIPMENT would be RATED for protection against particulate matter, IEC 60529 does address the possibility and it should be considered a valid option. The presence of any water or particulate matter inside the ENCLOSURE after testing in accordance with its IEC 60529 classification is regarded as a NORMAL CONDITION. The requirement is therefore to assess the possibility of a HAZARDOUS SITUATION due to such ingress in combination with a possible SINGLE FAULT CONDITION (such as an interrupted PROTECTIVE EARTH CONNECTION).

Subclause 11.6.8 – Compatibility with substances used with the ME EQUIPMENT

ME EQUIPMENT, ACCESSORIES and parts thereof should be designed to be used safely with the substances with which they are intended to come into contact in NORMAL USE.

Where appropriate, particular standards should specify the corresponding requirements.

Subclause 11.8 – * Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Interruption of the power supply could result in a ~~HAZARD~~ HAZARDOUS SITUATION due to loss of functionality. This ~~HAZARD~~ HAZARDOUS SITUATION is dealt with in 7.9.2.4. Restoration of the power source can also result in HAZARDOUS SITUATIONS. Examples could include unintended activation of moving parts or resumption of dangerous outputs. These potentially HAZARDOUS SITUATION and the duration of the power interruption that could result in the ~~HAZARDS~~ HAZARDOUS SITUATIONS need to be considered as part of the RISK MANAGEMENT PROCESS.

IEC 61000-4-11 [21] defines general and reproducible conditions for the operation of electrical and electronic equipment if they undergo voltage dips, short interruptions and voltage variations. The voltage level and duration of short interruptions are defined in Tables 210 and 211 of IEC 60601-1-2:2001. IEC 60601-1-2 treats these short interruptions as a NORMAL CONDITION.

For ME EQUIPMENT in which the safety of the PATIENT depends on the continuity of the power, particular standards should include requirements regarding power failure alarms or other precautions.

Clause 12 – Accuracy of controls and instruments and protection against hazardous outputs

IEC 60601-1 is the guideline for all particular standards and, therefore, contain some requirements of a more general character in order to serve this purpose. For this reason, it is necessary to have some generally formulated requirements in Clause 12.

Standardization bodies, including those outside IEC, have adopted the system of this IEC publication in order to have a single uniform system of standards. In such cases it is most important to give a guideline in this clause.

This clause introduces the concept of USABILITY. The term was chosen over the commonly used terms of “user error” or “human error” because not all errors are the result of oversight or carelessness on the part of the OPERATOR of the ME EQUIPMENT. All too frequently, use errors are the direct result of poor human interface design that seduces the OPERATOR into an incorrect decision. Use errors caused by inadequate USABILITY have become an increasing cause for concern. The USABILITY ENGINEERING PROCESS described in IEC 60601-1-6 is intended to achieve reasonable USABILITY, which in turn is intended to minimise use errors and to minimise use associated RISKS.

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Subclause 12.4.1 – Intentional exceeding of safety limits

If the control range of ME EQUIPMENT is such that the delivered output in a part of the range considerably differs from the output that is regarded as non-hazardous, means should be provided that prevent such a setting or that indicate to the OPERATOR (for example by means of an apparent additional resistance when the control is set or the bypassing of an interlock) that the selected setting is in excess of a safety limit.

Where appropriate, particular standards should specify safe output levels.

Subclause 12.4.3 – Accidental selection of excessive output values

Protection for the accidental selection of excessive output values can be obtained by appropriate steps to minimise the possibility to accidentally select excessive output, e.g. by interlocks in order to achieve deliberate action or by separated output terminals. In considering the measures for protection, the standard on human factors could be taken into account.

Clause 13 – HAZARDOUS SITUATIONS and fault conditions

ME EQUIPMENT or its parts could result in ~~HAZARDS~~ HAZARDOUS SITUATIONS due to abnormal operation or fault conditions, which, therefore, needs to be investigated. While this clause identifies specific fault conditions, 4.7 requires that the RISK ANALYSIS be used to identify other failures which should be investigated.

Subclause 13.1.1 – General

While separation requirements (CREEPAGE DISTANCES and AIR CLEARNACES) and insulation requirements are detailed in Clause 8, these requirements should not be viewed as applying only to RISKS associated with electrical HAZARDS. In addition to the potential for electric currents to cause fibrillation (due to electric shock), these currents can also be the root cause of injuries not directly related to electric shock.

Examples of these other HAZARDS (related to inadequate or faulty insulation or short circuits across physical spacing used as insulation) could include sparks that could become a source of ignition of flammable materials (as discussed in Clause 11) or functional failures that could cause a loss of ESENTIAL PERFORMANCE. In these cases, compliance with the insulation requirements of Clause 8 should always be considered evidence that RISKS arising from the failure of insulation or spacing have been adequately addressed when evaluating the safety of ME EQUIPMENT.

Finally, it should be noted that the requirements for CREEPAGE DISTANCES and AIR CLEARNACES are not intended to be required at the circuit board level where there is no significant RISK that spacings will be compromised (shorted) by contaminates (from NORMAL USE or the manufacturing PROCESS) such as fluids or particulate matter (see also IEC 60529). In most applications, spacing between (for example) circuit board traces and component leads are not considered likely to fail. In cases where there is doubt as to whether spacing could fail (wherethe CREEPAGE DISTANCE and AIR CLEARNACE requirements of 8.9 are not met), the MANUFACTURER'S RISK ANALYSIS should evaluate the likelihood of shorting across such gaps, but only where such short-circuiting could directly result in unacceptable RIRKS. Where shorting across spacing or insulation failures are clearly not likely to result in unacceptable RISKS, such analysis should not be required.

Subclause 13.1.2 – Emissions, deformation of ENCLOSURE or exceeding maximum temperature

The delivery of unintended hazardous quantities of energy or substances to a PATIENT or into the natural environment could be addressed by particular standards.

Hazardous quantities of poisonous or ignitable gas depend on the type of gas, concentration, place of emission etc.

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SINGLE FAULT CONDITIONS that might result in a small fire, but where the fire would remain contained within a fire ENCLOSURE, are acceptable because the containment will limit the effects to the area inside of the fire ENCLOSURE.

~~At a power dissipation of less than 15 W in the absence of an increased oxygen concentration (see 11.2.2), no fire HAZARD exists. Where circuits could dissipate 15 W or greater, it should be demonstrated that components within such circuits will not cause fire, molten metal, etc. to propagate in such a way as to result in a HAZARD (by setting the surroundings on fire for example). However, as in IEC 61010-1 [22], it is considered that when such components are enclosed in a fire ENCLOSURE as defined in 11.3, adequate protection from such propagation is provided.~~

The power level (15 Watts) cited in the original publication of this standard as the threshold below which ignition will not occur in normal ambient concentrations of oxygen was found to be significantly below the level used in IEC 61010-1 [22]. The original 15 W value was not based on any scientific test or research but came from “common practice” at some certification bodies (an anecdotal value only).

However, IEC 60950-1 provides a variety of energy levels based on voltage ranging from 100 VA to 150 VA. For purposes of simplicity, the lowest of these values (100 VA) with minimal restrictions on construction were used as an alternative to the 15 W limit (without construction restrictions) originally used in this standard for ME EQUIPMENT in general.

Direct application of the requirements for limited energy circuits in IEC 60950-1 can also be considered to assure that the RISK of fire has been reduced to acceptable levels at higher energies to demonstrate equivalent safety as well.

Since facilities where ME EQUIPMENT compliant with this standard is used will also contain information technology equipment (compliant with IEC 60950-1) and such equipment can be part of ME EQUIPMENT or ME SYSTEMS, it would be unreasonable to require the ME EQUIPMENT to offer a higher level of protection against ignition than does the other equipment used in the same environment.

It is felt that limiting the maximum temperatures for APPLIED PARTS to the NORMAL CONDITION values is appropriate because exceeding them is known to result in HARM and the PATIENT is frequently unable to pull away.

The restrictions of this subclause are regarded to be sufficient to avoid an enduring fire. A fire is not only dangerous by itself but has side effects such as destroying isolation barriers or destroying mechanical stability. These cannot be taken into account by the above limitations. Therefore, the MANUFACTURER needs to consider the following when coming to a conclusion:

– Obviously a limitation of 100 VA cannot guarantee 'no ignition'. Smaller components such as resistors, semiconductors etc. can be exposed to levels of power that could cause ignition. However, standards such as IEC 60950-1 and IEC 61010-1 and experience demonstrate that when such situations arise if the components are mounted on FV1 rated material an enduring fire is very unlikely to occur.

– Ignition could destroy isolation barriers exposing hazardous voltages. A device which is designed according to the requirements of this subclause should still be checked to determine whether such barriers would be affected and whether additional appropriate precautions independent of the requirements of this subclause.

  Since no enduring fire will occur, the mechanical stability is regarded as maintained.

Subclause 13.2.9 – Interruption and short circuiting of motor capacitors

The effect of functioning centrifugal switches can be taken into account. A locked rotor condition is specified because some capacitor motors might or might not start, causing variable results. Capacitor voltage is checked to assure that its dielectric will not be stressed causing the accumulation of hazardous gases including hydrogen.

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While the short circuit or open circuit of the capacitor is a SINGLE FAULT CONDITION and locking of the rotor is also a SINGLE FAULT CONDITION (see 13.2.8) this is regarded as an instance of the situation referred to in 4.7, where one SINGLE FAULT CONDITION can result unavoidably in another SINGLE FAULT CONDITION and the two failures are considered as one SINGLE FAULT CONDITION.

Subclause 13.2.10 – Additional test criteria for motor operated ME EQUIPMENT and Table 26, last line

Temperature limits of motor windings in ME EQUIPMENT are determined after the first hour as an arithmetic average because experience of test houses has shown that ME EQUIPMENT for non-CONTINUOUS OPERATION reaches variable values that could temporarily differ from the maximum values. Therefore, lower temperature limits are required. The values in Table 26 are based on the requirements of IEC 60950-1:~~2001~~2005.

Subclause 13.2.13.1 – General overload test conditions

The ball pressure test is not intended to represent the exact conditions experienced in use. The test is performed at elevated temperatures to test the robustness (adequate safety factor) of the mechanical properties of the insulation. The principle is not unlike dielectric withstand testing which subjects insulation to voltages far in excess of those seen in use.

Subclause 13.2.13.4 – ME EQUIPMENT RATED for non-CONTINUOUS OPERATION

Where ME EQUIPMENT or parts thereof are RATED for non-CONTINUOUS OPERATION but controls allow OPERATORS to leave it in operation (should a medical or other emergency occur), the CONTINUOUS OPERATION of the ME EQUIPMENT is considered reasonably foreseeable misuse. Where safety is dependent on switching the ME EQUIPMENT or parts thereof off after a prescribed period, steps should be taken to assure that intentional action is not required to do so.

Clause 14 – PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Computers are increasingly used in ME EQUIPMENT, often in safety-critical roles. The use of computing technologies increases the level of complexity in ME EQUIPMENT. This complexity means that systematic failures can escape the practical limits of testing. Accordingly, this clause goes beyond traditional test and measurement of the finished ME EQUIPMENT and includes requirements for the PROCESSES by which it is developed. Testing of the finished product is not, by itself, adequate to address the safety of PROGRAMMABLE ~~ME EQUIPMENT~~ MEDICAL ELECTRICAL SYSTEMS.

For these reasons, this clause requires that a PROCESS with specific elements be established and followed. The intention is to establish these specific PROCESS elements, leaving the user of this clause to determine in detail how to accomplish them. This is similar to the approach taken in the ISO 9000 series. Because users of this clause are expected to be qualified to perform the identified activities, detail has been kept to a minimum.

While iteration of some elements of the PROCESS is expected, no specific requirements to do so have been included. These requirements were omitted because the need to repeat PROCESSES or portions of them is unique to each particular device. In addition, the need for such iteration will arise from the more detailed understanding that emerges during the design PROCESS.

Because users of this standard are required to establish, maintain and apply a RISK MANAGEMENT PROCESS as part of compliance, this clause establishes those characteristics unique to programmable systems that should be considered as part of that PROCESS. Requirements for development and modification of medical device software have been specified in IEC 62304. The requirements from IEC 62304 that apply to development prior to placing a product in service are included by reference for the PEMS software.

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There are some requirements in IEC 62304 that apply to software maintenance after a product has been placed into service. These requirements have not been included in the reference.

The effective application of Clause 14 will require, subject to the task in hand, competence in the following:

– application of the specific ME EQUIPMENT with emphasis on safety considerations;

– ME EQUIPMENT development PROCESS;

– methods by which safety is assured;

– techniques of RISK ANALYSIS and RISK CONTROL.

Requirements have been minimized to those that are essential to assuring BASIC SAFETY and ESSENTIAL PERFORMANCE. This has been done in recognition of the extensive and growing literature in the fields of software assurance and RISK ASSESSMENT techniques as well as the rapid evolution of this discipline.

Subclause 14.1 – General

This standard requires the application of a RISK MANAGEMENT PROCESS in accordance with ISO 14971. This is particularly relevant to PEMS, because of the difficulty of showing the correctness of software or complex hardware. Therefore the design of a PEMS has to be performed within a RISK MANAGEMENT PROCESS, in which RISK CONTROL measures are related to the RISKS being controlled. For a software PESS, the software safety requirements from subclause 4.3 of IEC 62304:2006 and the software RISK MANAGEMENT requirements from Clause 7 of IEC 62304:2006 are included. If the application of ~~ISO 14971~~ RISK MANAGEMENT shows that a PESS has the potential to contribute to a HAZARDOUS SITUATION, and non-software RISK CONTROL measures external to the PESS have not reduced the RISK to an acceptable level, Clause 14 adds extra RISK MANAGEMENT and life-cycle PROCESSES for the PEMS.

Compliance VERIFICATION requires the MANUFACTURER'S internal assessment to cover not only the requirements of this clause but also those of ~~ISO 14971~~ IEC 62304 that have been included by reference.

Compliance with the requirements of Clause 14 is judged by examining the documentation produced by the PROCESSES required in the various subclauses. ~~Clause 14 should be applied as a whole and not selectively. All of this documentation is required to be in the RISK MANAGEMENT FILE.~~

The concept of assessment has been introduced in the compliance statement to allow for methods other than inspection where necessary, such as audit. Thus, although there is no general requirement for the MANUFACTURER to operate a quality management system in accordance with ISO 13485 [30], certain features of such a system are necessary. One feature that is commonly regarded as essential for a quality management system to be effective is a PROCESS of audit and review performed within the organisation to confirm that it is actually following its own PROCEDURES; this is separate from any external assessment that could be performed to demonstrate compliance with standards or regulatory requirements. This standard, therefore, requires that the MANUFACTURER not only document certain aspects of the design PROCESS but also carry out an assessment to confirm that the requirements of this clause have been followed.

Subclause 14.2 – Documentation

The expected way by which compliance with PROCESS requirements can be determined is by assuring that the documentation required for each PROCESS step has been generated. While most of the requirements of ~~ISO 14971~~ 4.2 are crucial components of an adequate software life-cycle, Clause 14 contains many additional PROCESS steps not required by ~~that standard~~ 4.2. Therefore, the documentation that these additional PROCESS steps (in Clause 14) require is necessary for a certification body to determine that the PROCESS steps have been performed.

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Because Clause 14 addresses those RISKS associated with PEMS, this documentation is ~~required to be included in~~ part of the RISK MANAGEMENT FILE.

Since compliance with Clause 14 is determined by inspection and assessment to assure that the required documentation has been generated, the quality and accuracy of these documents is important. Because demonstration of the safety of a PEMS depends on documentation, an effective system is needed to ensure the integrity of the documentation and, if different versions of a document exist, to identify the applicability of each version. Therefore it is required that the documents be generated, revised and maintained under a formal document control system. MANUFACTURERS should assure that this documentation is clear and comprehensive to assist in the assessment PROCESS.

Subclause 14.3 – RISK MANAGEMENT plan

~~ISO 14971~~ Subclause 4.2.2 requires that a RISK MANAGEMENT plan be prepared and maintained in the RISK MANAGEMENT FILE.

In addition to elements of the RISK MANAGEMENT plan required by ~~ISO 14971~~ 4.2.2, a PEMS VALIDATION plan is required because validation is seen as a necessary activity when developing a PEMS.

Subclause 14.4 – PEMS DEVELOPMENT LIFE-CYCLE

A documented life-cycle helps ensure that safety issues are considered throughout a product's development. This is important for all products and it is vital for PEMS. Safety cannot be added to a PEMS after it has been developed. Two reasons for this are as follows.

a) The actual PROCESSES used in the development of a PEMS, and the quality and rigour of those PROCESSES, are decided as a result of RISK ASSESSMENT. If it is discovered later on that inappropriate PROCESSES were used or that inadequate quality and rigour were applied, then the development will have to be repeated with correct PROCESSES.

b) Changes made at a late stage in the PEMS DEVELOPMENT LIFE-CYCLE are likely to be expensive (both in time and money). This is particularly true if a system requirement is incorrect or missing. System architecture can also be vulnerable to late changes. Often, the architecture is part of the safety case. Late changes can require significant rework in order to maintain the integrity of an architectural solution.

Framework

A life-cycle for the development of a product provides a framework that allows the necessary safety activities to take place in a timely and systematic manner. It should not impose unnecessary restrictions and it should ensure that all the required safety activities take place. The life-cycle needs to be decided early. Different life-cycle models are acceptable. Clause H.2 explains PEMS DEVELOPMENT LIFE-CYCLES in more detail. ~~IEC 62304 [26]~~ Clauses 5, 7, 8 and 9 of IEC 62304:2006 describe the PROCESSES to be included in the software development life-cycle for the development of safe medical device software.

Milestones and activities

The requirement for milestones, and activities with inputs and outputs for each, ensures that due consideration is given to:

– the activities,

– what needs to be done before the activity can start, and

– what the activity needs to provide,

so that VERIFICATION of the results can be performed.

The sequence of activities in the life-cycle is required to be defined in terms of milestones because this offers the greatest flexibility to the MANUFACTURER. No requirement is made concerning the number or nature of the milestones, nor is there any implication that all project activities have to pass through the milestones simultaneously. This standard has not used the

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term “phases” although this term was used in IEC 60601-1-4 [14]. The term has been avoided because it is difficult to express concurrency and overlap in a phase model.

In a good life-cycle:

– the necessary activities are defined in advance of their performance;
– the PROCESSES used in development activities could be specified as an outcome of RISK MANAGEMENT;
– the sequence of activities is defined so as to ensure that necessary inputs to an activity are available before the activity starts;
– criteria are defined for deciding whether the activity has been satisfactorily completed; and
– accountability is facilitated.

Activities are defined in terms of inputs and outputs because it is simple to measure whether those inputs and outputs exist. The MANUFACTURER is responsible for deciding how the milestones are achieved and how the required documentation is produced.

In order to determine whether each activity has been satisfactorily completed, it is required that the criteria for VERIFICATION of each activity be defined. VERIFICATION examines whether the inputs have been transformed into the outputs completely, correctly and according to the required PROCESS. No requirement is made concerning the type or extent of VERIFICATION, except for VERIFICATION of RISK CONTROL measures and ESSENTIAL PERFORMANCE (see 14.10).

Subclause 14.5 – Problem resolution

Where appropriate, a documented system for problem resolution is required by this standard.

Problems can arise:

– with the product;
– within a PROCESS;
– between PROCESSES.

Examples of problems are:

– inconsistent requirements;
– ambiguous requirements;
– missing specifications;
– coding errors;
– incorrect operation of the PEMS.

A system for problem resolution is needed to ensure that when a problem arises, its impact on HAZARDS and their consequent RISK is managed. Ad hoc methods for resolving problems can undermine the benefits obtained by using a systematic life-cycle approach. An appropriate place to document the system for problem resolution is as part of the PEMS DEVELOPMENT LIFE-CYCLE.

Subclause 14.6.1 – Identification of known and foreseeable HAZARDS

PEMS have extra initiating causes for HAZARDS.

Subclause 14.6.2 – RISK CONTROL

As the choice of the PROCEDURES and tools used by a MANUFACTURER for the development of a PEMS will be influenced by many factors, this subclause requires that one of the factors for the choice is the RISK reduction required for the RISK CONTROL measure. A RISK CONTROL measure that is developed using PROCEDURES and tools that are known to be good is more likely to carry out its intended functions than one developed using PROCEDURES and tools that are of unknown quality.

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Subclause 14.7 – Requirement specification

RISK CONTROL measures are used to control the RISK of identified HAZARDS. The requirements for these measures are documented in requirement specifications. The requirement should both specify what the measure does and how well it does it. ~~ISO 14971~~ Subclause 4.2 does not demand a requirements specification.

Verifiable requirements

Requirements should be verifiable. This applies to both the function of the RISK CONTROL measure and how likely it is to perform correctly. Quantitative VERIFICATION of failure rates is, generally, impractical for software. VERIFICATION of a qualitative approach would be by verifying that the appropriate PROCESSES were used.

Identifiable safety requirements

The requirement to distinguish the RISK CONTROL measures and ESSENTIAL PERFORMANCE is needed to ensure that they are implemented and to ensure that if there is a need to change the ESSENTIAL PERFORMANCE or a RISK CONTROL measure, the impact of the change on the RESIDUAL RISK can be assessed.

Decomposition

Examples of a PEMS structure are shown in Annex H. Requirements to implement the RISK CONTROL measures should be specified for the PEMS and for any PESS that implements or partially implements one or more RISK CONTROL measure. This can be in a single document or in several documents.

Subclause 14.8 – Architecture

An architecture specification is not required by ~~ISO 14971~~ 4.2. It is an additional requirement for PEMS because:

– often the architecture chosen will be part of a RISK CONTROL measure. RISK CONTROL measures need to be explicit for complex systems such as a PEMS;

– architecture specifications are recognized as a necessary part of a good software development PROCESS such as is required for a PEMS.

There is a list of architecture features for inclusion in the specification where appropriate. This list has been selected because in particular circumstances one or more of the features could be used to control the RISK of a HAZARD. For example, the use of a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS will effectively remove any RISK that would result from the failure of that component.

Subclause 14.8 e)

Partitioning of functionality can be useful when there is a significant need for rigorous safety validation of PEMS.

The software (firmware and application layers) is distinctly divided into critical, non-critical and supervisory sections. Partitioning is used so that the instructions and data of the critical, non-critical and supervisory sections do not interfere with each other and that there is separation of duties among the sections of the software. If there is no separation of duties among the sections of the software, all software should be defined as critical, to make sure that the analysis has taken into consideration the critical section of the software.

Requirements for separating critical code from non-critical code include RISK ASSESSMENT of the entire system, RISK CONTROL strategies employed, analysis of physical resources and an analysis of logical properties (e.g., control and data coupling). In general, partitioning should separate and isolate the safety-related functionality from the non-safety-related functionality in the design and implementation. This PROCESS can minimize, or at least reduce, the VERIFICATION necessary to assure that data shared by or passed to the critical section does not affect the specified operation of the safety critical code.

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Partitioning includes the following steps:

a) identification of critical, non-critical and supervisory sections. The means of identification depends upon the modularity of the code, the programming language, the code design and other specification attributes;

b) description of the interfaces between the critical and non-critical sections:
   1) identification of data or variables global to the critical and non-critical sections, modules, etc., identified in step a);
   2) identification of any parameters that are passed between critical and non-critical sections, modules, etc., identified in step a);
   3) description of the flow of the data, variables or parameters identified in steps b) 1) and b) 2);
   4) description of the mechanism which is used to prevent data corruption, overwriting or other errors of the above identified data, variables or parameters which would affect safety critical performance;

c) validation of the integrity of the partition. This can be accomplished by functional testing and stress testing techniques.

Subclause 14.8 g) to n)

There is a list of items to be taken into consideration in the architecture specification. This list has been selected because each of these items could influence the choice of architecture.

Subclause 14.9 – Design and implementation

The technical solutions chosen need to be defined. It is often appropriate to decompose a PEMS into subsystems. Figure H.1 shows examples of PEMS/ PESS structures with different amounts of decomposition. Reasons for decomposing a PEMS could include the following.

Keeping the complexity of subsystems manageable

The less complex the system the easier it is to understand and consequently easier to design and then maintain. The resulting design is more likely to be correct and easier to test. Coding standards should specify limits for complexity.

Architecture

The system architecture could make it logical to separate systems e.g. if diverse systems are needed they should be implemented as distinct subsystems.

Modularity

Modularity can facilitate the provision of different system options, reuse of an existing proven subsystem and the extension of system functionality.

Physical components

A sensible division of physical subsystems will help the diagnosis and repair of hardware faults.

Different technologies

Often different engineers will implement the hardware and the software design. In this case specifying each as a separate subsystem will enable each to be implemented independently.

The overall system will only function correctly if each of its constituent subsystems has been adequately specified. This leads to the requirement for a design specification for each subsystem. A design specification for a subsystem would typically include a detailed interface specification, and could include implementation details, e.g. algorithms.

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Each subsystem should be tested to show that the design specification has been correctly implemented. This leads to the requirement for a test specification for each subsystem.

The design and test specifications can be documented in whatever form is practicable, e.g. they can be separate documents or they can be combined in a larger document. The design specification and the test specification for each subsystem should be identifiable.

Examples of the elements of the design environment are given in H.4 a). Such elements will have an influence on the quality and correctness of the design. Some elements will have been identified as the suitably validated tools and PROCEDURES (see 14.6.2). The descriptive data regarding the design environment facilitates VERIFICATION that the suitably validated tools and PROCEDURES have been used.

Subclause 14.10 – VERIFICATION

~~ISO 14971~~ Subclause 4.2 requires VERIFICATION of RISK CONTROL measures. There are additional requirements for PEMS. These are that:

– the ESSENTIAL PERFORMANCE is verified; and

– there is a VERIFICATION plan.

ESSENTIAL PERFORMANCE is significant for PEMS because the PEMS uses a PESS to control its functions. ESSENTIAL PERFORMANCE will often depend on the PEMS functions being carried out correctly.

A VERIFICATION plan leaves it up to the MANUFACTURER how to achieve the requirements of this clause. This is a better and more flexible approach than specifying how to verify a PEMS in this clause. The MANUFACTURER is responsible for planning the VERIFICATION so that it is adequately thorough and then to implement the plan.

The requirement lists activities that affect the thoroughness of the VERIFICATION and which need to be planned.

Subclause 14.11 – PEMS VALIDATION

The final phase of any PEMS DEVELOPMENT LIFE-CYCLE model is PEMS VALIDATION. PEMS VALIDATION is intended to assure that the right product is built. Validation is important for PEMS because unexpected interactions between functions might occur that can only be discovered by validation.

PEMS VALIDATION can include tests for a high volume of data, heavy loads or stresses, human factors, security, performance, configuration compatibility, fault testing, documentation and safety.

Independence is needed to avoid conflicts of interest and because the assumptions of the designer should not influence or limit the extent of the PEMS VALIDATION. Examples of level of independence include:

– separate person;

– separate management;

– separate organization.

Subclause 14.12 – Modification

Typically the design of a PEMS is not completely new but is partly or even largely derived from earlier design(s). Nevertheless, it might be possible to treat the design as if it were completely new and to establish the RISK MANAGEMENT report and demonstrate compliance with the requirements of this standard without reference to previous documentation. If however the RISK MANAGEMENT report does need to include some information from the documentation of the previous design(s), it is then necessary to confirm that all such information remains valid despite the changes introduced in the new design.

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Subclause 14.13 – ~~Connection of a PEMS by NETWORK/DATA COUPLING to other equipment~~ PEMS intended to be incorporated into an IT-NETWORK

Many hospitals are operating ME EQUIPMENT in a networked environment today. Originally, these ~~networks~~ IT-NETWORKS were installed to optimize business economic and technical area. For this, a fast electronic data interchange is required. Today, these ~~networks~~ IT-NETWORKS are used for medical applications within the hospital, between hospitals, and from home.

Initially, the use was only the exchange of laboratory data. Now there are large amounts of data transported over the ~~networks~~ IT-NETWORKS, such as medical image data. There are further requests from the user to get "real time" solutions (e.g. control of operation robots via ~~network~~ an IT-NETWORK).

Additional guidance on ~~NETWORK/DATA COUPLING~~ incorporation of a PEMS into an IT-NETWORK is found in Annex H.

Subclause 15.1– Arrangements of controls and indicators of ME EQUIPMENT

Controls, instruments, indicating lamps, etc. that are associated with a specific function of the ME EQUIPMENT should be grouped together.

Subclause 15.2 – Serviceability

The exchange of such parts is expected to be easy to perform, preferably without special TOOLS. In addition, the disassembly of the worn out part or of the part exchanged preventively and the assembly of the spare one should not ~~create a HAZARD~~ result in a HAZARDOUS SITUATION. To ensure this, the instructions for performing such activities have to be easy to understand and to follow, without introducing any RISK of mix-up.

Subclause 15.3.2 – Push test

ENCLOSURES need to have adequate rigidity if they are to maintain a level of protection from internal live parts. This requirement is harmonized with the force test of IEC 60950-1. The force is dependent on the person handling the ME EQUIPMENT, not the weight of the ME EQUIPMENT. In most cases, the application of a force of 250 N is considered reasonably foreseeable. However there can be cases where a RISK ASSESSMENT finds that the 45 N force applied over an area of 625 mm^2, as required by the second edition of this standard, would continue to be an acceptable VERIFICATION method for determining an acceptable level of RISK. For example, ultrasound transducers and similar small HAND-HELD APPLIED PARTS, which balance the needs of robustness with other needs relating to efficacy and biocompatibility,have established track RECORDS of safety and effectiveness over many years, and therefore could continue to use the older VERIFICATION test.

Internal components are not subjected to the force test of IEC 60950-1 because their robustness is verified per the tests of 15.3.4 and 15.3.5.

Subclause 15.3.3 – Impact test

An ENCLOSURE'S resistance to impact is required to prevent unacceptable RISK during reasonably foreseeable misuse. The energy of the test impact approximates ME EQUIPMENT being accidentally struck by an object in the hand of a passer-by or by a broomstick or mop handle during cleaning of the floor. The test equipment has been simplified and harmonized with other standards containing ENCLOSURE impact requirements, including IEC 60950-1.

Where a MANUFACTURER feels the requirements of this subclause are not necessary to mitigate an unacceptable RISK, justification is documented in the RISK MANAGEMENT FILE per 4.5, along with an identification of alternate requirements met. For example, FIXED ME EQUIPMENT can have one side of the ENCLOSURE protected by the floor, wall or ceiling. The MANUFACTURER documents the evaluation of the probability that the ME EQUIPMENT could be moved or installed incorrectly. The MANUFACTURER also evaluates and identifies, through the RISK MANAGEMENT PROCESS, what resistance to impact the protected side of the ENCLOSURE

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needs to have to ensure no unacceptable RISKS are generated by failure to comply with the original requirements of this subclause.

Subclause 15.3.4 – Drop test

The tests for HAND-HELD ME EQUIPMENT or its parts that are hand held are different from the test for PORTABLE and MOBILE ME EQUIPMENT because of the difference in practical application.

A drop surface of wood of density > 600 kg/m^3 allows selection of most common hardwoods. Oak, beech, birch, ash and maple are acceptable. These varieties have similar hardness while hardwoods of density < 600 kg/m^3 (e.g. mahogany, elm, sweet gum, cherry) and softwoods have greatly decreased hardness in comparison.

Subclause 15.3.4.2 – PORTABLE ME EQUIPMENT

This test represents NORMAL USE, as explained in the rationale for 15.3.5. This test is not intended to represent reasonably foreseeable misuse. There is not currently a test that directly addresses free fall type reasonably foreseeable misuse, however it is felt the ball impact test in 15.3.3 represents foreseeable misuse, albeit indirectly. As stated in 4.2, if the RISK MANAGEMENT PROCESS concludes that a more severe test is appropriate, this should be done.

Subclause 15.3.5 – Rough handling test

Contrary to what is often assumed, ME EQUIPMENT can be used in a hostile environment. In case of emergency, ME EQUIPMENT is carried or wheeled on trolleys over doorsteps and into elevators and subjected to bumps and vibration. Such conditions can in fact typify NORMAL USE for some ME EQUIPMENT. Encountering obstacles is considered commonplace and quite reasonably foreseeable misuse. Not all obstacles are clearly marked and the OPERATOR cannot always stop the ME EQUIPMENT in time after having become aware of the obstacle

~~The test requirements of 15.3.5 are meant to judge resistance to rough handling, and not stability. Stability test requirements for MOBILE ME EQUIPMENT are in 9.4.~~

The 0,8 m/s speed together with the severity of the obstacles chosen, are considered to represent worst case reasonably foreseeable misuse levels of stress/shock energies. The intent of tis test is to ascertain the risks from damage caused by rough handling shock/stress. Instability is evaluated in 9.4.

The meaning of “in its normal direction of travel” is the direction(s) the ME EQUIPMENT is likely to travel at the maximum normal speed. For most cases, this would be the forward direction. Some ME EQUIPMENT, such as a bed, is likely to travel in a forward or backward direction, at normal speed, and therefore each test should be considered for each direction.

Subclause 15.3.6 – Mould stress relief test

Many thermoforming PROCESSES can leave residual stresses in plastics. Because polymer chains are held together by weak van der Waals bonds, these residual stresses can result in viscous flow (deformation). Elevated temperature results in weakening of van der Waals bonds and an increase in the rate of viscous flow. Thermoplastics with low melting temperatures, such as polyethylene and polypropylene, are more susceptible to stress relief deformation than polymers with higher melting temperatures, such as polycarbonate and polyetheramide.

Compliance should be verified by analysis of the polymer properties, when possible. This VERIFICATION should consist of a documented comparison of the maximum temperature the polymer will be exposed to in NORMAL USE and the polymer manufacturer’s recommended temperature use range.

Subclause 15.3.7 – Environmental influences

a) ME EQUIPMENT is often used or stored in environmental conditions that are within the INTENDED USE as declared by the MANUFACTER. In such cases no HAZARD is expected. However the environmental conditions could differ from those declared and still the

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ME EQUIPMENT is expected to remain safe. To ensure this, the RESPONSIBLE ORGANISATION has to perform the periodic inspection and maintenance prescribed by the MANUFACTURER. These activities are expected to prevent any deterioration of the safety level and also detect signs of commencing of any such deterioration. To ensure this, the instructions for preventive maintenance have to be easy to understand and to follow, without introducing any RISK for mix-ups or for overlooking of safety-relevant symptoms.

b) The exchange of such parts is expected to be easy to perform, preferably without special TOOLS. In addition, the disassembly of the worn out part or of the part exchanged preventively and the assembly of the spare one should not create a HAZARD. To ensure this, the instructions for performing such activities have to be easy to understand and to follow, without introducing any RISK of mix-up.

c) Corrosion of metal to metal interfaces should be taken into account.

Subclause 15.4.3 – Batteries

If a HAZARDOUS SITUATION might develop as a result of exhaustion of the battery, means should be provided to forewarn of this condition.

Where appropriate, particular standards should specify the corresponding requirement.

Subclause 15.4.3.5 – Excessive current and voltage protection

Subclause 4.7 requires the ME EQUIPMENT to be SINGLE FAULT SAFE. One possible fault could be the bridging of a CREEPAGE DISTANCE between the positive and negative terminals of an INTERNAL ELECTRICAL POWER SOURCE in the area between the INTERNAL ELECTRICAL POWER SOURCE and any protective device (see Figure A.23).

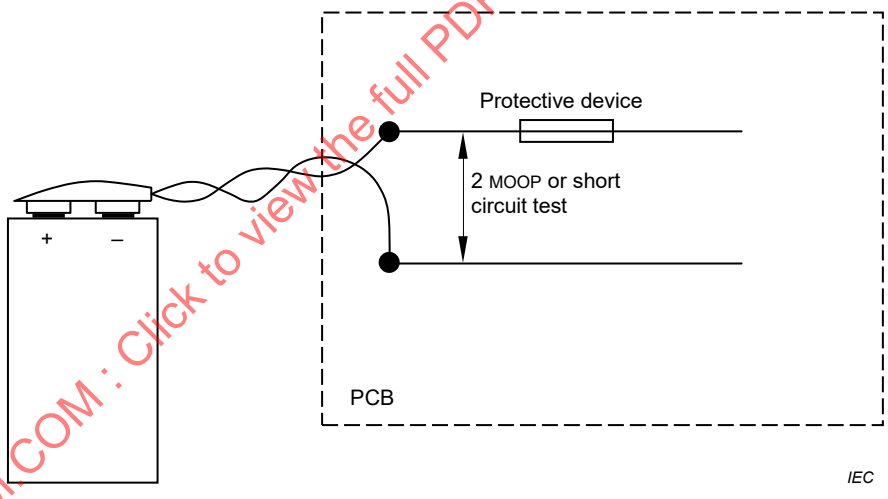


Figure A.23 – Example of the needed MEANS OF OPERATOR PROTECTION between the terminals of an INTERNAL ELECTRICAL POWER SOURCE and a subsequent protective device

A short circuit test would be required to demonstrate that this area is SINGLE FAULT SAFE unless two MEANS OF OPERATOR PROTECTION are present. In that case, the test can be omitted.

Subclause 15.4.4 – Indicators

It is important for an OPERATOR and SERVICE PERSONNEL to be able to determine the functional status of ME EQUIPMENT. In NORMAL USE, the OPERATOR needs to be able to distinguish between ME EQUIPMENT in stand-by and ME EQUIPMENT in a fully functional state. Some ME EQUIPMENT has an extended warm-up period. Other ME EQUIPMENT has standby or battery charging modes.

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It can be hazardous for ME EQUIPMENT to be left unattended in the wrong state. SERVICE PERSONNEL need to be able to determine when ME EQUIPMENT is energized to avoid HAZARDS.

Subclause 15.4.7.3 – Entry of liquids

The former IPX8 rating requirement for foot switches amounts to no more than "greater protection than IPX7." By making this requirement IPX6 minimum, the requirement sets a defined level of protection while allowing higher levels where appropriate.

For equipment used on the floor in areas where liquids are usually not found, the IPX1 requirement is included because it is considered extremely likely that some wetting will occur.

Subclause 15.5 – MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5

The addition of "and transformers providing separation in accordance with 8.5" to the original title that only identified "Mains transformers" is intentional. The tests for transformers should be utilized any time that the transformer is used to establish separation between OPERATORS, PATIENTS, etc. and a HAZARD.

Revisions to 15.5 do not change significantly current methods (including those of the second edition of this standard) of testing. The methods and requirements were simplified and now include all different types of protectors like: PTCs, feedback control (switch mode power supplies), primary or secondary over-current devices, etc. Those transformers that have not been tested in accordance with the 5X frequency and 5X voltage tests of 15.5.2 to establish the adequacy of insulation between the turns of a winding that are shorted at the terminals (rather than external to the transformer) to assure that failure of that insulation will not cause maximum allowable temperatures to be exceeded.

Because of the difficulties that would be encountered when trying to test transformers that are RATED for high frequencies (such as those used in switch mode power supplies), the 2X frequency and voltage tests are specified in those cases as well. The second edition only applied this test where the voltage exceeded 500 V.

Subclause 15.5.1.1 – Transformers

Output windings are required to be "tested in turn" because under overload conditions, testing all windings simultaneously can cause over temperature devices to operate which would not operate if only one winding was being overloaded. A single output winding being overloaded is actually quite likely. Therefore this combination of conditions is considered the likely worst case scenario.

The intent of the requirement is to test under the worst-case condition (nearly always with either a full load or no-load). Such a worst case can be determined through evaluation of the transformer design or by performing a few spot tests. Generally, testing all possible conditions to determine worst case is unnecessary.

The limits of Table 31 are applied at a 25 °C ambient because of the impracticality of performing the overload and short tests inside of a thermal chamber.

Subclause 15.5.2 – Dielectric strength

It is necessary to raise the frequency of the test voltage in proportion to the voltage to prevent saturation of the magnetic core and consequent very high current.

The electrical insulation between the primary winding and other windings, screens and the core of a MAINS SUPPLY TRANSFORMER is presumed to have been investigated by the dielectric strength tests performed on the assembled ME EQUIPMENT as described in 8.8.3. The dielectric strength tests of 8.8.3 need not be repeated.

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Subclause 15.5.3 – Construction of transformers used to provide separation as required by 8.5

~~The requirements specified in IEC 61558-1, Subclause 5.12 are generally similar to those in the second edition of this standard but transformers complying with them are likely to be more readily available.~~

The original citation of subclause 5.12 of IEC 61558-1 was made incorrect by modifications to the 61558 series. In reviewing the revised IEC 61558 standards, it was determined that citation of the standard would not reduce the cost of transformers or provide any other benefits since the spacing and dielectric requirements of IEC 60601-1 would be required to be applied to provide MEANS OF PATIENT PROTECTION. For this reason, the citation was deleted, and the principles of the second edition of IEC 60601-1 were employed with reference to spacing and dielectric requirements of the third edition. Where only MEANS OF OPERATOR PROTECTION is required, transformers constructed for use in IEC 60950-1 equipment should be considered acceptable.

Additionally, Annex U of IEC 60950-1:~~2001~~2005 includes requirements relating to the use of triple-insulated winding wire in transformers instead of a separate layer of insulation between windings (as would be traditionally be provided by bobbins for example). Transformers which use this method of separation between windings and which comply with all other requirements of this standard should generally be considered to provide an adequate level of BASIC SAFETY.

Clause 16 – ME SYSTEMS

Increasingly, ME EQUIPMENT is being combined with other pieces of equipment that might not have originally been intended for medical application to create systems where one or more of the elements of the system come into contact with the PATIENT. Clause 16 provides requirements to ensure the safety of the PATIENT who could come into contact with ME SYSTEMS.

Clause 16 on ME SYSTEMS is intended to be used by MANUFACTURERS of combinations of electrical equipment that include one or more items of ME EQUIPMENT. The equipment can be separate items or can be in a single ENCLOSURE or a combination of these cases.

Clause 16 is also intended to be used by personnel from institutions for medical practice who assemble or adapt ME SYSTEMS, as they can become the MANUFACTURER by that action. In this case, engineering expertise in the application of the electrical equipment design standards is required to ensure that the ME SYSTEM complies with all requirements of Clause 16.

More and more, such ME SYSTEMS comprise equipment originally manufactured for use in different specific application fields, not necessarily medical, that are connected with each other in a direct or indirect way. ME EQUIPMENT complying with this standard can be connected with other, non-ME EQUIPMENT. The latter equipment might fully meet the requirements in the safety standards applicable in their specific application field. However, they do not always comply with the safety requirements for ME EQUIPMENT and, thereby, influence the safety of the whole ME SYSTEM. It is for this reason that the MANUFACTURER is required to apply RISK MANAGEMENT to the whole ME SYSTEM. One example of an additional HAZARD is the ignition of fire when an ME SYSTEM containing non-ME EQUIPMENT is used in an OXYGEN RICH ENVIRONMENT, possibly accidentally.

The electrical equipment can be situated either in a medically used room that is intended for diagnosis, treatment or monitoring of PATIENTS, or in a non-medically used room where no medical practice is performed. Within a medically used room, electrical equipment might be placed inside or outside a volume that is defined as PATIENT ENVIRONMENT.

There are two situations possible in medical practice.

a) Where Clause 16 does not apply

Simultaneously operated ME EQUIPMENT, i.e. different ME EQUIPMENT connected at the same time to a PATIENT but not connected to each other. Such ME EQUIPMENT can influence each

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other. For example, high-frequency surgical equipment in the operating theatre can influence PATIENT monitoring.

NOTE Assistance can be available from the instructions for use for each ME EQUIPMENT.

b) Where Clause 16 applies

ME SYSTEMS, consisting of ME EQUIPMENT and possibly also non-ME EQUIPMENT, interconnected permanently or temporarily for a certain purpose such as diagnosis or treatment of a PATIENT. Examples: ME SYSTEMS for diagnostic X-ray examination, endoscopes with video camera, PATIENT monitoring, ultrasound equipment with a personal computer, computed tomography or magnetic resonance imaging.

The various parts of such an ME SYSTEM could be situated within the PATIENT ENVIRONMENT or outside it but still within a medically used room, or parts of the ME SYSTEM could be located in a non-medically used room containing, for example, electrical power distribution or data processing equipment.

Subclause 16.1 – General requirements for the ME SYSTEMS

The basic requirement for the safety of ME SYSTEMS is that, after installation or subsequent modification, an ME SYSTEM does not result in an unacceptable RISK. Compliance with the requirements imposed on ME SYSTEMS in this standard will imply that the RESIDUAL RISK is presumed to be acceptable, unless there is OBJECTIVE EVIDENCE to the contrary.

The MANUFACTURER of ME SYSTEMS that can be reconfigured by the OPERATOR or the RESPONSIBLE ORGANIZATION could be challenged to provide information on all possible combinations of the equipment, which could represent an unreasonable burden. RISK MANAGEMENT methods provide a very adequate means of determining which combination of items constitutes the largest RISKS, and which measures need to be taken to provide for the adequate level of safety. Ultimately, compliance testing can be done after assembly of the complete ME SYSTEM.

Appropriate documentation concerning the standards compliance can be a declaration of conformity by the MANUFACTURER or a certificate from a test house.

ME SYSTEMS, by their nature, can be frequently modified; Clause 16 does not apply to the modification of individual items in an ME SYSTEM

Subclause 16.2 – ACCOMPANYING DOCUMENTS of an ME SYSTEM

The documents that accompany an ME SYSTEM intended for DIRECT CARDIAC APPLICATION should provide data on such items as:

– use of rubber gloves;
– use of stop-cocks made of insulating material;
– minimum distances between PATIENT and equipment being part of the ME SYSTEM (PATIENT ENVIRONMENT);
– instructions about how to use the ME EQUIPMENT in the typical medical application, for example, use of a catheter.

For safety reasons, particular attention should be paid to the different levels of RISK when, within the PATIENT ENVIRONMENT, electrodes or other body sensors are used on the PATIENT, externally and internally, including direct connections to the heart.

Possible connections to the heart of a PATIENT should be kept isolated from the equipment.

The warning not to place MULTIPLE SOCKET-OUTLETS on the floor is to prevent the ingress of liquids and to prevent mechanical damage.

Furthermore, measures should be taken to ensure that, when assembling or modifying an ME SYSTEM incorporating MULTIPLE SOCKET-OUTLETS, these are mounted in such a way as to

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prevent ingress of liquids and to avoid mechanical damage during NORMAL USE and transportation.

Relevant safety standards for non-ME EQUIPMENT could specify or require disclosure of permissible environmental conditions. Accordingly, the environmental conditions permitted for various items in an ME SYSTEM can be different. The permissible environmental conditions for the ME SYSTEM is to be specified so that no ~~HAZARD~~ HAZARDOUS SITUATION will arise when operating it within these specified limits.

Subclause 16.3 – Power supply

This requirement is to ensure the safety according to IEC 60601-1 at the ME SYSTEM level.

BASIC SAFETY after assembly is maintained, for example, by one or more of the following measures:

– measures that are built-in within the ME EQUIPMENT, for example, separation of relevant circuits;

– SEPARATION DEVICES provided as ACCESSORIES to the ME EQUIPMENT (see 16.5);

– SEPARATION DEVICES provided as ACCESSORIES to the ME SYSTEM;

– separating transformer;

– additional PROTECTIVE EARTH CONDUCTORS.

Non-ME EQUIPMENT can provide the specified power supply for ME EQUIPMENT in accordance with 5.5 f), 7.9.2.14 and 8.2.1.

Subclause 16.5 – SEPARATION DEVICES

The BASIC SAFETY of some ME EQUIPMENT depends on the precondition that any SIGNAL INPUT/OUTPUT PARTS are connected only to equipment that is specified for this purpose, otherwise LEAKAGE CURRENTS could be increased by unwanted currents flowing through signal cables.

HAZARDOUS SITUATIONS could occur if the SIGNAL INPUT/OUTPUT PART of ME EQUIPMENT is connected to equipment outside the medically used room, possibly in another building and therefore connected to another mains supply branch circuit.

A SEPARATION DEVICE prevents a ~~HAZARD~~ HAZARDOUS SITUATION to the PATIENT or OPERATOR. Additionally, the inclusion of the SEPARATION DEVICE helps to avoid ~~HAZARDS~~ HAZARDOUS SITUATIONS through malfunction of equipment caused by unwanted currents flowing through cables.

The need for a SEPARATION DEVICE depends on the configuration of the ME SYSTEM.

Subclause 16.6 – LEAKAGE CURRENTS

Relevant standards for some non-ME EQUIPMENT can have limits for TOUCH CURRENTS that are higher than required by Clause 16; these higher limits are acceptable only outside the PATIENT ENVIRONMENT. It is essential to reduce TOUCH CURRENTS when non-ME EQUIPMENT is to be used within the PATIENT ENVIRONMENT. LEAKAGE CURRENT reduction measures can include:

– additional PROTECTIVELY EARTHED parts;

– a separating transformer;

– an additional non-conductive ENCLOSURE.

Interconnecting cables and their connector housings are parts of the ENCLOSURE and therefore the LEAKAGE CURRENT limits within the PATIENT ENVIRONMENT, as required in 16.6.1, are applicable.

If a MULTIPLE SOCKET-OUTLET without a separating transformer is used, the interruption of its protective earthing could result in TOUCH CURRENTS equal to the sum of the individual EARTH LEAKAGE CURRENTS.

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Subclause 16.6.3 – PATIENT LEAKAGE CURRENT

For ME EQUIPMENT, the maximum allowed values for PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT (applicable with several APPLIED PARTS connected to the ME EQUIPMENT) are given in Table 3 and Table 4; see also 8.7.3. An ME SYSTEM is to provide the equivalent level of safety as provided by ME EQUIPMENT within the PATIENT ENVIRONMENT (see 16.1). Therefore, the same maximum values for PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT apply, regardless whether the APPLIED PARTS are connected to the same element of the ME SYSTEM or not. This holds for the operation of the ME SYSTEM in NORMAL CONDITION, as the single fault concept is not applicable to an ME SYSTEM.

It should be noted that combinations of equipment or of APPLIED PARTS, made by the RESPONSIBLE ORGANIZATION or OPERATOR, that are outside the range of combinations indicated by the MANUFACTURER, could lead to HAZARDOUS SITUATIONS. This warning holds in particular when combinations of equipment are used for medical purposes on the same PATIENT, which have not been intended by their MANUFACTURER(S) to be used in such combinations.

Subclause 16.7 – Protection against MECHANICAL HAZARDS

Attention should be paid to the effects of interruptions causing unplanned movements, removal of compression forces, and the safe removal of PATIENTS from the PATIENT ENVIRONMENT when a HAZARDOUS SITUATION occurs.

Subclause 16.9.2.1 – MULTIPLE SOCKET-OUTLET

The second edition of this standard used the defined term “auxiliary mains socket-outlet (AMSO)” to describe a socket-outlet intended for provision of mains supply to other ME EQUIPMENT or to other separate parts of the ME EQUIPMENT. The systems collateral standard, IEC 60601-1-1 [13], defined a term “multiple portable socket-outlet (MPSO)”. The two terms have been combined into a new term, “MULTIPLE SOCKET-OUTLET (MSO).” Subclause 57.2 e) of the second edition required that an AMSO be designed so that it could not accept a MAINS PLUG. An exception for emergency trolleys was allowed. With the combination of the two definitions and the change to 8.11.2 to require any MSO on ME EQUIPMENT to comply with 16.9.2.1, the need for rapid exchange in an emergency situation is reconciled with the need to restrict LEAKAGE CURRENT.

Reassignment of the mains connection for the ME SYSTEM is a dangerous practice and beyond the scope of this clause. See 16.2 for disclosure requirements.

Excessive TOUCH CURRENTS can occur unless casual access for additional equipment connections is impeded or prevented.

~~**Subclause 16.9.2.1 c), 3rd dash**~~

~~ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD has an impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED that does not exceed 200 mΩ. Similarly, the MULTIPLE SOCKET-OUTLET has an impedance that does not exceed 200 mΩ between its MAINS PLUG and its socket-outlets. This results in an impedance that does not exceed 400 mΩ between the MULTIPLE SOCKET-OUTLET MAINS PLUG and any part of ME EQUIPMENT that is PROTECTIVELY EARTHED.~~

~~The impedance of PROTECTIVE EARTH CONNECTIONS is allowed to exceed 200 mΩ when the relevant circuits have limited current capability (see 8.6.4 b)). In such cases in ME EQUIPMENT, this results in an impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED that exceeds 400 mΩ.~~

Subclause 16.9.2.1 d)

The TOUCH CURRENT of the ME SYSTEM must be less than 500 μA in SINGLE FAULT CONDITION. A separating transformer can be used as a measure to reduce that TOUCH CURRENT. Therefore a separating transformer with BASIC INSULATION is sufficient. The DOUBLE or REINFORCED INSULATION as required for isolating transformers is not needed.

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Transformers providing a greater degree of safety e.g. ones constructed to IEC 60601-1 requirements or to the isolating transformer requirements in other parts of the IEC 61558 series, e.g. IEC 61558-2-4 [63] or IEC 61558-2-23 [64], are also acceptable.

The CLASS I requirement for the transformer assembly is necessary to provide connected equipment with a PROTECTIVE EARTH CONNECTION.

Isolation monitoring of the separating transformer is not necessary. SINGLE FAULT CONDITION can be detected during routine maintenance and the occurrence of two independent SINGLE FAULT CONDITIONS is of no concern. The transformer construction can be of a type with or without a PROTECTIVELY EARTHED centre tapped secondary winding.

Subclause 16.9.2.2 – PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS

All PROTECTIVE EARTH CONDUCTORS and POWER SUPPLY CORDS should be routed together.

When a MULTIPLE SOCKET-OUTLET is used to construct an ME SYSTEM, each individual item of equipment plugged in to the MULTIPLE SOCKET-OUTLET needs to meet the relevant ME EQUIPMENT or non-ME EQUIPMENT requirements. The total protective earth impedance when tested as a complete system according to 8.6.4 needs to meet the highest impedance requirement from 8.6.4. a) (i.e. shall not exceed 200 mΩ). This might require measures such as using short power supply cords within the ME SYSTEM and using a system POWER SUPPLY CORD of greater cross sectional area than is necessary for current carrying purposes to reduce its protective earth impedance. It is unacceptable practice to connect MULTIPLE SOCKET-OUTLETS in series.

Within the PATIENT ENVIRONMENT it is important to limit potential differences between different parts of an ME SYSTEM, and an adequate connection with a protective earthing system plays an important role in limiting that potential difference. It is therefore important to prevent interruption of that protective means to any part of the ME SYSTEM.

– The additional protective earthing could be used when the TOUCH CURRENT in SINGLE FAULT CONDITION exceeds the allowable limits.
– The additional protective earthing is not necessary for ME EQUIPMENT complying with this standard. However, in the case of non-ME EQUIPMENT this will prevent TOUCH CURRENTS exceeding allowable limits.
– The use of a TOOL is not required to disconnect the MAINS PLUG because the MAINS PLUG will disconnect both the mains and the protective earth.

Clause 17 – Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1-2 specifies electromagnetic immunity test levels to minimize the effect of the electromagnetic environment on the ME EQUIPMENT and ME SYSTEMS covered by this standard. It specifies electromagnetic emissions limits to minimize the effect on other equipment of electromagnetic disturbances that could be emitted, intentionally or unintentionally, by ME EQUIPMENT and ME SYSTEMS. It also specifies requirements for identification, marking and documents so that the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM provides information to the RESPONSIBLE ORGANIZATION that is essential in determining the suitability of the ME EQUIPMENT or ME SYSTEM for the electromagnetic environment of use, and in managing the electromagnetic environment of use to permit the ME EQUIPMENT or ME SYSTEM to maintain BASIC SAFETY and provide its ESSENTIAL PERFORMANCE without disturbing other equipment.

Electromagnetic emission requirements are necessary for the protection of:

– safety services (e.g. police, fire and ambulance communications);
– other ME EQUIPMENT and ME SYSTEMS;
– non-ME EQUIPMENT (e.g. computers);
– telecommunications (e.g. radio/TV, telephone, radio-navigation).

More importantly, electromagnetic immunity requirements are necessary to assure that ME EQUIPMENT and ME SYSTEMS maintain BASIC SAFETY and continue to provide their ESSENTIAL

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PERFORMANCE in the presence of the electromagnetic disturbances to which they can be expected to be exposed during NORMAL USE.

Annex G – Protection against HAZARDS of ignition of flammable anaesthetic mixtures (see also the rationale for 11.4)

Section six of the second edition of this standard has been moved to a normative annex. This was done in recognition of the fact that flammable anaesthetics are rarely used and their use is expected to cease entirely within a short period. However, it is also recognized that the practice of medicine changes frequently and that even now some MANUFACTURERS might still want to offer ME EQUIPMENT for such applications. In order to assure that the material contained in Section six along with the associated CATEGORY AP and CATEGORY APG RATINGS remain available while improving the readability of the standard for most users, the material has been moved to Annex G.

Subclause G.1.3 – Requirements for ME EQUIPMENT

The most devastating accidents with flammable anaesthetic agents occur when the mixture of the agent with oxygen normally used is that which will cause the most rapid combustion, a state that sometimes is described as “detonation optimum.” The worst example of such an agent is cyclopropane, while the oxygen/ether mixture normally used is far below that point.

Subclause G.5.3 – Low-energy circuits

The graphs of Figure G.1, Figure G.2 and Figure G.3 are given to assist in the design of circuits that fulfil the requirements for allowable limits stated for CATEGORY AP ME EQUIPMENT without performing the ignition test.

Extrapolation for higher voltages is not valid because the ignition condition of gases changes at higher voltages. The limit for inductances is introduced because high inductance values generally produce higher voltages.

Subclause G.5.4 – External ventilation with internal overpressure

The amount of air or inert gas escaping from the ME EQUIPMENT by leakage is assumed to be limited so that hygienic conditions in the medically used room are not disturbed appreciably.

For the purposes of G.5.4 and G.5.5 the term “enclosure” can represent either the ENCLOSURE as defined in 3.26 or a distinct compartment or housing.

Subclause G.5.5 – ENCLOSURES with restricted breathing

Subclause G.5.5 a)

This requirement is regarded as sufficient to prevent ignition in NORMAL USE during an operational period of several hours since average conditions in NORMAL USE are less stringent.

Subclause G.6.2 – Power supply

This requirement prevents the introduction of voltages higher than those permitted by G.6.3. Such voltages can exist on earth wiring.

Subclause G.6.3 – Temperatures and low-energy circuits

The graphs of Figure G.4, Figure G.5 and Figure G.6 are given to assist in the design of circuits that fulfil the requirements for allowable limits stated for CATEGORY APG ME EQUIPMENT, without performing the ignition test.

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Annex B
(informative)

Sequence of testing

B.1 General

Tests should, if applicable, be performed in the sequence indicated below, unless otherwise stated by particular standards. See also 5.8.

However, this does not preclude the possibility of conducting a test that preliminary inspection suggests might cause failure.

The tests for radiation HAZARDS in Clause 10, biocompatibility in 11.7, USABILITY in 12.2, ALARM SYSTEMS in 12.3, PEMS in Clause 14 and electromagnetic compatibility in Clause 17 can be performed independently from the tests in the following sequence.

The tests specified for ME SYSTEMS in Clause 16 should be performed in the same sequence as the tests for ME EQUIPMENT.

B.2 RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS and ESSENTIAL PERFORMANCE

See 4.2 and 4.3.

B.3 General requirements

See 4.1, 4.5 to 4.10 (inclusive) and 5.1 to 5.7(inclusive).

B.4 Classification of ME EQUIPMENT and ME SYSTEMS

See Clause 6.

B.5 Determination of APPLIED PARTS and ACCESSIBLE PARTS

See 5.9.

B.6 ME EQUIPMENT identification, marking and documents

See 7.2 to 7.8.2 (inclusive), Annex C.

B.7 Energy consumption (power input)

See 4.11.

B.8 Limitation of voltage, current or energy

See 8.4.

B.9 Separation of parts

See 8.5.1 to 8.5.4 (inclusive).

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B.10 CREEPAGE DISTANCES and AIR CLEARANCES

See 8.9.

B.11 HAZARDS associated with moving parts

See 9.2 except 9.2.2.4.1.

B.12 HAZARD associated with surfaces, corners and edges

See 9.3.

B.13 Serviceability

See 15.2.

B.14 Accuracy of controls and instruments and protection against hazardous outputs

See 12.1 and 12.4.

B.15 Instability HAZARDS

See 9.4.

B.16 Noise, vibration and acoustic energy

See 9.6.

B.17 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

See 11.8.

B.18 Protective earthing, functional earthing and potential equalization of ME EQUIPMENT

See 8.6.

B.19 Excessive temperatures in ME EQUIPMENT

See 11.1.

B.20 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS and dielectric strength at steady-state operating temperature

See 8.4.2 and 8.7 and 8.8.3.

B.21 Humidity preconditioning treatment

See 5.7.

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B.22 ~~Dielectric strength (COLD CONDITION)~~ LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS and dielectric strength after humidity preconditioning at ambient temperature in the laboratory

See 8.4.2 and 8.7 and 8.8.3.

B.23 Defibrillation protection

See 8.5.5.

B.24 Expelled parts HAZARD

See 9.5.

B.25 Pressure vessels and parts subject to pneumatic and hydraulic pressure

See 9.7.

B.26 HAZARDS associated with support systems

See 9.8.

B.27 Mechanical strength

See 15.3 and 9.2.2.4.1.

B.28 HAZARDOUS SITUATIONS and fault conditions

See Clause 13.

B.29 MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5

See 15.5.

B.30 ME EQUIPMENT components and general assembly

See 15.4 and 8.10.

B.31 MAINS PARTS, components and layout

See 8.11.

B.32 Insulation other than wire insulation

See 8.8.4.

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B.33 Fire prevention and constructional requirements for fire ENCLOSURES of ME EQUIPMENT

See 11.2 and 11.3.

B.34 Overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT

See 11.6.

B.35 CATEGORY AP and CATEGORY APG ME EQUIPMENT

See 11.4 and Annex G.

B.36 VERIFICATION of markings

See 7.2 to 7.8.2 (inclusive), Annex C and 7.1.

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Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

The requirements for marking on the outside of ME EQUIPMENT and its parts are found in 7.2. Additional requirements for marking on the outside of ME EQUIPMENT, ME SYSTEMS and their parts are found in the subclauses listed in Table C.1. Symbols and safety signs used in marking on the outside of ME EQUIPMENT are found in Annex D.

Table C.1– Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts [22)]

Description of marking	Subclause
CATEGORY APG ME EQUIPMENT: marking of	G.3.1
CATEGORY AP ME EQUIPMENT: marking of	G.3.2
CATEGORY AP and APG: marking of major parts	G.3.3
CATEGORY AP and APG ME EQUIPMENT: marking of parts	G.3.5
Depressurizing pressure system elements: warning about	9.7.2
Emergency stop device actuator: marking of	9.2.4
Hazardous voltage: warning of	8.11.1 i)
Mass of PATIENT, if designed for less than 135 kg: marking of	9.8.3.1
Moving parts: warning of	9.2.1
MULTIPLE SOCKET-OUTLET: marking of	16.9.2.1 b)
Overbalancing during transport: warning about	9.4.2.2
POTENTIAL EQUALIZATION CONDUCTOR terminal: marking of	8.6.7
Prohibition against pushing, leaning, resting: warning of	9.4.2.3 a)
Prohibition against sitting or stepping: warning of	9.4.2.3 b)
Reservoir or liquid storage chamber: marking of overflow HAZARD	11.6.2
MECHANICAL PROTECTIVE DEVICE intended to function only once: marking of	9.8.4.3
Separating transformer assembly: marking of	16.9.2.1 d)
Surfaces where application of force results in a RISK of overbalancing: marking of	9.4.2.3
Transport conditions: warning for	9.4.2.2

C.2 Marking on the inside of ME EQUIPMENT, ME SYSTEMS or their parts

The requirements for marking on the inside of ME EQUIPMENT and its parts are found in 7.3. Additional requirements for marking on the inside of ME EQUIPMENT, ME SYSTEMS and their parts are found in the subclauses listed in Table C.2. Symbols used in marking on the inside of ME EQUIPMENT are found in Annex D.

22) See 7.2.1 for the minimum requirements for marking on ME EQUIPMENT and on interchangeable parts.

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Table C.2 – Marking on the inside of ME EQUIPMENT, ME SYSTEMS or their parts

Description of marking	Subclause
Hazardous energies: marking of capacitors or the connected circuit parts	8.4.4
Hazardous voltage: marking of parts	8.11.1 i)
MAINS TERMINAL DEVICES: marking of terminals other than terminal blocks	8.11.4.1
Marking of pressure vessels and pipes: national certification mark	9.7.5
Separating transformer assembly: marking of	16.9.2.1 d)

C.3 Marking of controls and instruments

The requirements for marking of controls and instruments are found in 7.4. Additional requirements for marking of controls and instruments are found in the subclauses listed in Table C.3.

Table C.3 – Marking of controls and instruments

Description of marking	Subclause
Controls: scale marking of	15.4.6.1 b)
Varying the temperature setting of THERMOSTATS: clear indication of	15.4.2.2 ~~a)~~

C.4 ACCOMPANYING DOCUMENTS, general

The requirements for general information to be included in the ACCOMPANYING DOCUMENTS are found in 7.9.1. Additional requirements for general information to be included in the ACCOMPANYING DOCUMENTS are found in the subclauses listed in Table C.4.

Table C.4 – ACCOMPANYING DOCUMENTS, general

Description of requirement	Clause
CATEGORY AP and CATEGORY APG ME EQUIPMENT and parts	G.3.4
CLASS II ME EQUIPMENT with isolated internal screens: explanation of	8.6.9
Defibrillation voltage, any necessary recovery time	8.5.5.1 b)
Fixing of structures to floor, wall, ceiling, etc.	9.8.1
Instability excluding transport: placement and loading of doors, drawers and shelves	9.4.2.2 e)
IT-NETWORK: instructions for connecting ME EQUIPMENT	14.13
Isolation device: requirements for	8.11.4.4
Lifting points: indication of	9.4.4 a)
Mass of PATIENT, if support systems designed for less than 135 kg	9.8.3.1
Mass of PATIENT, if support systems designed for more than 135 kg	9.8.3.1
MECHANICAL PROTECTIVE DEVICE intended to function only once: instruction to call SERVICE PERSONNEL	9.8.4.3
ME EQUIPMENT: placement of SAFE WORKING LOAD	9.4.2.4.3 ~~c)~~
ME SYSTEMS: addition requirements	16.2
Noise: protective means	9.6.2.1 b)
Passing over an obstruction: instructions for	9.4.2.4.3
~~SAFETY DEVICE intended to function only once: instruction to call SERVICE PERSONNEL~~	~~9.8.4.3~~
Working conditions	5.4 a)

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C.5 ACCOMPANYING DOCUMENTS, Instructions for use

The requirements for information to be included in the instructions for use are found in 7.9.2. Additional requirements for information to be included in the instructions for use are found in the subclauses listed in Table C.5.

Table C.5 – ACCOMPANYING DOCUMENTS, instructions for use

Description of requirement	Subclause
ACCESSIBLE PARTS: instruction not to touch them and the PATIENT simultaneously	8.4.2 c)
ACCESSIBLE PARTS: instructions to the OPERATOR to open ACCCESS COVERS	8.4.2 c)
APPLIED PARTS (hot or cold): temperatures and clinical effects of	11.1.2.1
APPLIED PARTS not intended to deliver heat: temperature exceeding 41 °C	11.1.2.2
Cleaning or disinfection PROCESSES: specification of	11.6.6
Effect of multiple cleanings/disinfections	11.6.6
Foot-operated controls: intended for use in areas where liquids are likely to be found	15.4.7.3 b)
Mass of ACCESSORIES	9.8.3.~~2~~1
ME SYSTEMS: other equipment intended to provide power to ME EQUIPMENT	16.3
MOBILE ME EQUIPMENT: requirement that more than one person is needed to move	9.4.2.4.2 ~~a)~~
Moving parts: warning of	9.2.1
POTENTIAL EQUALIZATION CONDUCTOR terminal: information on the function and use of	8.6.7
Reservoir or liquid storage chamber: information on overflow HAZARD	11.6.2
Transport conditions: warning for	9.4.2.2

C.6 ACCOMPANYING DOCUMENTS, technical description

The requirements for information to be included in the technical description are found in 7.9.3. Additional requirements for information to be included in the technical description are found in the subclauses listed in Table C.6.

Table C.6 – ACCOMPANYING DOCUMENTS, technical description

Description of requirement	Clause
~~CLASS II ME EQUIPMENT with isolated internal screens: explanation of~~	~~8.6.9~~
External means of isolation: description of	8.11.1 b)
ME SYSTEM large transient currents: disclosure of	16.3
Non-automatic discharging device for internal capacitors: specification of	8.4.4
~~Network requirements for PEMS intended to be connected to an outside network~~	~~14.13~~

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Annex D
(informative)

Symbols on marking
(see Clause 7)

Symbols are frequently used on ME EQUIPMENT in preference to words with the intention of obviating language differences and permitting easier comprehension of a marking or indication, sometimes in a restricted space. New and improved symbols and safety signs have been introduced since the publication of the second edition of IEC 60601-1 which necessitates changes in the list of approved symbols and safety signs for use on ME EQUIPMENT.

Chief among these changes is the revision of the usage of symbol 24 in Table D.1. This symbol was formally used to indicate a warning as well as an informative marking (e.g. this is where the HIGH VOLTAGE is connected). A new safety sign (3) in Table D.2 has been added to indicate, "Warning: Dangerous Voltage." In this edition of the standard, the safety signs of Table D.2 are required where a warning is intended while the symbols in Table D.1 are used when the intention is solely to inform.

Similarly is the revision of the usage of symbol 10 in Table D.1, which was formerly used to indicate "attention: consult ACCOMPANYING DOCUMENTS". That symbol is now used to indicate caution. A new symbol (11) in Table D.1 has been added to indicate, "follow operating instructions". Additionally, a new safety sign (10) in Table D.2 has been added to mark ME EQUIPMENT where failure to follow operating instructions could place the PATIENT or OPERATOR at RISK.

Consistent use of these symbols and safety signs in all fields of use (e.g., medical, consumer products, and general transportation) will help ME EQUIPMENT OPERATORS to become familiar with their meaning. Conversely, any inconsistent use will lead to confusion and mistakes and jeopardize safety.

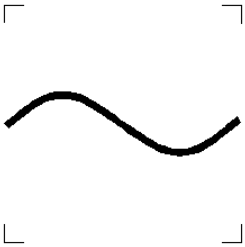
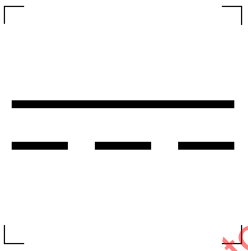
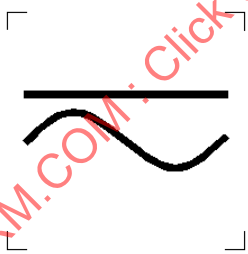
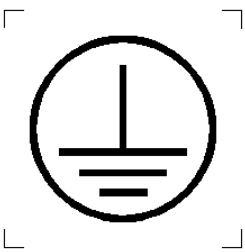
IEC 60878 [60] provides a useful compendium of graphical symbols and safety sign used on electrical equipment in medical practice that were complied from relevant ISO and IEC standards. See also 7.5 and 7.6.

For symbol requirements not met by the symbols in IEC 60878, refer in the first instance to published IEC or ISO symbols, noting that, where necessary, two or more symbols can be grouped together to convey a particular meaning and that, provided the essential communicative characteristics of the basic symbol are maintained, some latitude in graphic design is permissible. The colours of symbols are not specified, except for the background of the AP and APG symbols (see Clause G.3). The colours of safety signs are specified in ISO 3864-1.

In the following tables, the symbol graphic and title are provided for information.

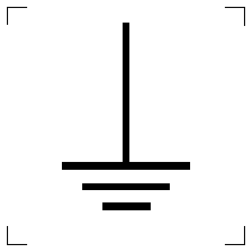
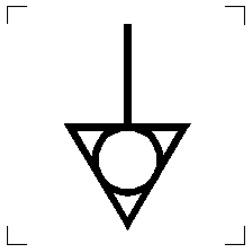
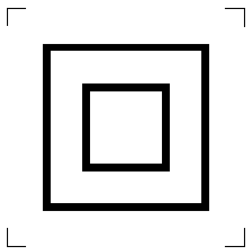
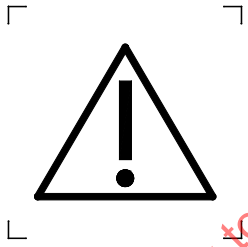
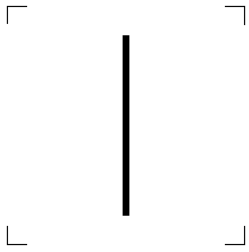
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Table D.1 – General symbols

No.	Symbol	Reference	Title
1		IEC 60417-5032	Alternating current
2		IEC 60417-5032-1	Three-phase alternating current
3		IEC 60417-5032-2	Three-phase alternating current with neutral conductor
4		IEC 60417-5031	Direct current
5		IEC 60417-5033	Both direct and alternating current
6		IEC 60417-5019	Protective earth (ground)

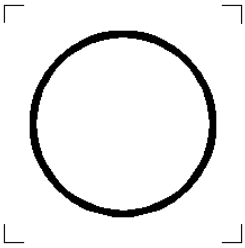
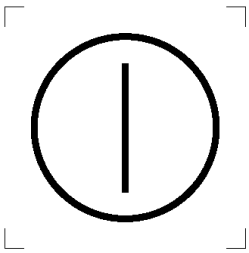
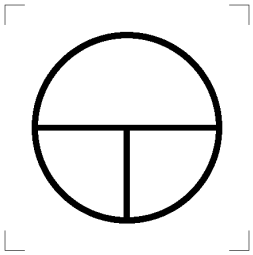
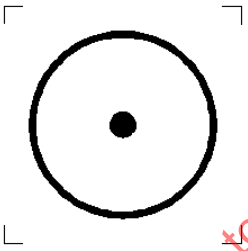
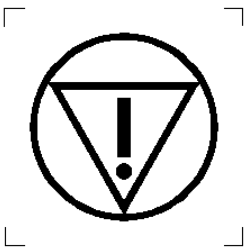
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Table D.1 *(continued)*

No.	Symbol	Reference	Title
7		IEC 60417-5017	Earth (ground)
8		IEC 60417-5021	Equipotentiality
9		IEC 60417-5172	CLASS II equipment
10		ISO 7000-0434A	Caution In case of application as a safety sign, the rules according to ISO 3864-1 are to be adhered to. See safety sign ISO 7010-W001 (Table D.2, safety sign 2).
11		ISO 7000-1641	Operating instructions
12		IEC 60417-5007	“ON” (power)

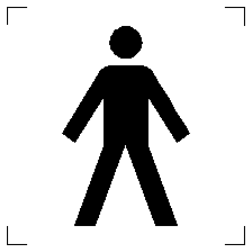
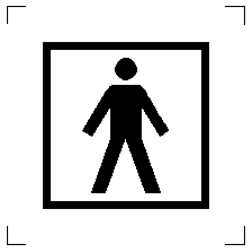
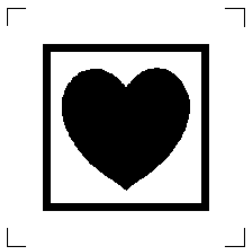
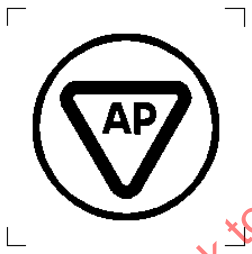
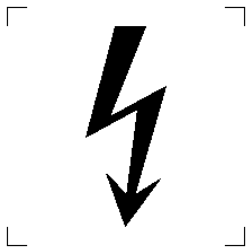
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Table D.1 *(continued)*

No.	Symbol	Reference	Title
13		IEC 60417-5008	“OFF” (power)
14		IEC 60417-5010	“ON” / “OFF” (push-push) NOTE Each position, "ON" or "OFF", is a stable position.
15		IEC 60417-5011	“ON” / “OFF” (push button) NOTE "OFF" is a stable position, whilst the "ON" position only remains during the time the button is depressed.
16		IEC 60417-5264	“ON” for part of equipment
17		IEC 60417-5265	“OFF” for part of the equipment
18		IEC 60417-5638	Emergency stop

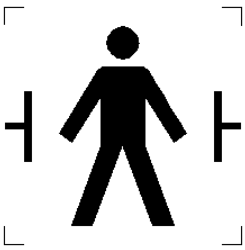
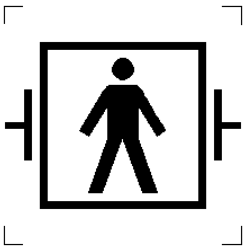
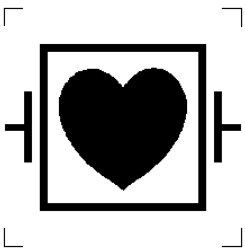
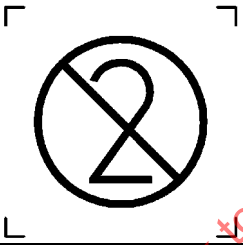
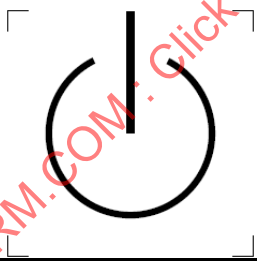
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Table D.1 *(continued)*

No.	Symbol	Reference	Title
19		IEC 60417-5840	TYPE B APPLIED PART NOTE Subclause 7.2.10 requires that, for clear differentiation with symbol 20, symbol 19 is not to be applied in such a way as to give the impression of being inscribed within a square.
20		IEC 60417-5333	TYPE BF APPLIED PART
21		IEC 60417-5335	TYPE CF APPLIED PART
22		IEC 60417-5331	CATEGORY AP equipment
23		IEC 60417-5332	CATEGORY APG equipment
24		IEC 60417-5036	Dangerous voltage

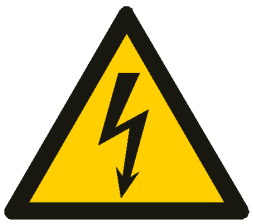
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Table D.1 *(continued)*

No.	Symbol	Reference	Title
25		IEC 60417-5841	DEFIBRILLATION-PROOF TYPE B APPLIED PART
26		IEC 60417-5334	DEFIBRILLATION-PROOF TYPE BF APPLIED PART
27		IEC 60417-5336	DEFIBRILLATION-PROOF TYPE CF APPLIED PART
28		ISO 7000-1051	Do not reuse
29		IEC 60417-5009	Stand-by

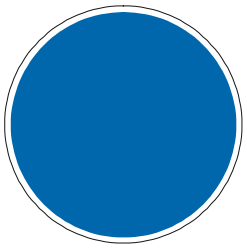
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Table D.2 – Safety signs

No.	Safety sign	Reference	Title
1		ISO 3864-1, Figure 3	Template for constructing a warning sign NOTE Background colour: yellow Triangular band: Black Symbol or text: Black
2		ISO 7010-W001	General warning sign
3		~~IEC 60878~~ ~~ISO 3864-B.3.6~~ [a] ISO 7010-W012	~~Warning; dangerous voltage~~ Warning, electricity
4		ISO 7010-P001 and ISO 3864-1, Figure 1	General prohibition sign and Template for constructing a prohibition sign NOTE Background colour: white Circular band and slash: red Symbol or text: black
5		ISO 7010-P017	No pushing
6		ISO 7010-P018	No sitting

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Table D.2 *(continued)*

No.	Safety sign	Reference	Title
7		ISO 7010-P019	No stepping on surface
8		ISO 3864-1 Figure 2	Template for constructing a mandatory action sign NOTE Background colour: blue Symbol or text: white
9		ISO 7010-M001	General mandatory action sign
10		ISO 7010-M002	Refer to instruction manual/ booklet NOTE On ME EQUIPMENT "Follow instructions for use"

[a] The description of this commonly used safety sign appeared in Annex B of ISO 3864:1984. When the safety signs were collected in ISO 7010, this sign was not migrated to the new standard. ISO 3864:1984 was superseded by ISO 3864-1 and ISO 7010 in January 2003. It is expected that this safety sign will be added to ISO 7010 in an upcoming amendment.

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Table D.3 – General codes

1	**N**	IEC 60445	Connection point for the neutral conductor on PERMANENTLY INSTALLED equipment
2	**IPN_1N_2**	IEC 60529	N_1 = 0 Non-protected 1 Protected against solid foreign objects of 50 mm ∅ and greater 2 Protected against solid foreign objects of 12,5 mm ∅ and greater 3 Protected against solid foreign objects of 2,5 mm ∅ and greater 4 Protected against solid foreign objects of 1,0 mm ∅ and greater 5 Dust-protected 6 Dust-tight N_2 = 0 Non-protected 1 Protection against vertically falling water drops 2 Protection against vertically falling water drops when ENCLOSURE tilted up to 15° 3 Protected against spraying water 4 Protected against splashing water 5 Protected against water jets 6 Protected against powerful water jets 7 Protected against the effects of temporary immersion in water 8 Protected against the effects of continuous immersion in water NOTE When a characteristic numeral is not required to be specified, it is replaced by the letter “X” (“XX” if both numerals are omitted).

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Annex E
(informative)

Examples of the connection of the measuring device (MD) for measurement of the PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT
(see 8.7)

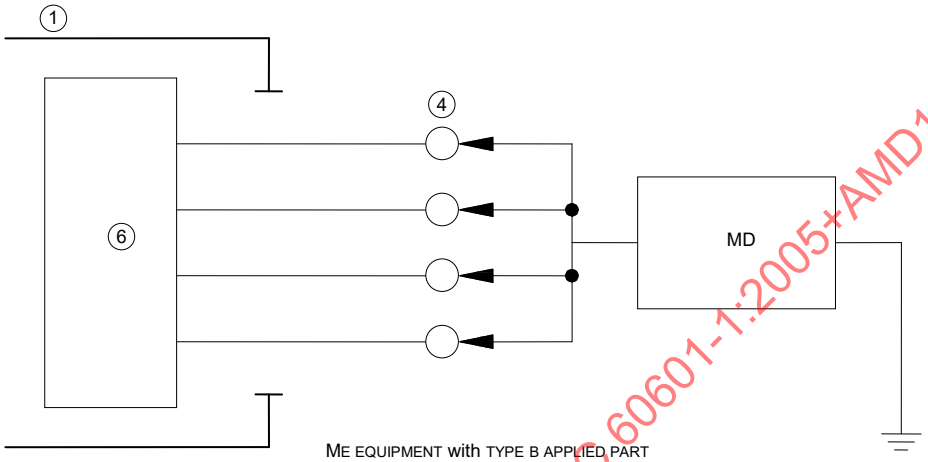


Figure E.1 – TYPE B APPLIED PART

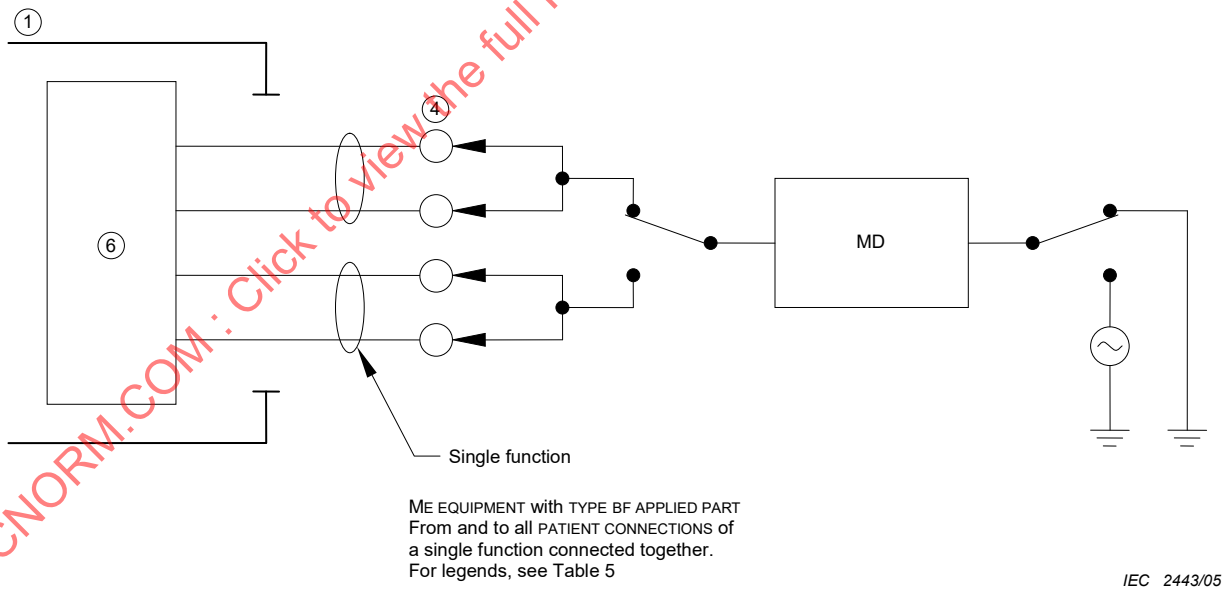


Figure E.2 – TYPE BF APPLIED PART

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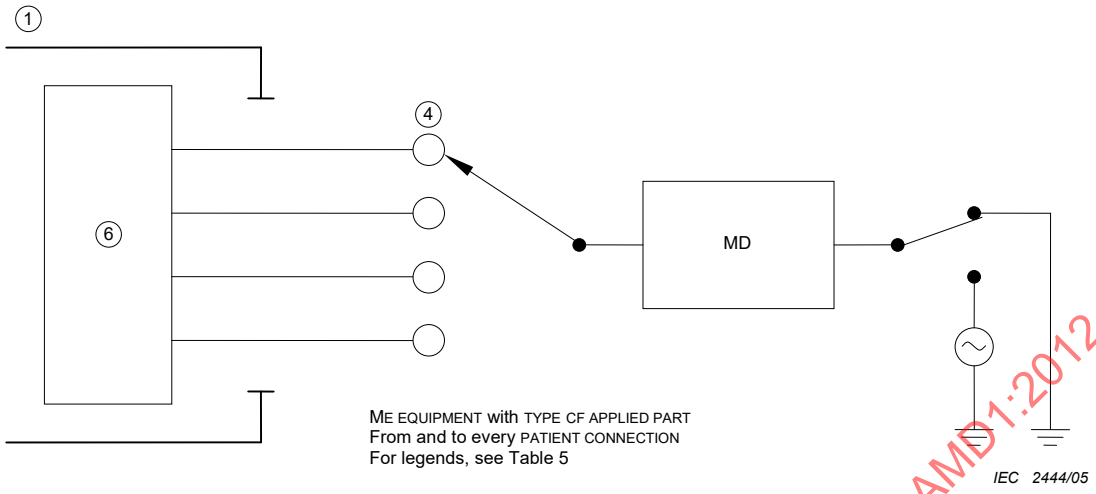


Figure E.3 – TYPE CF APPLIED PART

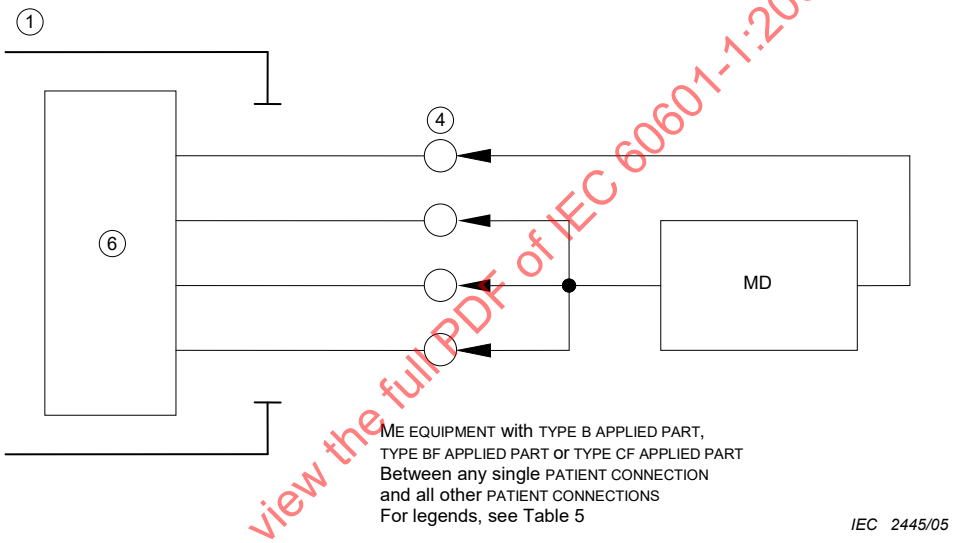


Figure E.4 – PATIENT AUXILIARY CURRENT

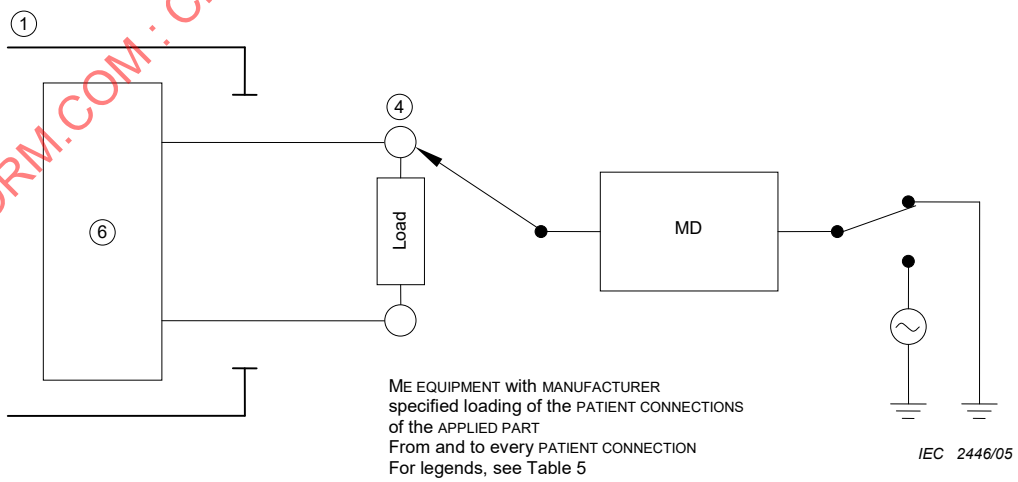
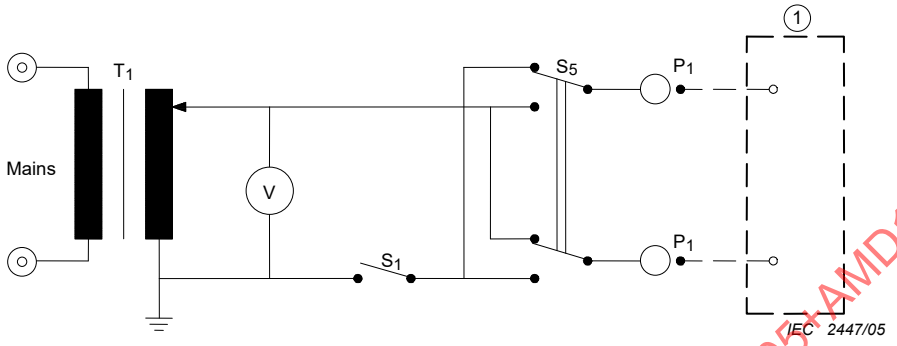


Figure E.5 – Loading of the PATIENT CONNECTIONS if specified by the MANUFACTURER

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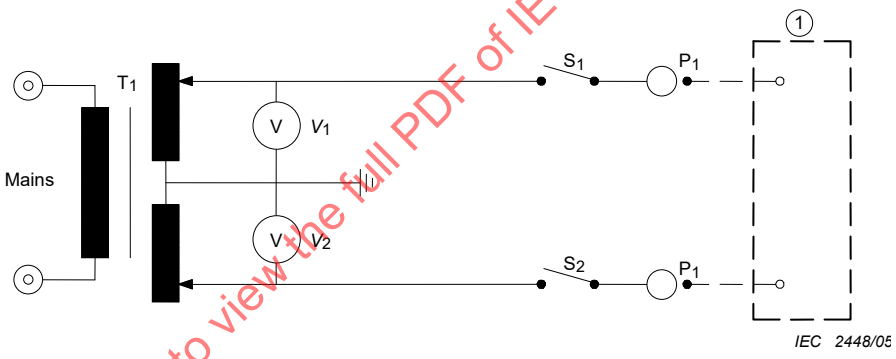
Annex F
(informative)

Suitable measuring supply circuits



For legends, see Table 5.

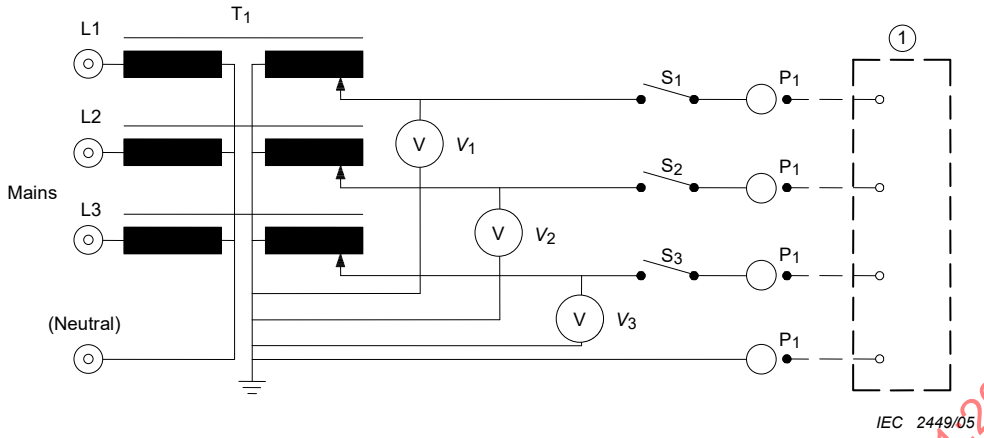
Figure F.1 – Measuring supply circuit with one side of the SUPPLY MAINS at approximately earth potential
(see 8.7.4.2)



For legends, see Table 5.

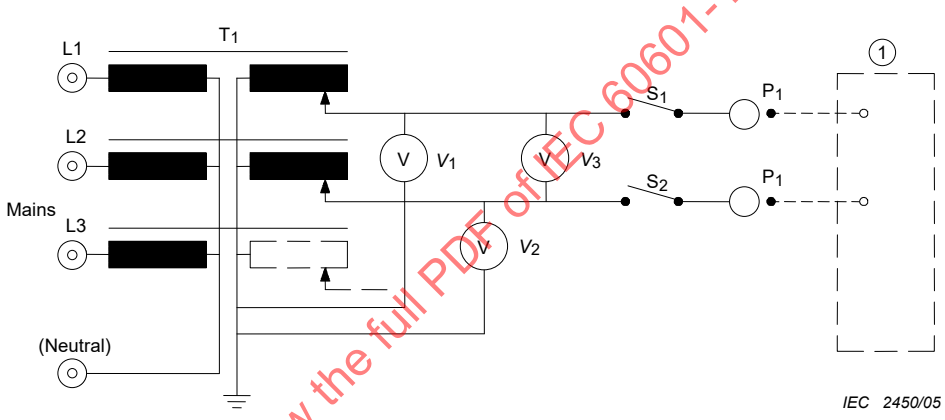
Figure F.2 – Measuring supply circuit with SUPPLY MAINS approximately symmetrical to earth potential
(see 8.7.4.2)

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For legends, see Table 5.

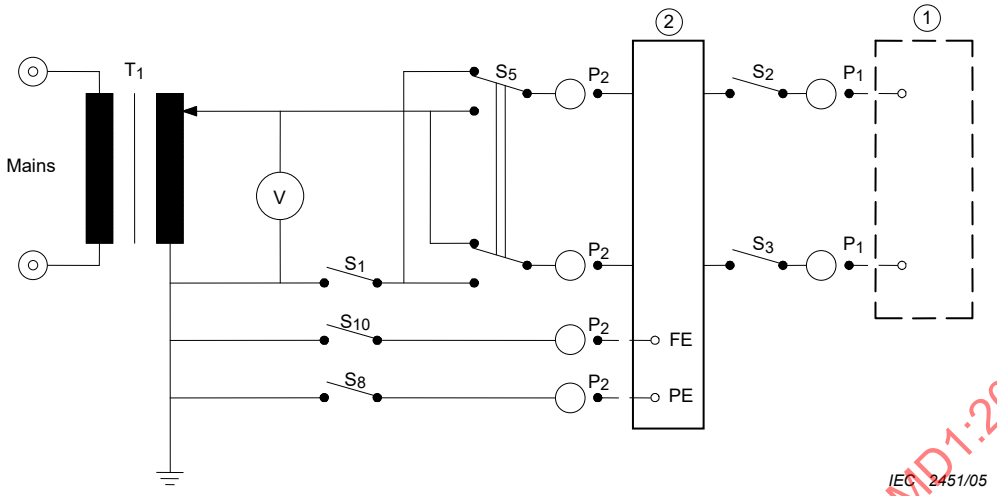
Figure F.3 – Measuring supply circuit for polyphase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS
(see 8.7.4.2)



For legends, see Table 5.

Figure F.4 – Measuring supply circuit for single-phase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS
(see 8.7.4.2)

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For legends, see Table 5.

Figure F.5 – Measuring supply circuit for ME EQUIPMENT having a separate power supply unit or intended to receive its power from another equipment in an ME SYSTEM
(see 8.7.4.2)

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Annex G
(normative)

Protection against HAZARDS of ignition of flammable anaesthetic mixtures

NOTE This annex replaces the former Section Six: "Protection against HAZARDS of ignition of flammable anaesthetic mixtures" of the second edition.

G.1 Introduction

G.1.1 Applicability

Where ME EQUIPMENT is used in areas in which flammable anaesthetics or flammable agents for disinfection or skin cleaning are applied, an explosion RISK can exist if such anaesthetics or agents are mixed with air, or with oxygen or nitrous oxide.

Ignition of such a mixture can be caused by sparks or by contact with parts having a high surface temperature.

Sparks can be caused where electrical circuits are opened or closed by operation of switches, connectors, fuses or OVER-CURRENT RELEASES and the like.

In HIGH VOLTAGE parts, sparks can be caused by corona. Static discharges can cause sparks.

The probability of occurrence of the ignition of such anaesthetic mixtures depends on their concentration, the appropriate minimum ignition energy, the presence of high surface temperatures and the energy of sparking.

G.1.2 Industrial equipment and components

The constructional requirements of IEC 60079-0 are generally not appropriate for ME EQUIPMENT for several reasons:

a) they lead to constructions of a size, weight or design that are not applicable for medical reasons or that cannot be sterilizable;

b) some constructions allow an explosion inside an ENCLOSURE, but prevent propagation outside it. Such a construction, which might be inherently safe, would be unacceptable in an operating theatre where continuity of operation of ME EQUIPMENT is essential;

c) industrial requirements were made for flammable agents mixed with air. They cannot be applied to mixtures with oxygen or nitrous oxide used in medical practice;

d) in medical practice flammable anaesthetic mixtures occur only in relatively small quantities.

However some of the constructions described in IEC 60079-0 are acceptable for CATEGORY AP ME EQUIPMENT (see G.5.1).

G.1.3 * Requirements for ME EQUIPMENT

In this annex, the location of flammable anaesthetic mixtures is described:

– as much as necessary for the construction of ME EQUIPMENT, as minimum for specified conditions of exhaust and absorption;

– as much as necessary for the allocation of ME EQUIPMENT and the construction of the electrical installation in the IEC 60364 series.

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The recommendations, limits and tests of this annex are based on the results of statistical considerations obtained from experiments with the most readily flammable mixtures of ether vapour with air and with oxygen, using the test apparatus described in Clause G.7. This is justified because combinations with ether have the lowest ignition temperatures and the lowest ignition energies of commonly used agents.

Where temperatures or circuit parameters of ME EQUIPMENT used in a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR exceed allowable limits and sparking cannot be avoided the relevant parts and circuits can be enclosed in ENCLOSURES with pressurized inert gas or clean air or in ENCLOSURES with restricted breathing.

ENCLOSURES with restricted breathing delay the build-up of an ignitable concentration. They are recognized because it is assumed that a period in which ME EQUIPMENT is used in a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR is followed by a period of ventilation during which such a concentration will disappear.

For ME EQUIPMENT containing or used in a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE, requirements, limits and tests are far more stringent.

These recommendations apply not only to NORMAL CONDITION but, additionally, in the SINGLE FAULT CONDITION, as indicated in 4.7. Only two exemptions from an actual ignition test are recognized, these being either the absence of sparks and limited temperature or limited temperature and restricted circuit parameters.

G.2 Locations and basic requirements

G.2.1 Parts of CATEGORY APG ME EQUIPMENT

Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs shall be CATEGORY AP or APG ME EQUIPMENT and shall comply with the requirements of Clause G.3, G.4 and G.5.

G.2.2 FLAMMABLE ANAESTHETIC MIXTURE WITH AIR

Where a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs because of a leakage or discharge of a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE from an ENCLOSURE, it is considered to propagate to a volume surrounding the leakage or discharge point at a distance from 5 cm to 25 cm from such a point.

G.2.3 FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE

A FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE may be contained in a completely or partly enclosed ME EQUIPMENT part and in the PATIENT'S respiratory tract. Such a mixture is considered to propagate to a distance of 5 cm from an ENCLOSURE part where leakage or discharge occurs.

G.2.4 ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH AIR

ME EQUIPMENT or parts thereof specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH AIR (in a location defined in G.2.2) shall be CATEGORY AP or APG ME EQUIPMENT and shall comply with the requirements of Clause G.4 and G.5.

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G.2.5 ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE

ME EQUIPMENT or parts thereof specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE (in a location defined in G.2.2) shall be CATEGORY APG ME EQUIPMENT and shall comply with the requirements of G.4 and G.6.

Compliance with the requirements of ~~G.2.3 through~~ G.2.4 and G.2.5 ~~(inclusive)~~ is checked by inspection and by the appropriate tests of Clause G.3, G.4 and G.5.

These tests shall be performed after applicable tests according to 11.6.6 and 11.6.7.

G.3 Marking, ACCOMPANYING DOCUMENTS

G.3.1 CATEGORY APG marking

CATEGORY APG ME EQUIPMENT shall be marked on a prominent location with a green-coloured band at least 2 cm wide imprinted with the characters "APG" (see symbol IEC 60417-5332 (~~DB:~~2002-10) (Table D.1, symbol 23)). The length of the green-coloured band should be at least 4 cm. The size of the marking should be as large as possible for the particular case. If this marking is impossible, the relevant information shall be given in the instructions for use.

Compliance is checked by inspection and by application of the tests and criteria in 7.1.2 and 7.1.3.

G.3.2 CATEGORY AP marking

CATEGORY AP ME EQUIPMENT shall be marked on a prominent location with a green-coloured circle of at least 2 cm diameter, imprinted with the characters "AP" (see symbol IEC 60417-5331 (~~DB:~~2002-10) (Table D.1, symbol 22)).

The size of the marking should be as large as possible for the particular case. If this marking is impossible, the relevant information shall be given in the instructions for use.

Compliance is checked by inspection and by application of the tests and criteria in 7.1.2 and 7.1.3.

G.3.3 Placement of markings

The marking according to G.3.1 and G.3.2 ~~and G.3.3~~ shall be present on the major part of the ME EQUIPMENT if this part is CATEGORY AP or CATEGORY APG. It need not be repeated on detachable parts that can only be used together with the marked ME EQUIPMENT.

Compliance is checked by inspection.

G.3.4 ACCOMPANYING DOCUMENTS

ACCOMPANYING DOCUMENTS shall contain an indication to enable the RESPONSIBLE ORGANIZATION to distinguish the parts of ME EQUIPMENT (see G.3.5) that are CATEGORY AP and CATEGORY APG.

Compliance is checked by inspection.

G.3.5 Marking when parts of ME EQUIPMENT are CATEGORY AP or CATEGORY APG

On ME EQUIPMENT in which only certain ME EQUIPMENT parts are CATEGORY AP or CATEGORY APG, the marking shall clearly indicate which parts are CATEGORY AP or CATEGORY APG.

Compliance is checked by inspection.

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G.4 Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT

G.4.1 Electrical connections

a) CREEPAGE DISTANCES and AIR CLEARANCES between the connection points of POWER SUPPLY CORD shall be according to THE Table 12 values for one MEANS OF PATIENT PROTECTION.

b) Connections, except those in the circuits described in G.5.3 and G.6.3, shall be protected against accidental disconnection in NORMAL USE or shall be so designed that connection or disconnection can be performed only with the use of a TOOL.

c) CATEGORY AP and CATEGORY APG ME EQUIPMENT shall not be provided with a DETACHABLE POWER SUPPLY CORD unless the circuit complies with the requirements of G.5.3 and G.6.3.

Compliance is checked by inspection or measurement.

G.4.2 Construction details

a) Opening of an ENCLOSURE providing protection against the penetration of gases or vapours into the ME EQUIPMENT or into parts thereof shall be possible only with the aid of a TOOL.

Compliance is checked by inspection.

b) To minimize arcing and sparking due to foreign objects penetrating the ENCLOSURE:

- top covers of ENCLOSURES shall have no openings; openings for controls are permitted if these openings are covered by the control knob;
- openings in side-covers shall have such dimensions that penetration by a solid cylindrical object of more than 4 mm diameter is prevented;
- openings in base plates shall have such dimensions that penetration by a solid cylindrical object of more than 12 mm diameter is prevented.

Compliance is checked by means of a cylindrical test rod of 4 mm diameter for side-covers and 12 mm diameter for base plates. The test rod is not to enter the ENCLOSURE when applied in all possible directions without appreciable force.

c) Where insulation of electrical conductors equal to one MEANS OF PATIENT PROTECTION may contact a part containing a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE or ignitable gases alone or oxygen, a short circuit of these conductors or a short circuit of one conductor to a conductive part containing the gas or mixture shall not result in loss of integrity of such a part or result in an inadmissible temperature ~~or in a HAZARD~~ in such a part (see G.6.3 a)) or in any HAZARDOUS SITUATION.

Compliance is checked by inspection. In case of doubt, a short-circuit test (without explosive gases) should be performed and the temperature in the relevant part should be measured if possible. The short-circuit test need not be performed if the product of the open-circuit voltage in volts and the short-circuit current in amperes does not exceed 10.

G.4.3 Prevention of electrostatic charges

a) Electrostatic charges shall be prevented on CATEGORY AP and CATEGORY APG ME EQUIPMENT by a combination of appropriate measures such as:

- the use of antistatic materials with a limited electrical resistance as specified in G.4.3 b), and

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– provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor or to the protective earth system or the potential equalization system or via wheels to an antistatic floor of the medically used room.

b) The electrical resistance limits of anaesthetic tubing, mattresses and pads, castor tyres and other antistatic material shall comply with ISO 2882.

Compliance with the allowable resistance limits given in ISO 2882 is checked by measurements according to ISO 1853, ISO 2878 and ISO 23529.

G.4.4 Corona

Parts and components of ME EQUIPMENT operating at more than 2 000 V a.c. or more than 2 400 V d.c. that are not included in ENCLOSURES in compliance with G.5.4 or G.5.5 shall be so designed that corona cannot be produced.

Compliance is checked by inspection and measurement.

G.5 Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components thereof

G.5.1 General

ME EQUIPMENT, its parts or components shall not ignite FLAMMABLE ANAESTHETIC MIXTURES WITH AIR in NORMAL USE and NORMAL CONDITION.

ME EQUIPMENT, its parts or components complying with one of Subclauses G.5.2 to G.5.5 (inclusive) are considered to comply with the requirement of this subclause.

ME EQUIPMENT, its parts or components complying with the requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2), for sand-filled ENCLOSURES (IEC 60079-5) or for oil-immersed equipment (IEC 60079-6) as well as with the requirements of this standard (excluding those of G.5.2 to G.5.5), are considered to comply with the requirements for CATEGORY AP ME EQUIPMENT.

G.5.2 Temperature limits

ME EQUIPMENT, its parts or components not producing sparks and not producing operating temperatures of surfaces in contact with gas mixtures in NORMAL USE and NORMAL CONDITION, exceeding 150 °C in case of restricted vertical air circulation by convection, or exceeding 200 °C in case of unrestricted vertical air circulation, if measured at an ambient temperature of 25 °C, are considered to comply with the requirements of G.5.1.

The operating temperatures are measured during the tests mentioned in 11.1.

G.5.3 * Low-energy circuits

ME EQUIPMENT, its parts or components that may produce sparks in NORMAL USE and NORMAL CONDITION of the ME EQUIPMENT (for example, switches, relays, plug connections that can be detached without the use of a TOOL, including connections inside ME EQUIPMENT that are not sufficiently locked or secured, and brush motors) shall comply with the temperature requirements of G.5.2 and additionally the voltage U_{max} and the current I_{max}, which can occur in their circuits, taking into account the capacitance C_{max} and the inductance L_{max} shall comply with the following:

$U_{max} \leq U_{zR}$ with a given current I_{zR}, see Figure G.1,

$U_{max} \leq U_c$ with a given capacitance C_{max}, see Figure G.2,

$I_{max} \leq I_{zR}$ with a given voltage U_{zR}, see Figure G.1, and

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$I_{max} \leq I_{zL}$ with a given inductance L_{max} and a $U_{max} \leq 24$ V, see Figure G.3.

– The graphs of Figure G.1, Figure G.2 and Figure G.3 have been obtained with the test apparatus according to ~~G.6~~ Figure G.7 with the most readily flammable mixtures of ether vapour with air (ether volume percentage 4,3 ± 0,2 %) for an ignition probability (without safety factor) of 10^{-3}.

– Extrapolation of the graph of Figure G.1 is allowed for combinations of currents and corresponding voltages within the limitations $I_{zR} \cdot U_{zR} \leq 50$ W.

Extrapolation for voltages of more than 42 V is not valid.

– Extrapolation of the graph of Figure G.2 is allowed for combinations of capacitances and corresponding voltages within the limitations:

$$\frac{C}{2} U^2 \leq 1{,}2 \text{ mJ}$$

Extrapolation for voltages of more than 242 V is not valid.

If the equivalent resistance R is less than 8 000 Ω, U_{max} is additionally determined with the actual resistance R.

– Extrapolation of the graph of Figure G.3 is allowed for combinations of currents and corresponding inductances within the limitations

$$\frac{L}{2} I^2 \leq 0{,}3 \text{ mJ}$$

Extrapolation for inductances larger than 900 mH is not valid.

– Voltage U_{max} is taken as the highest supply voltage occurring in the circuit under investigation with the sparking contact open, taking into account the MAINS VOLTAGE variations required in 4.10.

– Current I_{max} is taken as the highest current flowing in the circuit under investigation with the sparking contact closed, taking into account the MAINS VOLTAGE variations required in 4.10.

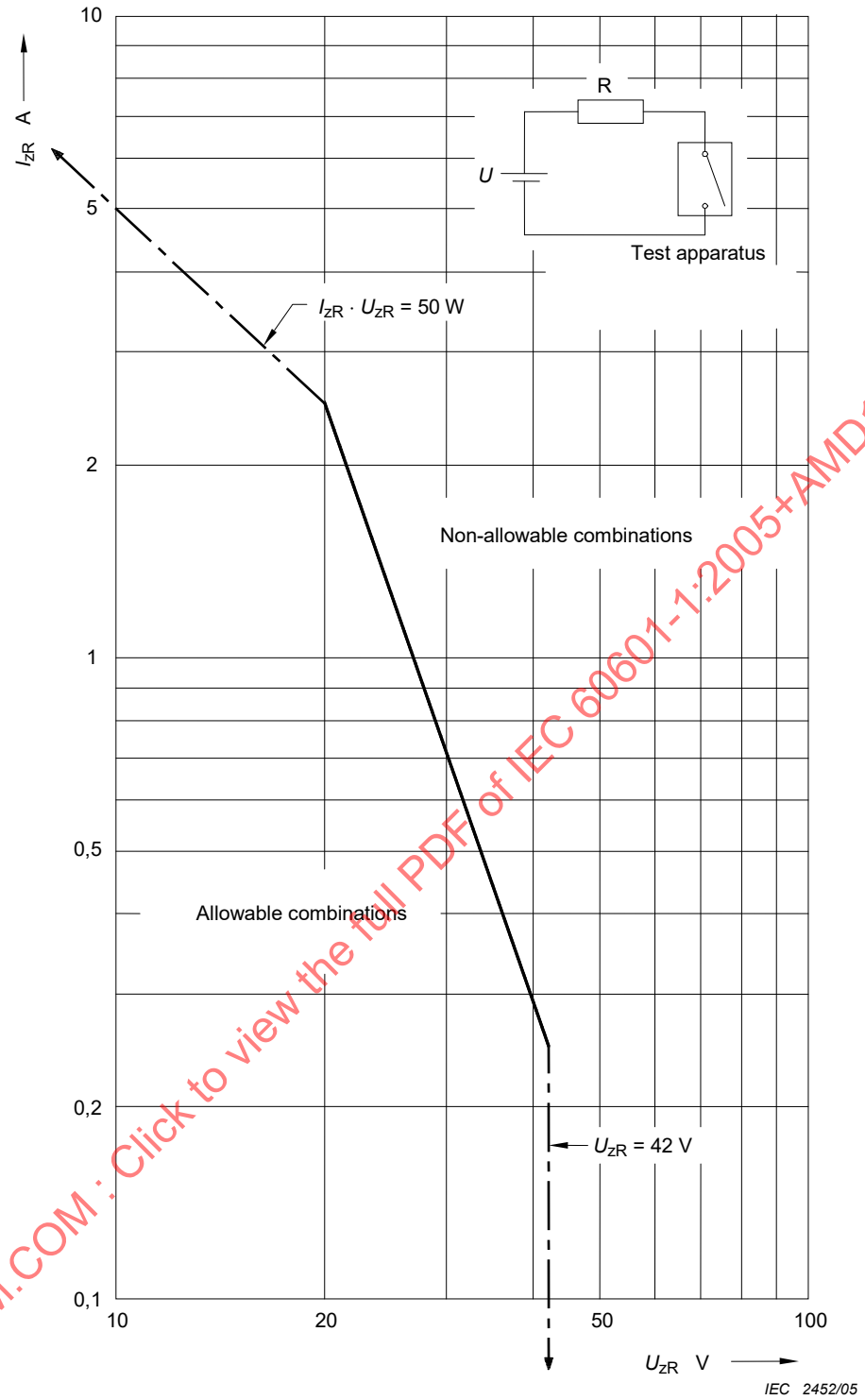
– Capacitance C_{max} and inductance L_{max}, are taken as the values that occur at the component under investigation that produces sparks in the ME EQUIPMENT.

– If the circuit is supplied with a.c., the peak value is taken into account.

– If the circuit is complicated and consists of more than one capacitance, inductance and resistance, or a combination thereof, an equivalent circuit is calculated to determine the equivalent maximum capacitance, the equivalent maximum inductance and additionally the equivalent U_{max} and I_{max}, either as d.c. values or as a.c. peak values.

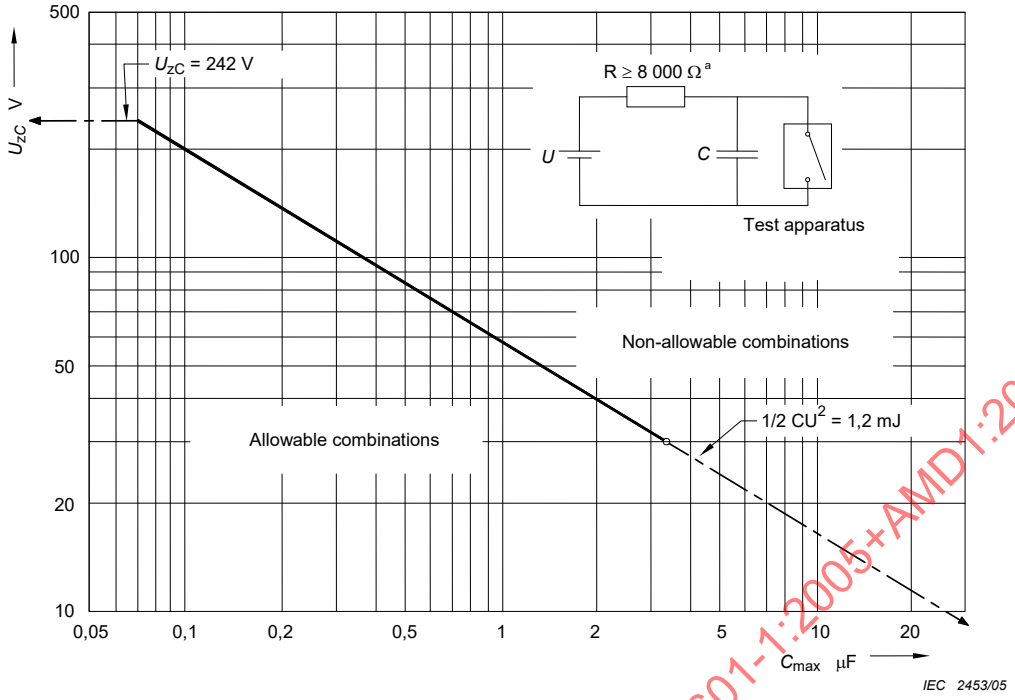
Compliance is checked either by temperature measurement and determination of U_{max}, I_{max}, R, L_{max} and C_{max} and application of Figure G.1, Figure G.2 and Figure G.3, or by examination of the design data.

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Figure G.1– Maximum allowable current I_{zR} as a function of the maximum allowable voltage U_{zR} measured in a purely resistive circuit with the most flammable mixture of ether vapour with air



[a] 8 000 Ω or the actual resistance, if R is less than 8 000 Ω

Figure G.2 – Maximum allowable voltage U_{zC} as a function of the capacitance C_{max} measured in a capacitive circuit with the most flammable mixture of ether vapour with air

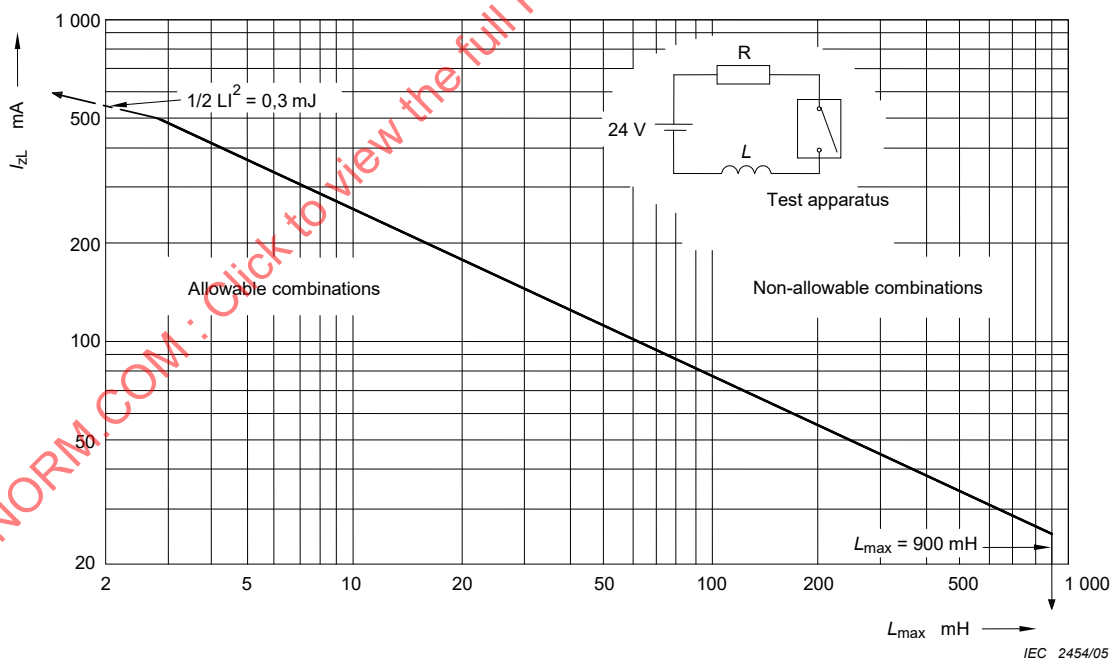


Figure G.3 – Maximum allowable current I_{zL} as a function of the inductance L_{max} measured in an inductive circuit with the most flammable mixture of ether vapour with air

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G.5.4 * External ventilation with internal overpressure

Where ME EQUIPMENT, its parts or components are enclosed in an ENCLOSURE with external ventilation by means of internal overpressure the following requirements shall apply.

a) FLAMMABLE ANAESTHETIC MIXTURES WITH AIR that might have penetrated into the ENCLOSURE of ME EQUIPMENT or of an ME EQUIPMENT part shall be removed by ventilation before the ME EQUIPMENT or the ME EQUIPMENT part can be energized, and subsequently the penetration of such mixtures during operation shall be prevented by maintenance of overpressure within the ME EQUIPMENT or the ME EQUIPMENT part by means of air not containing flammable gases or vapours or by means of a physiologically acceptable inert gas (for example nitrogen).

b) The overpressure inside the ENCLOSURE shall be at least 75 Pa in NORMAL CONDITION. The overpressure shall be maintained at the site of potential ignition even if the air or inert gas can escape through openings in the ENCLOSURE that are necessary for the normal operation of ME EQUIPMENT or its parts.

Energizing ME EQUIPMENT shall only be possible after the required minimum overpressure has been present for a time sufficient to ventilate the relevant ENCLOSURE so that the displaced volume of air or of inert gas is at least five times the volume of the ENCLOSURE. (However, ME EQUIPMENT may be energized at any time or repeatedly if the overpressure is continuously present.)

c) If the overpressure drops below 50 Pa during operation, ignition sources shall be de-energized automatically by means that either shall be located in a place where the requirements and tests of Clause G.4 do not apply, or comply with the requirements of Clause G.5.

d) The external surface of the ENCLOSURE in which the internal overpressure is maintained shall not attain in NORMAL CONDITION and NORMAL USE an operating temperature exceeding 150 °C, measured in an ambient temperature of 25 °C.

Compliance with the requirements of G.5.4 a) to G.5.4 d) is checked by temperature, pressure and flow measurements and inspection of the pressure monitoring device.

G.5.5 ENCLOSURES with restricted breathing

Where ME EQUIPMENT, its parts or components are enclosed in an ENCLOSURE with restricted breathing the following requirements shall apply:

a) * ENCLOSURES with restricted breathing shall be so designed that the formation of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR inside the ENCLOSURE does not occur whilst the ENCLOSURE is surrounded by a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR of a high concentration for a period of at least 30 min but without any pressure difference to the space inside the ENCLOSURE.

b) If the required tightness is obtained by gaskets or sealing, the material used shall therefore be resistant to ageing.

Compliance is checked by application of test B-b of IEC 60068-2-2, Clause 15, temperature 70 °C ± 2 °C, duration 96 h.

c) If the ENCLOSURE contains inlets for flexible cords, their gas-tightness shall be maintained when the cords are stressed by bending or pulling. The cords shall be fitted with adequate anchorages to limit these stresses (see 8.11.3.5).

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Compliance with the requirements of G.5.5 a), G.5.5 b) and G.5.5 c) is checked by application of the following tests:

After completion of the test of G.5.4 b) if relevant, an internal overpressure of 400 Pa is created and 30 pulls of the value shown in Table G.1 are applied to each flexible cord alternately, in the axial direction of the cord inlet and in the least favourable perpendicular direction, each pull without jerks and of 1 s duration. At the end of the test the overpressure is not be reduced to less than 200 Pa.

Table G.1 – Gas-tightness of cord inlets

Mass (*m*) of ME EQUIPMENT kg	**Pull** N
$m \leq 1$	30
$1 < m \leq 4$	60
$m > 4$	100

When the ENCLOSURE of ME EQUIPMENT parts or components is sealed or gas-tight and no doubt exists that the ENCLOSURE complies with the aforementioned requirement, the ENCLOSURE is tested by inspection only.

The operating temperature of the external surface of the ENCLOSURE shall not exceed 150 °C measured at an ambient temperature of 25 °C. The steady state operating temperature of the ENCLOSURE is also measured.

G.6 Requirements and tests for CATEGORY APG ME EQUIPMENT, parts and components thereof

G.6.1 General

ME EQUIPMENT, its parts or components shall not ignite FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE. This requirement applies both in NORMAL USE and in the event of any applicable SINGLE FAULT CONDITION, as described in 4.7.

ME EQUIPMENT, its parts or components that do not comply with the requirements of G.6.3 are tested by a CONTINUOUS OPERATION test over a period of 10 min in an ether/oxygen mixture (ether volume percentage 12,2 % ± 0,4 %) after the thermal steady state condition has been attained, but not longer than 3 h after switching on.

G.6.2 * Power supply

Parts or components of CATEGORY APG ME EQUIPMENT that operate in a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE shall be supplied from a source that is isolated from earth by at least insulation equal to one MEANS OF PATIENT PROTECTION and from electrical parts by insulation equal to two MEANS OF PATIENT PROTECTION.

Compliance is checked by inspection of circuit diagrams and measurement.

G.6.3 * Temperatures and low-energy circuits

ME EQUIPMENT, and its parts or components are considered to comply with the requirements of G.6.1 without being tested according to G.6.1 if, in NORMAL USE, NORMAL CONDITION and SINGLE FAULT CONDITIONS (see 4.7):

a) no sparks are produced and no temperatures exceeding 90 °C occur, or

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b) a temperature limit of 90 °C is not exceeded, ME EQUIPMENT or its parts contain components that may produce sparks in NORMAL USE, NORMAL CONDITION and applicable SINGLE FAULT CONDITIONS, but the voltage U_{max} and the current I_{max} that can occur in their circuits, taking into account the capacitance C_{max} and the inductance Lmax, comply with the following:

$U_{max} \leq$ ~~L~~U_{zR} with a given I_{zR}, see Figure G.4, and

$U_{max} \leq U_{zC}$ with given C_{max}, see Figure G.5, as well as

$I_{max} \leq I_{zR}$ with a given voltage U_{zR}, see Figure G.4, and

$I_{max} \leq I_{zL}$ with a given inductance L_{max} and $U_{max} \leq 24$ V, see Figure G.6.

– The graphs in Figure G.4, Figure G.5 and Figure G.6 have been obtained with the test apparatus according to ~~F.8~~ Figure G.7 with the most readily flammable mixture of ether vapour with oxygen (ether volume percentage ~~12,2 ± 0,4 %~~ 4,3 ± 0,2 %) for an ignition probability of 10^{-3}. The maximum allowable values of I_{zR} (Figure G.4), U_{zC} (Figure G.5) and I_{zL} (Figure G.6) include a safety factor of 1,5.

– Extrapolation of the curves of Figure G.4, Figure G.5 and Figure G.6 is limited to the areas indicated.

– Voltage U_{max} is taken as the highest no-load voltage occurring in the circuit under investigation, taking into account MAINS VOLTAGE variations as required in 4.10.

– Current I_{max} is taken as the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as required in 4.10.

– Capacitance C_{max} and inductance L_{max} are taken as values that occur in the relevant circuit.

– If the equivalent resistance R in Figure G.5 is less than 8 000 Ω, U_{max} is additionally determined with the actual resistance R.

– If the circuit is supplied with a.c., the peak value is taken into account.

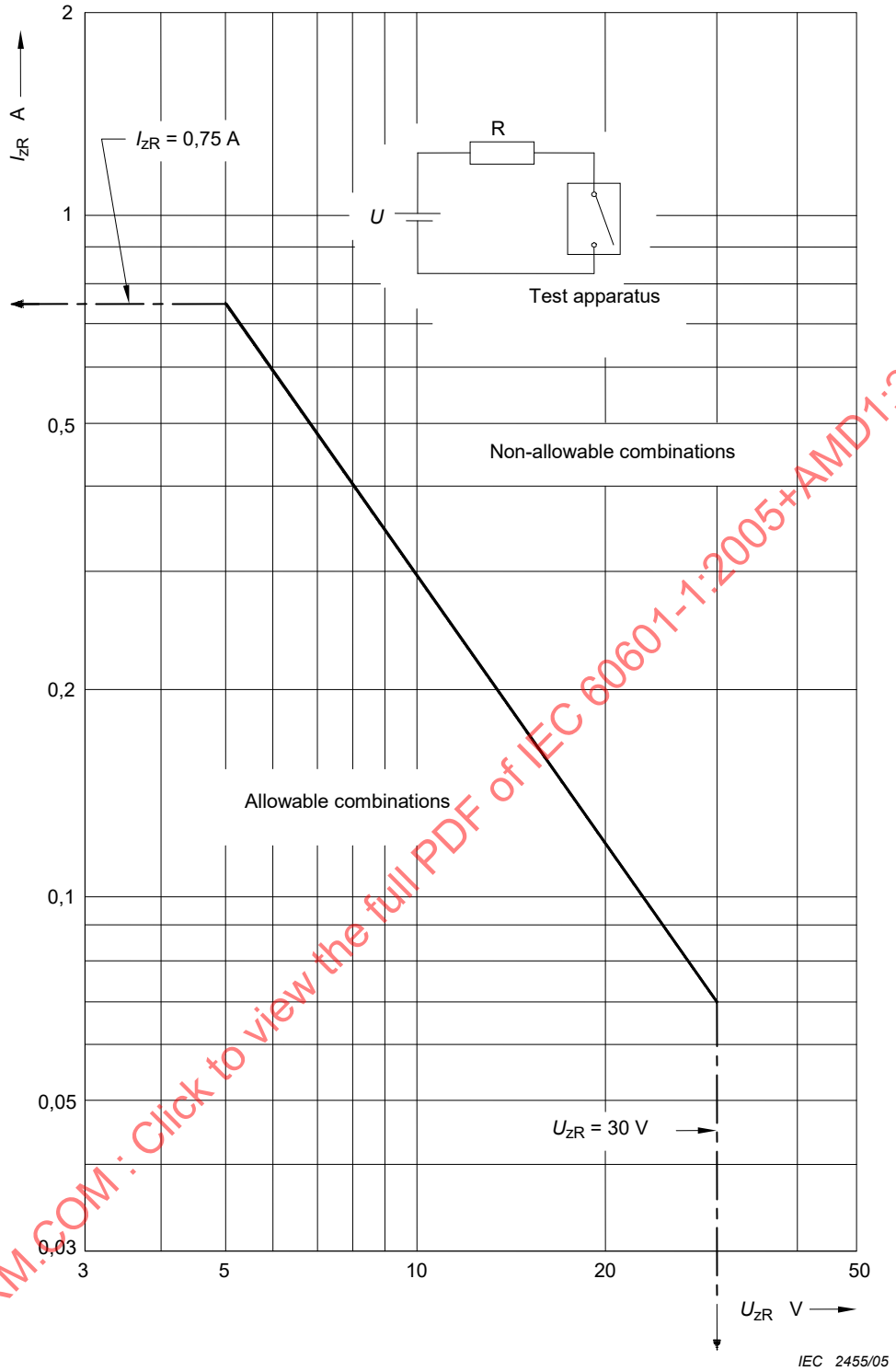
– If the circuit is complicated and consists of more than one capacitance, inductance and resistance or a combination thereof an equivalent circuit is calculated to determine the equivalent maximum capacitance, the equivalent maximum inductance and, additionally, the equivalent U_{max} and I_{max} either as d.c. values or a.c. peak values.

– If the energy produced in an inductance or capacitance in a circuit is limited by voltage-limiting or current-limiting devices preventing the limits of Figure G.4, Figure G.5 and Figure G.6 being exceeded, two independent components shall be applied, so that the required limitation of voltage or current is obtained even in the case of a first fault (short circuit or open circuit) in one of these components.

This requirement does not apply to transformers designed and made according to this standard and to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in the event of rupture.

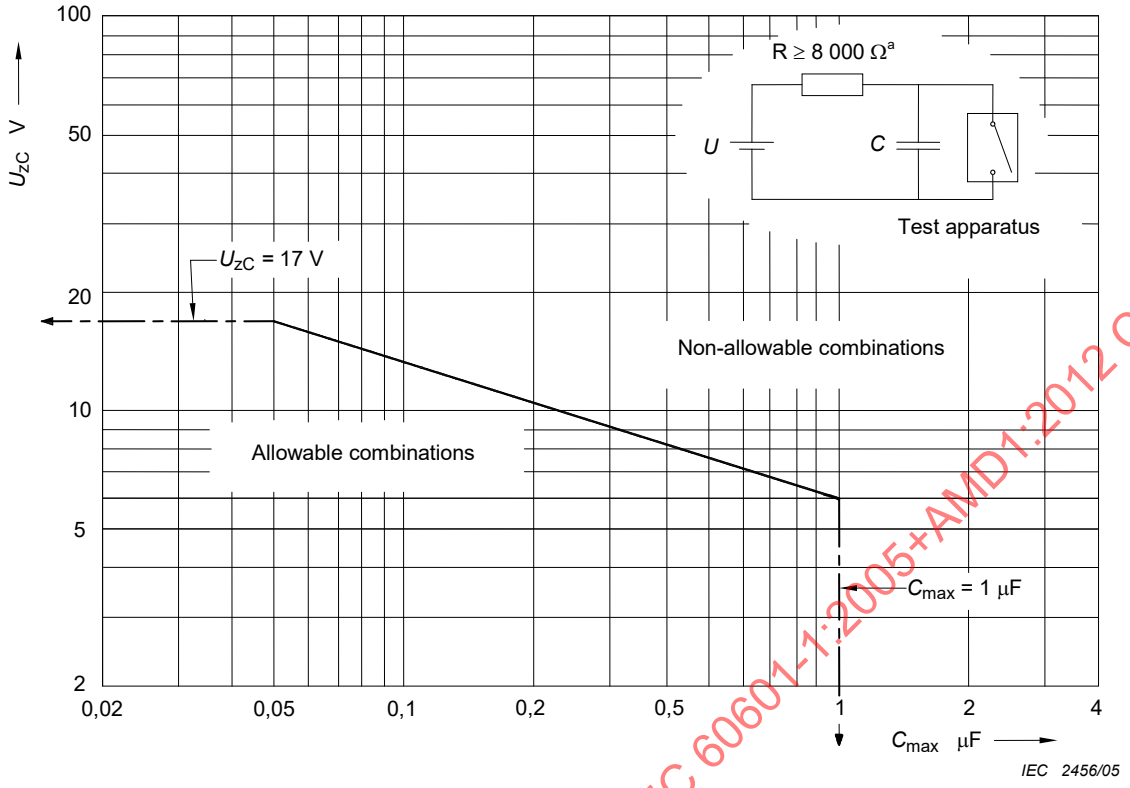
Compliance is checked by inspection, temperature measurements, comparison with design data or by measurement of U_{max}, I_{max}, R, L_{max} and C_{max} and using Figure G.4, Figure G.5 and Figure G.6.

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Figure G.4 – Maximum allowable current I_{zR} as a function of the maximum allowable voltage U_{zR} measured in a purely resistive circuit with the most flammable mixture of ether vapour with oxygen



[a] 8 000 Ω or the actual resistance, if *R* is less than 8 000 Ω

Figure G.5 – Maximum allowable voltage U_{zc} as a function of the capacitance C_{max} measured in a capacitive circuit with the most flammable mixture of ether vapour with oxygen

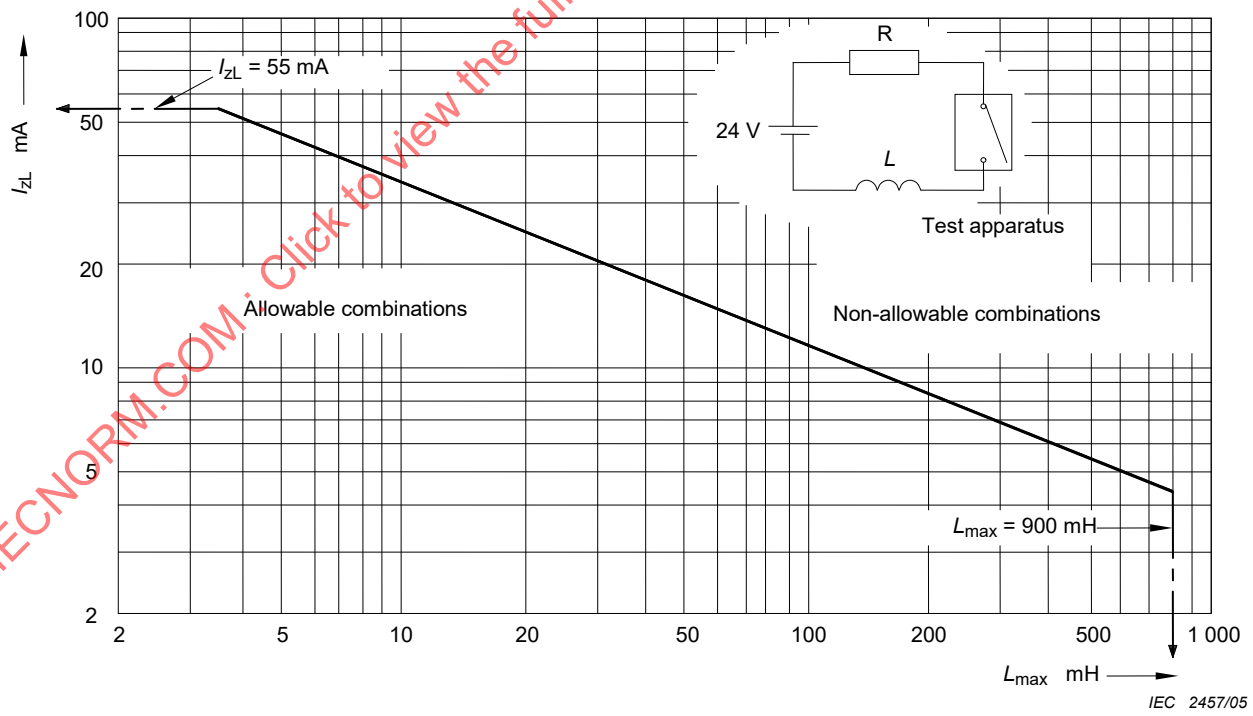


Figure G.6 – Maximum allowable current I_{zL} as a function of the inductance L_{max} measured in an inductive circuit with the most flammable mixture of ether vapour with oxygen

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G.6.4 Heating elements

ME EQUIPMENT, its parts and components that heat a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE shall be provided with a non-SELF-RESETTING THERMAL CUT-OUT, as an additional protection against overheating.

Compliance is checked by the corresponding test of 15.4.2.1.

The current-carrying part of the heating element shall not be in direct contact with the FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE.

Compliance is checked by inspection.

G.7 Test apparatus for flammable mixtures

NOTE Formally Appendix F of the second edition.

The test apparatus comprises an ignition space with a volume of at least 250 cm^3, which contains the prescribed atmosphere or mixture and a contact arrangement (see Figure G.7) providing sparks by opening and closing.

The contact arrangement consists of a cadmium disk with two groves and a second disk with four tungsten wires having a diameter of 0,2 mm that slides over the first disk. The free length of the tungsten wires is 11 mm. The shaft to which the tungsten wires are connected rotates with a speed of 80 r/min. The shaft connected to the cadmium disk turns in opposite direction to the shaft connected to the disk with wires.

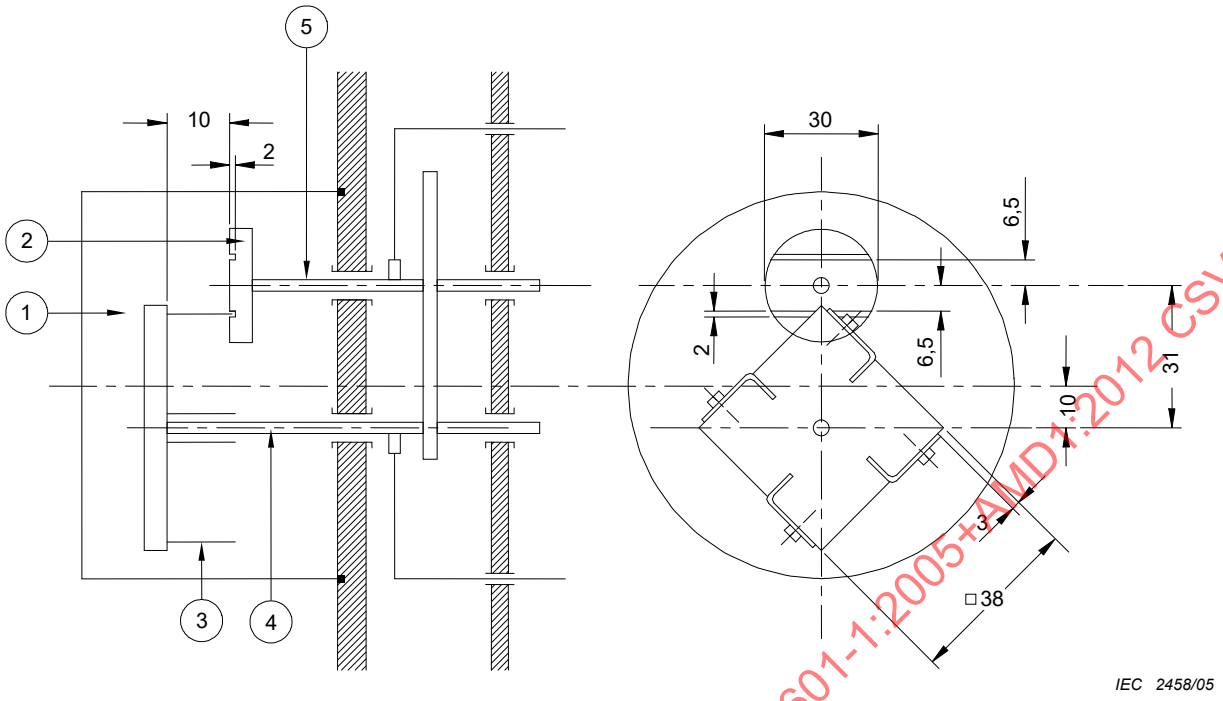
The ratio of the rotation speed of the shaft connected to the wires and the other shaft is 50:12.

Both shafts are isolated from each other and from the frame.

The ignition space must be able to support an internal overpressure of 1,5 MPa.

With the contact arrangement, the circuit to be tested is closed or opened and it is checked if the sparks will ignite the atmosphere or mixture under test.

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Dimensions in millimetres

Legend

1 Ignition space
2 Cadmium disk
3 Tungsten wire
4 Shaft of wire disk
5 Shaft of disk with grooves

Figure G.7 – Test apparatus

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Annex H
(informative)

PEMS structure, PEMS DEVELOPMENT LIFE-CYCLE and documentation

H.1 Examples for PEMS/PESS structures

A PEMS can be a very simple piece of ME EQUIPMENT or a complex ME SYSTEM or anything in between.

Figure H.1 shows some possible examples of a PEMS.

Figure H.1 a) shows a complex system. The PEMS breaks down into a number of major subsystems, which in turn are made up of subsystems, which include a PESS.

Figure H.1 b) shows a simpler implementation. In this case the intermediate major subsystem level is missing and the PESS is a subsystem of the PEMS itself.

Figure H.1 c) illustrates the simplest implementation of a PEMS. In this case the PEMS and the PESS are the same.

The structure of the PEMS is extremely important for implementing safety requirements. An architecture should be documented for the PEMS that describes the structure of the PEMS and the relationship between each PESS and the PEMS as a whole. The architecture should indicate:

– the division of the PEMS into components, especially those implemented in each PESS and including software components;
– the functions to be performed by each PESS and its components (including where appropriate safety-related functions);
– the interfaces between software components;
– the interfaces between software components and components external to the software.

H.2 PEMS DEVELOPMENT LIFE-CYCLE model

Compliance with the PEMS clause of this standard (Clause 14) requires that a PEMS DEVELOPMENT LIFE-CYCLE be specified and then followed; it does not require that any particular PEMS DEVELOPMENT LIFE-CYCLE is used, but it does require that the PEMS DEVELOPMENT LIFE-CYCLE has certain attributes. These requirements can be found in 14.4.

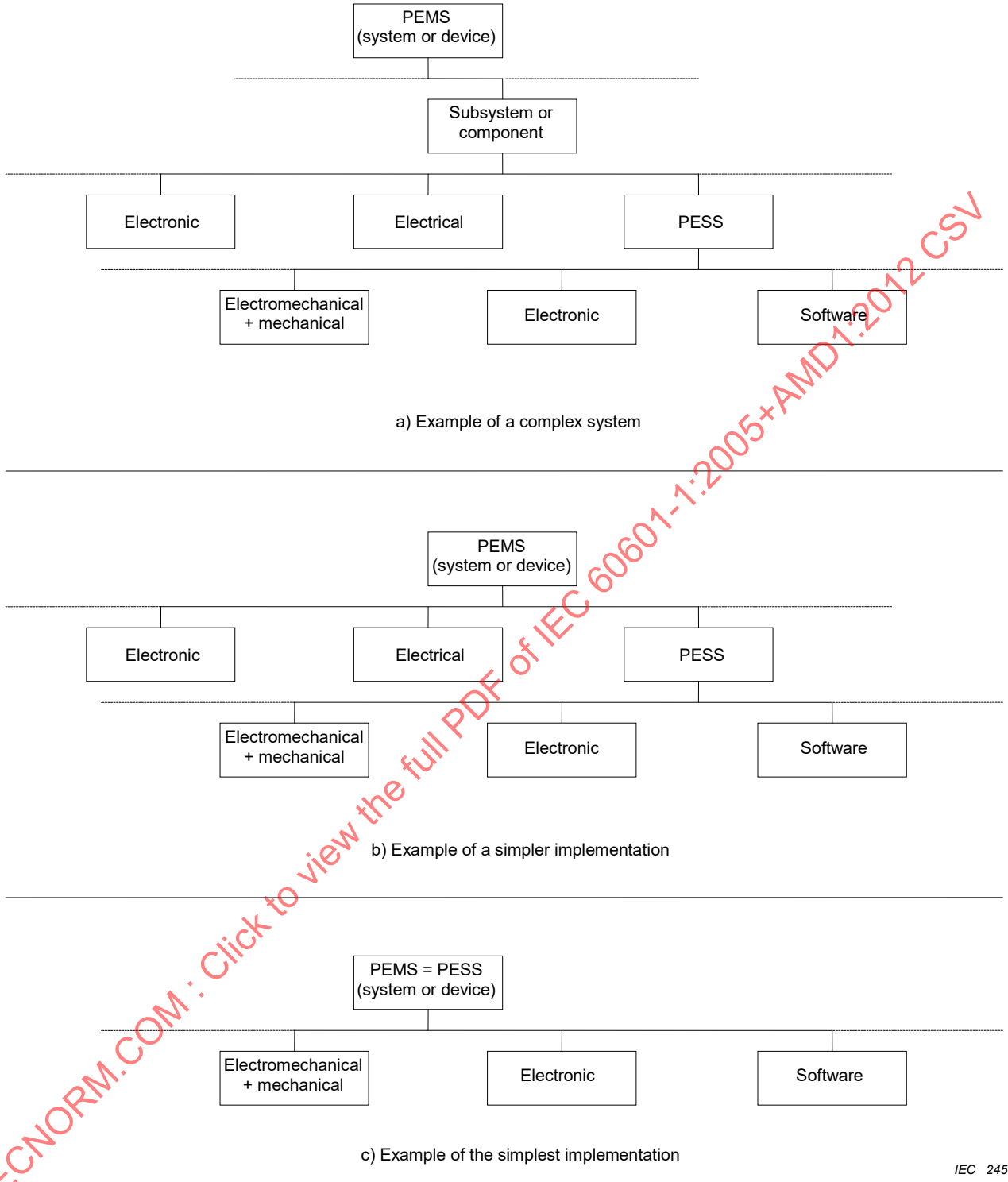
The PEMS DEVELOPMENT LIFE-CYCLE is a part of the overall product life-cycle.

Figure H.2 is a view of the PEMS DEVELOPMENT LIFE-CYCLE which shows activities grouped into two main PROCESSES. On the left is decomposition PROCESS and on the right is the integration PROCESS.

Figure H.2 illustrates:

– layered design activities;
– for each layer of design, a corresponding layer of integration and VERIFICATION;
– verified parts are integrated to assemble the next higher layer;
– problem resolution PROCESS interactions.

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Figure H.1 – Examples of PEMS/ PESS structures

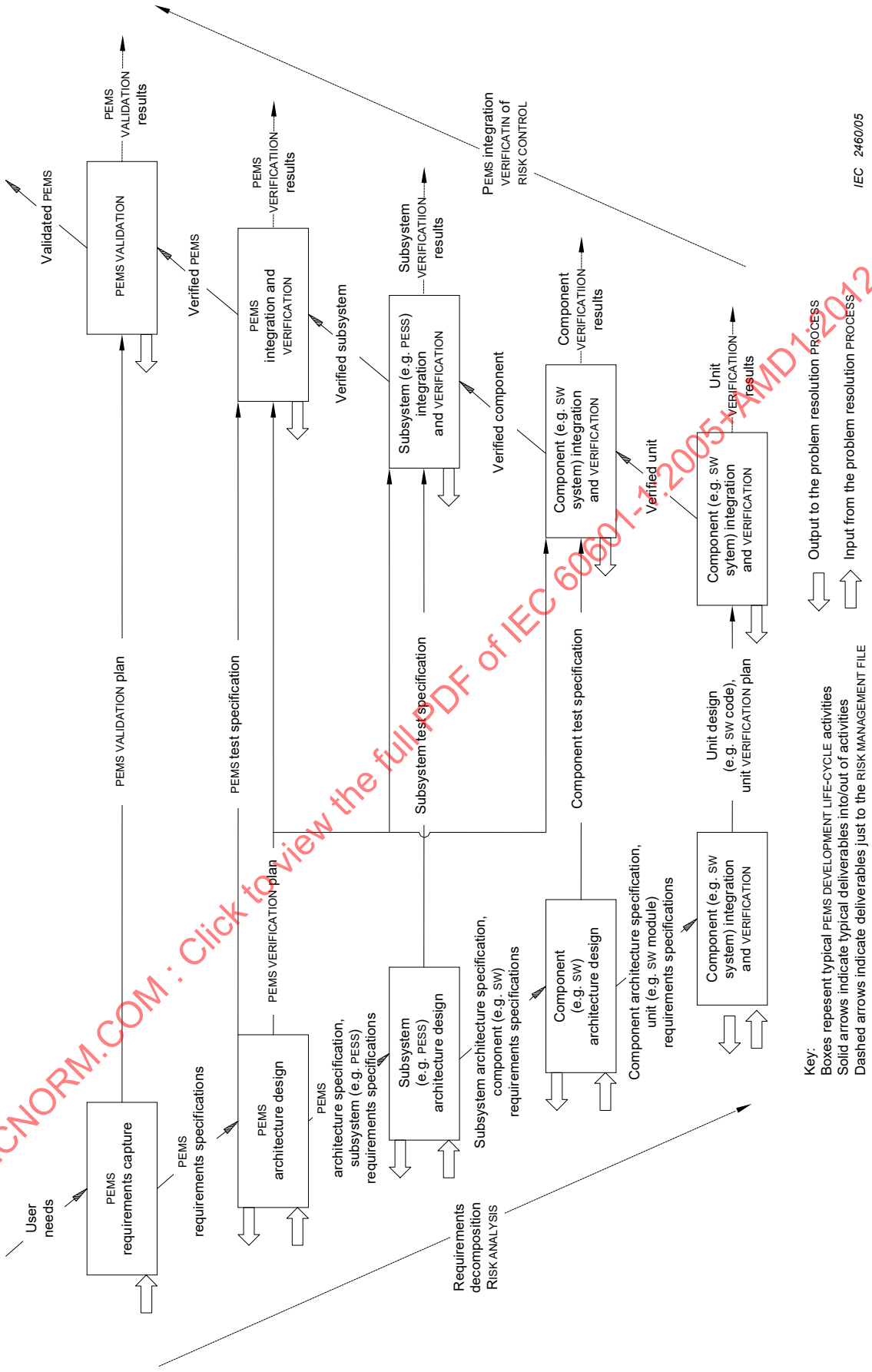


Figure H.2 – A PEMS DEVELOPMENT LIFE-CYCLE model

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As the design is decomposed from the requirements, the functional building blocks, architecture and technology are decided. The decomposition PROCESS concludes when the design information enables the components of the PEMS to be built (examples of such design information are circuit diagrams and software code). The decomposition components are integrated together. VERIFICATION is performed as the components are integrated to determine whether or not the implementation satisfies the requirements. At the conclusion of the integration PROCESS, a PEMS VALIDATION is performed to determine whether or not the PEMS works as intended.

H.3 Software PROCESSES

H.3.1 PEMS DEVELOPMENT LIFE-CYCLE

A PEMS DEVELOPMENT LIFE-CYCLE, such as the one illustrated in Figure H.2, consists of a number of PROCESSES that are composed of activities. Each activity is performed to accomplish specific goals. To apply RISK MANAGEMENT, confidence in the engineering activities on which the RISK MANAGEMENT is based is needed. In particular, this is a requirement for the software life-cycle.

IEC 62304 [26] (under development) describes the processes to be included in the software development life-cycle for the development of safe medical device software.

H.3.2 Requirements specification

To determine which functions create or control RISKS, it is necessary to fully identify the requirements of the PEMS/PESS. It is not possible to do an adequate RISK ASSESSMENT without a complete requirement specification and an architectural design that meets that specification. The requirements should include, as appropriate to the PEMS software:

- functional and capability requirements, including ESSENTIAL PERFORMANCE, physical characteristics, and environmental conditions under which the software is to perform;
- interfaces external to the software;
- safety requirements including RISK CONTROL measures for hardware failures and potential software defects and specifications related to methods of operation and maintenance, environmental influences, and RISK CONTROL;
- software driven alarm signals, warnings and OPERATOR messages;
- security requirements, where lack of security would compromise safety;
- human-factors engineering requirements related to the use of the PEMS, including those related to support for manual operations, human-equipment interactions, constraints on personnel, and areas needing concentrated human attention that are sensitive to human errors and training;
- data definition and database requirements;
- installation and acceptance requirements for the PEMS software;
- documentation to be developed;
- operation and execution requirements;
- maintenance requirements.

RISK ASSESSMENT should be used to determine the extent to which the architecture design can be used to mitigate the RISKS.

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H.3.3 Third-party and off-the-shelf (OTS) software

To have the ability to identify known or foreseeable HAZARDS, it is also necessary to characterise any third-party or OTS software used in the PEMS. The developer should establish software requirements for third-party or OTS software. These requirements should include the following:

– title and manufacturer, version level, release date, patch number and upgrade designation;

– the system hardware and software necessary to support proper operation (e.g. processor type and speed, memory type and size, and system, communication and display software requirements);

– interfaces to the software component;

– safety critical and RISK CONTROL measure functions dependent on the software component.

H.3.4 Integration

The developer should establish an integration plan to integrate the components of each PESS and of the PEMS. The plan should include the approach, responsibilities and sequence, and include all software components. If the PESS software is built using incremental integration methods, sufficient regression testing should be performed to ensure that previous VERIFICATION is still sufficient. Integration tests should include test cases which expose software behaviour not only in response to the normal case, but also in response to exceptional, stress or worst case conditions.

H.3.5 Configuration management

Because the RISK ANALYSIS relies on the requirements of the software, configuration management and change control are necessary to ensure that additional software functionality is not added during development without being considered by the RISK MANAGEMENT PROCESS. A configuration management plan should be established that describes:

– the items to be controlled;

– the configuration management activities;

– PROCEDURES and schedule for performing these activities;

– responsibilities for performing these activities;

– PROCEDURES to control the receipt, installation, and acceptance of each software component.

A scheme should be established for the unique identification of software configuration items and version control. This scheme should include any third-party and OTS software components.

H.3.6 Modification/change control

For modification/change control, the following should be performed:

– identification and recording of change requests;

– analysis and evaluation of the changes;

– approval or disapproval of the request;

– implementation, VERIFICATION and release of the modified software.

An audit trail should be maintained, whereby each modification, the reason for the modification, and authorization of the modification can be traced. RECORDS of the history of controlled items should be retrievable.

IEC 62304 describes the processes to be included in the software development life-cycle for the development of safe medical device software.

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H.4 Design and implementation

During application of the PEMS DEVELOPMENT LIFE-CYCLE model, design and implementation will include the selection of:

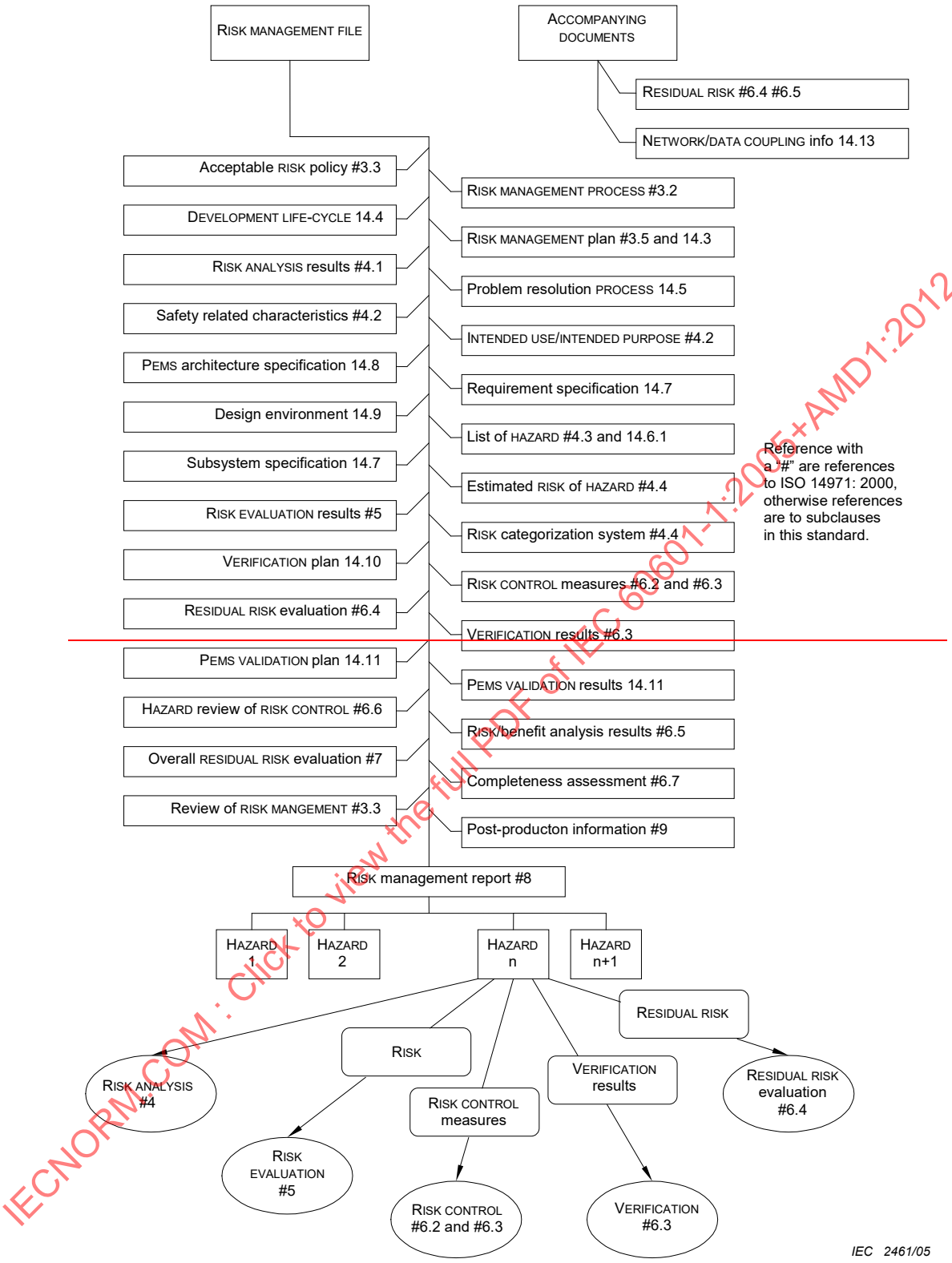
a) the design environment, for example:
   – software development methods;
   – computer aided software engineering (CASE) tools;
   – programming language;
   – hardware and software development platforms;
   – simulation tools;
   – design and coding standards;
b) electronic components;
c) redundant hardware;
d) human-PEMS interface;
e) energy sources;
f) environmental conditions;
g) third-party software;
h) networking options.

These elements of the design environment can be characterized in general and in the specific manner of their use in the design and implementation PROCESS.

H.5 Documentation

~~Figure H.3 includes all of the documentation required by Clause 14 and ISO 14971:2000. It is intended to show an example structure only. Particular documentary references can be consolidated or distributed among several documents. The clause numbers proceeded by a "#" are references to the clause numbers in ISO 14971:2000. Other numbers refer to the subclauses of this standard.~~ Not used.

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Figure H.3 – ~~PEMS documentation requirements from Clause 14 and ISO 14971:2000~~
Not used

H.6 ~~NETWORK/DATA COUPLING~~ PEMS intended to be incorporated into an IT-NETWORK

H.6.1 General

In the context of this standard, the information transmitted ~~as a part of NETWORK/DATA COUPLING~~ over an IT-NETWORK is that intended by the MANUFACTURER to be transmittable (i.e. not through illegal or illicit actions of unauthorized persons).

~~NETWORK/DATA COUPLING as used in this standard does not include information transferred across user interfaces. The MANUFACTURER stipulates the possible information types and their transmission protocols in the technical description (see 14.13).~~

H.6.2 System integration responsibilities

ME EQUIPMENT and ME SYSTEMS will sometimes be used together ~~to create a system~~ on an IT-NETWORK. This is likely to become more frequent with the increasing use of computers to analyze clinical data and control treatment.

Sometimes ME EQUIPMENT will have been designed by the MANUFACTURER to work on an IT-NETWORK with other ME EQUIPMENT, however, it will often be the case that ~~the separate~~ ME EQUIPMENT will not have been designed to work with ~~each other~~ all other ME EQUIPMENT on an IT-NETWORK. Someone has to be responsible for ensuring that all the separate ME EQUIPMENT on an IT-network work together satisfactorily ~~in the integrated system~~; in other words, someone has to be responsible for designing the ~~integrated system~~ IT-NETWORK.

It is recognized that the ~~system~~ IT-NETWORK integrator often has to comply with particular regulatory requirements.

In order to perform its function, the ~~system~~ IT-NETWORK integrator needs to know:

– how the integrated ~~system~~ IT-NETWORK is intended to be used;
– the required performance of the integrated ~~system~~ IT-NETWORK;
– the intended configuration of the ~~system~~ IT-NETWORK;
– the constraints on the extendibility of the ~~system~~ IT-NETWORK;
– the specifications of all ME EQUIPMENT and other equipment to be integrated;
– the performance of each ME EQUIPMENT and other equipment; and
– the information flow in and around the ~~system~~ IT-NETWORK.

This information will not be available to the individual MANUFACTURERS, and for this reason each individual MANUFACTURER cannot carry out the role of ~~system~~ IT-NETWORK integrator. In any case the ~~system~~ IT-NETWORK integrator has to be a single person or organisation that has overall responsibility, this overall responsibility can not be shared between several different MANUFACTURERS. The responsibility of a MANUFACTURER is limited to providing the required information on their equipment (see 14.13).

Obviously a RESPONSIBLE ORGANIZATION can employ a MANUFACTURER to integrate their ~~system~~ IT-NETWORK. In this case the whole ~~system~~ IT-NETWORK can become an ME SYSTEM and it will be the MANUFACTURER'S responsibility to provide a correctly integrated system. In this case the system could be separately regulated.

The ~~system~~ IT-NETWORK integrator should be competent to assess and address the HAZARDS that are likely to arise from integrating a ~~system~~ IT-NETWORK and to ensure that the RESIDUAL RISKS of the individual PEMS are maintained.

Typically a ~~system~~ IT-NETWORK integrator would:

– plan the integration of any ME EQUIPMENT or ME SYSTEM and non-medical equipment in accordance with the instructions provided by the various MANUFACTURERS;

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– perform RISK MANAGEMENT on the integrated ~~system~~ IT-NETWORK; and

– pass on any MANUFACTURER'S instructions to the RESPONSIBLE ORGANIZATION where these are required for the safe operation of the integrated ~~system~~ IT-NETWORK. These instructions should include warnings about the HAZARDS of any change of configuration.

H.7 Design considerations for ~~NETWORK/DATA COUPLING~~ IT-NETWORKS

H.7.1 ~~Introduction~~ Overview

From the viewpoint of a PEMS MANUFACTURER, any type of ~~a NETWORK/DATA COUPLING~~ an IT-NETWORK is a source of additional ~~causes for HAZARDS~~ HAZARDOUS SITUATIONS. In principle any ~~NETWORK/DATA COUPLING~~ IT-NETWORK that is outside the control of the PEMS MANUFACTURER should never be presumed to be 100 % reliable.

H.7.2 Causes of ~~HAZARDS~~ HAZARDOUS SITUATIONS associated with ~~NETWORK/DATA COUPLING~~ IT-NETWORKS

In ~~NETWORK/DATA COUPLED systems~~ IT-NETWORKS, likely causes for ~~HAZARDS~~ HAZARDOUS SITUATIONS are:

– loss of data;

– inappropriate data interchange;

– corrupted data;

– inappropriate timing of data;

– unexpected receipt of data;

– unauthorized access to data.

~~Supplementing Annex A of ISO 14971:2000 when identifying the causes of HAZARDS associated with NETWORK/DATA COUPLING, at least the following should be considered:~~

Supplementing Annex E of ISO 14971:2007, at least the following initiating events or circumstances that can lead to HAZARDOUS SITUATIONS associated with IT-NETWORKS should be considered:

– remote servicing (external access to the network);

– operating system (compatibility of operating systems);

– modification/upgrades of software (operating systems, applications, etc.);

– interface compatibility (data collisions, data formats):

  • connections (modification of hardware, network connectors);

  • network interface boards (compatibility);

  • network protocols (DICOM, HL7, etc.);

– packet address structure/timing;

– normal network loads/bandwidth;

– peak network load;

– data media (longevity and retrievability);

– security (viruses, worms, unauthorized software updates or upgrades);

– maximum acceptable response time;

– acceptable failure rate of the network;

– availability of the network (planned and unplanned maintenance);

– inconsistency in interfaces/formats resulting in loss of fidelity during information transfer;

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– heterogeneous network topologies.

~~Supplementing Annex D of ISO 14971:2000 when considering the potential causes for HAZARDS listed above, the following questions should be taken into account:~~

Supplementing Annex C of ISO 14971:2007, the following questions should be taken into account when identifying the characteristics that could impact on safety:

a) Reasonably foreseeable misuses

Is connection to the network inconsistent with the INTENDED USE of each constituent PEMS?

b) Incorrect data flow to or from each constituent PEMS

What are the data transferred by the network used for, and to which tasks are they related? What are the consequences of a breakdown of the ~~NETWORK/DATA COUPLING~~ IT-NETWORK ?

c) Deviation from the specified operational characteristics of any constituent PEMS

What are the operational characteristics of the PEMS and to what degree are they affected by the ~~NETWORK/DATA COUPLING~~ IT-NETWORK?

d) Incomplete characterization of ~~NETWORK/DATA COUPLING~~ IT-NETWORK parameters

Is the network topology, configuration, parameters (e.g. open or closed, bandwidth, transmission protocol) completely characterized? Are there any breakdown characteristics/concepts and what are these?

e) Excessive use/load of the ~~NETWORK/DATA COUPLING~~ IT-NETWORK by the network nodes

What is the planned number of network nodes and their assumed degree of use? Are the resources sufficient to meet the needs of both the ~~NETWORK/DATA COUPLING~~ IT-NETWORK itself and the devices connected to it?

f) Use errors

What skills are required by the OPERATOR for the effective operation of the system?

g) Inadequate configuration management

Do periodic service tasks alter the ~~network's~~ IT-NETWORK'S characteristics (e.g. after remote access, updates or upgrades)? Does the RESPONSIBLE ORGANIZATION ensure that modifications to each constituent PEMS are reviewed and approved?

h) Information in wrong place

Does data arrive at a convenient and predictable location? Is it accompanied by irrelevant data that could confuse the OPERATOR or obscure the wanted data? When it arrives, is its source adequately indicated?

H.7.3 ~~Network classification based on the consequence to the PATIENT~~ Not used

~~H.7.3.1 Consequence to the PATIENT~~

~~In order to relate the causes in H.7.2 to the consequences for the PATIENT, it may be useful to classify NETWORK/DATA COUPLINGS both by the consequences and the reaction time, where reaction time is the time delay between a NETWORK/DATA COUPLING failure and the onset of HARM to the PATIENT.~~

~~Table H.1 contains an example of a NETWORK/DATA COUPLING classification based on these considerations.~~

~~H.7.3.2 Class C NETWORK/DATA COUPLING (PATIENT vital data, time critical)~~

~~This is the NETWORK/DATA COUPLING for all time critical application/PROCESSES. It is not linked to any other network, because a link could result in uncontrollable RISKS. All resources are available only for the nodes of this network. The availability needs to be close to 100 %. Disruptions need to be avoided and last for only a few minutes per year. Responsibility is~~

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assigned to a single PEMS MANUFACTURER/system contractor only. Network nodes comply with the requirements established by this MANUFACTURER/contractor. An example of this class is a PATIENT monitoring network.

Table H.1 – NETWORK/DATA COUPLING classification Not used

Consequence	Reaction time	Class	Example(s)
Death/serious injury	Second(s)	C	Infusion (closed loop); false control of a surgical robot
	Minute(s)	C	Suppressed alarm transmission
	Hour(s)	C/B	False therapy data to ventilator
Medium injury	Second(s)	C	Wrong alarm transmission, false control of a surgical robot
	Minute(s)	C/B	Wrong alarm transmission, false control of a surgical robot
	Hour(s)	C/B	Falsified image; loss of a therapy report
Minor injury	Second(s)	B	
	Minute(s)	B	Loss of a radiograph
	Hour(s)	B/A	
Negligible	Second(s)	A	
	Minute(s)	A	
	Hour(s)	A	

H.7.3.3 Class B NETWORK/DATA COUPLING (PATIENT vital data, non-time critical)

This is the NETWORK/DATA COUPLING for non-time critical application/PROCESSES that handle therapeutic or diagnostic PATIENT data. This NETWORK/DATA COUPLING can be linked to another one by a defined and controllable/secured interface. The availability needs to be very high, and because of a lack of alternatives, disruptions should last only for short periods.

– The responsibility is assigned to the RESPONSIBLE ORGANIZATION or system integrator. In the case of multiple PEMS, the contention of data priority needs to be defined.

– The network nodes should follow selected criteria/minimum set of parameters. A radiology network can serve as an example.

H.7.3.4 Class A NETWORK/DATA COUPLING

This is the NETWORK/DATA COUPLING for any applications (including PATIENT administrative/demographic data) that operate on validated PATIENT data only and are not assigned to class "C" or "B" networks. Also, it can be accepted that these applications are unavailable for a longer period because there are alternatives. An example is a general hospital administration network where:

– the responsibility is assigned to the RESPONSIBLE ORGANIZATION;

– there are many types of network nodes.

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H.7.4 ~~NETWORK/DATA COUPLING~~ IT-NETWORK parameters

The use of ~~a NETWORK/DATA COUPLING~~ an IT-NETWORK for exchange of data either between PEMS or between PEMS and other information technology equipment requires the knowledge about both the structure of the ~~NETWORK/DATA COUPLING~~ IT-NETWORK and the PROCESSES/functions running inside them. This is important because MANUFACTURERS of PEMS or ~~NETWORK/DATA COUPLINGS~~ IT-NETWORKS should select the configuration of their products such that:

– they comply with internationally recognized network standards (Ethernet, Fast Ethernet, GigaBitEthernet, FDDI, etc.) and use the available bandwidth appropriately according to the INTENDED USE;

– they achieve the optimal performance for their application

A mixture of different ~~NETWORK/DATA COUPLINGS~~ IT-NETWORK configurations/parameter settings can emerge which are not always compatible for the different ~~NETWORK/DATA COUPLINGS~~ IT-NETWORK nodes in spite of the fact that they comply to valid international standards.

To avoid or at least to minimize the resulting potential of disruption, a match of a minimum set of ~~NETWORK/DATA COUPLINGS~~ IT-NETWORK parameters derived from the relevant standards is required.

~~To ensure a reliable installation of NETWORK/DATA COUPLED PEMS and minimize the RISK to PATIENTS, the PEMS MANUFACTURER, the RESPONSIBLE ORGANIZATION, and the system integrator need to communicate all relevant technical parameters to each other. This level of detail is necessary to avoid inappropriate assumptions that result in unacceptable RISK.~~

Figure H.4 contains a list of parameters potentially required to be specified. Due to the rapid evolution of ~~NETWORK/DATA COUPLING~~ IT-NETWORK technology, this table should be seen as a starting point. It should be clear if the table should be maintained and who should be responsible for maintaining it.

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Objects	Description		Value/Comment
Application and Operating System:			
Operating System / Version:			
Network protocols:			
Detailed data for specific application / transport protocol (if used)			
HL7	HL 7 version		
	Formats of message types used		
	Free fields (~~which~~ that are used)		
	Ports		
	HL7 Protocol (TCP/IP Lower Layer)		
DICOM Service classes	**A) Test:**	Verification	
	B) Transfer:	Storage	
		Query/Retrieve	
	C) Documentation:	Print management	
	D) Organization:	Modality work list management	
		Performed procedure step	
	E) Information:	Study contents notification	
		Patient management	
		Storage commitment	
		Study component management	
		Results management	
	F) External Storage:	Media storage	
DICOM Objects	e.g. COMPUTER RADIOGRAPHY IMAGE		
	Other Modality Objects		
DICOM host name			
DICOM AET called			
DICOM AET calling			
DICOM Port called			
DICOM Port calling			
Detailed Parameters with respect to the lower protocol layers			
Network data	**Physical connection**		
	Network interface card parameters		
Network-Administration			
Port number of connected Switch / HUB / Router			
IP-Address			
Subnet mask			
Host-Name			
IT-Domain			
Active-Directory / LDAP Server			
Default Gateway (Access via Router)			
Remote Control			
Remote Monitoring			
Modem Connection			
Remote Service IP-Address			
Other Parameters			

Figure H.4 – Example of potential parameters required to be specified for ~~NETWORK/DATA COUPLING~~ an IT-NETWORK

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Annex I
(informative)

ME SYSTEMS aspects

I.1 Combinations of ME EQUIPMENT and non-ME EQUIPMENT

I.1.1 Introduction

This annex provides a summary of situations that could occur when different combinations of equipment are used in various medical environments. To keep this summary short, no more than two items of equipment (A and B) are used per situation.

I.1.2 Localities in a medical environment

The following localities are foreseen (see also Table I.1):

– the PATIENT ENVIRONMENT as part of a medically used room;

– a medically used room, excluding the PATIENT ENVIRONMENT;

– the non-medically used room (a room not designed for medical treatment, for example, an office or a storage room).

A protective earth can be dedicated to each of the three localities listed above.

NOTE A potential difference *(V)* can exist between the protective earths in different localities. In case of an interruption of protective earthing (fault condition) for equipment in the PATIENT ENVIRONMENT, this potential difference can appear on the ENCLOSURE of the equipment ~~causing a HAZARD~~ resulting in a HAZARDOUS SITUATION for the OPERATOR or for the PATIENT if the OPERATOR simultaneously touches the equipment and the PATIENT, or for the PATIENT if the ~~ME EQUIPMENT~~ APPLIED PART is of TYPE B.

I.1.3 Basic principles

– PATIENTS should only be connected to APPLIED PARTS of ME EQUIPMENT complying with this standard. Other equipment should comply with relevant IEC or ISO standards.

– In fault condition the allowable TOUCH CURRENT is 500 μA.

– All equipment complying with the safety standard applicable to the originally intended, non-medical use, herein called IEC XXXXX, and placed in the PATIENT ENVIRONMENT needs measures to limit the TOUCH CURRENT, if this exceeds the values specified in 16.6.1.

I.1.4 Examples of ME SYSTEMS

Two items of equipment are placed within the PATIENT ENVIRONMENT (see situation No. 1 in Table I.1).

There are several possibilities designated 1a through 1f:

1a: Items A and B both comply with IEC 60601: Subclause 16.6 is satisfied.

1b: Items A and B both comply with IEC 60601 and are powered through a MULTIPLE SOCKET-OUTLET: LEAKAGE CURRENTS might be too high when the earth conductor in the MULTIPLE SOCKET-OUTLET is broken.

1c: Item A complies with IEC 60601 and item B complies with IEC XXXXX: only the TOUCH CURRENT of item B has to be limited when any single PROTECTIVE EARTH CONDUCTOR or the equivalent conductor of the equipment, is interrupted, if necessary, by applying an additional protective earth or a separating transformer to item B.

1d: Same as 1c, with both items powered through a MULTIPLE SOCKET-OUTLET: LEAKAGE CURRENTS might be too high for causes as listed under 1b and 1c.

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1e: Item A is powered from item B with item A complying to IEC 60601 and being an insert to item B, complying to IEC XXXXX. Item B needs the measures for a power supply as described by the MANUFACTURER and needs to fulfil the requirement of 16.3. If necessary, apply an additional protective earth or a separating transformer to item B.

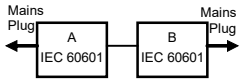
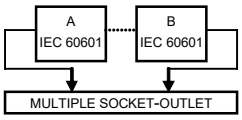
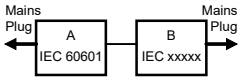
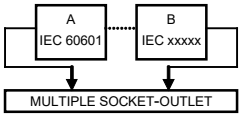
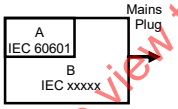
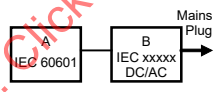
1f: Same as 1e, with item A not being an insert to item B: see 1e.

Situations 2 and 3 can be derived from situation 1 of Table I.1.

NOTE The practical means of compliance indicated in Table I.1 are not intended to be an exhaustive list.

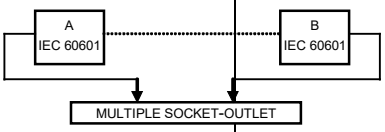
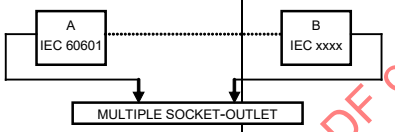
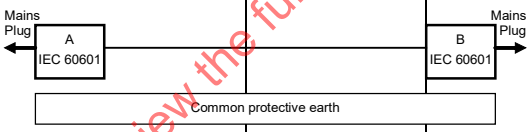
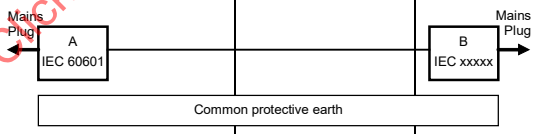
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Table I.1 – Some examples of ME SYSTEMS for illustration

Situation No.		Medically used room: Inside the PATIENT ENVIRONMENT	Medically used room: Outside the PATIENT ENVIRONMENT	Non-medically used room	Examples of possible causes for exceeding LEAKAGE CURRENT limits	Practical means of compliance Apply 16.5 in all situations
1	**1a** Items A and B are ME EQUIPMENT				Multiplied APPLIED PARTS of the same type can cause the total PATIENT LEAKAGE CURRENT to exceed limits See Note 1.	– Verify total PATIENT LEAKAGE CURRENT
	1b Items A and B are ME EQUIPMENT powered via a MULTIPLE SOCKET-OUTLET				Earth conductor of the MULTIPLE SOCKET-OUTLET is broken See also 1a.	– Additional PROTECTIVE EARTH CONNECTION (for A or B) or, – Separating transformer
	1c Item A is ME EQUIPMENT and B is Non-ME EQUIPMENT				Due to high TOUCH CURRENT of B	– Additional PROTECTIVE EARTH CONNECTION (for B) or, – Separating transformer (for B)
	1d Item A is ME EQUIPMENT and B is non-ME EQUIPMENT powered via a MULTIPLE SOCKET-OUTLET				The earth conductor of the MULTIPLE SOCKET-OUTLET is broken or, Due to high TOUCH CURRENT of B	– Additional PROTECTIVE EARTH CONNECTION (for A or B) or, – Separating transformer
	1e Item A is ME EQUIPMENT powered from specified power supply in item B				Due to high TOUCH CURRENT of B	– Additional PROTECTIVE EARTH CONNECTION (for B) or, – Separating transformer (for B)
	1f Item A is ME EQUIPMENT powered from NON-ME EQUIPMENT power supply in B					

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Table I.1 *(continued)*

Situation No.		Medically used room: Inside the PATIENT ENVIRONMENT	Medically used room: Outside the PATIENT ENVIRONMENT	Non-medically used room	Examples of possible causes for exceeding LEAKAGE CURRENT limits	Practical means of compliance Apply 16.5 in all situations
2	**2a** Items A and B are ME EQUIPMENT				No causes of exceeding LEAKAGE CURRENT	– No further measures are necessary
	2b Items A and item B are ME EQUIPMENT powered via a MULTIPLE SOCKET-OUTLET				Earth conductor of the MULTIPLE SOCKET-OUTLET is broken	– Additional PROTECTIVE EARTH CONNECTION (for A or B) or, – Separating transformer
	2c Item A is ME EQUIPMENT and item B is non-ME EQUIPMENT				Due to high TOUCH CURRENT of B See rationale for 16.5.	– Do not use metal connector housing or, – SEPARATION DEVICE
	2d Item A is ME EQUIPMENT and item B is non-ME EQUIPMENT powered via a MULTIPLE SOCKET-OUTLET				The earth conductor of the MULTIPLE SOCKET-OUTLET is broken	– Additional PROTECTIVE EARTH CONNECTION (for A or B) or, – Separating transformer
3	**3a** Items A and B are ME EQUIPMENT				No causes of exceeding LEAKAGE CURRENT	– No further measures are necessary
	3b Item A is ME EQUIPMENT and item B is non-ME EQUIPMENT				Due to high TOUCH CURRENT of B See rationale for 16.5.	– Do not use metal connector housing for SIGNAL INPUT/OUTPUT PART or, – SEPARATION DEVICE
	3c Item A is ME EQUIPMENT and item B in is ME EQUIPMENT or non-ME EQUIPMENT				a) Potential difference between PROTECTIVE EARTH CONNECTIONS of A and B b) Due to high TOUCH CURRENT of B See rationale for 16.5.	– Additional PROTECTIVE EARTH CONNECTION for (A), or – SEPARATION DEVICE, or – Do not use metal connector housing in the PATIENT ENVIRONMENT

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Table I.1 *(continued)*

NOTE 1 No causes of TOUCH CURRENT or EARTH LEAKAGE CURRENT exceeding limits.
NOTE 2 IEC 60601: MEDICAL ELECTRICAL EQUIPMENT in compliance with IEC 60601.
NOTE 3 IEC xxxxx: Non-medical equipment in compliance with relevant IEC safety standards.
NOTE 4 Separating transformer: see 16.9.2.1.
NOTE 5 If equipment "B" is outside the PATIENT ENVIRONMENT and if equipment "A" is a CLASS II equipment and has accessible conductive parts connected to the PROTECTIVE EARTH CONNECTION of equipment "B" then additional safety measures could be necessary, for example: additional protective earth for "B" or separating transformer or SEPARATION DEVICE.

I.2 Examples of application of MULTIPLE SOCKET-OUTLETS (MSO)

Figure I.1 shows an example of the construction of a MULTIPLE SOCKET-OUTLET. Figure I.2 shows some examples of application of MUPTILE SOCKET-OUTLETS.

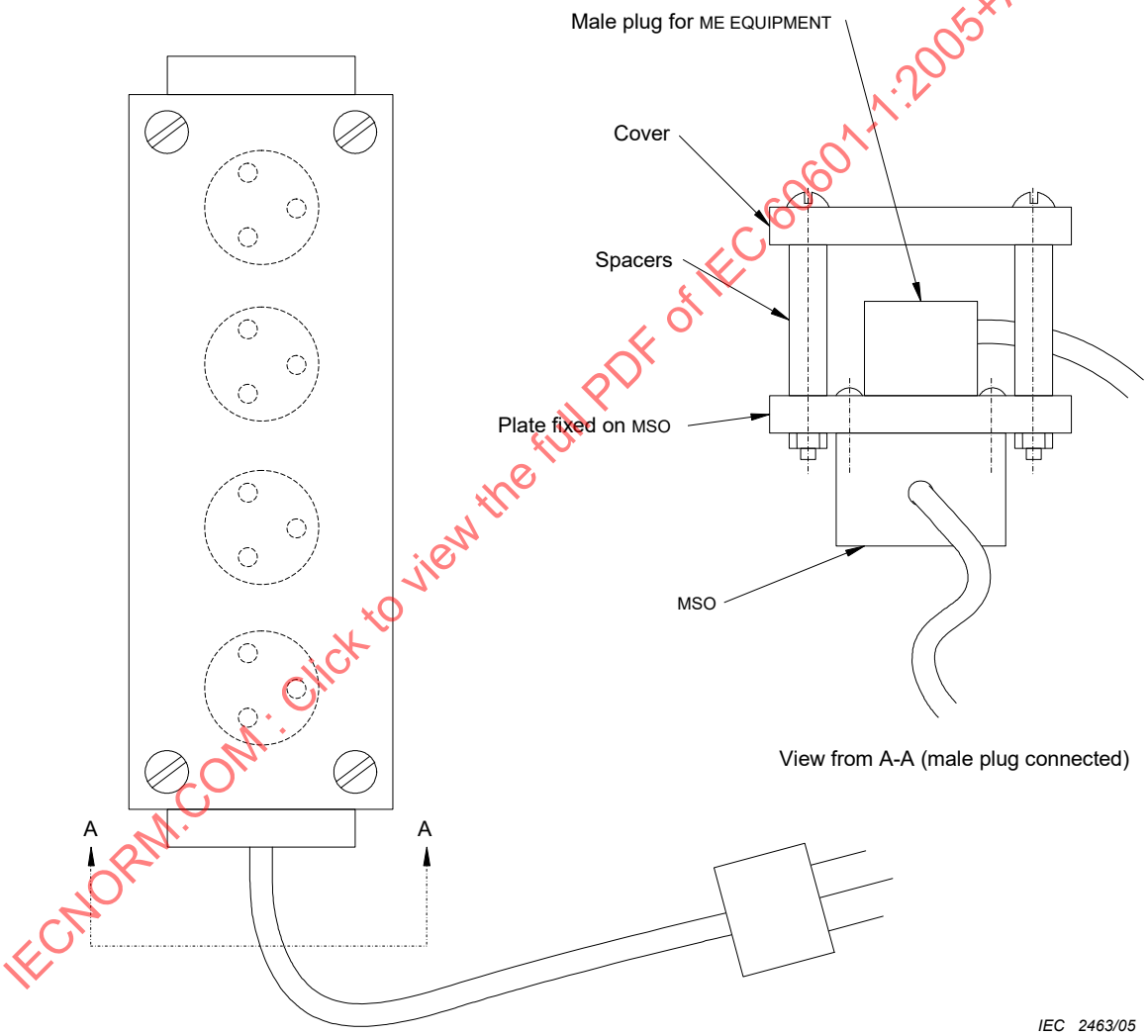


Figure I.1 – Example of the construction of a MULTIPLE SOCKET-OUTLET (MSO) (accessible only with the use of a TOOL)

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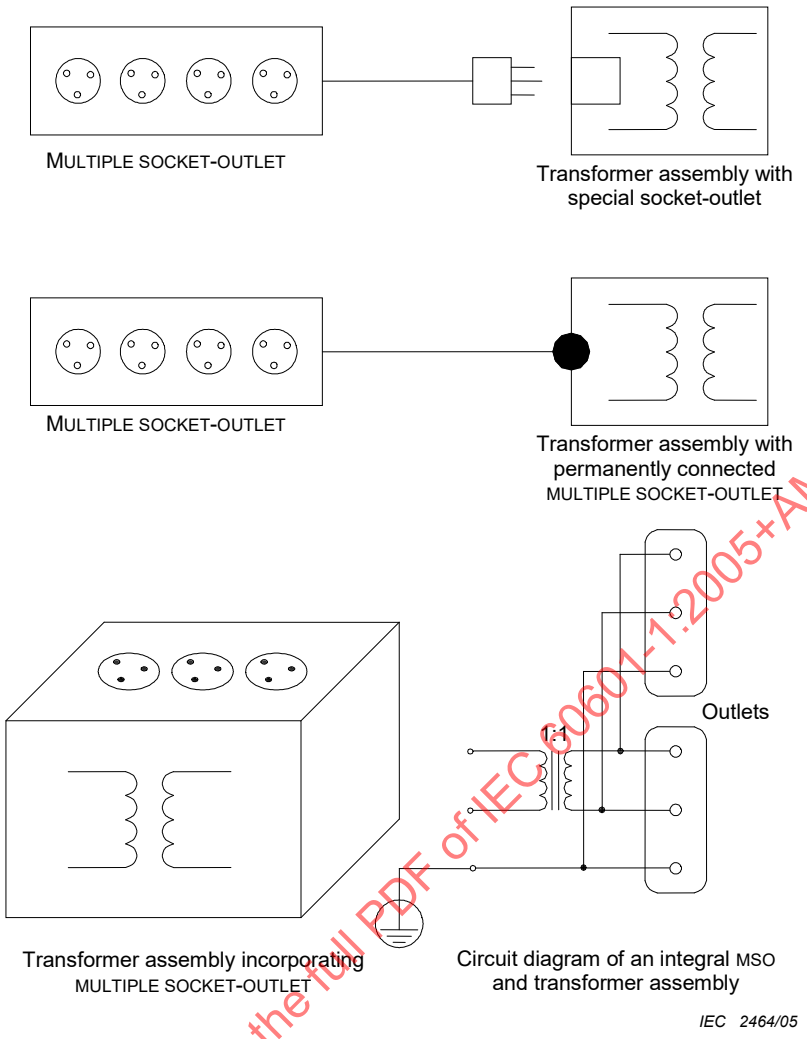


Figure I.2 – Examples of application of MULTIPLE SOCKET-OUTLETS (MSO)

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Annex J
(informative)

Survey of insulation paths

(see 8.5.1)

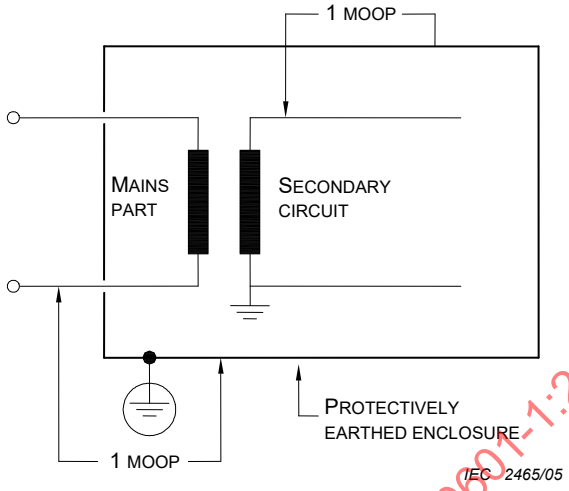


Figure J.1 – Insulation example 1

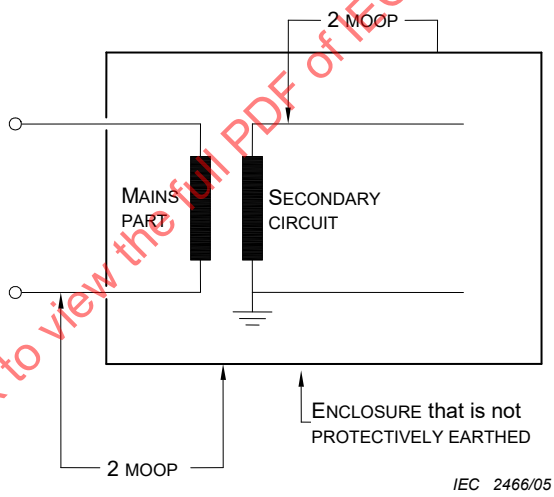


Figure J.2 – Insulation example 2

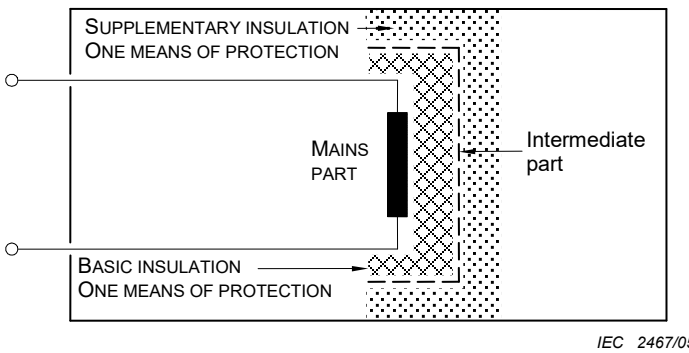


Figure J.3 – Insulation example 3

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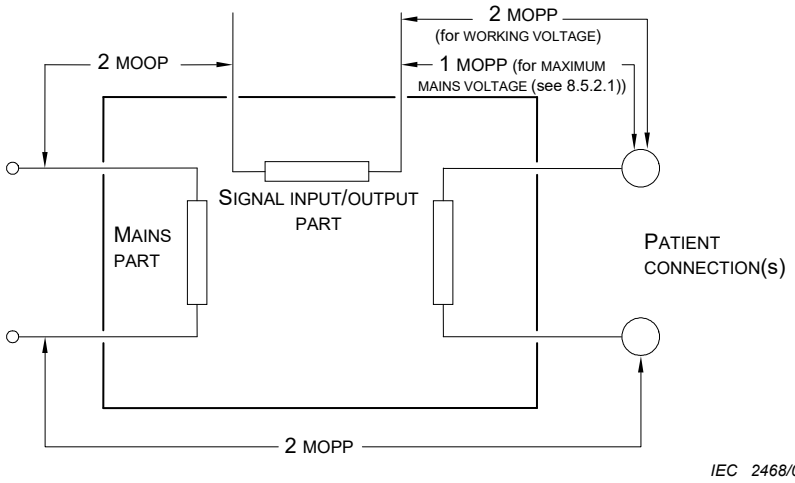


Figure J.4 – Insulation example 4

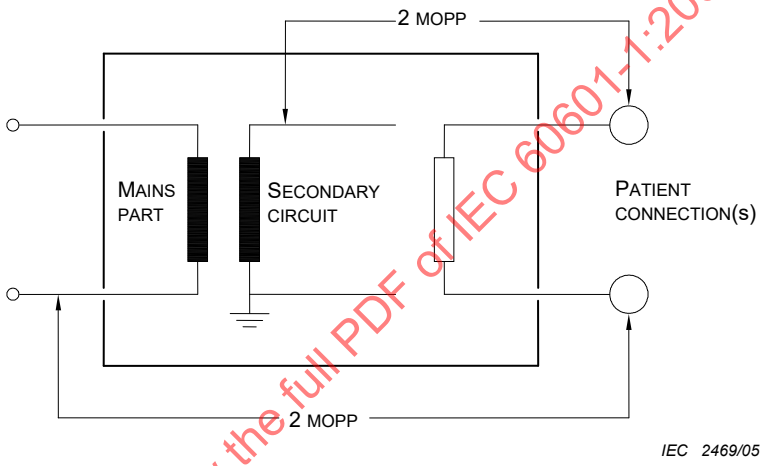


Figure J.5 – Insulation example 5

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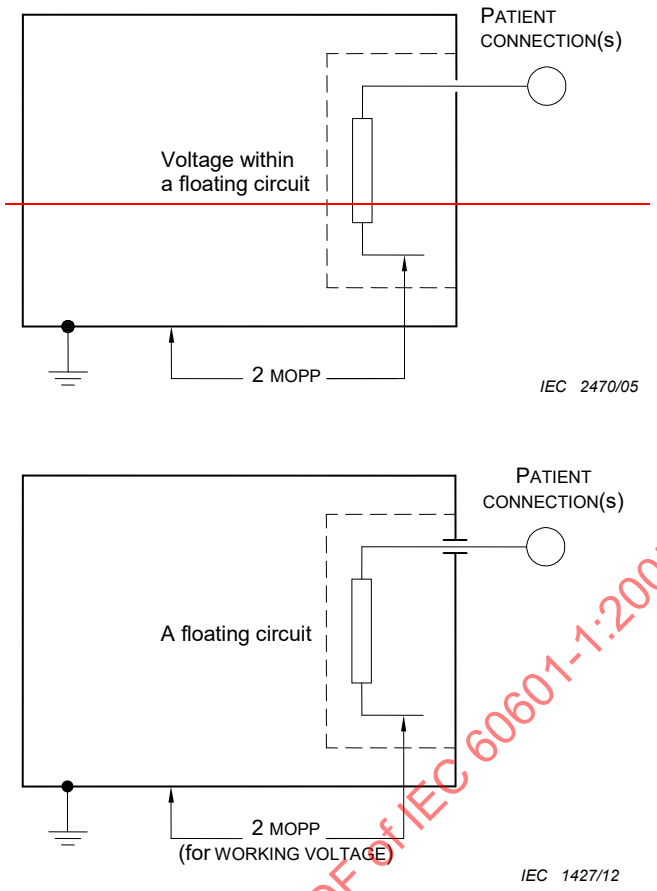
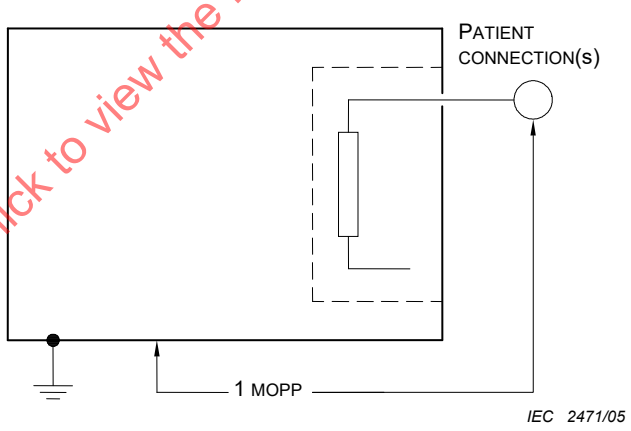


Figure J.6 – Insulation example 6



NOTE WORKING VOLTAGE is the MAXIMUM MAINS VOLTAGE.

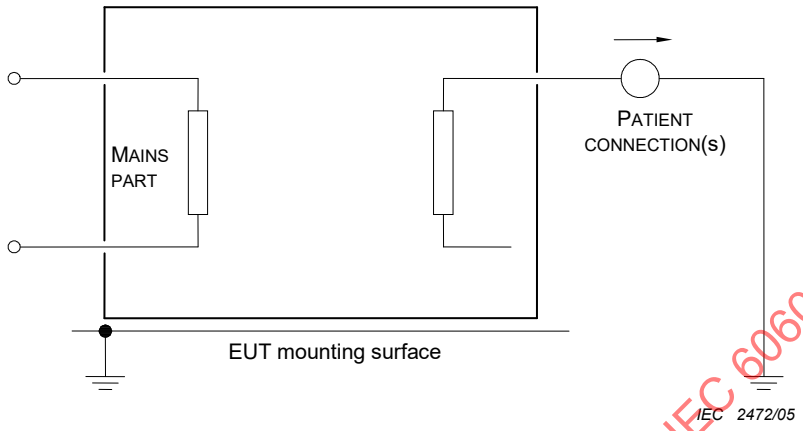
Figure J.7 – Insulation example 7

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Annex K
(informative)

Simplified PATIENT LEAKAGE CURRENT diagrams

Figure K.2, Figure K.4 and Figure K.5 illustrate a special test condition in Table 4, which is neither a NORMAL CONDITION nor a SINGLE FAULT CONDITION.

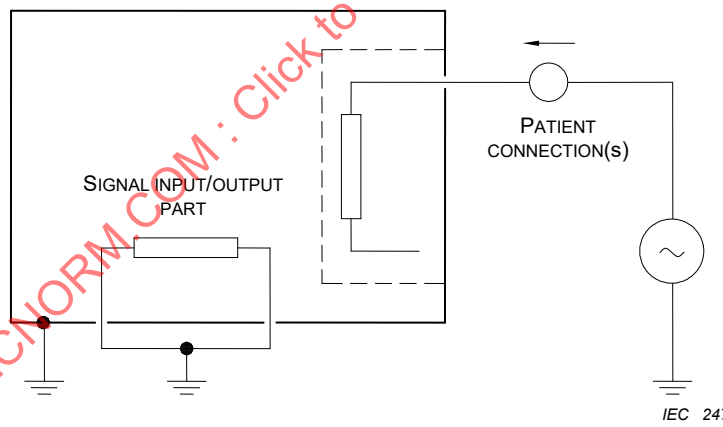


Current in μA

APPLIED PART TYPE	NORMAL CONDITION	SINGLE FAULT CONDITION
CF	10	50
BF	100	500
B	100	500

Example with the measuring supply circuit of Figure F.1.

Figure K.1 – ME EQUIPMENT with an ENCLOSURE made of insulating material
(simplified Figure 15)
(see 8.7.4.7 a))



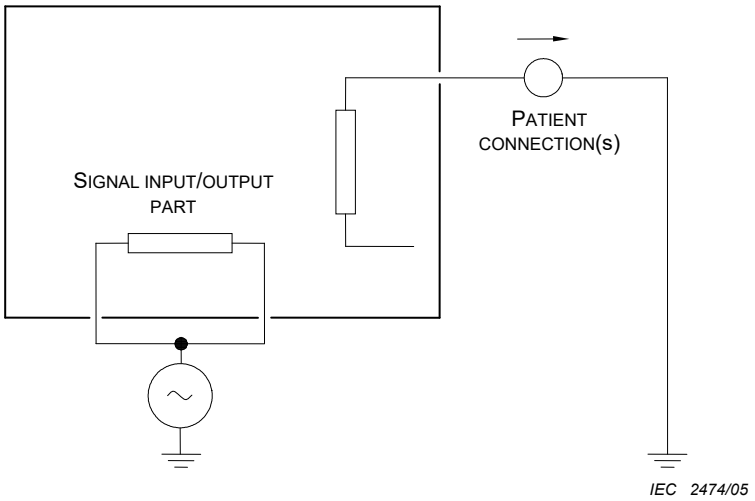
Current in μA

APPLIED PART TYPE	Special test condition
CF	50
BF	5 000
B	—

Example with the measuring supply circuit of Figure F.1.

Figure K.2 – ME EQUIPMENT with an F-TYPE APPLIED PART
(simplified Figure 16)
(see 8.7.4.7 b))

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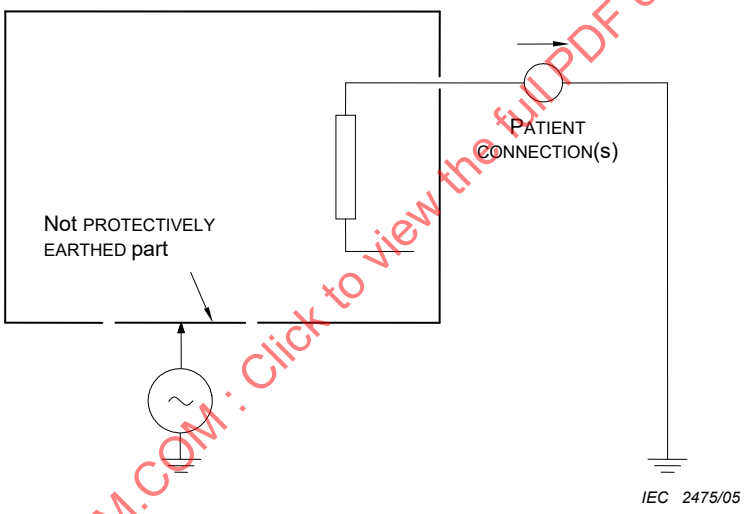


Current in μA

APPLIED PART TYPE	NORMAL CONDITION	SINGLE FAULT CONDITION
CF	10	50
BF	100	500
B	100	500

Example with the measuring supply circuit of Figure F.1.

Figure K.3 – ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART
(simplified Figure 17)
(see 8.7.4.7 c))



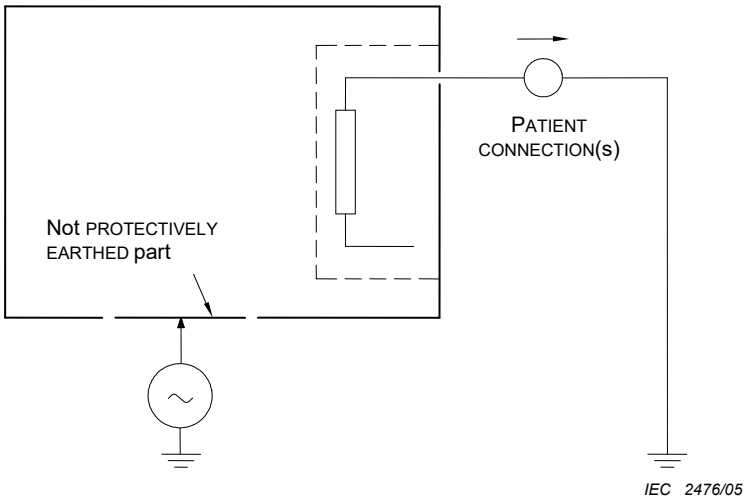
Current in μA

APPLIED PART TYPE	Special test condition
CF	—
BF	—
B	500

Example with the measuring supply circuit of Figure F.1.

Figure K.4 – ME EQUIPMENT with a PATIENT CONNECTION of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED
(simplified Figure 18)
(see 8.7.4.7 d))

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Current in μA

APPLIED PART TYPE	Special test condition
CF	—
BF	500
B	—

Example with the measuring supply circuit of Figure F.1.

Figure K.5 – ME EQUIPMENT with a PATIENT CONNECTION of a TYPE BF APPLIED PART that is not PROTECTIVELY EARTHED
(simplified Figure 18)
(see 8.7.4.7 d))

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Annex L
(normative)

Insulated winding wires for use without interleaved insulation
(see 8.8.2)

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L.1 Introduction

This annex specifies winding wire whose insulation may be used to provide BASIC INSULATION, SUPPLEMENTARY INSULATION, DOUBLE INSULATION or REINFORCED INSULATION in wound components without interleaved insulation.

This annex covers round winding wires having diameters between 0,05 mm and 5,00 mm.

L.2 Wire construction

If the wire is insulated with two or more spirally wrapped layers of tape, the overlap of layers shall be adequate to ensure continued overlap during manufacture of the wound component. The layers of spirally wrapped wire insulation shall be sufficiently secured to maintain the amount of overlap.

L.3 TYPE TEST

The wire shall pass the tests of L.3.1 to L.3.4, carried out at a temperature between 15 °C and 35 °C and a relative humidity between 45 % and 75 %, unless specified otherwise.

L.3.1 Dielectric strength

The test sample is prepared according to IEC 60851-5:~~1996~~2008, Subclause 4.4.1 (for a twisted pair). The sample is then subjected to the test of 8.8.3 for the appropriate type and number of MOP(s). The test voltage is at least twice the appropriate voltage in Table 6 and Table 7 (see 8.8.3), with a minimum of:

– *3 000 V for BASIC INSULATION or SUPPLEMENTARY INSULATION; or*

– *6 000 V for REINFORCED INSULATION.*

L.3.2 Flexibility and adherence

The sample is subjected to test 8 of IEC 60851-3:~~1996~~2009, Subclause 5.1.1, using the mandrel diameters of Table L.1. The test sample is then examined in accordance with IEC 60851-3:~~1997~~2009, Subclause 5.1.1.4, followed by the test of 8.8.3, for the appropriate type and number of MOP(s), except that the test voltage is applied between the wire and the mandrel. The test voltage is at least the appropriate voltage in Table 6 and Table 7 (see 8.8.3) with a minimum of:

– *1 500 V for BASIC INSULATION or SUPPLEMENTARY INSULATION; or*

– *3 000 V for REINFORCED INSULATION.*

Table L.1– Mandrel diameter

NOMINAL conductor diameter mm	Mandrel diameter mm ± 0,2 mm
0,05 – 0,34	4,0
0,35 – 0,49	6,0
0,50 – 0,74	8,0
0,75 – 2,49	10,0
2,50 – 5,00	four times the conductor diameter [a]
[a] In accordance with IEC 60317-43 [9].	

The tension to be applied to the wire during winding on the mandrel is calculated from the wire diameter to be equivalent to 118 MPa ± 11,8 MPa (118 N/mm² ± 11,8 N/mm²).

L.3.3 Heat shock

The sample is subjected to test 9 of IEC 60851-6:1996, followed by the dielectric strength test of 8.8.3 for the appropriate type and number of MOP(s), except that the test voltage is applied between the wire and the mandrel. The voltage is not less than the appropriate voltage in Table 6 and Table 7 (see 8.8.3) with a minimum of:

– *1 500 V for BASIC INSULATION or SUPPLEMENTARY INSULATION; or*

– *3 000 V for REINFORCED INSULATION.*

The oven temperature is the relevant temperature for the thermal class of insulation in Table L.2.

The mandrel diameter and tension applied to the wire during winding on the mandrel are as in L.3.2.

The electric strength test is conducted at room temperature after removal from the oven.

Table L.2 – Oven temperature

Thermal class	A (105)	E (120)	B (130)	F (155)	H (180)
Oven temperature °C ± 5 °C	200	215	225	240	260

L.3.4 Retention of electric strength after bending

Five samples are prepared as in L.3.2 above and tested as follows. Each sample is removed from the mandrel, placed in a container and positioned so that it can be surrounded by at least 5 mm of metal shot. The ends of the conductor in the sample are to be sufficiently long to avoid flash over. The shot is to be not more than 2 mm in diameter and consists of balls of stainless steel, nickel or nickel plated iron. The shot is gently poured into the container until the sample under test is covered by at least 5 mm of shot. The shot is cleaned periodically with a suitable solvent (for example, 1,1,1-trichloroethane).

NOTE The above test PROCEDURE is reproduced from 4.6.1.c) of IEC 60851-5:1988 (second edition including amendment 1), now withdrawn. It is not included in the ~~third~~ fourth edition of that standard.

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The test voltage is at least the appropriate test voltage in Table 6 and Table 7 (see 8.8.3) for the appropriate type and number of MOP(s), with a minimum of:

– *1 500 V for BASIC INSULATION or SUPPLEMENTARY INSULATION; or*

– *3 000 V for REINFORCED INSULATION.*

The test voltage is applied between the shot and the conductor.

The mandrel diameter and tension applied to the wire during winding on the mandrel are as in L.3.2.

L.4 Tests during manufacture

L.4.1 General

The wire is subjected by the wire manufacturer to electric strength tests during manufacture as specified in L.4.2 and L.4.3.

L.4.2 Routine testing

The test voltage for routine testing is to be the appropriate voltage in Table 6 and Table 7 (see 8.8.3) for the appropriate type and number of MOP(s), with a minimum of:

– *1 500 V r.m.s. or 2 100 V peak for BASIC INSULATION or SUPPLEMENTARY INSULATION; or*

– *3 000 V r.m.s. or 4 200 V peak for REINFORCED INSULATION.*

L.4.3 Sampling tests

Twisted pair samples are tested in accordance with IEC 60851-5:~~1996~~2008, Subclause 4.4.1. The minimum breakdown voltage is twice the appropriate voltage in Table 6 and Table 7 (see 8.8.3) for the appropriate type and number of MOP(s),with a minimum of:

– *3 000 V r.m.s. or 4 200 V peak for BASIC INSULATION or SUPPLEMENTARY INSULATION; or*

– *6 000 V r.m.s. or 8 400 V peak for REINFORCED INSULATION.*

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Annex M
(normative)

Reduction of pollution degrees
(see 8.9.1.8)

Table M.1 shows additional protective measures that may be used to reduce the pollution degree.

Table M.1 – Reduction of the pollution degree of internal environment through the use of additional protection

Additional protection	From pollution degree 2 of external environment to:	From pollution degree 3 of external environment to:
ENCLOSURE IPX4 of IEC 60529	2	2
ENCLOSURE IPX5 or IPX6 of IEC 60529	2	2
ENCLOSURE IPX7 or IPX8 of IEC 60529	2 (see note)	2 (see note)
Hermetically sealed ENCLOSURE	1	1
Constantly heated	1	1
Encapsulated	1	1
Coated	1	2
NOTE Reduction can be to pollution degree 1, if the equipment is manufactured with a low internal humidity and the manufacturer's instructions specify that, after opening the ENCLOSURE, the ENCLOSURE is reassembled in a controlled humidity environment or a desiccant is used.		

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INDEX OF ABBREVIATIONS AND ACRONYMS

Abbreviation	Term
a.c.	Alternating current
AEL	Accessible emission limit
AMSO	Auxiliary mains socket-outlet
AP	Anaesthetic-proof
APG	Anaesthetic-proof category G (gas)
CASE	Computer aided software engineering
CAT	Computer assisted tomography
CRT	Cathode ray tube
CTI	Comparative tracking index
d.c.	Direct current
DICOM	Digital imaging and communication in medicine
ELV	Extra-low voltage
EUT	Equipment under test
FDDI	Fibre distributed data interface
FMEA	Failure modes and effects analysis
FV	Flammability classification according to IEC 60695-11-10
HL7	Health Level 7
IBP	Invasive blood pressure catheter
ICRP	International commission for radiation protection
IEV	International Electrotechnical Vocabulary
IP	International protection in relation to the protection requirements of IEC 60529 or Internet protocol in relation to NETWORK/DATA COUPLING
IPS	Isolated power supply
IT	Information technology
LDAP	Light weight directory access protocol
LED	Light emitting diode
MAR	Minimum angle resolvable
MD	Measuring device, see 8.7.4.4
ME	MEDICAL ELECTRICAL, see 3.63 and 3.64
MOOP	MEANS OF OPERATOR PROTECTION, see 3.58
MOP	MEANS OF PROTECTION, see 3.60
MOPP	MEANS OF PATIENT PROTECTION, see 3.59
MPSO	Multiple portable socket-outlet
MSO	MULTIPLE SOCKET-OUTLET, see 3.67
OTS	Off the shelf
PEMS	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM, see 3.90
PESS	PROGRAMMABLE ELECTRONIC SUBSYSTEM, see 3.91
PTC	Positive temperature coefficient device
PTFE	Polytetrafluoroethylene
PVC	Polyvinyl chloride

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Abbreviation	Term
RFID	Radio-frequency identification
r.m.s.	Root mean square
SAR	Specific absorption rate
SELV	Safety extra-low voltage
SI	System international
SIP/SOP	SIGNAL INPUT/OUTPUT PART, see 3.115.
TCP	Transport connection protocol
TENS	Transcutaneous electronic nerve stimulator
TFE	Tetrafluoroethylene
UPS	Uninterruptible power supply
VDU	Video display unit

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INDEX

Abnormal condition, 38
ACCESS COVER, 52, 53, 76, 78, 79, 138, 144
  Definition, 21
ACCESSIBLE PART, 228
ACCESSIBLE PART, 26, 74, 77, 80, 81, 96, 141, 229, 230, 237, 238, 247, 253, 254, 258
  Actuating mechanisms, 56
  Defibrillation protection, 264
  Definition, 22
  Determination of, 53, 75, 246, 255, 327
  Fuse-holder, 61
  Internal screens and internal wiring, 92, 268
  LEAKAGE CURRENTS, 76, 256
  MAXIMUM MAINS VOLTAGE on, 256
  MEANS OF PROTECTION, 79, 258
  Metal, 82, 113, 138, 266, 276
  Moving, 188
  of ENCLOSURES, 221
  TOUCH CURRENT, 257
  Voltage limits for, 186
ACCESSORY, 52, 59, 88, 152, 163, 233, 249, 287, 300
  ACCOMPANYING DOCUMENTS definition, 22
  Biocompatibility, 183
  Cleaning, 71, 182
  Definition, 22
  Definition of HAND-HELD, 29
  Definition of PORTABLE, 34
  Disposal, 72
  List of, 72
  ME EQUIPMENT definition, 32
  Means of attachment, 161
  Method of sterilization, 62
  Minimum marking, 58
  MODEL OR TYPE REFERENCE definition, 32
  Multiple cleanings/disinfections, 182
  Operating instructions, 71
  Other power source, 60
  Pneumatic and hydraulic parts, 158
  Single use, 58
  Start-up PROCEDURE, 71
  Sterile, 62, 72
  Sterilization, 183
ACCOMPANYING DOCUMENT, 31, 35, 52, 53, 58, 60, 63, 64, 68, 74, 76, 92, 145, 152, 154, 156, 157, 161, 163, 166, 180, 196, 197, 199, 211, 213, 216, 217, 241, 242, 247, 251, 253, 264, 275, 287, 332, 350
  COMPONENT WITH HIGH-INTEGRITY CHARACTERISITCS, 229
  Consult, 58, 249, 334
  Defibrillation voltage and any recovery time, 83
  Definition, 22
  Inspection, 49, 68, 75, 156, 163, 167, 201, 206
  Instructions for use, 68, 333
  ME SYSTEM, 211, 322
  Mechanism for isolating the SUPPLY MAINS, 139
  MODEL OR TYPE REFERENCE, 233
  Recovery time, 88
  SAFE WORKING LOAD, 164
  Surface temperature, 219
  Technical description, 68, 333
  Working conditions, 51
Active implantable medical device, 16, 32
AIR CLEARANCE, 31, 74, 75, 77, 79, 80, 81, 82, 83, 119, 120, 121, 122, 123, 124, 126, 127, 128, 129, 130, 131, 132, 139, 142, 143, 154, 155, 164, 165, 173, 197, 198, 212, 215, 232, 236, 237, 244, 255, 259, 279, 280, 281, 283, 288, 299, 308, 328, 351
  Complying with IEC 60950-1, 120, 259
  DEFIBRILLATION-PROOF APPLIED PARTS, 124, 282
  Definition, 22
  High altitude, 121
  Interpolation, 121, 282
  MEANS OF OPERATOR PROTECTION, 80
  MEANS OF PATIENT PROTECTION, 79
  Short circuit of, 74
  Transformer, 210
  Values, 120
AIR KERMA
  Definition, 41
ALARM CONDITION, 41, 241
  Definition, 41
ALARM SIGNAL, 41, 46, 230, 241
  Definition, 41
ALARM SYSTEM, 41, 184, 241
  Definition, 41
Ambient humidity, 51, 62, 201, 252, 388
Ambient illuminance, 57
Ambient pressure, 33, 51, 235, 252
Ambient temperature, 26, 51, 119, 171, 173, 207, 252, 300, 320, 352, 356, 357
APPLIANCE COUPLER, 23, 27, 30, 70, 140, 141, 284
  Definition, 22
APPLIANCE INLET, 22, 30, 63, 90, 91, 111, 132, 144, 152
  Definition, 23
APPLIED PART, 22, 27, 28, 32, 33, 37, 39, 40, 47, 56, 61, 74, 76, 80, 81, 82, 83, 84, 87, 88, 93, 95, 96, 111, 113, 114, 171, 172, 182, 186, 214, 221, 225, 226, 227, 242, 253, 256, 265, 272, 280, 309, 324, 376, 385, 386
  Classification, 56, 76
  Cold, 171
  Definition, 23
  Determination of, 53, 327
  DIRECT CARDIAC APPLICATION, 76, 229
  DIRECT CARDIAC APPLICATION, 27
  HAND-HELD, 317
  High altitude, 301
  Intended to supply heat, 171
  Marking of, 61
  Maximum surface temperature, 300
  Maximum temperature, 186
  MEANS OF PROTECTION, 79
  Moving, 188

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Multiple, 81, 261
Not intended to supply heat, 171, 301
Specified in the instructions for use, 70
Temperature, 171
BASIC INSULATION, 26, 27, 38, 115, 211, 215, 228, 229, 230, 232, 237, 243, 256, 258, 266, 277, 279, 280, 324, 388, 389, 390
Definition, 23
MEANS OF PROTECTION, 254
BASIC SAFETY, 16, 17, 22, 27, 45, 51, 75, 88, 154, 163, 164, 165, 181, 182, 183, 192, 193, 194, 195, 196, 197, 217, 219, 220, 228, 229, 233, 237, 238, 243, 244, 245, 246, 247, 249, 252, 254, 258, 264, 288, 298, 299, 300, 311, 321, 323, 325
Defibrillation protection, 83
Definition, 26
Flow rate, 62
Loss of, 214
Testing, 73
Batch or lot identifier
ACCESSORY, 59
ME EQUIPMENT, 58
Biocompatibility, 183, 238, 317, 327
BODY-WORN, 83
Definition, 41
Equipment, 39
CATEGORY AP, 180, 306, 326, 330, 331, 332, 348, 349, 350, 351, 352
Definition, 26
Symbol, 338
CATEGORY APG, 180, 306, 326, 330, 331, 332, 349, 350, 351, 357
Definition, 26
Symbol, 338
CLASS I, 35, 56, 69, 112, 144, 212, 215, 243, 251, 256, 266, 272, 274, 285, 325
Definition, 26
CLASS II, 26, 56, 60, 92, 112, 144, 230, 268, 274, 332, 336, 380
Definition, 26
Class III, 247
CLEARLY LEGIBLE, 57, 61, 64, 153, 248
Definition, 26
COLD CONDITION, 188, 329
Definition, 26
Comparative tracking index, 121
COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS, 47, 48, 74, 186, 194, 207, 229, 244, 314
Definition, 26
CONTINUOUS OPERATION, 56, 61, 173, 191, 213, 229, 247, 310, 357
Definition, 26
DUTY CYCLE, 229
Non-, 56, 61, 172, 189, 190, 191, 213, 229, 247, 310
CREEPAGE DISTANCE, 31, 74, 75, 77, 79, 80, 81, 82, 83, 115, 119, 120, 125, 129, 130, 131, 132, 139, 142, 143, 154, 155, 164, 165, 173, 197, 198, 212, 215, 232, 236, 244, 255, 259, 262, 279, 280, 281, 282, 283, 288, 299, 308, 319, 328, 351
Complying with IEC 60950-1, 120, 259
DEFIBRILLATION-PROOF APPLIED PARTS, 124, 282
Definition, 27
High altitude, 121
Interpolation, 121, 282
MEANS OF OPERATOR PROTECTION, 80, 124
MEANS OF PATIENT PROTECTION, 79
Moulded transformer, 210
Short circuit of, 74
SINGLE FAULT CONDITION, 245
Transformer, 210
Values, 120
WORKING VOLTAGE above 1 000 V, 281
Date of manufacture
ACCESSORY, 59
ME EQUIPMENT, 58
DEFIBRILLATION-PROOF APPLIED PART, 83, 229, 249, 264, 266
Classification, 56, 81, 83
Common-mode test, 84
CREEPAGE DISTANCES and AIR CLEARANCES, 124
Definition, 27
Differential-mode test, 87
Energy reduction test, 88
Marking of, 61
WORKING VOLTAGE, 83, 264
Design documentation
Evaluation of, 186
Inspection, 119, 201
DETACHABLE POWER SUPPLY CORD, 90, 111, 152, 229, 262, 267, 351
Definition, 27
Non-, 74, 90, 142, 284
Diagnostic or therapeutic radiation, 184, 185
DIRECT CARDIAC APPLICATION, 39, 40, 76, 229, 237, 238, 257, 268, 322
Definition, 27
DOUBLE INSULATION, 26, 48, 74, 83, 229, 243, 255, 258, 259, 279, 280, 286, 388
Definition, 27
MEANS OF PROTECTION, 27, 254
Short circuiting, 93, 268
WORKING VOLTAGE, 264
DUTY CYCLE, 67, 172, 190, 229, 300
Definition, 27
Marking of, 61
EARTH LEAKAGE CURRENT, 30, 93, 95, 112, 234, 269, 380
Definition, 27
Measurement, 96, 112, 275
MULTIPLE SOCKET-OUTLET, 323
Total, 213
Value, 92, 93
Value for a MULTIPLE SOCKET-OUTLET, 213
Electrical equipment, 69, 74, 75, 110, 216, 219, 247, 321
ACCESS COVER definition, 21
ACCESSIBLE PART definition, 22
APPLIANCE COUPLER definition, 22
APPLIANCE INLET definition, 23
CLASS II definition, 26
COLD CONDITION definition, 26
DETACHABLE POWER SUPPLY CORD definition, 27

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

INTERNAL ELECTRICAL POWER SOURCE definition, 29
INTERNALLY POWERED definition, 30
MAINS CONNECTOR definition, 30
MAINS PLUG definition, 30
MAINS TRANSIENT VOLTAGE definition, 30
ME EQUIPMENT definition, 32
PEAK WORKING VOLTAGE definition, 34
POTENTIAL EQUALIZATION CONDUCTOR definition, 34
POWER SUPPLY CORD definition, 34
SELF-RESETTING THERMAL CUT-OUT definition, 37
SIGNAL INPUT/OUTPUT PART definition, 37
TERMINAL DEVICE definition, 38
THERMAL CUT-OUT definition, 38
WORKING VOLTAGE definition, 41
ENCLOSURE, 30, 39, 78, 81, 83, 93, 110, 112, 113, 115, 116, 132, 140, 146, 178, 221, 229, 237, 254, 255, 256, 265, 270, 279, 280, 287, 291, 323, 326, 348, 349, 351, 352, 356, 357, 376
ACCESS COVER, 21, 247
ACCESSIBLE PART, 221
Ball-pressure test, 119
Definition, 27
Deformation of, 185
Fire, 174, 179, 186, 288, 305, 309, 330
Greater than IPX0, 53
HAND HELD switches and footswitches, 283
HIGH VOLTAGE parts, 250
Impact, 198, 317
Impairment of cooling, 187
IP Classification, 56, 61, 182, 206, 220, 246, 307
IPX0, 52
Main, 112, 267
ME SYSTEM, 212, 321
Minimum marking, 58
Moulded, 200, 201
MULTIPLE SOCKET-OUTLET, 215
Non-conductive, 110
Opening in, 77, 351
Rigidity, 198, 317
Separate, 75
TOUCH CURRENT, 39, 275
Equipment, 59, 60, 70, 72, 210, 211, 212, 213, 215, 216, 221, 232, 233, 234, 237, 244, 247, 280, 284, 287, 288, 298, 306, 317, 320, 321, 322, 323, 324, 325, 370, 376
ACCESSORY definition, 22
ACCOMPANYING DOCUMENTS definition, 22
BODY-WORN, 39
Class III, 247
GUARD definition, 28
HAND-HELD definition, 29
IT-NETWORK, 196, 197
MAINS SUPPLY TRANSFORMER definition, 30
ME SYSTEM definition, 32
MOBILE, 39, 290
MOBILE definition, 32
MODEL OR TYPE REFERENCE definition, 32
NETWORK/DATA COUPLING definition, 32
PERMANENTLY INSTALLED, 342
Polyphase, 263
PORTABLE, 39
PROTECTIVE EARTH TERMINAL definition, 35
SAFE WORKING LOAD definition, 37
Separate power supply, 52
SERVICE PERSONNEL definition, 37
STATIONARY definition, 38
TRANSPORTABLE definition, 34, 39
TRAPPING ZONE definition, 39
TYPE TEST definition, 40
ESSENTIAL PERFORMANCE, 229
ESSENTIAL PERFORMANCE, 16, 17, 22, 27, 45, 46, 51, 88, 154, 163, 164, 165, 182, 192, 193, 194, 195, 196, 202, 217, 219, 220, 228, 229, 233, 238, 239, 244, 245, 249, 264, 288, 290, 298, 311, 313, 314, 325, 327
d.c. SUPPLY MAINS, 75
Defibrillation protection, 83
Definition, 27
Disclosure of, 73
Flow rate, 62
Information about, 73
Testing, 73
VERIFICATION, 195, 316
EXPECTED SERVICE LIFE, 26, 38, 46, 47, 48, 56, 57, 68, 75, 90, 119, 161, 167, 168, 182, 201, 242, 243, 244, 266, 278, 295
Definition, 27
Disposal, 72
Faults, 246
Simultaneous independent, 51, 246
Fire, 63, 144, 174, 177, 178, 179, 180, 181, 203, 217, 257, 285, 293, 303, 304, 305, 309, 321, 330
FIXED
APPLIANCE INLET, 23
Connections, 266
Definition, 28
GUARD, 146
Installations, 234
Mains socket-outlets, 234
ME EQUIPMENT, 57, 112, 151, 153, 179, 198, 317
POWER SUPPLY CORD, 34
PROTECTIVE EARTH CONDUCTOR, 90
Supply conductors, 90
SUPPLY MAINS, 28
Terminals, 143
Wiring, 144
FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, 26, 306, 349, 356
Definition, 28
FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE, 26, 349, 350, 351, 357, 361
Definition, 28
Flammable anaesthetic mixtures, 218, 326, 348
F-TYPE APPLIED PART, 34, 40, 81, 83, 113, 223, 261, 262, 271, 280
Classification, 28
Definition, 28
F-TYPE ISOLATED (FLOATING) APPLIED PART. See F-TYPE APPLIED PART
Function, 22, 23, 26, 57, 62, 65, 68, 70, 71, 73, 81, 92, 114, 116, 145, 166, 167, 177, 183, 186, 194, 195, 201, 202, 204, 214, 217, 222, 224, 225, 226, 227, 229, 230, 235, 244, 256, 261, 264, 266, 271, 272, 273, 276, 277,

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

287, 288, 313, 314, 315, 316, 317, 331, 332, 333, 363, 370, 374
FUNCTIONAL CONNECTION, 32, 212, 230
Definition, 28
FUNCTIONAL EARTH CONDUCTOR, 26, 67, 268, 274
Definition, 28
LEAKAGE CURRENT
Value, 93
FUNCTIONAL EARTH TERMINAL, 26, 28, 87, 92, 110, 230
Definition, 28
Marking of, 62, 63
Functional test
ESSENTIAL PERFORMANCE, 46
Speed of movement, 149, 165
Strength of PATIENT or OPERATOR support or suspension systems, 163
Fuseholder, 53, 76, 247
GUARD, 146, 287
ACCESS COVER, 21
Definition, 28
FIXED, 146
Hot or cold accessible surfaces, 173
Movable, 148
TRAPPING ZONE, 146
HAND-HELD, 41
ACCESSORY, 199
APPLIED PART, 317
Control device, 138, 205, 206
Definition, 29
ME EQUIPMENT, 49, 151, 172, 188, 191, 198, 199, 318
Part, 138, 152, 198, 199
Switches and footswitches, 283
HARM, 241
HARM, 29, 36, 61, 148, 150, 154, 164, 165, 197, 229, 230, 231, 239, 241, 243, 265, 286, 288, 291, 293, 298, 300, 309
Definition, 29
HAZARD, 16, 26, 29, 31, 33, 36, 37, 39, 43, 44, 45, 61, 63, 73, 74, 145, 149, 150, 151, 156, 161, 193, 202, 203, 210, 213, 217, 218, 221, 228, 231, 232, 235, 238, 239, 240, 243, 244, 245, 246, 248, 249, 250, 252, 253, 262, 263, 269, 272, 282, 283, 284, 286, 287,288, 293, 295, 304, 306, 307, 308, 313, 314, 317, 318, 320, 321, 323, 327, 331, 333, 351, 370, 371, 376
Definition, 29
Excessive temperatures, 169, 300
Expelled parts, 145, 156, 291, 329
Impairment of cooling, 187
Instability, 151, 288, 328
Moving parts, 328
Rough surfaces, corners and edges, 151, 288, 328
Support systems, 161, 294, 329
Temperature of APPLIED PARTS, 300
Unwanted and excessive radiation, 167, 299
HAZARDOUS SITUATION, 41, 43, 44, 45, 48, 51, 74, 75, 96, 145, 178, 185, 186, 204, 231, 239, 240, 241, 262, 284, 305, 308, 311, 323, 324, 329, 371
Adjustment of controls, 204
Battery replacement, 203
Conditions or faults, 44
Damage during assembly, 138
Damage to insulation, 138
Definition, 29
Detachment of conductors and connectors, 75, 137, 138
Exhaustion of a battery, 319
Failure of any one component at a time, 185
Failure of components, 47, 48
Heaters, 204
Incorrect connection, 214
Ingress of water and particulate matter, 182, 307
Interruption of SUPPLY MAINS, 183
Interruption of the power supply, 214, 307
Limitation of movement, 205
Mechanism for isolating the SUPPLY MAINS, 139
Overflow, 181, 182
Overheating of transformers, 207, 208
Poor contact, 138
Prolonged operation, 204
Short circuiting of a battery, 203
Short circuiting of CREEPAGE DISTANCES or AIR CLEARANCES, 130
Speed of movement, 149
Spillage, 182
THERMAL CUT-OUTS and OVER-CURRENT RELEASES, 201, 202
THERMOSTAT, 202
Transformer failure, 208
Health care professional, 234
HIGH VOLTAGE, 62
Defibrillation protection, 264
Definition, 29
Part, 250, 348
Part, Marking of, 63, 334
Humidity preconditioning, 52, 92, 116, 130, 208, 246, 279, 328
HYDRAULIC TEST PRESSURE, 159, 160
Definition, 29
Installation instruction
Transient current, 212
Instructions for use, 33, 50, 51, 52, 53, 56, 61, 66, 68, 69, 70, 73, 76, 77, 88, 92, 111, 114, 116, 145, 152, 154, 164, 171, 181, 182, 212, 218, 234, 243, 247, 249, 251, 252, 264, 322, 333, 350
Inspection, 72, 77, 172
Unique version identifier, 72
INSULATION CO-ORDINATION
Definition, 29
IEC 60950-1, 80, 81, 115, 120, 237, 238
INTENDED USE, 22, 34, 41, 69, 146, 158, 167, 201, 228, 234, 239, 252, 266, 282, 287, 290, 306, 318, 372, 374
Definition, 29
ESSENTIAL PERFORMANCE, 230
EXPECTED SERVICE LIFE, 242
Identification of ESSENTIAL PERFORMANCE, 45
NORMAL USE definition, 33
INTERNAL ELECTRICAL POWER SOURCE, 30, 37, 49, 52, 70, 203, 204, 251, 319
Definition, 29
INTERNALLY POWERED, 56, 82, 111, 112, 123, 263, 264

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Definition, 30
IP Classification, 56, 61, 206, 215
Isolated power supply (IPS), 212
IT-NETWORK, 196, 197, 317, 370, 371
Configuration, 197
Connection of additional items, 197
Definition, 42
Disconnecting items, 197
Update of equipment, 197
Upgrade of equipment, 197
Lampholder, 63, 76, 173
Layperson, 36, 234
LEAKAGE CURRENT, 30, 39, 76, 77, 82, 92, 93, 110, 111, 186, 212, 213, 221, 235, 240, 245, 251, 254, 256, 258, 261, 262, 263, 268, 270, 271, 272, 274, 275, 284, 323, 324, 328, 329, 376
Definition, 30
Measurement, 75, 81, 82, 91, 96, 111, 181, 182, 183, 214, 246, 256, 269, 274, 275
SINGLE FAULT CONDITION, 245
TYPE B APPLIED PART, 262
Value, 93
OPERATOR, 40
LEDs, 300
MAINS CONNECTION
Total protective earth path, 216
MAINS CONNECTOR, 22, 30, 141, 142, 262, 263, 284
Definition, 30
MAINS PART, 27, 51, 52, 92, 117, 119, 120, 122, 123, 124, 126, 127, 130, 138, 139, 144, 145, 231, 237, 245, 253, 277, 280, 282, 286, 329
Definition, 30
Overvoltage category, 123
Separation from SECONDARY CIRCUIT, 37
MAINS PLUG, 70
MAINS PLUG, 74, 90, 91, 92, 140, 214, 215, 231, 258, 324, 325
Definition, 30
Total protective earth path, 216
MAINS SUPPLY TRANSFORMER, 206, 215, 320, 329
Definition, 30
MAINS TERMINAL DEVICE, 142, 143, 144, 215, 285, 332
Definition, 30
MAINS TRANSIENT VOLTAGE, 122, 123, 126, 139
Definition, 30
MAINS VOLTAGE, 82, 96, 110, 126, 127, 223, 231, 271, 272, 274, 275, 276, 280, 353, 358
Definition, 30
NOMINAL, 32, 122
RATED, 168
RATED, 92, 122, 167, 213, 263, 264
MANUFACTURER
ESSENTIAL PERFORMANCE, 240, 241
MANUFACTURER, 29, 32, 33, 35, 37, 44, 45, 56, 70, 72, 73, 74, 81, 90, 112, 121, 132, 141, 144, 156, 157, 159, 160, 161, 163, 168, 169, 172, 178, 181, 182, 183, 184, 185, 192, 193, 195, 197, 201, 202, 204, 216, 219, 220, 225, 227, 229, 238, 239, 243, 245, 247, 249, 250, 251, 252, 259, 261, 263, 266, 275, 285, 289, 290, 293, 295, 300, 306, 308, 311, 312, 313, 316, 317, 319, 325, 370, 377
Acceptance criteria, 44, 240
Alternative measure or test method, 46
Alternative RISK CONTROL measures, 290, 296
Calculations or test results, 168
Calculations or test results, 45
calculations, analyses or test results, 240
Definition, 31
Detachable components, 58
Equivalent safety, 242
ESSENTIAL PERFORMANCE, 27, 230
Expected service life, 27, 46, 242
Flammable anaesthetic mixtures, 326
Identification of ESSENTIAL PERFORMANCE, 45, 46
INTENDED USE, 68
Marking of name or trademark and contact information, 58
Marking of name or trade-name, 68
Marking of name or trade-name and address, 69
Marking of name or trade-name and contact information, 59
ME SYSTEM, 210, 211, 212, 233, 238, 321, 322, 324
PEMS, 196, 371, 374
Qualification of SERVICE PERSONNEL, 73
Reasonably foreseeable misuse, 238
RISK ASSESSMENT, 295
Single use, 71
Specification of overvoltage category, 50
System integration, 370
Marking, 240
Overflow, 181
Material group classification, 121
MAXIMUM MAINS VOLTAGE, 74, 81, 82, 93, 96, 113, 212, 232, 256, 263, 271, 276, 384
Definition, 31
MAXIMUM PERMISSIBLE WORKING PRESSURE, 159, 160, 232, 293
Definition, 31
ME EQUIPMENT
FIXED, 152
PERMANENTLY INSTALLED, 285
See MEDICAL ELECTRICAL EQUIPMENT, 32
ME SYSTEM
Large transient currents, 212
See MEDICAL ELECTRICAL SYSTEM, 32
MEANS OF OPERATOR PROTECTION, 80, 120, 124, 131, 204, 207, 212, 232, 259, 282, 305, 319, 321, 396
Additional AIR CLEARNACE, 127
Capacitors, 80
Classification, 79, 81
Definition, 31
IEC 60950-1, 80, 81, 89, 115, 120, 121
Minimum AIR CLEARANCE, 126, 128
Minimum CREEPAGE DISTANCE, 124, 129
PROTECTIVE EARTH CONNECTION, 80
Solid insulation forming, 80
Test voltage for, 118
Test voltage for solid insulation, 117
MEANS OF OPERTOR PROTECTION
Coatings, etc. complying with IEC 60950-1, 79

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MEANS OF PATIENT PROTECTION, 89, 121, 131, 178, 210, 222, 223, 232, 259, 321, 351, 357, 396
Capacitors, 80
Classification, 79, 81
Coatings, etc. complying with IEC 60950-1, 79
Definition, 31
F-TYPE APPLIED PART, 81, 261
PATIENT CONNECTION, 82
PROTECTIVE EARTH CONNECTION, 79
Solid insulation forming, 79
Spacing, 125, 281
Test voltage for solid insulation, 117
TYPE B APPLIED PART, 82
Y capacitors, 261
MEANS OF PROTECTION, 23, 27, 30, 31, 79, 120, 141, 144, 164, 165, 241, 388, 389, 390, 396
AIR CLEARANCE, 130
Ball-pressure test, 189
Classification, 79, 81
Coatings, etc. not considered as, 79
Components and wiring, 79
Components used as, 48
CREEPAGE DISTANCE or AIR CLEARANCE not considered as, 79
CREEPAGE DISTANCE or AIR CLEARANCE, 79, 131, 143
Definition, 31
DOUBLE INSULATION, 83
Insulating characteristics and mechanical strength, 119
Insulating material in which heating conductors are embedded, 119
Internal screens and internal wiring, 92, 268
Pollution degree 4, 122
REINFORCED INSULATION, 36, 114, 115
Resistors bridging, 243
SECONDARY CIRCUIT, 37
Separation from MAINS PART, 138
Sheath of a flexible cord, 139
Short circuit of, 74, 143, 173
Short circuit of CREEPAGE DISTANCE or AIR CLEARANCE, 74
SUPPLEMENTARY INSULATION, 38, 115
Test voltage for, 209, 279
Test voltage for solid insulation, 117
Transformer, 210
Transformers forming, 210
Wetting of, 181
WORKING VOLTAGE for, 82
RISK CONTROL, 290
RISK CONTROL, 298
MECHANICAL HAZARD, 145, 146, 148, 186, 189, 214, 218, 286, 324
Definition, 31
Sharp edges, 151
MECHANICAL PROTECTIVE DEVICE, 47, 162, 165, 166, 167, 298, 331
Definition, 31
When not required, 167
Medical device, 31, 43, 192, 219, 310, 312, 367
MEDICAL ELECTRICAL EQUIPMENT, 206
a.c SUPPLY MAINS, 51
Accessibility of connections, 144
Acoustic energy and vibration, 157
Adapting, 31
Applicability of requirements, 16
Arrangement of controls and indicators, 197
Automatically or remotely controlled, 188
Battery, 70, 203
Battery replacement, 203
Biocompatibility, 183
CATEGORY AP, 348, 349, 350, 351, 352
CATEGORY APG, 349, 350, 351, 357
CLASS I, 69, 112, 144
CLASS II, 60, 92, 112, 144
Classification, 56
Cleaning, 71, 182
Compatibility with substances, 183
Component, 44, 48, 180
COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS, 26, 48
Condition for application, 42
Conductors and connectors, 137
Connection to SUPPLY MAINS, 74
Connectors, 201
CONTINUOUS OPERATION, 56, 61, 173
Contraindication, 68
Controls, 204
Cooling provisions, 62
d.c., 82
d.c. SUPPLY MAINS, 52, 75
Definition, 32
Description, 70, 73
Detachable components, 58
Diagnostic or therapeutic radiation, 185
Disabling of controls, 190
Disposal, 72
DUTY CYCLE, 27, 190
Educational materials, 69
Emergency stop, 150, 151
Emitting radiation, 72
Equivalent safety, 46
Excessive radiation, 184
EXPECTED SERVICE LIFE, 46, 47, 48, 56, 57, 75, 90, 119, 161, 167, 168, 201
Expelled parts, 156
FIXED, 57, 112, 153, 179
FIXED or HAND-HELD, 151
Fixing of components, 137
Fluid reservoir, 181
Foot-operated control device, 205, 206
Function, 23, 70, 73
Guiding rollers, 138
Hand loaded, 191
HAND-HELD, 49, 172, 188, 191, 198, 199
HAND-HELD control device, 205
Heating elements, 172, 189, 190
Identification, 58, 68
Identification of ESSENTIAL PERFORMANCE, 45
In vitro diagnostic equipment, 16
Indicator lights, 204
Input supply voltage, 82
Inspection, 79, 206
Instability, 152
Installation, 70
INTENDED USE, 68, 146, 158, 201, 239
INTERNALLY POWERED, 56, 82, 111, 112, 123
Interruption and short circuiting of motor capacitors, 188
Interruption of SUPPLY MAINS, 183

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

IP Classification, 182, 206
Isolation from SUPPLY MAINS, 73, 139, 140
Large, 201
Load-reducing device, 191
Mains operated, 70
Manual MOBILE, 154
Manually switched on, 191
Maximum supply pressure, 158
MECHANICAL PROTECTIVE DEVICE, 166
MEDICAL ELECTRICAL SYSTEM, 32
Method of sterilization, 62
MOBILE, 62, 154, 155, 181, 200, 206, 250, 289, 290
MOBILE Part, 200
MOBILE, power-driven, 155
Modification, 73
Motor, 190
Motor operated, 172, 188
Motor-driven MOBILE, 154
Moving parts, 145, 148, 151
Multiple cleanings/disinfections, 182
Multiple PATIENT CONNECTION, 114
MULTIPLE SOCKET-OUTLET, 60, 69, 140
Non-, 48, 211, 212, 215, 325
Non-SI Units, 65
Oil-filled, 73, 206
Operating instructions, 71
Overcharging, 203
Overtravel, 149
Overvoltage category, 122
OXYGEN RICH ENVIRONMENT, 56
Part, 26, 31, 37, 38, 52, 53, 56, 57, 58, 61, 62, 64, 70, 71, 74, 75, 78, 81, 90, 91, 138, 148, 149, 152, 153, 156, 161, 163, 169, 170, 172, 180, 186, 197, 206, 349, 350, 352, 356, 357, 358, 361
Part biocompatibility, 183
Part cleaning, 71, 182
Part sterilization, 183
Part, HAND-HELD, 198, 199
Part, heating, 190
Part, multiple cleanings/disinfections, 182
Parts that contact the PATIENT, 47
PATIENT ENVIRONMENT, 34
PERMANENTLY INSTALLED, 58, 60, 64, 73, 75, 87, 90, 93, 111, 139, 142, 144
PERMANENTLY INSTALLED, 157
Physiological effects, 61
Physiological function, 16
Platen glass, 199
Pneumatic and hydraulic parts, 158
Polyphase, 75, 82, 191
PORTABLE, 156, 199, 200, 206
PORTABLE part, 199
Power input, 50
Pressure control device, 160
Pressure relief device, 160
PROTECTIVE EARTH CONNECTION, 67
Protective measure, 148, 149
RATED altitude, 121
RATED voltage, 52
Ready for NORMAL USE, 204
Rechargeable battery, 72
Reciprocal interference, 69
Release of PATIENT, 151
RESPONSIBLE ORGANIZATION, 36
RISK
of fire, 174
RISK MANAGEMENT PROCESS, 42
Rough surfaces, sharp corners and edges, 151
Routine maintenance, 71
Separate power supply, 52, 59, 70, 72, 75, 212
Shutdown PROCEDURE, 71
SI Units, 65
SINGLE FAULT CONDITION, 47
SINGLE FAULT CONDITION definition, 38
SINGLE FAULT SAFE, 47
Single use, 58
Single-phase, 111
Source of power, 49
Spark source, 174
Spillage, 182
Stand-by or a warm-up state, 204
Start-up PROCEDURE, 71
STATIONARY, 142, 179
Sterile, 62, 72
Sterilization, 183
SUPPLY MAINS, 49, 50
Surface, 170
Surface coating, 91
Thermostatically controlled, 189
Timer, 191
Transformer, 206, 208, 210
TRANSPORTABLE, 57, 179, 181, 306
Unpacking, 62
MEDICAL ELECTRICAL SYSTEM, 37, 38, 70, 72, 75, 92, 178, 180, 181, 210, 211, 212, 213, 214, 215, 216
Adapting, 31
Applicability or requirements, 16
Biocompatibility, 183
Cleaning, 182
Component, 44
Components, 48
Condition for application, 42
Creation of, 69, 70
Definition, 32
Equivalent safety, 46
EXPECTED SERVICE LIFE, 46
Function, 23
Identification of ESSENTIAL PERFORMANCE, 45
INTENDED USE, 146, 239
IP Classification, 182
Multiple cleanings/disinfections, 182
OXYGEN RICH ENVIRONMENT, 56
Part, 213
Parts that contact the PATIENT, 47
PATIENT ENVIRONMENT, 34
Physiological function, 16
Power input, 50
RESPONSIBLE ORGANIZATION, 36
RISK MANAGEMENT PROCESS, 42
RISK of fire, 174
Spillage, 182
Sterilization, 183
Supplied from a UPS or IPS, 212
SUPPLY MAINS, 49, 50
Total PATIENT LEAKAGE CURRENT, 213
Total protective earth path, 216

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

TOUCH CURRENT, 213
Medical gas pipeline system, 16
MOBILE, 155, 290, 333
Definition, 32
EQUIPMENT, 39
ME EQUIPMENT, 62, 154, 155, 181, 198, 200, 206, 250, 289, 290, 318
ME EQUIPMENT parts, 200
MODEL OR TYPE REFERENCE, 58, 59, 68, 69, 233, 248, 249
Definition, 32
Detachable components, 58
MOOP
See MEANS OF OPERATOR PROTECTION, 31
MOP
See MEANS OF PROTECTION, 31
MOPP
See MEANS OF PATIENT PROTECTION, 31
MSO
See MULTIPLE SOCKET-OUTLET, 32
MULTIPLE SOCKET-OUTLET, 32, 60, 69, 140, 211, 212, 213, 214, 215, 233, 234, 274, 284, 322, 323, 324, 325, 331, 376, 380, 396
Definition, 32
NETWORK/DATA COUPLING, 70, 193, 194, 234, 317, 371, 372, 374
Definition, 32
NOMINAL
Capacitance, 80
Conductor diameter, 389
Cross-sectional area of conductors, 140, 141, 143
Definition, 32
Frequency, 50, 60
MAINS VOLTAGE, 32, 50, 122, 123, 126, 127, 128
Supply voltage, 59, 60
NORMAL CONDITION, 26, 33, 47, 64, 74, 75, 77, 79, 81, 83, 92, 93, 95, 97, 114, 139, 149, 157, 158, 159, 169, 171, 174, 177, 182, 186, 187, 190, 210, 213, 217, 234, 235, 253, 254, 255, 256, 258, 268, 269, 270, 271, 272, 276, 280, 293, 305, 307, 309, 324, 349, 352, 356, 357, 358, 385
Definition, 33
Identification of ESSENTIAL PERFORMANCE, 45
NORMAL USE, 23, 26, 32, 33, 37, 39, 41, 42, 51, 53, 57, 61, 64, 65, 70, 71, 76, 77, 79, 83, 91, 113, 114, 115, 116, 138, 139, 140, 146, 150, 151, 152, 153, 154, 155, 156, 157, 158, 160, 163, 164, 167, 168, 169, 172, 178, 181, 182, 191, 199, 200, 201, 204, 205, 206, 207, 208, 209, 213, 215, 217, 222, 224, 225, 226, 227, 231, 239, 243, 244, 264, 265, 287, 288, 290, 294, 300, 303, 305, 306, 307, 308, 318, 319, 323, 326, 351, 352, 356, 357, 358
Definition, 33
INTENDED USE definition, 29
OBJECTIVE EVIDENCE, 40, 44, 240, 322
Definition, 33
Operating temperature, 64, 92, 96, 116, 169, 170, 213, 279, 303, 328, 352, 356, 357
OPERATOR, 22, 33, 39, 40, 41, 42, 57, 58, 61, 66, 68, 69, 71, 72, 76, 91, 148, 152, 163, 166, 177, 184, 188, 196, 204, 211, 212, 217, 218, 219, 221, 225, 229, 230, 232, 233, 234, 241, 242, 243, 245, 247, 248, 249, 251, 252, 257, 258, 259, 265, 266, 269, 279, 286, 287, 288, 291, 307, 308, 310, 318, 319, 320, 322, 323, 324, 333, 372, 376
Contact with, 112, 212, 254, 255, 257, 265, 301
Contact with PATIENT, 76
Definition, 33
Emergency stop, 150
Expected position of, 70, 157, 299
Exposure to hazardous materials, 70
Home use, 36
Interface, 40
Language acceptable to, 66
Mass of, 163, 296
Mechanism for isolating the SUPPLY MAINS, 139
MOBILE MEDICAL ELECTRIC EQUIPMENT, 250
Moving parts, 146, 149
RISK to, 334
Sensitivity to acoustic energy and vibration, 157
Sensitivity to vibration, 158
Spurious microwave radiation, 168
Spurious X-radiation, 167
Support, 163, 164, 167, 294
Unwanted or excessive radiation, 184
OVER-CURRENT RELEASE, 63, 120, 144, 186, 201, 202, 203, 243, 250, 256, 282, 285, 348
Definition, 33
OXYGEN RICH ENVIRONMENT, 56, 174, 176, 177, 178, 189, 235, 303, 304, 305, 321
Definition, 33
PATIENR LEAKAGE CURRENT, 244
PATIENT, 23, 27, 31, 32, 33, 34, 39, 42, 47, 61, 65, 152, 163, 167, 196, 204, 217, 218, 219, 221, 228, 229, 232, 234, 237, 241, 245, 266, 269, 271, 286, 288, 320, 323, 324, 349
Acting as an OPERATOR, 251
Adult human, 163
APPLIED PART exceed 41°C, 171
APPLIED PARTS intended to supply heat to, 171
APPLIED PARTS not intended to supply heat to, 171
Cable, 61, 111, 201, 214, 222, 224, 227, 249, 264, 275
Circuit, 223
Condition, 274
Contact with, 47, 71, 76, 82, 112, 113, 149, 171, 212, 219, 221, 222, 224, 225, 229, 235, 236, 242, 243, 255, 257, 258, 259, 262, 266, 268, 269, 271, 275, 277, 280, 287, 301, 321, 333, 376
Current flowing in, 33, 235, 237, 238, 263, 276
Defibrillation of, 83, 249, 264, 265
Definition, 33
Disconnection from, 114, 276
Earthing of, 34, 83, 235, 262, 271, 280
Electric shock to, 31, 247
Expected position of, 70, 71, 157
Exposure to hazardous materials, 70
Exposure to toxic gases, 178
Heart, 27, 229, 254, 322
Home use, 36, 234

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Incorrect delivery of energy or substances, 184, 308
Lead, 82, 83, 201, 214, 222, 224, 227, 262
Mass of, 163, 296, 331, 332
Moving of, 145, 164
Moving parts, 145, 146, 151
Number of APPLIED PARTS, 271
PATIENT ENVIRONMENT, 34
PATIENT is an intended OPERATOR, 69
Release of, 151, 288
RISK to, 230, 273, 334
Sensitivity to acoustic energy, 291
Sensitivity to acoustic energy and vibration, 157
Sensitivity to vibration, 158, 291
Special needs, 149, 309
Support, 153, 154, 163, 164, 167, 222, 236, 246, 257, 286, 294
Support of, 298
Transfer of energy, 76, 257
Unintended voltage on, 28, 34, 232, 261, 262, 263, 272, 276, 376
Unwanted or excessive radiation, 184, 299
PATIENT AUXILIARY CURRENT, 76, 92, 93, 95, 111, 114, 222, 224, 235, 244, 271, 277, 328, 329, 344
Definition, 33
Limit, 39
Measurement, 96, 114, 235
Value, 92, 93, 272
Values, 257, 258, 269
PATIENT CONNECTION, 23, 28, 33, 34, 39, 76, 81, 82, 83, 84, 88, 95, 110, 113, 114, 117, 222, 224, 225, 226, 227, 235, 236, 245, 249, 254, 257, 258, 269, 272, 274, 275, 277
DEFIBRILLATION-PROOF APPLIED PART, 83, 87, 264
Definition, 33
Energy reduction test, 88
F-TYPE APPLIED PART, 83, 96, 261, 271, 280
Multiple, 114, 276
Single, 114, 276
TYPE B APPLIED PART, 113, 237, 262, 276
TYPE BF APPLIED PART, 237, 276
TYPE CF APPLIED PART, 238, 254, 271, 272
WORKING VOLTAGE, 83
PATIENT ENVIRONMENT, 210, 211, 212, 213, 214, 236, 321, 322, 323, 324, 325, 376
Definition, 34
PATIENT LEAKAGE CURRENT, 30, 95, 96, 110, 114, 222, 224, 235, 251, 269, 271
Definition, 34
Limit, 28, 39, 76, 81, 91, 271, 275, 276
ME SYSTEM, 213, 324
Measurement, 96, 113, 114, 275, 277
MULTIPLE SOCKET-OUTLET, 213
Total, 95, 96, 114, 213, 271, 272, 324
TYPE B APPLIED PART, 262
TYPE BF APPLIED PART, 272, 276
TYPE CF APPLIED PART, 238, 270
Value, 92, 93, 96, 271, 272
PEAK WORKING VOLTAGE, 115, 117, 118, 122, 123, 127, 232, 236, 238
Definition, 34
Interpolation, 121
PEMS
See PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM, 35
PEMS DEVELOPMENT LIFE-CYCLE, 192, 193, 312, 313, 316, 363, 368
Definition, 34
PEMS VALIDATION, 34, 316, 366
Definition, 34
Methods, 195
Plan, 193, 195, 312
Results, 195
Team, 195
PERMANENTLY INSTALLED
Definition, 34
ME EQUIPMENT, 58, 60, 64, 73, 75, 87, 90, 93, 111, 139, 142, 144, 157, 253, 285
MEDICAL ELECTRICAL EQUIPMENT, 64
Non-, 93, 139, 213
PESS
See PROGRAMMABLE ELECTRONIC SUBSYSTEM, 35
Placed into service, 29, 32, 34, 38, 39
Pollution degree 1, 131
Pollution degree 2, 131
Pollution degree 3, 131
Pollution degree classification, 122
PORTABLE
Definition, 34
Equipment, 39
ME EQUIPMENT, 156, 198, 199, 206, 318
ME EQUIPMENT part, 199, 200
POTENTIAL EQUALIZATION CONDUCTOR, 67, 91, 92, 268, 331, 333
Definition, 34
POWER SUPPLY CORD, 30, 141, 284, 285, 304, 325
Clamping means, 90
CLASS II ME EQUIPMENT, 92
Colour of conductors, 67, 230
Conductors, 141, 142
Cord anchorage, 141
Cord connection, 138, 143, 351
Cord guard, 142
Cross-sectional area of conductors, 140, 144
Definition, 34
Incorporating switches, 139
Insulation of, 141
MAINS PLUG, 140
MULTIPLE SOCKET-OUTLET, 215, 234
Neutral conductor, 67
POTENTIAL EQUALIZATION CONDUCTOR, 92
PROTECTIVE EARTH CONDUCTOR, 90
Replaceable, 74, 144
Sheathing, 140
Strain relief, 141
Testing with, 111, 132, 152
PRIMARY OPERATING FUNCTION, 149
Definition, 42
PROCEDURE, 37, 259, 270, 304, 311, 313, 316
Cleaning, 182, 212
Definition, 35
Document control, 192
Energy reduction test, 88
LEAKAGE CURRENT measurement, 96
Maintenance, 270
Measuring X-radiation, 299
Modification/change, 195

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

RISK CONTROL, 194
RISK MANAGEMENT, 238
Shutdown, 71
Start-up, 71, 221
Sterilization, 92, 116, 183
Test, 112, 168, 169, 181, 182, 264, 280, 389
Thermal cycling, 130
PROCESS, 23, 29, 44
Assessment of APPLIED PARTS, 222
Cleaning, 333
Cleaning or disinfection, 182
Definition, 35
Design, 238
Handling of PATIENT, 164
Manufacturing, 91, 161, 244, 308
Multiple cleanings/disinfections, 182
PEMS DEVELOPMENT LIFE-CYCLE, 192, 310, 311, 312, 313, 314, 363, 366, 368
PEMS VALIDATION, 34
Procedure, 35
RISK ASSESSMENT, 36
RISK CONTROL, 36
RISK EVALUATION, 36
RISK MANAGEMENT, 39, 40, 43, 45, 47, 48, 75, 79, 82, 157, 168, 169, 171, 177, 181, 182, 183, 184, 185, 187, 192, 193, 197, 204, 206, 216, 218, 221, 224, 231, 238, 239, 241, 242, 243, 245, 250, 288, 291, 304, 307, 310, 311, 317, 318, 327
Software development, 192
Thermoforming, 318
USABILITY ENGINEERING, 68, 184, 197, 238, 251, 307
USABILITY ENGINEERING, 42
VERIFICATION, 313
PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM (PEMS), 34, 35, 58, 192, 193, 194, 195, 196, 219, 310, 317, 396
PROGRAMMABLE ELECTRONIC SUBSYSTEM (PESS), 35, 192, 193, 194, 396
Definition, 35
PROPERLY INSTALLED, 61, 145
Definition, 35
PROTECTIVE EARTH CONDUCTOR, 27, 30, 34, 35, 39, 67, 75, 87, 90, 91, 110, 112, 141, 143, 144, 213, 215, 234, 243, 252, 268, 269, 285, 323, 325, 376
Definition, 35
ME SYSTEM, 216
Non-PERMANENTLY INSTALLED, 213
PROTECTIVE EARTH CONNECTION, 31, 75, 79, 80, 81, 90, 91, 92, 93, 215, 232, 234, 250, 255, 256, 262, 265, 266, 267, 275, 277, 279, 283, 285, 307, 325, 380
Colour of, 67
Definition, 35
ME SYSTEM, 216
PROTECTIVE EARTH TERMINAL, 35, 63, 90, 91, 110, 143, 215, 250, 258, 266
Definition, 35
PROTECTIVELY EARTHED, 26, 39, 82, 84, 88, 90, 91, 110, 112, 123, 216, 237, 258, 262, 266, 323, 325
Definition, 35
Non-, 93, 96, 112, 113, 141, 237, 255, 264
RATED
Altitude, 121
CATEGORY AP, 306
CATEGORY APG, 306
Characteristics, 139
Components, 215
Current, 73, 90, 141, 208
Definition, 35
DUTY CYCLE, 190
Fire protection device, 203
Flow rate, 62
Frequency, 51, 52, 92, 207, 208, 209, 280, 320
Input, 50
Input power, 49, 60
IP Classification, 246
Load, 160
MAINS VOLTAGE, 122, 127, 167, 168, 263, 264
Marked, 60
Maximum supply pressure, 158
Non-CONTINUOUS OPERATION, 189, 190, 191
On and off periods, 172, 213
Operating time, 190
Operation, 229, 247, 310
Output current or power, 60
Output power, 215
Output voltage, 60
Phase to neutral supply voltage, 82
Pressure, 62
Protection against particulate matter, 307
Supply frequency, 60
Supply frequency range, 60
SUPPLY MAINS, 51
SUPPLY MAINS voltage, 78
Supply voltage, 59, 82, 190, 213, 264, 274, 275
Supply voltage range, 59
Temperature, 140
Voltage, 49, 50, 52, 72, 78, 79, 82, 172, 188, 191, 207, 208, 209, 261
Voltage (maximum), 172
Voltage (minimum), 172
Voltage range, 60, 82, 191
SUPPLY MAINS, 60
Reasonably foreseeable misuse, 26, 42, 48, 145, 146, 150, 174, 194, 217, 238, 247, 290, 310, 317, 318
RECORD, 37, 44, 192, 239, 317
Definition, 36
Examination of, 43
USABILITY ENGINEERING FILE, 42
REINFORCED INSULATION, 26, 47, 48, 114, 115, 119, 154, 197, 229, 237, 254, 255, 258, 259, 277, 279, 280, 286, 324, 388, 389, 390
Definition, 36
Removable protective means, 62
RESIDUAL RISK, 43, 240, 241
Acceptability criteria, 44, 45
Acceptability of, 259, 266, 286, 322
Alternative measure or test method, 242
Definition, 36
Equivalent safety, 242
ESSENTIAL PERFORMANCE, 241
Evaluation, 44
Identifiable safety requirements, 314
Indication of, 152, 287
Moving parts, 145

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

of fire, 177
SERVICE PERSONNEL, 234
System integrator, 370
Unacceptable, 240
RESPONSIBLE ORGANIZATION, 22, 31, 37, 68, 69, 71, 73, 77, 196, 197, 210, 211, 212, 213, 242, 246, 249, 251, 252, 269, 299, 301, 305, 322, 324, 325, 350, 370, 371, 372
Definition, 36
EXPECTED SERVICE LIFE, 242
Home use, 36
Instructions for use, 69
Mechanism for isolating the SUPPLY MAINS, 139
Periodic inspection and maintenance, 319
HAZARDOUS SITUATION, 196
RISK, 45, 46, 240
Acceptability criteria, 44
Acceptability of, 240
Acceptable, 31, 36, 44, 45, 47, 150, 151, 152, 194, 231, 239, 240, 290, 311, 317
Acceptance criteria, 36
Accidental disconnection, 91
Accidental selection of excessive output values, 184
Accuracy of controls and instruments, 183
Alpha, beta, gamma and neutron radiation, 168
Arrangement of controls and indicators, 197
Benefit analysis, 240
Burn, 257, 268, 274
Compatibility with substances, 183
COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS, 314
Consequent, 313
Definition, 36
Diagnostic or therapeutic acoustic pressure, 185
Diagnostic or therapeutic radiation, 185
Disconnection, 285
Earthing the PATIENT, 261
Electric shock, 31
Electric shock to others than the PATIENT, 31
Electric shock to PATIENT, 31
Electromagnetic compatibility, 216
ESSENTIAL PERFORMANCE, 241
Evaluation, 44
Expelled parts, 156
Explanation, 211, 212
Failure of component, 47
Fault, 285
Fire, 309
Flammable agent, 306
HIGH VOLTAGE, 250
Identification of ESSENTIAL PERFORMANCE, 45
Identified, 194
Ignition, 178
Incorrect delivery of energy or substances, 184
Incorrect output, 184
Infra- and ultrasound, 157
Infrared radiation, 169
Initial movement, 155
Insulation breakdown, 245, 259
Intentional exceeding of safety limits, 184
Mechanical rupture, 293
Mix-up, 317, 319
Moulding and mechanical stress, 197
Moving part, 286
Moving parts, 145
Multiple PATIENT CONNECTIONS, 274, 276, 277
New, 197
of accumulation and ignition, 203
of contact, 262
of explosion, 348
of fire, 174, 285
Overbalancing, 153, 331
Overtravel, 149
PATIENT ENVIRONMENT, 322
PATIENT support, 163
PEMS, 312
PEMS problem resolution, 193
Poor USABILITY, 184
Pre-set controls, 204
Previously unidentified, 196
Radiotherapy, 185
Reciprocal interference, 69
Reduction, 38, 47, 293, 313
Replacement of lithium batteries or fuel cells, 63
Safety sign, 66
Servicing, 235
Sharp edge, 288
SINGLE FAULT CONDITION, 245
Slow, unwanted movement, 290
Spillage, 306
to PATIENT, 221, 230, 242, 263, 271, 273
to PATIENT or OPERATOR, 334
TYPE B APPLIED PART, 82
Ultraviolet radiation, 169
Unacceptable, 26, 27, 38, 44, 48, 62, 65, 70, 74, 75, 82, 119, 137, 146, 149, 151, 154, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 171, 174, 181, 182, 183, 187, 192, 197, 198, 199, 200, 201, 202, 203, 205, 206, 210, 211, 214, 229, 230, 240, 243, 248, 288, 290, 295, 308, 317, 322
USABILITY ENGINEERING, 307
Ventricular fibrillation, 269, 270
Vibration, 291
Visible electromagnetic radiation, 169
RISK ANALYSIS, 240
COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS, 244
Definition, 36
Identification of ESSENTIAL PERFORMANCE, 45
Identification of failures, 308
Interruption of any one power-carrying conductor, 75
PEMS DEVELOPMENT LIFE-CYCLE, 311
Results of, 47, 48
Revision of, 51
RISK ASSESSMENT, 36
Second fault, 243
Shorting of gaps, 308
SINGLE FAULT CONDITION, 272
Support system, 161
TOUCH CURRENT, 270
RISK ASSESSMENT, 295
Definition, 36
HAND-HELD APPLIED PARTS, 317
PEMS DEVELOPMENT LIFE-CYCLE, 311, 312, 314

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Source of ignition, 178
RISK ASSESSMENT, 45
RISK CONTROL, 43, 240
Alternative measure or test method, 46
Alternative measures, 46
Compatibility with substances, 183
Definition, 36
Measure, 44, 145, 148, 192, 194, 195, 240, 241, 242, 245, 249, 290, 311, 313, 314, 316
Measures, 45
Option analysis, 241
PEMS DEVELOPMENT LIFE-CYCLE, 194, 311
RESIDUAL RISK, 36
RISK EVALUATION, 240
Definition, 36
RISK ASSESSMENT, 36
RISK MANAGEMENT, 46, 192
Activities, 193
Application of, 218, 222, 224, 225, 226, 227, 238, 272, 321
Contents of, 37
Definition, 37
Methods, 211, 322
PEMS DEVELOPMENT LIFE-CYCLE, 192, 311
Plan, 44, 45, 193, 240, 312
PROCESS, 23, 37, 39, 40, 43, 45, 47, 48, 75, 79, 82, 157, 168, 169, 171, 177, 181, 182, 183, 184, 185, 187, 192, 193, 197, 204, 206, 216, 218, 221, 224, 231, 238, 239, 240, 241, 242, 243, 245, 250, 288, 291, 304, 307, 310, 311, 318, 327
RECORD, 44
RECORDS required by this standard, 44, 45
Report, 316
Results of, 313
SINGLE FAULT CONDITION, 48
Support systems, 295
System integration, 371
Temperature limits, 301
RISK MANAGEMENT FILE, 44, 45, 51, 240
Alternative means of compliance, 179
Alternative methods of temperature measurement, 173
Cleaning/disinfection, 182
Contents of, 195, 239, 283, 306, 311, 312, 317
Definition, 37
Equivalent safety, 242
Examination of, 45
EXPECTED SERVICE LIFE, 46
Fuses and OVER-CURRENT RELEASES, 144
Inspection, 46, 47, 48, 56, 77, 82, 90, 119, 137, 138, 144, 148, 150, 151, 156, 157, 158, 159, 160, 161, 162, 163, 164, 167, 168, 169, 172, 178, 181, 182, 183, 184, 185, 187, 197, 198, 199, 200, 201, 202, 203, 204, 206, 214, 216, 239, 240
Omission of OVER-CURRENT RELEASES, 203
Probability and duration of contact, 172
Professional relationships of PEMS VALIDATION TEAM members, 195
Spillage, 182
Temperature limits, 170, 171
Temperature test corner, 172
Worst case limits of oxygen concentration of flammable fuels, 174
RISK MANAGEMENT FILE, 149
RISK MANAGEMENT FILE, 165
SAFE WORKING LOAD, 39, 62, 150, 154, 155, 163, 164, 165, 167, 199, 200, 332
Definition, 37
MOBILE MEDICAL ELECTRIC EQUIPMENT, 250
Safety notice
Overflow, 181
Safety sign, 57, 58, 61, 62, 63, 66, 69, 73, 153, 166, 215, 249, 250, 331, 334, 336, 340, 341
SECONDARY CIRCUIT, 117, 123, 128, 237, 255, 274, 279, 280
Definition, 37
SELF-RESETTING THERMAL CUT-OUT, 202
Definition, 37
Non-, 189, 190, 202, 361
SEPARATION DEVICE, 212, 237, 323, 379, 380
Definition, 37
Serial number
ACCESSORY, 59
ME EQUIPMENT, 58
SERVICE PERSONNEL, 38, 51, 58, 63, 69, 72, 73, 74, 76, 91, 142, 166, 234, 247, 250, 253, 284, 285, 319
Definition, 37
Mechanism for isolating the SUPPLY MAINS, 139
Qualification of, 73
Rough surfaces, corners and edges, 288
Spurious microwave radiation, 168
Spurious X-radiation, 167
Servicing, 197, 235, 284, 287, 371
SEVERITY, 36, 231, 241, 243, 265, 291
Definition, 37
SIGNAL INPUT/OUTPUT PART, 70, 74, 83, 95, 105, 110, 112, 113, 117, 237, 265, 275, 323, 379, 386, 397
Definition, 37
SINGLE FAULT CONDITION, 26, 31, 33, 38, 44, 47, 48, 74, 77, 78, 81, 91, 92, 93, 95, 96, 97, 99, 101, 105, 108, 110, 112, 137, 148, 149, 158, 159, 171, 174, 177, 178, 182, 185, 186, 187, 188, 189, 207, 217, 234, 239, 243, 245, 246, 253, 254, 255, 256, 258, 265, 268, 269, 270, 271, 272, 275, 276, 283, 293, 298, 303, 304, 305, 306, 307, 309, 310, 324, 325, 349, 357, 358, 385
Definition, 38
Identification of ESSENTIAL PERFORMANCE, 45
Undetected, 246
SINGLE FAULT SAFE, 47, 148, 149, 187, 188, 243, 305, 319
Definition, 38
SIP/SOP
See SIGNAL INPUT/OUTPUT PART, 37
Software, 192, 195, 252, 310, 367
Maintenance, 311
STATIONARY
Definition, 38
Equipment, 287
ME EQUIPMENT, 57, 142, 179, 198
SUPPLEMENTARY INSULATION, 27, 115, 119, 154, 197, 229, 232, 258, 279, 388, 389, 390
Definition, 38

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SUPPLY MAINS, 30, 31, 32, 34, 46, 49, 56, 59, 60, 70, 73, 74, 75, 78, 88, 91, 110, 111, 120, 123, 145, 153, 209, 212, 213, 214, 232, 233, 234, 237, 241, 247, 251, 262, 263, 264, 274, 279, 280, 345
a.c., 51, 123, 263
Apparent impedance of, 73, 253
Characteristics of, 49, 50, 269
d.c., 52, 75, 263
Definition, 38
Interruption of, 183, 307, 328
Isolation from, 73, 139, 140, 252, 253, 284
Overvoltage category, 122, 123, 280
Polyphase, 82, 139, 191, 346
RATED values, 51
Single-phase, 82
Socket-outlet, 28
Switch, 139
Symbol, 39, 40, 58, 60, 61, 62, 63, 64, 65, 66, 67, 69, 71, 79, 92, 140, 151, 250, 274, 331, 334, 350
Technical description, 31, 50, 51, 53, 64, 68, 69, 70, 73, 79, 139, 234, 333
Ambient temperature, 119
Inspection, 79, 206
Installation instructions, 172
Operating temperature, 169, 173
Transient current, 212
Unique version identifier, 73
TENSILE SAFETY FACTOR, 47, 48, 161, 162, 165, 167, 293, 294, 295, 296, 298
Definition, 38
TENSILE STRENGTH, 38, 162
Definition, 38
TERMINAL DEVICE
Definition, 38
HIGH-VOLTAGE, 62, 250
MAINS TERMINAL DEVICE, 30
THERMAL CUT-OUT, 63, 169, 173, 186, 188, 190, 201, 202, 250
Definition, 38
Manual reset, 202
SELF-RESETTING THERMAL CUT-OUT, 37
THERMAL STABILITY, 172, 173, 188, 190, 191, 207, 208, 213
Definition, 38
THERMOSTAT, 189, 203, 332
Definition, 39
Failure of, 187, 202
TOOL, 22, 28, 34, 39, 52, 53, 56, 57, 62, 63, 75, 76, 77, 78, 79, 90, 91, 138, 143, 146, 148, 160, 166, 167, 168, 173, 201, 204, 212, 214, 215, 216, 247, 257, 287, 317, 319, 325, 351, 352, 380
Definition, 39
TOTAL LOAD, 38, 161, 162, 165, 294
Definition, 39
TOUCH CURRENT, 30, 95, 244, 251, 257, 269, 270, 271, 324, 378, 380
Definition, 39
Limit, 76, 91, 213, 237, 256, 305, 323, 376
ME SYSTEM, 93
Measurement, 96, 99, 112, 275
MULTIPLE SOCKET-OUTLET, 213, 323
SINGLE FAULT CONDITION, 234, 325
Value, 92, 93, 324
Transport and storage
Conditions, 62, 73, 201, 212, 253
Covers used during, 52
Data for, 73
Protective packaging, 62
TRANSPORTABLE
Definition, 39
Equipment, 32, 34, 41
ME EQUIPMENT, 57, 179, 181, 306
TRAPPING ZONE, 146, 148, 288
Definition, 39
TYPE B APPLIED PART, 40, 82, 113, 114, 237, 257, 262, 276, 386
Classification, 39, 47, 56, 76, 257, 268
DEFIBRILLATION-PROOF symbol, 339
Definition, 39
Marking of, 39, 61
Measurement, 109
PATIENT LEAKAGE CURRENT, 271
Symbol, 338
Total PATIENT LEAKAGE CURRENT, 271
TYPE BF APPLIED PART, 40, 113, 114, 237, 243, 257, 262, 271, 276, 277, 387
Classification, 28, 40, 47, 56, 76, 81, 257, 268
DEFIBRILLATION-PROOF symbol, 339
Definition, 40
Marking of, 40, 61
MEASUREMENT, 109
PATIENT LEAKAGE CURRENT, 271
Symbol, 338
Total PATIENT LEAKAGE CURRENT, 272
TYPE CF APPLIED PART, 76, 96, 114, 238, 243, 254, 257, 262, 269, 270, 276, 277
Classification, 28, 47, 56, 76, 81, 257, 268
DEFIBRILLATION-PROOF symbol, 339
Definition, 40
Marking of, 40, 61
MEASUREMENT, 109
PATIENT LEAKAGE CURRENT, 271
Symbol, 338
Total PATIENT LEAKAGE CURRENT, 272
TYPE TEST, 50, 115, 245, 388
COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS, 244
Definition, 40
Samples, 51, 246
Uninterruptible power supply (UPS), 212
USABILITY, 40, 184, 218, 247, 251, 307, 327
Definition, 40
USABILITY ENGINEERING, 68, 184, 238, 307
Definition, 40
PROCESS, 42, 197, 251
USABILITY ENGINEERING FILE
Definition, 42
Use by date
ACCESSORY, 59
ME EQUIPMENT, 58
VERIFICATION
Coverage criteria, 195, 311, 313, 314
Definition, 40
fuse or OVER-CURRENT RELEASE, 144
Methods, 193
Milestones, 195

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

of Markings, 330
PEMS, 195, 363
Plan, 195, 316
Polymer properties, 318
Results, 195, 312
RISK CONTROL measures, 316
Strategies, 195, 366
Tools, 195, 316, 317
Warning, 57, 61, 63, 66, 68, 69, 70, 71, 73, 74, 140, 145, 152, 153, 158, 211, 249, 251, 284, 287, 289, 322, 324, 331, 333, 334, 340, 371
Overflow, 181
WORKING VOLTAGE, 34, 81, 82, 83, 115, 116, 124, 125, 126, 128, 129, 209, 212, 232, 237, 238, 243, 244, 255, 259, 264, 279, 280, 281, 384
Definition, 41
Interpolation, 121, 282
Y1 Capacitor, 80
Y2 Capacitor, 80

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Publication IEC 60601-1 (Troisième édition – 2005) I-SH 01

APPAREILS ÉLECTROMÉDICAUX – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles

FEUILLE D'INTERPRÉTATION 1

La présente feuille d'interprétation a été établie par le SC 62A: Aspects généraux des équipements électriques utilisés en pratique médicale.

Le texte de la présente feuille d'interprétation est issu des documents suivants:

ISH	Rapport de vote
62A/599/ISH	62A/613/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette feuille d'interprétation.

Paragraphe 1.1

Ce paragraphe est clarifié par ce qui suit:

L'IEC 60601-1 ne s'applique pas aux systèmes de distribution de gaz médicaux couverts par l'ISO 7396-1, *Systèmes de distribution de gaz médicaux – Partie 1: Systèmes de distribution de gaz médicaux comprimés et de vide*.

NOTE Le paragraphe 6.3 de l'ISO 7396-1 applique l'exigence de l'IEC 60601-1-8 à certains signaux de surveillance et d'alarme.

Cette clarification reste valable jusqu'à la publication d'une nouvelle version de l'IEC 60601-1.

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Publication IEC 60601-1 (Troisième édition – 2005) I-SH 02

APPAREILS ÉLECTROMÉDICAUX –

Partie 1: Exigences générales pour la sécurité de base et les performances essentielles

FEUILLE D'INTERPRÉTATION 2

La présente feuille d'interprétation a été établie par le sous-comité 62A: Aspects généraux des équipements électriques utilisés en pratique médicale, du comité d'études 62 de l'IEC: Equipements électriques dans la pratique médicale.

Le texte de la présente feuille d'interprétation est issu des documents suivants:

ISH	Rapport de vote
62A/634/ISH	62A/640/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette feuille d'interprétation.

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Paragraphe 11.3

Ce paragraphe est clarifié par ce qui suit:

Tel qu'il est énoncé dans les justifications pour ce paragraphe, les ENVELOPPES pare-feu sont destinées à être utilisées uniquement lorsqu'il existe une probabilité importante de feu à cause de la présence d'une source d'inflammation (comme décrit dans le paragraphe) *et* une source *importante* de combustible. La plupart des matériaux utilisés pour la fabrication des APPAREILS EM ne sont pas considérés comme étant une source de combustible, sauf s'ils se trouvent en présence d'un ENVIRONNEMENT RICHE EN OXYGENE. Il convient que les fabricants déterminent, par des analyses documentées dans le DOSSIER DE GESTION DES RISQUES, si l'APPAREIL EM comprend des matériaux combustibles (carburant) dans des quantités suffisantes pour alimenter la combustion conjointement avec des sources d'inflammation (capables de dissiper plus de 900 J).

Paragraphe 13.1.2

Ce paragraphe est clarifié par ce qui suit:

Tel qu'il est énoncé au paragraphe 4.7, c'est l'ANALYSE DE RISQUE du FABRICANT qui détermine quels sont les composants susceptibles aux défaillances à l'essai, basé sur les RISQUE associés. Lorsque le RISQUE associé de feu dépasse les critères du fabricant pour l'acceptabilité du RISQUE, il convient d'accepter l'analyse de la simulation du fabricant (telle que l'analyse de modes de défaillance et de leurs effets – *FMEA, en anglais*) à la place de l'essai physique. Tel qu'il est également énoncé en 4.7, il est nécessaire de prendre en compte la fiabilité et les caractéristiques du composant dans les analyses de simulation de défaillance. Il convient que les composants électroniques usuels, dont l'historique d'utilisation ne les mentionne pas comme avoir été la cause d'incendies dans les appareils, ne soient pas considérés comme une source probable d'inflammation.

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Lorsque le paragraphe identifie "l'émission de flammes, de métal fondu, de substance toxique ou inflammable, en quantités dangereuses" comme une situation dangereuse, il est fait référence aux émissions de l'*ENVELOPPE*, et non pas des composants eux même. Lorsque le paragraphe identifie le "dépassement de 1,5 fois les valeurs autorisées pour 'autres composants et matières' identifiés au Tableau 22, moins 12,5 °C", cela s'applique uniquement au cas où cette situation aurait comme résultat un RISQUE inacceptable (tel qu'identifié dans l'ANALYSE DE RISQUE du FABRICANT selon 4.7). Typiquement, il s'agit des cas où les PERFORMANCES ESSENTIELLES ne seraient pas maintenues ou lorsque des énergies supérieures à 900 J seraient dissipées en présence de matériaux inflammables qui pourraient alimenter la combustion.

La première exemption à l'analyse de défaut ou à l'essai identifiée en 13.1.2 ("La construction ou le circuit d'alimentation limite la puissance dissipée en CONDITION DE PREMIER DÉFAUT à moins de 15 W ou l'énergie dissipée à moins de 900 J") est prévue pour être appliquée lorsque la conception même du composant ("La construction") ou l'utilisation de fusibles (ou d'autres dispositifs limiteurs de courant) dans le circuit d'alimentation ("ou le circuit d'alimentation") assurent le fait que l'énergie dissipée pendant les défaillances ne dépassera pas les limites. Pour la plupart des composants habituels des circuits, prévus pour fonctionner à une puissance inférieure à 5 Watt, l'énergie dissipée lorsque l'on court-circuite les sorties ne dépassera pas la limite de 900 J.

Cette clarification restera valable jusqu'à la publication d'une nouvelle version de l'IEC 60601-1.

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SC 62A/Publication IEC 60601-1:2005, y inclus l'Amendement 1:2012,
Troisième édition/I-SH 03

APPAREILS ÉLECTROMÉDICAUX – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles

FEUILLE D'INTERPRÉTATION 3

Cette feuille d'interprétation a été établie par le sous-comité 62A: Aspects généraux des équipements électriques utilisés en pratique médicale, du comité d'études 62 de l'IEC: Equipements électriques dans la pratique médicale.

Le texte de cette feuille d'interprétation est issue des documents suivants:

ISH	Rapport de vote
62A/858/ISH	62A/875/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette feuille d'interprétation.

Paragraphe 13.1.2 quatrième tiret (Emissions, déformation d'ENVELOPPE ou dépassement de température maximale)

Ce paragraphe stipule ce qui suit:

Les SITUATIONS DANGEREUSES suivantes ne doivent pas apparaître:

– ....

– températures de parties d'APPAREILS EM qui ne sont pas des PARTIES APPLIQUEES mais qui sont susceptibles d'être touchées et qui dépassent les valeurs autorisées du Tableau 23 lorsqu'elles sont mesurées et réglées comme indiqué en 11.1.3;

Ce point est clarifié comme suit:

L'exigence ci-dessus est considérée comme satisfaite conformément au Paragraphe 4.5 pour les températures à la surface de l'enveloppe, si les conditions suivantes sont remplies:

– la température maximale autorisée sur les surfaces accessibles à l'OPERATEUR en CONDITION DE PREMIER DEFAUT est de 105 °C; et

– les instructions d'utilisation contiennent un avertissement indiquant que, dans certaines CONDITIONS DE PREMIER DEFAUT, la température de: (*indiquer la surface concernée*) peut devenir très élevée créant un RISQUE potentiel de brûlure en cas de contact, et

– si l'ANALYSE DE RISQUE démontre qu'un symbole d'avertissement est nécessaire sur l'ENVELOPPE, le signe de sécurité ISO 7010-W018 () doit être utilisé sur où près de l'emplacement chaud sur l'ENVELOPPE; et

– l'APPRECIATION DU RISQUE démontre que la température atteinte en CONDITION DE PREMIER DEFAUT est acceptable, et

– l'APPRECIATION DU RISQUE démontre que l'application des mesures alternatives de GESTION DES RISQUES dans la présente feuille d'interprétation engendre un RISQUE RESIDUEL qui est comparable au RISQUE RESIDUEL qui résulte de l'application de l'exigence de la norme.

NOTE 1 La présente feuille d'interprétation est destinée à être utilisée à la fois avec l'Edition 3.0 et avec l'Edition 3.1 de l'IEC 60601-1.

Mai 2013 ICS 11.040

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NOTE 2 Un exemple d'une analyse qui démontre une probabilité jugée suffisamment faible d'apparition de DOMMAGE est donné ci-dessous.

Exemple d'APPRECIATION DU RISQUE:

Le taux de défaillance cumulé pour les parties qui pourraient augmenter la température de surface des parties de l'enveloppe de l'appareil XYZ touchables uniquement par l'OPERATEUR à des valeurs supérieures à celles du Tableau 23 obtenu par calcul est de 60 FIT (1 FIT = 1E-9/h) selon la norme américaine MIL-HDBK-217F où FIT est l'abréviation de "failure in time" (en français "fréquence de défaillance"). Dans le cas de telles défaillances, l'appareil émettrait une odeur et ne fonctionnerait plus correctement. On estime que dans un cas sur trois seulement l'appareil ne serait pas mis hors tension immédiatement et la surface chaude entraînerait une brûlure.

La probabilité globale qui résulterait d'un tel DOMMAGE lorsqu'un signe approprié est indiqué dans les instructions d'utilisation avec le signe de sécurité ISO 7010 W018 serait: probabilité = 1/3 * 60 FIT = 2 E-8/h =approx. 0,0002 par an.

Dans cet exemple, le critère d'acceptation du RISQUE WXW pour la société exige qu'un DOMMAGE de cette sévérité ait une probabilité inférieure à 0,0003 par an pour que le RISQUE associé soit considéré acceptable. Sur la base de ce critère d'acceptation du RISQUE, le RISQUE associé à la température excessive de l'ENVELOPPE causé par des défauts isolés dans les circuits est acceptable.

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SOMMAIRE

AVANT-PROPOS 421
INTRODUCTION 424
INTRODUCTION À L'AMENDEMENT 426
1 Domaine d'application, objet et normes connexes 427
1.1 * Domaine d'application 427
1.2 Objet 427
1.3 * Normes collatérales 428
1.4 * Normes particulières 428
2 * Références normatives 428
3 * Terminologie et définitions 433
4 Exigences générales 454
4.1 * Conditions d'application aux APPAREILS EM ou aux SYSTEMES EM 454
4.2 * PROCESSUS de GESTION DES RISQUES pour les APPAREILS EM ou SYSTEMES EM 455
4.3 * PERFORMANCE ESSENTIELLE 458
4.4 * DUREE DE VIE PREVUE 459
4.5 * ~~Sécurité équivalente~~ Mesures de MAITRISE DU RISQUE ou méthodes d'essai alternatives pour les APPAREILS EM ou les SYSTEMES EM 459
4.6 * Parties D'APPAREIL EM ou de SYSTEME EM en contact avec le PATIENT 459
4.7 * CONDITION DE PREMIER DEFAUT pour APPAREILS EM 460
4.8 * Composants des APPAREILS EM 460
4.9 * Utilisation de COMPOSANTS AUX CARACTERISTIQUES A HAUTE FIABILITE dans les APPAREILS EM 461
4.10 * Alimentation 462
4.11 Puissance absorbée 463
5 * Exigences générales relatives aux essais des APPAREILS EM 464
5.1 * ESSAIS DE TYPE 464
5.2 * Nombre de spécimens 464
5.3 Température ambiante, humidité, pression atmosphérique 464
5.4 Autres conditions 464
5.5 Tensions d'alimentation, type de courant, nature de l'alimentation, fréquence 465
5.6 Réparations et modifications 466
5.7 * Pré-conditionnement humide 466
5.8 Ordre des essais 466
5.9 * Détermination des PARTIES APPLIQUEES ET DES PARTIES ACCESSIBLES 467
6 * Classification des APPAREILS EM ET DES SYSTEMES EM 470
6.1 Généralités 470
6.2 * Protection contre les chocs électriques 470
6.3 * Protection contre les effets nuisibles de la pénétration d'eau ou de corps solides 470
6.4 Méthode(s) de stérilisation 470
6.5 Adaptation à l'utilisation dans un ENVIRONNEMENT RICHE EN OXYGENE 470
6.6 * Mode de fonctionnement 470
7 Identification, marquage et documentation des APPAREILS EM 471
7.1 Généralités 471
7.2 Marquage sur l'extérieur des APPAREILS EM ou parties d'APPAREILS EM (voir aussi Tableau C.1) 472

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

7.3 Marquage à l'intérieur des APPAREILS EM ou parties d'APPAREILS EM (voir aussi Tableau C.2) 477
7.4 Marquage des organes de commande et des instruments (voir aussi Tableau C.3) 479
7.5 Signes de sécurité 480
7.6 Symboles 481
7.7 Couleurs de l'isolation des conducteurs 482
7.8 * Voyants lumineux et organes de commande 482
7.9 DOCUMENTS D'ACCOMPAGNEMENT 483
8 * Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM 489
8.1 Règle fondamentale de protection contre les chocs électriques 489
8.2 Exigences liées aux sources d'énergie électrique 490
8.3 Classification des PARTIES APPLIQUEES 491
8.4 Limitation de la tension, du courant ou de l'énergie 491
8.5 Séparation des parties 494
8.6 * Mise à la terre de protection, mise à la terre fonctionnelle et égalisation des potentiels des APPAREILS EM 506
8.7 COURANTS DE FUITE et COURANTS AUXILIAIRES PATIENT 508
8.8 Isolation 532
8.9 * LIGNES DE FUITE ET DISTANCES DANS L'AIR 538
8.10 Composants et câblage 555
8.11 PARTIES RELIEES AU RESEAU, composants et montage 557
9 * Protection contre les DANGERS MECANIQUES des APPAREILS EM et SYSTEMES EM 563
9.1 DANGERS MECANIQUES des APPAREILS EM 563
9.2 * DANGERS MECANIQUES associés aux parties en mouvement 564
9.3 * DANGER MECANIQUE associé aux surfaces, angles et arêtes 571
9.4 * DANGERS d'instabilité 571
9.5 * DANGER de projections de pièces 577
9.6 Energie acoustique (y compris infra- et ultrasons) et vibrations 577
9.7 * Réservoirs et parties sous pression pneumatique et hydraulique 579
9.8 * DANGERS MECANIQUES associés aux systèmes de support 582
10 * Protection contre les DANGERS dus aux rayonnements involontaires ou excessifs 588
10.1 Rayonnements X 588
10.2 Rayonnements alpha, bêta, gamma, neutroniques et d'autres particules 589
10.3 Rayonnements à micro-ondes 589
10.4 * Lasers ~~et diodes émettrices lasers (LED)~~ 590
10.5 Autres rayonnements électromagnétiques visibles 590
10.6 Rayonnements infrarouges 590
10.7 Rayonnements ultraviolets 590
11 * Protection contres les températures excessives et les autres DANGERS 591
11.1 * Températures excessives à l'intérieur des APPAREILS EM 591
11.2 * Prévention du feu 595
11.3 * Exigences de construction pour les ENVELOPPES contre le feu des APPAREILS EM 600
11.4 * APPAREILS EM et SYSTEMES EM destinés à être utilisés avec des produits anesthésiques inflammables 603
11.5 * APPAREILS EM et SYSTEMES EM destinés à être utilisés avec des produits inflammables 603

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11.6 Débordement, renversement, fuites, pénétration d'eau ou de particules, nettoyage, désinfection, stérilisation et compatibilité avec des substances utilisées avec des APPAREILS EM 603
11.7 Biocompatibilité des APPAREILS EM et des SYSTEMES EM 605
11.8 * Coupure de l'alimentation / du RESEAU D'ALIMENTATION vers L'APPAREIL EM 606
12 * Précision des commandes, des instruments et protection contre les caractéristiques de sortie présentant des risques 606
12.1 Précision des commandes et des instruments 606
12.2 APTITUDE A L'UTILISATION de l'APPAREIL EM 606
12.3 SYSTEMES D'ALARME 606
12.4 Protection contre les caractéristiques de sortie présentant des risques 606
13 * SITUATIONS DANGEREUSES et conditions de défaut pour les APPAREILS EM 608
13.1 SITUATIONS DANGEREUSES particulières 608
13.2 CONDITIONS DE PREMIER DEFAUT 609
14 * SYSTEMES ELECTROMEDICAUX PROGRAMMABLES (SEMP) 615
14.1 * Généralités 615
14.2 * Documentation 616
14.3 * Plan de GESTION DES RISQUES 616
14.4 * CYCLE DE DEVELOPPEMENT DE SEMP 616
14.5 * Résolution des problèmes 617
14.6 PROCESSUS de GESTION DES RISQUES 617
14.7 * Spécification des exigences 618
14.8 * Architecture 618
14.9 * Conception et réalisation 618
14.10 * VERIFICATION 618
14.11 * VALIDATION SEMP 619
14.12 * Modification 619
14.13 * ~~Connexion de SEMP par un COUPLAGE DE RESEAUX / DONNEES à d'autres appareils~~ SEMP destiné à être incorporé dans un RESEAU INFORMATIQUE 620
15 Construction de L'APPAREIL EM 621
15.1 * Groupements des commandes et indicateurs des APPAREILS EM 621
15.2 * Aptitude à l'entretien 621
15.3 Résistance mécanique 621
15.4 Composants et assemblage général des APPAREILS EM 626
15.5 * TRANSFORMATEURS D'ALIMENTATION des APPAREILS EM et transformateurs assurant la séparation conformément à 8.5 632
16 * SYSTEMES EM 636
16.1 * Exigences générales pour les SYSTEMES EM 636
16.2 * DOCUMENTS D'ACCOMPAGNEMENT d'un SYSTEME EM 637
16.3 * Alimentation 638
16.4 ENVELOPPES 638
16.5 * DISPOSITIFS DE SEPARATION 638
16.6 * COURANTS DE FUITE 639
16.7 * Protection contre les DANGERS MECANIQUES 640
16.8 Interruption de l'alimentation électrique de parties d'un SYSTEME EM 640
16.9 Connexions et câblage de SYSTEME EM 640
17 * Compatibilité électromagnétique des APPAREILS ET DES SYSTEMES EM 642
Annexe A (informative) Lignes directrices générales et justifications 644
Annexe B (informative) Ordre des essais 765

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Annexe C (informative) Guide pour le marquage et exigences d'étiquetage pour les APPAREILS EM et les SYSTEMES EM 769
Annexe D (informative) Symboles des marquages (voir Article 7) 773
Annexe E (informative) Exemples de connexion du dispositif de mesure (DM) pour la mesure du COURANT DE FUITE PATIENT et du COURANT AUXILIAIRE PATIENT (voir 8.7) 782
Annexe F (informative) Circuits d'alimentation de mesure adaptés 784
Annexe G (normative) Protection contre les DANGERS d'inflammation des mélanges anesthésiques inflammables 787
Annexe H (informative) Structure de SEMP, CYCLE DE DEVELOPPEMENT SEMP et documentation 803
Annexe I (informative) Aspects des SYSTEMES EM 817
Annexe J (informative) Etude des chemins d'isolation 823
Annexe K (informative) Schémas simplifiés de COURANT DE FUITE PATIENT 826
Annexe L (normative) Fils de bobinage isolés pour utilisation sans isolation intercalée 829
Annexe M (normative) Réduction des degrés de pollution 832
Bibliographie 833
INDEX 837
INDEX DES ABREVIATIONS ET ACRONYMES 857

Figure 1 – Raccordement au réseau non fixé à demeure (voir définitions) 435
Figure 2 – Exemple de bornes et conducteurs définis (voir définitions) 436
Figure 3 – Exemple d'APPAREIL EM DE CLASSE I 437
Figure 4 – Exemple d' APPAREIL EM DE CLASSE II sous enveloppe métallique 437
Figure 5 – Schéma fonctionnel pour la qualification des composants 462
Figure 6 – Doigt d'essai normalisé 468
Figure 7 – Crochet d'essai 469
Figure 8 – Broche d'essai 493
Figure 9 – Application de la tension d'essai ~~aux~~ à des CONNEXIONS PATIENT reliées entre elles pour les PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION 501
Figure 10 – Application de la tension d'essai ~~aux~~ à des CONNEXIONS PATIENT individuelles pour les PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION 503
Figure 11 – Application de la tension d'essai pour tester l'énergie de défibrillation délivrée 505
Figure 12 – Exemple de dispositif de mesure et de ses caractéristiques de fréquence 511
Figure 13 – Circuit de mesure pour le COURANT DE FUITE A LA TERRE des APPAREILS EM de la CLASSE I, avec ou sans PARTIE APPLIQUEE 514
Figure 14 – Circuit de mesure pour le COURANT DE CONTACT 516
Figure 15 – Circuit de mesure pour le COURANT DE FUITE PATIENT provenant de la CONNEXION PATIENT à la terre 518
Figure 16 – Circuit de mesure pour le COURANT DE FUITE PATIENT ~~à travers~~ via la ~~ou~~ (les) CONNEXION(S) PATIENT d'une PARTIE APPLIQUEE DE TYPE F ~~vers~~ à la terre, ~~causé~~ provoqué par une tension externe sur la ~~ou~~ (les) CONNEXION(S) PATIENT 520
Figure 17 – Circuit de mesure pour le COURANT DE FUITE PATIENT ~~provenant~~ de la ou des CONNEXION(S) PATIENT ~~vers~~ à la terre, ~~causé~~ provoqué par une tension externe sur une ENTREE/SORTIE DE SIGNAL 522

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Figure 18 – Circuit de mesure pour le COURANT DE FUITE PATIENT ~~provenant~~ de la ou des CONNEXION(S) PATIENT ~~vers~~ à la terre, ~~causé~~ provoqué par une tension externe sur une PARTIE ACCESSIBLE métallique qui n'est pas PROTEGEE PAR MISE A LA TERRE) 524

Figure 19 – Circuit de mesure pour le COURANT AUXILIAIRE PATIENT 525

Figure 20 – Circuit de mesure pour le COURANT DE FUITE PATIENT total avec toutes les CONNEXIONS PATIENT de toutes les PARTIES APPLIQUEES du même type (PARTIES APPLIQUEES DE TYPE B, BF ou TYPE CF) connectées ensemble 526

Figure 21 – Appareillage pour l'essai à la bille 538

Figure 22 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 1 551

Figure 23 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 2 551

Figure 24 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 3 551

Figure 25 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 4 552

Figure 26 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 5 552

Figure 27 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 6 552

Figure 28 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 7 553

Figure 29 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 8 553

Figure 30 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 9 554

Figure 31 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 10 555

Figure 32 – Rapport entre la PRESSION d'essai HYDRAULIQUE et la PRESSION MAXIMALE ADMISSIBLE DE FONCTIONNEMENT 581

Figure 33 – ~~Masse d'essai~~ Module de chariot supérieur représentant le corps ~~humain~~ 587

Figure 34 – Appareillage d'essai d'inflammation par étincelles 597

Figure 35 – Courant maximal admissible *I* en fonction de la tension maximale admissible *U* mesuré dans un circuit purement résistif dans un ENVIRONNEMENT RICHE EN OXYGENE 597

Figure 36 – Tension maximale admissible *U* en fonction de la capacité *C* mesurée dans un circuit capacitif utilisé dans un ENVIRONNEMENT RICHE EN OXYGENE 598

Figure 37 – Courant maximal admissible *I* en fonction de l'inductance *L* mesurée dans un circuit inductif dans un ENVIRONNEMENT RICHE EN OXYGENE 598

Figure 38 – Déflecteur 602

Figure 39 – Zone du fond d'une ENVELOPPE comme spécifié en 11.3 b) 1) 602

Figure A.1 – Identification de l'APPAREIL EM, des PARTIES APPLIQUEES et des CONNEXIONS PATIENT dans un moniteur d'électrocardiogramme 650

Figure A.2 – Exemple d'isolation d'une PARTIE APPLIQUEE DE TYPE F avec isolation incorporée dans l'APPAREIL EM 651

Figure A.3 – Identification de l'APPAREIL EM, DES PARTIES APPLIQUEES et des CONNEXIONS PATIENT dans un moniteur PATIENT avec dispositifs de surveillance endovasculaire de la pression 651

Figure A.4 – Identification de l'APPAREIL EM, DES PARTIES APPLIQUEES et des CONNEXIONS PATIENT dans un moniteur PATIENT multifonctions avec dispositifs de surveillance endovasculaire de la pression 652

Figure A.5 – Identification des PARTIES APPLIQUEES et des CONNEXIONS PATIENT dans un SYSTEME EM A RAYONS X 653

Figure A.6 – Identification de l'APPAREIL EM, des PARTIES APPLIQUEES et des CONNEXIONS PATIENT dans un neurostimulateur électrique transcutané (TENS) destiné à être porté sur la ceinture du PATIENT et connecté à des électrodes sur le haut du bras du PATIENT 654

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Figure A.7 – Identification de l'APPAREIL EM ou du SYSTEME EM, des PARTIES APPLIQUEES et des CONNEXIONS PATIENT dans un micro-ordinateur avec un module d'électrocardiogramme 655

Figure A.8 – Représentation graphique de la relation du DANGER, de la séquence d'évènements, de SITUATION DANGEREUSE et de DOMMAGE 659

Figure A.9 – Exemple d'ENVIRONNEMENT DU PATIENT 665

Figure A.10 – Circuit flottant 685

Figure A.11 – Interruption d'un conducteur d'alimentation entre des parties de l'APPAREIL EM dans des ENVELOPPES séparées 688

Figure A.12 – Identification des MOYENS DE PROTECTION DU PATIENT et des MOYENS DE PROTECTION DE L'OPERATEUR 693

Figure A.13 – Impédance de terre de protection admissible avec courant de défaut limité 700

Figure A.14 – Probabilité de fibrillation ventriculaire 706

Figure A.15 – Exemple d'un circuit de mesure pour le COURANT DE FUITE PATIENT entre une CONNEXION PATIENT et la terre pour un APPAREIL EM avec CONNEXIONS PATIENT multiples 711

Figure A.16 – Conditions de l'essai d'instabilité 723

Figure A.17 – Exemple de détermination du FACTEUR DE TRACTION DE SECURITE au moyen du Tableau 21 731

Figure A.18 – Exemple de détermination des charges de calcul et d'essai 732

Figure A.19 – Exemple de distribution de masse du corps humain 732

Figure A.20 – Relations entre les termes utilisés pour décrire les appareils, les ACCESSOIRES ou les parties d'appareils 661

Figure A.21 – Exemple d'APPAREIL EM disposant de deux fonctions différentes sur un circuit commun de PARTIE APPLIQUEE 698

Figure A.22 – Température autorisée maximale pour les surfaces et les PARTIES APPLIQUEES à des altitudes plus élevées 737

Figure A.23 – Exemple de MOYEN DE PROTECTION DE L'OPERATEUR nécessaire entre les bornes d'une ALIMENTATION ELECTRIQUE INTERNE et un dispositif de protection complémentaire 756

Figure E.1 – PARTIE APPLIQUEE DE TYPE B 782

Figure E.2 – PARTIE APPLIQUEE DE TYPE BF 782

Figure E.3 – PARTIE APPLIQUEE DE TYPE CF 783

Figure E.4 – Courant auxiliaire patient 783

Figure E.5 – Charge des CONNEXIONS PATIENT si elles sont spécifiées par le FABRICANT 783

Figure F.1 – Circuit d'alimentation de mesure avec un côté du RESEAU D'ALIMENTATION approximativement au potentiel de terre 784

Figure F.2 – Circuit d'alimentation de mesure avec RESEAU D'ALIMENTATION approximativement symétrique au potentiel de terre 784

Figure F.3 – Circuit d'alimentation de mesure pour les APPAREILS EM polyphasés spécifiés pour connexion à un RESEAU D'ALIMENTATION polyphasé 785

Figure F.4 – Circuit d'alimentation de mesure pour les APPAREILS EM monophasés spécifiés pour connexion à un RESEAU D'ALIMENTATION polyphasé 785

Figure F.5 – Circuit d'alimentation de mesure pour les APPAREILS EM ayant une unité d'alimentation séparée ou destiné à recevoir sa puissance d'un autre appareil du SYSTEME EM 786

Figure G.1 – Courant maximal admissible I_{ZR} en fonction de la tension maximale admissible U_{ZR} mesuré dans un circuit purement résistif avec le mélange le plus facilement inflammable de vapeur d'éther et d'air 793

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Figure G.2 – Tension maximale admissible U_{ZC} en fonction de la capacité C_{max} mesurée dans un circuit capacitif avec le mélange le plus facilement inflammable de vapeur d'éther et d' air 794

Figure G.3 – Courant maximal admissible I_{ZL} en fonction de l'inductance L_{max} mesurée dans un circuit inductif avec le mélange le plus facilement inflammable de vapeur d'éther et d'air 794

Figure G.4 – Courant maximal admissible I_{ZR} en fonction de la tension maximale admissible U_{ZR} mesuré dans un circuit purement résistif avec le mélange le plus facilement inflammable de vapeur d'éther et d'oxygène 799

Figure G.5 – Tension maximale admissible U_{ZC} en fonction de la capacité C_{max} mesurée dans un circuit capacitif avec le mélange le plus facilement inflammable de vapeur d'éther et d'oxygène 800

Figure G.6 – Courant maximal admissible I_{ZL} en fonction de l'inductance L_{max} mesurée dans un circuit inductif avec le mélange le plus facilement inflammable de vapeur d'éther et d'oxygène 800

Figure G.7 – Appareillage d'essai 802

Figure H.1 – Exemples de structures SEMP/ SSEP 804

Figure H.2 – Modèle de CYCLE DE DEVELOPPEMENT DE SEMP 805

Figure H.3 – ~~Exigences de documentation de SEMP de l'Article 14 et de l'ISO 14971:2000~~ Non utilisée 809

Figure H.4 – Exemple de paramètres potentiels dont la spécification peut être exigée pour ~~le COUPLAGE DE RESEAUX/DONNEES~~ un RESEAU INFORMATIQUE 816

Figure I.1 – Exemple de construction de SOCLE DE PRISES MULTIPLES (SPM) (accessible uniquement à l'aide d'un outil) 821

Figure I.2 – Exemples d'application de SOCLES DE PRISES MULTIPLES (SPM) 822

Figure J.1 – Isolation, exemple 1 823

Figure J.2 – Isolation, exemple 2 823

Figure J.3 – Isolation, exemple 3 823

Figure J.4 – Isolation, exemple 4 824

Figure J.5 – Isolation, exemple 5 824

Figure J.6 – Isolation, exemple 6 825

Figure J.7 – Isolation, exemple 7 825

Figure K.1 – APPAREIL EM avec ENVELOPPE en matière isolante 826

Figure K.2 – APPAREIL EM avec PARTIE APPLIQUEE DE TYPE F 826

Figure K.3 – APPAREIL EM avec une PARTIE APPLIQUEE et une PARTIE E/S DE SIGNAL 827

Figure K.4 – APPAREIL EM avec une CONNEXION PATIENT d'une PARTIE APPLIQUEE DE TYPE B qui n'est pas PROTEGEE PAR MISE A LA TERRE 827

Figure K.5 – APPAREIL EM avec une CONNEXION PATIENT d'une PARTIE APPLIQUEE DE TYPE BF qui n'est pas PROTEGEE PAR MISE A LA TERRE 828

Tableau 1 – Unités n'appartenant pas au système SI qui peuvent être utilisées sur les APPAREILS EM 480

Tableau 2 – Couleurs des voyants lumineux et leur signification pour les APPAREILS EM 483

Tableau 3 – * Valeurs admissibles des COURANTS DE FUITE PATIENT et des COURANTS AUXILIAIRES PATIENT EN CONDITION NORMALE ET EN CONDITION DE PREMIER DEFAUT 512

Tableau 4 – * Valeurs admissibles des COURANTS DE FUITE PATIENT dans les conditions d'essais particulières identifiées en 8.7.4.7 513

Tableau 5 – Légendes des symboles pour les Figures 9 à 11 et 13 à 20, Figure A.15, Annexes E et F 527

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Tableau 6 – Tensions d'essai pour l'isolation solide formant un MOYEN DE PROTECTION 535
Tableau 7 – Tensions d'essai pour les MOYENS DE PROTECTION DE L'OPERATEUR 536
Tableau 8 – Facteurs de multiplication pour les distances dans l'air pour des altitudes jusqu'à 5 000 m 539
Tableau 9 – Classification des groupes de matériaux 540
Tableau 10 – TENSION TRANSITOIRE RESEAU 541
Tableau 11 – ~~LIGNES DE FUITE et DISTANCES DANS L'AIR minimales entre parties de polarité opposée de la PARTIE RELIEE AU RESEAU~~ Non utilisé 543
Tableau 12 – LIGNES DE FUITE et DISTANCES DANS L'AIR minimales assurant des MOYENS DE PROTECTION DU PATIENT 544
Tableau 13 – DISTANCES DANS L'AIR minimales assurant un MOYEN DE PROTECTION à L'OPERATEUR vis à vis de la PARTIE RELIEE AU RESEAU 545
Tableau 14 – DISTANCES DANS L'AIR complémentaires pour l'isolation dans les PARTIES RELIEES AU RESEAU avec des TENSIONS DE SERVICE CRETE dépassant la valeur de crête de la TENSION RESEAU NOMINALE [a] 546
Tableau 15 – DISTANCES DANS L'AIR minimales pour MOYENS DE PROTECTION DE L'OPERATEUR dans des CIRCUITS SECONDAIRES 547
Tableau 16 – LIGNES DE FUITE minimales assurant un MOYEN DE PROTECTION DE L'OPERATEUR [a] 548
Tableau 17 – Section NOMINALE des conducteurs d'un CABLE D'ALIMENTATION 559
Tableau 18 – Essais des dispositifs d'arrêt de traction 560
Tableau 19 – DANGERS MECANIQUES couverts par le présent article 564
Tableau 20 – Espaces acceptables [a] 566
Tableau 21 – Détermination du FACTEUR DE SECURITE EN TRACTION 583
Tableau 22 – Températures maximales admissibles des parties 591
Tableau 23 – Températures maximales admissibles pour les parties des APPAREILS EM qui sont susceptibles d'être touchées 592
Tableau 24 – Températures maximales admissibles pour le contact de la peau avec des PARTIES APPLIQUEES des APPAREILS EM 592
Tableau 25 – Perforation acceptable du fond d'une ENVELOPPE 601
Tableau 26 – * Limites de température des enroulements de moteurs 612
Tableau 27 – Température maximale stabilisée d'un enroulement moteur 614
Tableau 28 – Matrice d'essai de résistance mécanique 622
Tableau 29 – Hauteur de chute 624
Tableau 30 – Couples d'essai pour les commandes par rotation 630
Tableau 31 – Températures maximales admissibles des enroulements des transformateurs dans des conditions de surcharge et de court-circuit à une température ambiante de 25 °C (± 5 °C) 633
Tableau 32 – Courant d'essai pour les transformateurs 634
Tableau 33 – Conditions d'essai pour l'essai des butées d'extrémité pour dépassement de course 570
Tableau A.1 – Valeurs de la DISTANCE DANS L'AIR et de la LIGNE DE FUITE tirées du Tableau 7 de l'IEC 61010-1:2001 et du Tableau 12 714
Tableau A.2 – LIGNES DE FUITE pour éviter les défaillances dues au cheminement de l'IEC 60664-1 715
Tableau A.3 – Conditions de l'essai d'instabilité 723
Tableau A.4 – Durée d'exposition admissible pour le niveau d'accélération 726

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Tableau A.5 – Conseils sur les températures de surface pour les APPAREILS EM qui génèrent des températures basses (fraîches) pour des besoins thérapeutiques ou dans le cadre de leur fonctionnement 737
Tableau C.1 – Marquage à l'extérieur des APPAREILS EM, des SYSTEMES EM ou de leurs parties 769
Tableau C.2 – Marquage à l'intérieur des APPAREILS EM, des SYSTEMES EM ou de leurs parties 770
Tableau C.3 – Marquage des commandes et des instruments 770
Tableau C.4 – DOCUMENTS D'ACCOMPAGNEMENT, généralités 771
Tableau C.5 – DOCUMENTS D'ACCOMPAGNEMENT, instructions d'utilisation 772
Tableau D.1 – Symboles généraux 774
Tableau D.2 – Signes de sécurité 779
Tableau D.3 – Codes généraux 781
Tableau G.1 – Etanchéité aux gaz des entrées de câbles 796
Tableau H.1 – ~~Classification de COUPLAGE DE RESEAUX / DONNEES~~ Non utilisé 814
Tableau I.1 – Exemples de SYSTEMES EM pour illustration 819
Tableau L.1 – Diamètre du mandrin 830
Tableau L.2 – Température du four 830
Tableau M.1 – Réduction du degré de pollution de l'environnement interne grâce à l'utilisation d'une protection supplémentaire 832

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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APPAREILS ÉLECTROMÉDICAUX –

Partie 1: Exigences générales pour la sécurité de base et les performances essentielles

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Cette version consolidée de l'IEC 60601-1 porte le numéro d'édition 3.1. Elle comprend la troisième édition (2005-12) [documents 62A/505A/FDIS et 62A/512/RVD] et son amendement 1 (2012-07) [documents 62A/805/FDIS et 62A/820/RVD]. Le contenu technique est identique à celui de l'édition de base et à son amendement.

Cette version consolidée inclut le contenu des corrigenda 1 (2006-12) et 2 (2007-12), le contenu du corrigendum à l'Amendement 1 (2014-07), ainsi que les feuilles d'interprétation 1 (2008-04), 2 (2009-01) et 3 (2013-05).

Dans cette version Redline, une ligne verticale dans la marge indique où le contenu technique est modifié par l'amendement 1. Les ajouts sont en vert, les suppressions sont en rouge, barrées. Une version Finale avec toutes les modifications acceptées est disponible dans cette publication.

La Norme internationale IEC 60601-1 a été établie par le sous-comité 62A: Aspects généraux des équipements électriques utilisés en pratique médicale, du comité d'études 62 de l'IEC: Equipements électriques dans la pratique médicale.

Cette troisième édition annule et remplace la deuxième édition publiée en 1988, son Amendement 1 (1991) et son Amendement 2 (1995), la deuxième édition de l'IEC 60601-1-1 publiée en 2000 et la première édition de l'IEC 60601-1-4 publiée en 1996 ainsi que son Amendement 1 (1999). Cette édition constitue une révision technique. Des modifications importantes de structure ont été apportées à la présente édition. L'alignement des exigences électriques sur celles applicables aux matériels de traitement de l'information couverts par l'IEC 60950-1 a été poursuivi et il a été ajouté l'exigence d'inclure un PROCESSUS de GESTION DES RISQUES. Se reporter à l'~~Article~~ Annexe A.3 pour une description développée de cette révision.

Cette publication a été rédigée selon les Directives ISO/IEC, Partie 2.

Dans la présente norme, les caractères suivants sont employés:

– Exigences et définitions: caractères romains

– *Modalités d'essais : caractères italiques*

– Les indications de nature informative apparaissant hors des tableaux, comme les notes, les exemples et les références: petits caractères. Le texte normatif à l'intérieur des tableaux est également en petits caractères.

– TERMES UTILISES DANS LA PRESENTE NORME QUI SONT DEFINIS A L'ARTICLE 3 ET EGALEMENT INDIQUES DANS L'INDEX: PETITES MAJUSCULES.

Concernant la structure de la présente norme, le terme:

– "article" désigne l'une des dix-sept sections numérotées dans la table des matières, avec toutes ses subdivisions (par exemple, l'Article 7 inclut les Paragraphes 7.1, 7.2, etc.) ;

– "paragraphe" désigne une subdivision numérotée d'un article (par exemple 7.1, 7.2 et 7.2.1 sont tous des paragraphes appartenant à l'Article 7).

Dans la présente norme, les références à des articles sont précédées du mot "Article" suivi du numéro de l'article concerné. Dans la présente norme, les références aux paragraphes utilisent uniquement le numéro du paragraphe concerné.

Dans la présente norme, la conjonction "ou" est utilisée avec la valeur d'un "ou inclusif", ainsi un énoncé est vrai si une combinaison des conditions quelle qu'elle soit est vraie.

Les formes verbales utilisées dans la présente norme sont conformes à l'usage donné à l'Annexe G des Directives ISO/IEC, Partie 2. Pour les besoins de la présente norme:

– "devoir" mis au présent de l'indicatif signifie que la satisfaction à une exigence ou à un essai est obligatoire pour la conformité à la présente norme ;

– "il convient/il est recommandé" signifie que la satisfaction à une exigence ou à un essai est recommandée mais n'est pas obligatoire pour la conformité à la présente norme ;

– "pouvoir" mis au présent de l'indicatif est utilisé pour décrire un moyen admissible pour satisfaire à une exigence ou à un essai.

Lorsqu'un astérisque (*) est utilisé comme premier caractère devant un titre, au début d'un titre d'alinéa ou de tableau, il indique l'existence d'une ligne directrice ou d'une justification à consulter à l'Annexe A.

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- reconduite;
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- remplacée par une édition révisée, ou
- amendée.

NOTE L'attention des Comités Nationaux est attirée sur le fait que les fabricants d'appareils et les organismes d'essai peuvent avoir besoin d'une période transitoire après la publication d'une nouvelle publication IEC ou ISO, ou d'une publication amendée ou révisée, pour fabriquer des produits conformes aux nouvelles exigences et pour adapter leurs équipements aux nouveaux essais ou aux essais révisés. Le comité recommande que le contenu de cette publication soit entériné au niveau national au plus tôt 3 ans après la date de publication.

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INTRODUCTION

En 1976, le sous-comité 62A a publié la première édition de l'IEC/TR 60513, *Aspects fondamentaux des normes de sécurité pour les appareils électromédicaux*. La première édition de l'IEC/TR 60513 a servi de base à l'établissement:

– de la première édition de l'IEC 60601-1 (la norme de SECURITE CHAPEAU pour les APPAREILS ELECTROMEDICAUX) ;

– de la série IEC 60601-1-xx des normes collatérales pour les APPAREILS ELECTROMEDICAUX ;

– de la série IEC 60601-2-xx des normes particulières pour les différents types D'APPAREILS ELECTROMEDICAUX, et

– de la série IEC 60601-3-xx des normes de performances pour les différents types D'APPAREILS ELECTROMEDICAUX.

Consciente qu'il était nécessaire et urgent d'avoir une norme traitant des appareils utilisés dans la pratique médicale, la majorité des comités nationaux a émis, en 1977, un vote favorable pour la première édition de l'IEC 60601-1, issue d'un projet qui, à l'époque, représentait une première approche de ce problème. L'étendue du domaine d'application, la complexité des appareils concernés, la spécificité de certaines mesures de protection et des essais de vérification correspondants avaient exigé des années d'effort pour aboutir à cette première norme dont on peut à présent affirmer qu'elle a servi de référence universelle depuis sa publication.

L'application fréquente de la première édition a cependant montré que des améliorations étaient possibles. Ces améliorations étaient d'autant plus souhaitables que cette norme a connu un large succès depuis sa publication.

Le travail de révision qui a été entrepris et poursuivi avec soin pendant des années a donné lieu à la deuxième édition en 1988. Cette édition comporte toutes les améliorations qu'il était raisonnable d'envisager à l'époque. D'autres développements ont fait l'objet d'études de manière suivie. La deuxième édition a été modifiée en 1991 puis une nouvelle fois en 1995.

A l'origine, l'approche de l'IEC consistait à établir séparément des normes de "SECURITE DE BASE" et des normes de "PERFORMANCES ESSENTIELLES" pour les APPAREILS ELECTROMEDICAUX. Cela s'inscrivait naturellement dans l'approche historique qui prévalait au niveau national et international pour d'autres normes sur les appareils électriques (par exemple celles pour les appareils électrodomestiques), à savoir que la SECURITE DE BASE obéissait à des normes obligatoires mais que les autres spécifications de "performances" obéissaient aux demandes du marché. Dans ce contexte, il a été dit que "L'aptitude d'une bouilloire électrique à faire bouillir de l'eau est sans importance pour son utilisation en toute sécurité!"

Il est maintenant reconnu que cela ne correspond pas à la situation de nombreux éléments constituant les APPAREILS ELECTROMEDICAUX, et les ORGANISMES RESPONSABLES doivent se référer à des normes pour assurer à la fois les PERFORMANCES ESSENTIELLES et la SECURITE DE BASE. Parmi ces domaines, il y a la précision avec laquelle l'appareil contrôle la délivrance d'énergie ou de substances thérapeutiques à un PATIENT ou traite et affiche les données physiologiques qui influeront sur le suivi du patient.

Reconnaître cela signifie qu'il est d'une certaine façon inapproprié de séparer la "SECURITE DE BASE" et les "performances" lorsqu'on s'intéresse aux DANGERS qui résultent d'une conception inadéquate des APPAREILS ELECTROMEDICAUX. De nombreuses normes particulières de la série IEC 60601-2-xx traitent d'un ensemble d'exigences de PERFORMANCES ESSENTIELLES qui ne peuvent pas être directement évaluées par L'ORGANISME RESPONSABLE si celui-ci n'applique pas de telles normes. (Cependant, la série actuelle IEC 60601 comprend moins d'exigences de PERFORMANCES ESSENTIELLES que de SECURITE DE BASE).

Dans la perspective d'une troisième édition de l'IEC 60601-1, le sous-comité 62A de l'IEC avait établi, en 1994, une deuxième édition de l'IEC/TR 60513 [12] [1)]. Il était prévu que la deuxième édition de l'IEC/TR 60513 de l'IEC donnerait des lignes directrices pour

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l'établissement de la présente édition de l'IEC 60601-1 et pour l'évolution ultérieure des séries IEC 60601-1-xx et IEC 60601-2-xx.

Pour assurer la cohérence entre les normes internationales, pour répondre aux attentes actuelles des milieux médicaux et pour s'aligner sur les évolutions dans la série IEC 60601-2-xx, la deuxième édition de l'IEC/TR 60513 inclut deux principes majeurs nouveaux:

– la première modification concerne le concept de "SECURITE" qui a été étendu à partir des aspects de SECURITE DE BASE dans la première et dans la deuxième édition de l'IEC 60601-1 pour inclure les aspects de PERFORMANCES ESSENTIELLES (par exemple la précision des appareils de surveillance physiologique). L'application de ce principe conduit à la modification du titre de "Appareils électromédicaux – Partie 1: Règles générales de sécurité" dans la deuxième édition en "Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles";

– la deuxième modification concerne la spécification d'exigences minimales de sécurité, prévoyant l'évaluation de l'adéquation du PROCESSUS de conception lorsque celle-ci constitue la seule méthode pratique d'évaluation de la sécurité de certaines technologies comme les systèmes électroniques programmables. L'application de ce principe est un des facteurs qui conduit à l'introduction d'une exigence générale d'application d'un PROCESSUS de GESTION DES RISQUES. Parallèlement à la préparation de cette troisième édition de l'IEC 60601-1, un projet conjoint avec le TC 210 de l'ISO a donné lieu à la publication d'une norme générale pour la GESTION DES RISQUES des appareils médicaux. La conformité avec la présente édition de l'IEC 60601-1 ~~exige que le FABRICANT possède un PROCESSUS D'ANALYSE DES RISQUES conforme à l'ISO 14971 en vigueur~~ nécessite que le FABRICANT mette en place un PROCESSUS de GESTION DES RISQUES qui soit conforme aux parties de l'ISO 14971 (voir 4.2).

La présente norme contient les exigences concernant la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES qui sont généralement applicables aux APPAREILS ELECTROMEDICAUX. Pour certains types D'APPAREIL ELECTROMEDICAUX, ces exigences sont soit complétées soit modifiées par des exigences spécifiques données dans une norme collatérale ou une norme particulière. Lorsqu'il existe une norme particulière, il est recommandé de ne pas utiliser la présente norme générale seule.

L'Amendement 1 à la présente norme est destiné à traiter:

– les sujets identifiés par les Comités Nationaux et d'autres parties prenantes depuis la publication de l'IEC 60601-1:2005;

– la manière dont la GESTION DES RISQUES a été introduite dans l'IEC 60601-1:2005; et

– la manière dont le concept de PERFORMANCE ESSENTIELLE est utilisé dans la IEC 60601-1:2005.

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INTRODUCTION À L'AMENDEMENT

La troisième édition de l'IEC 60601-1 a été publiée en 2005. À la date de la publication, l'on trouvait 94 commentaires des Comités nationaux sur le 2ème CDV et le FDIS qui furent différés à un amendement ou une révision futur(e). Chacun de leurs commentaires différés a été saisi dans une fiche spéciale par le secrétariat du SC 62A. Au moment de la réunion d'Auckland en avril 2008, les Sous-comités avaient développé deux fiches d'interprétation et le secrétariat du SC 62A avait reçu 15 commentaires supplémentaires des Comités nationaux et d'autres parties prenantes.

À la réunion d'Auckland, l'IEC/CE 62 a approuvé un projet de développement du 1er amendement à l'IEC 60601-1:2005 basé sur les sujets en cours à ce moment. Le CE a approuvé le développement du 1er amendement en vue de traiter les problèmes en cours, comprenant sans limitation:

– ceux qui sont énumérés dans le 62A/593/DC et le 62A/602/INF;
– la manière dont la gestion des risques a été introduite dans l'IEC 60601-1:2005; et
– la manière dont le concept de performances essentielles est utilisé dans l'IEC 60601-1:2005.

Depuis la réunion d'Auckland, le secrétariat a reçu 73 commentaires supplémentaires des Comités nationaux ou d'autres parties prenantes, pour un total de 182 fiches. Le présent amendement est destiné à traiter ces sujets.

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APPAREILS ÉLECTROMÉDICAUX –

Partie 1: Exigences générales pour la sécurité de base et les performances essentielles

1 Domaine d'application, objet et normes connexes

1.1 * Domaine d'application

La présente Norme internationale s'applique à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des APPAREILS ELECTROMEDICAUX et des SYSTEMES ELECTROMEDICAUX, désignés ci-après sous le terme APPAREILS EM et SYSTEMES EM.

Si un article ou un paragraphe est spécifiquement destiné à être applicable uniquement aux APPAREILS EM ou uniquement aux SYSTEMES EM, le titre et le contenu de cet article ou de ce paragraphe l'indiquent. Si cela n'est pas le cas, l'article ou le paragraphe s'applique à la fois aux APPAREILS EM et aux SYSTEMES EM, selon le cas.

Les DANGERS inhérents à la fonction physiologique prévue de L'APPAREIL EM ou des SYSTEMES EM dans le cadre du domaine d'application de la présente norme ne sont pas couverts par des exigences spécifiques contenues dans la présente norme, à l'exception de 7.2.13 et 8.4.1.

NOTE 1 Voir aussi 4.2.

~~La présente norme peut également être appliquée aux appareils utilisés pour l'atténuation d'une maladie, la compensation ou l'atténuation d'une blessure ou d'une incapacité.~~

~~Les appareils de diagnostic in vitro qui n'entrent pas dans la définition des APPAREILS EM sont couverts par la série IEC 61010 [2)]. La présente norme ne s'applique pas aux parties implantables des dispositifs médicaux implantables actifs couverts par l'ISO 14708-1 [3)].~~

La série de normes IEC 60601 ne s'applique pas aux:

– appareils de diagnostic in vitro qui n'entrent pas dans la définition des APPAREILS EM, qui sont couverts par la série IEC 61010 [61];
– pièces implantables de dispositifs médicaux implantables actifs couverts par la série ISO 14708 [69]; ou
– systèmes de distribution de gaz médicaux couverts par l'ISO 7396-1 [68].

NOTE 2 L'ISO 7396-1 applique l'exigence de l'IEC 60601-1-8 à certains signaux de surveillance et d'alarme.

1.2 Objet

La présente Norme est destinée à spécifier des exigences générales et à servir de base pour les normes particulières.

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~~2) IEC 61010 (toutes les parties), *Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire*~~

~~3) ISO 14708-1, *Implants chirurgicaux – Dispositifs médicaux implantables actifs – Partie 1 : Exigences générales pour la sécurité, le marquage et pour les informations à fournir par le fabricant*~~

1.3 * Normes collatérales

Dans la série IEC 60601, les normes collatérales spécifient des exigences générales pour la SECURITE DE BASE et pour les PERFORMANCES ESSENTIELLES applicables à:

– un sous-groupe d'APPAREILS EM (par exemple appareils de radiologie) ;

– une caractéristique spécifique à tous les APPAREILS EM qui n'est pas complètement traitée dans la présente norme.

Les normes collatérales applicables prennent une valeur normative à la date de leur publication et elles doivent s'appliquer avec la présente norme.

NOTE 1 Lors de l'évaluation de la conformité à l'IEC 60601-1, il est admissible d'évaluer de manière indépendante la conformité aux normes collatérales.

NOTE 2 Lorsqu'il déclare qu'un appareil est conforme à l'IEC 60601-1, il convient que le déclarant donne spécifiquement la liste des normes collatérales qui ont été appliquées. Cela permet à toute personne lisant la déclaration de connaître quelles normes collatérales ont fait partie de l'évaluation.

NOTE 3 ~~Les membres de l'IEC tiennent à jour le registre des Normes internationales en vigueur. Il convient que les utilisateurs de la présente norme consultent ce registre pour déterminer quelles normes collatérales ont été publiées.~~ Les normes collatérales de la famille IEC 60601 sont numérotées IEC 60601-1-xx. L'IEC tient à jour un fichier des Normes Internationales en vigueur. Il convient que les utilisateurs de la présente norme consultent ce fichier sur le site "http://webstore.iec.ch" pour déterminer quelles normes collatérales ont été publiées.

Si une norme collatérale s'applique à des APPAREILS EM pour lesquels il existe une norme particulière, cette norme particulière prévaut sur la norme collatérale.

1.4 * Normes particulières

Dans la série IEC 60601, des normes particulières peuvent modifier, remplacer ou supprimer des exigences contenues dans la présente norme en fonction de ce qui est approprié à l'APPAREIL EM considéré et elles peuvent ajouter d'autres exigences de SECURITE DE BASE et de PERFORMANCES ESSENTIELLES.

NOTE ~~Les membres de l'IEC et de l'ISO possèdent le registre des Normes internationales en vigueur. Il convient que les utilisateurs de la présente norme consultent ces registres pour déterminer quelles normes spécifiques ont été publiées.~~ Les normes particulières de la famille IEC 60601, développées par les comités IEC, sont numérotées IEC 60601-2-xx. De plus, les normes particulières développées par des projets conjoints entre l'ISO et l'IEC peuvent être numérotées, soit IEC 80601-2-xx, soit ISO 80601-2-xx, selon le comité qui a géré le projet. L'IEC et l'ISO tiennent à jour des fichiers des Normes Internationales en vigueur. Il convient que les utilisateurs de la présente norme consultent ces fichiers sur les sites "http://webstore.iec.ch" et "http://www.iso.org/iso/store.htm" pour déterminer quelles normes particulières ont été publiées.

Une exigence d'une norme particulière prévaut sur l'exigence correspondante de la présente norme.

2 * Références normatives

Les documents de référence suivants sont indispensables pour l'application du présent document. Pour les références datées, seule l'édition citée s'applique. Pour les références non datées, la dernière édition du document de référence s'applique (y compris les éventuels amendements).

ATTENTION: Les normes collatérales complémentaires de la série des IEC 60601, qui sont émises après la publication de la présente norme, deviennent normatives à la date de leur publication et doivent être considérées comme incluses dans les références normatives indiquées ci- après. Voir 1.3.

NOTE Une liste de références informatives est donnée dans la Bibliographie.

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IEC 60065:2001, *Appareils audio, vidéo et appareils électroniques analogues – Exigences de sécurité* [4)]
Amendement 1:2005
Amendement 2:2010

IEC 60068-2-2:~~1974~~ 2007, *Essais d'environnement –~~ Deuxième partie:~~ Partie 2-2: Essais – Essais B : Chaleur sèche*
~~Amendement 1 (1993)~~
~~Amendement 2 (1994)~~

IEC 60079-0, *Matériel électrique pour atmosphères explosives gazeuses – Partie 0: Règles générales*

IEC 60079-2, *Matériel électrique pour atmosphères explosives gazeuses – Partie 2: Enveloppes à surpression interne "p"*

IEC 60079-5, *Matériel électrique pour atmosphères explosives gazeuses – Partie 5: Remplissage pulvérulent "q"*

IEC 60079-6, *Matériel électrique pour atmosphères explosives gazeuses – Partie 6: Immersion dans l'huile "o"*

IEC 60083, *Prises de courant pour usages domestiques et analogues normalisées par les pays membres de l'IEC*

IEC 60085, *Isolation électrique – Classification thermique*

IEC 60086-4, *Piles électriques – Partie 4: Sécurité des piles au lithium*

IEC 60112, *Méthode de détermination des indices de résistance et de tenue au cheminement des matériaux isolants solides*

IEC 60127-1, *Coupe-circuit miniatures – Première partie: Définitions pour coupe-circuit miniatures et prescriptions générales pour éléments de remplacement miniatures*

IEC 60227-1:~~1993~~ 2007, *Conducteurs et câbles isolés au polychlorure de vinyle, de tension nominale au plus égale à 450/750 V – Partie 1:~~ Prescriptions~~ Exigences générales*[~~5)~~]
~~Amendement 1 (1995)~~
~~Amendement 2 (1998)~~

IEC 60245-1:2003, *Conducteurs et câbles isolés au caoutchouc – Tension assignée au plus égale à 450/750 V – Partie 1: Exigences générales* [6]
Amendement 1:2007

IEC 60252-1, *Condensateurs des moteurs à courant alternatif – Partie 1: Généralités – Caractéristiques fonctionnelles, essais et valeurs assignées – Règles de sécurité – Guide d'installation et d'utilisation*

IEC 60320-1, *Connecteurs pour usages domestiques et usages généraux analogues – Partie 1: Prescriptions générales*

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4 Il existe une édition consolidée 7.2 comprenant l'IEC 60065:2001 et son Amendement 1 (2005) et son Amendement 2 (2010).

~~5) Il existe une édition consolidée 2.2 comprenant l'IEC 60227-1 :1993, son Amendement 1 (1995) et son Amendement 2 (1998).~~

6 Il existe une édition consolidée 4.1 comprenant l'IEC 60245-1:2003 et son Amendement 1 (2007).

IEC 60335-1:~~2001~~ 2010, *Appareils électrodomestiques et analogues – Sécurité – Partie 1: ~~Prescriptions~~ Exigences générales*

IEC 60364-4-41, *Installations électriques des bâtiments – Partie 4-41: Protection pour assurer la sécurité – Protection contre les chocs électriques*

IEC 60384-14:2005, *Fixed capacitors for use in electronic equipment – Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains*

IEC 60417~~-DB:2002~~, *Symboles graphiques utilisables sur le matériel*~~—[7]~~ Disponible à <http://www.graphical-symbols.info/equipment>

IEC 60445, *Principes fondamentaux et de sécurité pour les interfaces homme-machines, le marquage et l'identification – Identification des bornes de matériels et des extrémités de certains conducteurs désignés et règles générales pour un système alphanumérique*

IEC 60447, *Principes fondamentaux et de sécurité pour l'interface homme-machine, le marquage et l'identification – Principes de manœuvre*

IEC 60529:1989, *Degrés de protection procurés par les enveloppes (code IP)*[8] Amendement 1 (1999)

IEC 60601-1-2, *Appareils électromédicaux – Partie 1-2: Règles générales de sécurité – Norme Collatérale: Compatibilité électromagnétique – Prescriptions et essais*

IEC 60601-1-3, *Appareils électromédicaux – Partie 1-3: ~~Règles générales de sécurité – 3. Norme Collatérale: Règles générales pour la radioprotection dans les équipements à rayonnement X de diagnostic~~ Exigences générales pour la sécurité de base et les performances essentielles: Norme collatérale: Radioprotection dans les appareils à rayonnement X de diagnostic*

IEC 60601-1-6, *Appareils électromédicaux – Partie 1-6: Règles générales de sécurité – Norme collatérale: Aptitude à l'utilisation*

IEC 60601-1-8, *Appareils électromédicaux – Partie 1-8: Règles générales de sécurité – Norme collatérale: Règles générales, essais et guides pour les systèmes d'alarme dans l'équipement électromédical et les systèmes électromédicaux*

IEC 60664-1:~~1992~~ 2007, *Coordination de l'isolement des matériels dans les systèmes (réseaux) à basse tension - Partie 1: Principes, prescriptions et essais*~~[9]~~
~~Amendement 1 (2000)~~
~~Amendement 2 (2002)~~

IEC 60695-11-10, *Essais relatifs aux risques du feu – Partie 11-10: Flammes d'essai – Méthodes d'essai horizontale et verticale à la flamme de 50 W*

IEC 60730-1:~~1999~~ 2010, *Dispositifs de commande électrique automatiques à usage domestique et analogue – Partie 1: ~~Règles~~ Exigences générales*~~[10]~~
~~Amendement 1 (2003)~~

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~~7) "DB" se réfère à la base de données en ligne conjointe de l'IEC et de l'ISO.~~

8) Il existe une édition consolidée 2.1 comprenant l'IEC 60529:1989 et son Amendement 1 (1999).

~~9) Il existe une édition consolidée 1.2 comprenant l'IEC 60664-1:1992, son Amendement 1 (2000) et son Amendement 2 (2002).~~

IEC 60825-1:~~1993~~ 2007, *Sécurité des appareils à laser – Partie 1: Classification des matériels~~, prescriptions et guide de l'utilisateur~~ et exigences*~~ [11]~~
~~Amendement 1 (1997)~~
~~Amendement 2 (2001)~~

IEC 60851-3:~~1996~~ 2009, *Fils de bobinage – Méthodes d'essai – Partie 3: Propriétés mécaniques*~~ [12]~~
~~Amendement 1 (1997)~~
~~Amendement 2 (2003)~~

IEC 60851-5:~~1996~~ 2008, *Fils de bobinage – Méthodes d'essai – Partie 5: Propriétés électriques*~~ [13]~~
~~Amendement 1 (1997)~~
~~Amendement 2 (2004)~~

IEC 60851-6:1996, *Fils de bobinage – Méthodes d'essai – Partie 6: Propriétés thermiques*
Amendement 1 (1997)

~~IEC 60878:2003, *Symboles graphiques des équipements électriques en pratique médicale*~~

IEC 60884-1, *Prises de courant pour usages domestiques et analogues – Partie 1: Règles générales*

IEC 60950-1:2001, *Matériels de traitement de l'information – Sécurité – Partie 1: Prescriptions générales*

IEC 61058-1:2000, *Interrupteurs pour appareils – Partie 1: Règles générales* [14]
Amendement 1:2001
Amendement 2:2007

~~IEC 61558-1:1997, *Sécurité des transformateurs, blocs d'alimentation et analogues – Partie 1: Règles générales et essais*~~ [15]
~~Amendement 1(1998)~~

IEC 61558-2-1, *Sécurité des transformateurs, blocs d'alimentation et analogues – Partie 2: Règles particulières pour les transformateurs d'isolement à enroulement séparés pour usage général*

IEC 61672-1, *Electroacoustique – Sonomètres – Partie 1: Spécifications*

IEC 61672-2, *Electroacoustique – Sonomètres – Partie 2: Essais d'évaluation d'un modèle*

IEC 61965, *Sécurité mécanique des tubes cathodiques*

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~~10) Il existe une édition consolidée 3.1 comprenant l'IEC 60730-1:1999 et son Amendement 1 (2003).~~

~~11) Il existe une édition consolidée 1.2 comprenant l'IEC 60825-1:1993, son Amendement 1 (1997) et son Amendement 2 (2001).~~

~~12) Il existe une édition consolidée 2.1 comprenant l'IEC 60851-3:1996, son Amendement 1 (1997) et son Amendement 2 (2003).~~

~~13) Il existe une édition consolidée 3.1 comprenant l'IEC 60851-5:1996, son Amendement 1 (1997) et son Amendement 2 (2004).~~

14) Il existe une édition consolidée ~~3.1~~ 3.2 comprenant l'IEC 61058-1:2000, son Amendement 1 (2001) et son Amendement 2 (2007).

~~15) Il existe une édition consolidée 1.1 comprenant l'IEC 61558-1:1997 et son Amendement 1 (1998).~~

IEC 62133, *Accumulateurs alcalins et autres accumulateurs à électrolyte non acide – Exigences de sécurité pour les accumulateurs portables étanches, et pour les batteries qui en sont constituées, destinés à l'utilisation dans les applications portables*

IEC 62304:2006, *Logiciels de dispositifs médicaux – Processus du cycle de vie du logiciel*

~~ISO 31 (toutes les parties), *Grandeurs et unités*~~

ISO 780, *Emballages – Marquages graphiques relatifs à la manutention des marchandises*

~~ISO 1000, *Unités SI et recommandations pour l'emploi de leurs multiples et de certaines autres unités*~~

ISO 1853, *Caoutchoucs vulcanisés ou thermoplastiques conducteurs et dissipants – Mesurage de la résistivité*

ISO 2878, *Caoutchouc vulcanisé – Produits antistatiques et conducteurs – Détermination de la résistance électrique*

ISO 2882 [16], *Caoutchouc vulcanisé – Produits antiélectrostatiques et conducteurs à usage médico-hospitalier – Limites pour la résistance électrique*

ISO 3746, *Acoustique – Détermination des niveaux de puissance acoustique émis par les sources de bruit à partir de la pression acoustique – Méthode de contrôle employant une surface de mesure enveloppante au-dessus d'un plan réfléchissant*

ISO 3864-1:2002, *Symboles graphiques – Couleurs de sécurité et signaux de sécurité – Partie 1: Principes de conception pour les signaux de sécurité sur les lieux de travail et dans les lieux publics*

ISO 5349-1, *Vibrations mécaniques – Mesurage et évaluation de l'exposition des individus aux vibrations transmises par la main – Partie 1: Exigences générales*

ISO 7000-DB:2004 [17], *Symboles graphiques utilisables sur le matériel – Index et tableau synoptique*

ISO 7010:~~2003~~ 2011, *Symboles graphiques – Couleurs de sécurité et signaux de sécurité – Signaux de sécurité ~~utilisés sur les lieux de travail et dans les lieux publics~~ enregistrés*

ISO 9614-1, *Acoustique – Détermination par intensimétrie des niveaux de puissance acoustique émis par les sources de bruit – Partie 1: Mesurages par points*

ISO 10993 (toutes les parties), *Evaluation biologique des dispositifs médicaux*

~~ISO 11134, *Stérilisation des produits de santé – Prescriptions pour la validation et le contrôle de routine – Stérilisation industrielle à la vapeur d'eau* (disponible en anglais seulement)~~

~~ISO 11135, *Dispositifs médicaux – Validation et contrôle de routine de la stérilisation à l'oxyde d'éthylène*~~

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16) L'ISO 2882 a été annulée le 1er février 2005 et aucune norme de remplacement n'a été identifiée.

17) "DB" se réfère à la base de données en ligne conjointe de l'IEC et de l'ISO.

ISO 11135-1:2007, *Stérilisation des produits de santé – Oxyde d'éthylène – Partie 1: Exigences de développement, de validation et de contrôle de routine d'un processus de stérilisation pour des dispositifs médicaux*

~~ISO 11137, *Stérilisation des produits médicaux – Prescriptions pour la validation et le contrôle de routine – Stérilisation par irradiation*~~

ISO 11137-1:2006, *Stérilisation des produits de santé – Irradiation – Partie 1: Exigences relatives à la mise au point, à la validation et au contrôle de routine d'un procédé de stérilisation pour les dispositifs médicaux*

~~ISO 13852, *Sécurité des machines – Distances de sécurité pour empêcher l'atteinte des zones dangereuses par les membres supérieurs*~~

ISO 13857:2008, *Sécurité des machines – Distances de sécurité empêchant les membres supérieurs et inférieurs d'atteindre les zones dangereuses*

ISO 14971:~~2000~~ 2007, *Dispositifs médicaux – Application de la gestion des risques aux dispositifs médicaux*

~~ISO 15223, *Dispositifs médicaux – Symboles à utiliser avec les étiquettes, l'étiquetage et les informations à fournir relatifs aux dispositifs médicaux* (disponible en anglais seulement)~~

ISO 15223-1:2012, *Dispositifs médicaux – Symboles à utiliser avec les étiquettes, l'étiquetage et les informations à fournir relatifs aux dispositifs médicaux – Partie 1: Exigences générales*

ISO 17665-1:2006, *Stérilisation des produits de santé – Chaleur humide – Partie 1: Exigences pour le développement, la validation et le contrôle de routine d'un processus de stérilisation des dispositifs médicaux*

ISO 23529, *Caoutchouc – Procédures générales pour la préparation et le conditionnement des éprouvettes pour les méthodes d'essais physiques* (disponible en anglais seulement)

ISO 80000-1:2009, *Grandeurs et unités – Partie 1: Généralités*

3 * Terminologie et définitions

Pour les besoins du présent document, les termes et définitions suivants s'appliquent.

NOTE 1 Dans le cadre de la présente norme, les termes "tension" et "courant", là où ils sont utilisés, signifient, sauf indication contraire, des valeurs efficaces des tensions ou courants d'un courant alternatif, continu ou complexe.

NOTE 2 Le terme "appareil électrique" est utilisé dans le sens d'appareil em ou autre appareil électrique (voir 3.63). La présente norme utilise le terme "appareil" pour appareil em ou autre appareil électrique ou non électrique dans le cadre d'un système em (voir 3.64).

NOTE 3 Lorsque le terme "sécurité" est utilisé dans le présent document en caractères romains ou italiques, il ne signifie pas "sécurité" tel que ce terme est défini dans l'ISO 14971 mais est plutôt utilisé pour signifier "l'existence d'une protection ou d'une barrière contre une blessure ou une lésion; l'absence de tout danger".

NOTE ~~3~~ 4 Un index est donné à la page 748.

3.1
CAPOT D'ACCES
partie d'une ENVELOPPE ou d'une PROTECTION permettant d'accéder à des parties de l'appareil électrique en vue d'un réglage, d'une inspection, d'un remplacement ou d'une réparation

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3.2
PARTIE ACCESSIBLE
partie d'un appareil électrique autre qu'une PARTIE APPLIQUEE qui peut être touchée au moyen d'un doigt d'essai normalisé

NOTE Voir aussi 5.9.2.1.

3.3
ACCESSOIRE
composant additionnel destiné à être utilisé avec l'appareil de manière à:

– assurer son UTILISATION PREVUE,
– l'adapter à une utilisation spécifique,
– faciliter son utilisation,
– accroître ses performances, ou
– permettre l'intégration de ses fonctions à celles d'autres appareils

[IEC 60788:2004, rm-83-06 modifiée]

3.4
DOCUMENT D'ACCOMPAGNEMENT
document accompagnant un APPAREIL EM, un SYSTEME EM, un appareil ou un ACCESSOIRE et qui contient des informations pour l'ORGANISME RESPONSABLE ou l'OPERATEUR concernant en particulier la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES

3.5
DISTANCE DANS L'AIR
trajet le plus court dans l'air entre deux parties conductrices

NOTE Adapté de l'IEC 60664-1, définition ~~1.3.2, modifiée~~ 3.2.

3.6
CONNECTEUR
dispositif permettant d'effectuer sans OUTIL, la liaison d'un câble souple avec un appareil électrique et comprenant deux parties: une PRISE RESEAU et un SOCLE DE CONNECTEUR

NOTE Voir Figure 1.

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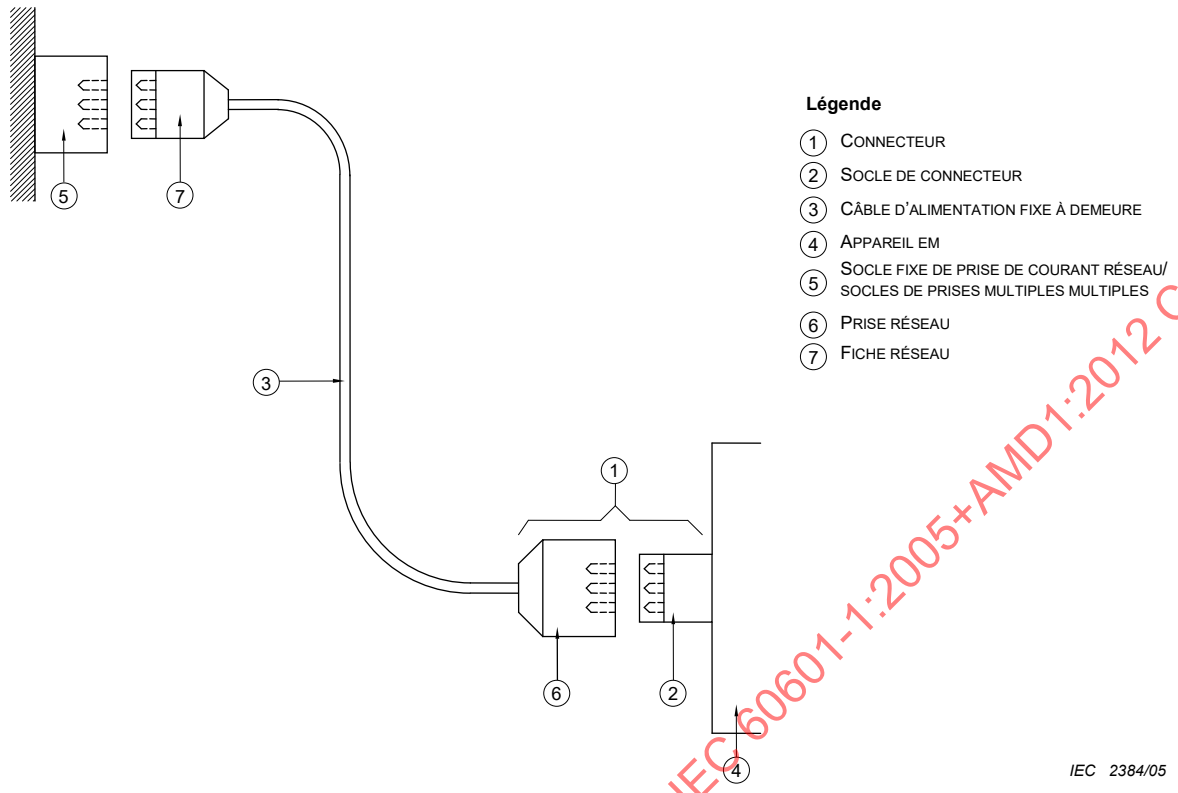


Figure 1 – Raccordement au réseau non fixé à demeure
(voir définitions)

3.7
SOCLE DE CONNECTEUR
élément d'un CONNECTEUR qui est soit intégré dans l'appareil électrique soit FIXE sur celui-ci

NOTE Voir Figures 1 et 2.

3.8
*** PARTIE APPLIQUEE**
partie de L'APPAREIL EM qui en UTILISATION NORMALE vient nécessairement en contact physique avec le PATIENT pour que L'APPAREIL EM ou le SYSTEME EM assure sa fonction

NOTE 1 Voir la Figure 3, la Figure 4 et les Figures A.1 à A.7 (comprise).

NOTE 2 Voir aussi 4.6 concernant le traitement des parties qui n'entrent pas dans la définition des PARTIES APPLIQUEES mais qui doivent être traitées comme de telles parties lorsqu'on applique le PROCESSUS de GESTION DES RISQUES.

NOTE 3 Voir aussi 3.78 pour la définition du terme associé CONNEXION PATIENT.

3.9
*** ISOLATION PRINCIPALE**
isolation assurant la protection principale contre les chocs électriques

[VEI 826-12-14, modifiée]

NOTE L'ISOLATION PRINCIPALE fournit un MOYEN DE PROTECTION.

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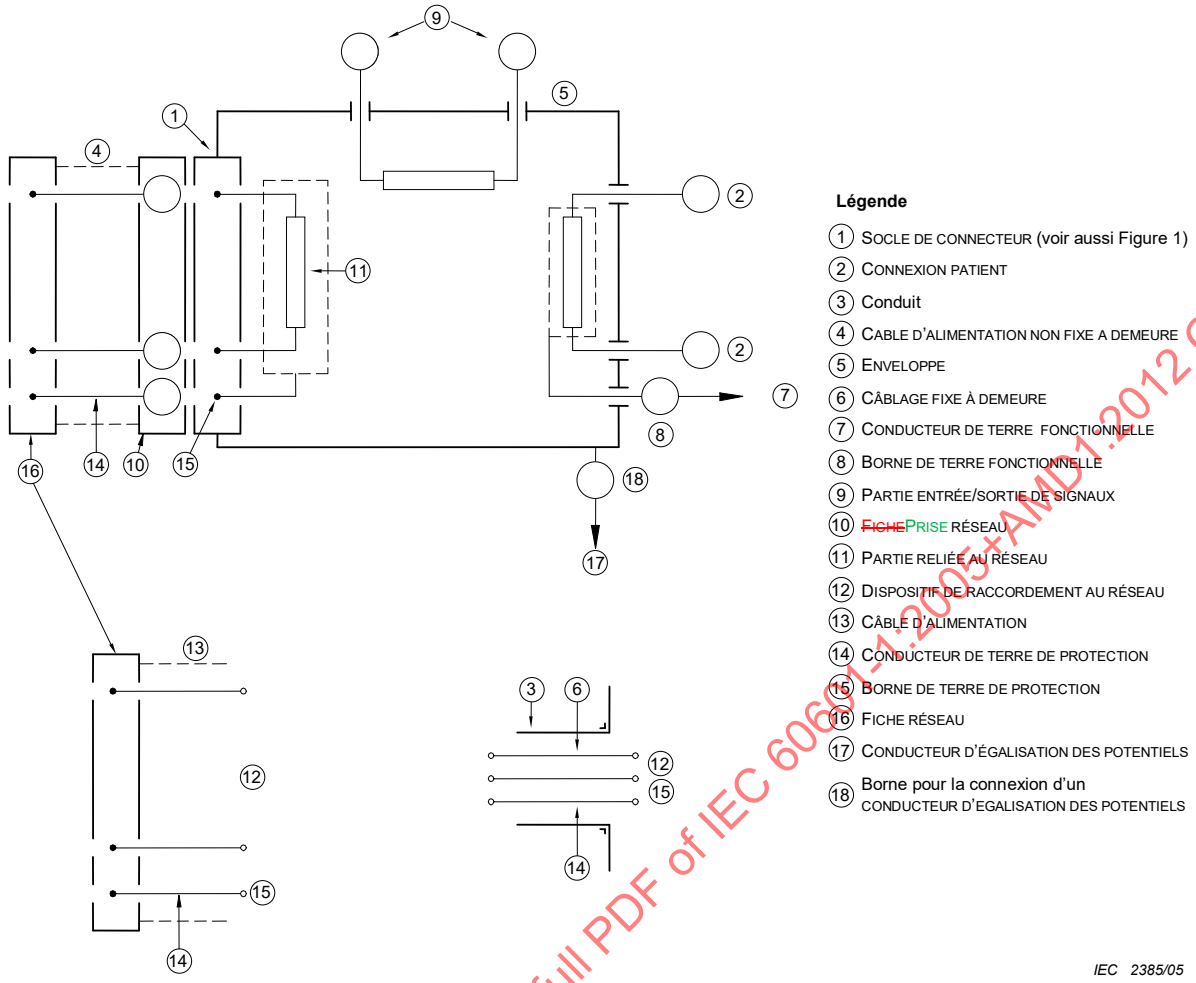
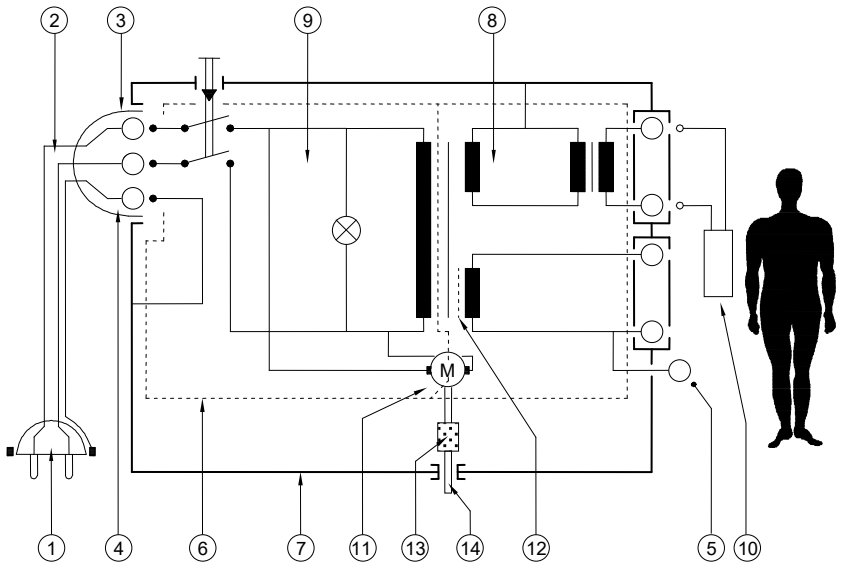


Figure 2 – Exemple de bornes et conducteurs définis
(voir définitions)

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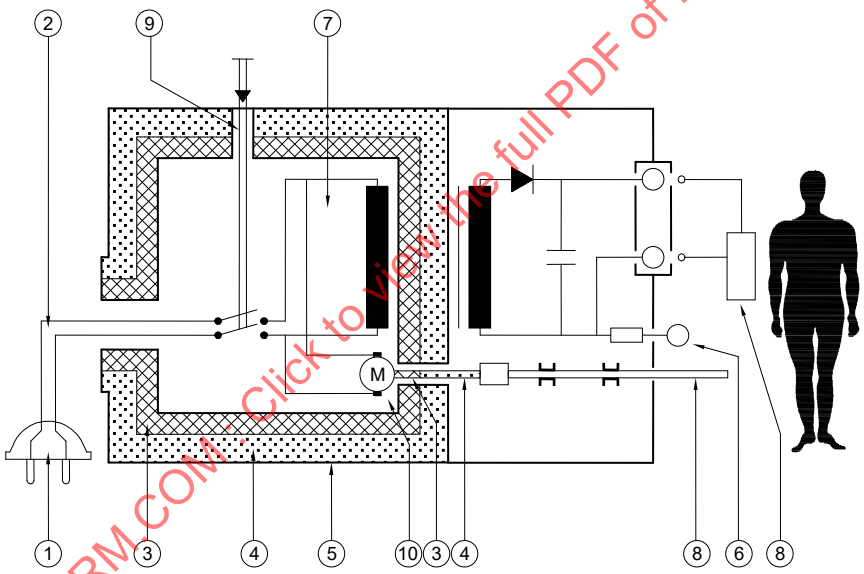


Légende

1. FICHE RÉSEAU AVEC CONTACT DE TERRE DE PROTECTION
2. CÂBLE D'ALIMENTATION NON FIXE À DEMEURE
3. CONNECTEUR
4. CONTACT ET BROCHE DE TERRE DE PROTECTION
5. BORNE DE TERRE DE PROTECTION
6. ISOLATION PRINCIPALE
7. CONDUCTEUR DE TERRE FONCTIONNELLE
8. CIRCUIT SECONDAIRE
9. PARTIE RELIÉE AU RÉSEAU
10. PARTIE APPLIQUÉE
11. Moteur
12. ECRAN PROTÉGÉ PAR MISE À LA TERRE
13. ISOLATION SUPPLÉMENTAIRE
14. Arbre de rotation qui est une partie accessible

IEC 2386/05

Figure 3 – Exemple d'APPAREIL EM DE CLASSE I
(voir définitions)



Légende

1. FICHE RÉSEAU
2. CÂBLE D'ALIMENTATION
3. ISOLATION PRINCIPALE
4. ISOLATION SUPPLÉMENTAIRE
5. ENVELOPPE
6. BORNE DE TERRE FONCTIONNELLE
7. PARTIE RELIÉE AU RÉSEAU
8. PARTIE APPLIQUÉE
9. ISOLATION RENFORCÉE
10. Moteur

IEC 2387/05

Figure 4 – Exemple d' APPAREIL EM DE CLASSE II sous enveloppe métallique
(voir définitions)

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3.10
*** SECURITE DE BASE**
absence de RISQUE inacceptable directement causé par des DANGERS physiques lorsque l'APPAREIL EM est utilisé dans des CONDITIONS NORMALES et dans des CONDITIONS DE PREMIER DEFAUT

3.11
CATEGORIE AP
caractéristiques d'un APPAREIL EM ou d'une partie d'APPAREIL EM conforme aux exigences spécifiées en ce qui concerne la construction, le marquage et la documentation afin d'éviter l'apparition de sources d'inflammation dans un MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'AIR

3.12
CATEGORIE APG
caractéristiques d'un APPAREIL EM ou d'une partie d'APPAREIL EM conforme aux exigences spécifiées en ce qui concerne la construction, le marquage et la documentation afin d'éviter l'apparition de sources d'inflammation dans un MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'OXYGENE OU DU PROTOXYDE D'AZOTE

3.13
CLASSE I
terme faisant référence à un appareil électrique dans lequel la protection contre les chocs électriques ne repose pas uniquement sur l'ISOLATION PRINCIPALE, mais qui comporte une mesure de sécurité supplémentaire dans laquelle les PARTIES ACCESSIBLES métalliques ou les parties internes métalliques sont PROTEGEES PAR MISE A LA TERRE

NOTE Voir Figure 3.

3.14
CLASSE II
terme faisant référence à un appareil électrique dans lequel la protection contre les chocs électriques ne repose pas uniquement sur l'ISOLATION PRINCIPALE, mais qui comporte des mesures complémentaires de sécurité telles que la DOUBLE ISOLATION ou l'ISOLATION RENFORCEE, cette protection est réalisée sans moyen de mise à la terre de protection et ne dépendant pas des conditions d'installation

NOTE 1 Voir Figure 4.

NOTE 2 Les appareils de la CLASSE II peuvent être équipés d'une BORNE DE TERRE FONCTIONNELLE ou d'un CONDUCTEUR DE TERRE FONCTIONNELLE. Voir aussi 8.6.8 et 8.6.9.

3.15
*** CLAIREMENT LISIBLE**
qui peut être lu par une personne ayant une vision normale

NOTE Voir ~~aussi~~ l'essai en 7.1.2.

3.16
CONDITION A FROID
condition obtenue lorsque l'appareil électrique a été mis hors tension suffisamment longtemps pour lui permettre de revenir à la température ambiante

3.17
*** COMPOSANT AUX CARACTERISTIQUES A HAUTE FIABILITE**
composant dont une ou plusieurs caractéristiques assurent que sa fonction ne présente aucun défaut par rapport aux exigences de sécurité de la présente norme au cours de la DUREE DE VIE PREVUE d'un APPAREIL EM en UTILISATION NORMALE et en cas de mauvais usage raisonnablement prévisible

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3.18
*** SERVICE CONTINU**
fonctionnement en UTILISATION NORMALE d'une durée illimitée sans dépassement des limites de température spécifiées

3.19
LIGNE DE FUITE
distance la plus courte à la surface d'un matériau isolant entre deux parties conductrices

[VEI 151-15-50, modifiée]

3.20
*** PARTIE APPLIQUEE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION**
PARTIE APPLIQUEE qui est protégée contre les effets d'une décharge d'un défibrillateur cardiaque appliquée au PATIENT

3.21
*** CABLE D'ALIMENTATION NON FIXE A DEMEURE**
câble souple destiné à être relié à l'appareil électrique à l'aide d'un CONNECTEUR approprié pour l'alimentation réseau

NOTE Voir Figure 1, Figure 2 et Figure 3.

3.22
*** APPLICATION CARDIAQUE DIRECTE**
utilisation d'une PARTIE APPLIQUEE qui peut entrer en contact direct avec le cœur du PATIENT

3.23
*** DOUBLE ISOLATION**
isolation comprenant à la fois une ISOLATION PRINCIPALE et une ISOLATION SUPPLEMENTAIRE

[VEI 195-06-08]

NOTE La double isolation fournit deux moyens de protection.

3.24
*** CYCLE D'UTILISATION**
durée maximale d'activation (de marche) suivie de la durée minimale de désactivation (d'arrêt) nécessaire au fonctionnement en toute sécurité de l'APPAREIL EM

3.25
COURANT DE FUITE A LA TERRE
courant qui s'écoule de la PARTIE RELIEE AU RESEAU dans le CONDUCTEUR DE MISE A LA TERRE DE PROTECTION ou une connexion fonctionnelle mise à la terre conforme à 8.6.9, en traversant ou contournant l'isolation

3.26
*** ENVELOPPE**
surface externe de l'appareil électrique ou de parties de celui-ci

NOTE A des fins d'essais selon la présente norme, une feuille métallique, de dimensions spécifiées, mise en contact avec des parties de la surface externe en matériau de faible conductivité ou en matière isolante est considérée comme une partie de l'ENVELOPPE (voir Figures 2, 3 et 4).

3.27
*** PERFORMANCES ESSENTIELLES**
performance ~~nécessaire pour assurer l'absence d'un RISQUE inacceptable~~ d'une fonction clinique différente de celle relative à la SECURITE DE BASE, pour laquelle la perte ou la dégradation au-delà des limites précisées par le FABRICANT entraîne un RISQUE inacceptable

NOTE Le terme PERFORMANCE ESSENTIELLE est plus facilement compris lorsqu'on examine si son absence ou sa dégradation donnerait lieu à un risque inacceptable.

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3.28
DUREE DE VIE PREVUE
~~durée maximale de vie utile telle qu'elle est définie par le FABRICANT~~
période spécifiée par le FABRICANT durant laquelle l'APPAREIL EM ou le SYSTEME EM est censé rester d'utilisation sûre (c'est-à-dire censé assurer la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES)

NOTE La maintenance peut être nécessaire pendant la DUREE DE VIE PREVUE

3.29
PARTIE APPLIQUEE ISOLEE DE TYPE F (FLOTTANTE) (ABREGE EN PARTIE APPLIQUEE DE TYPE F)
PARTIE APPLIQUEE dans laquelle les CONNEXIONS PATIENT sont isolées des autres parties de l'APPAREIL EM à un degré tel qu'aucun courant supérieur au COURANT DE FUITE PATIENT admissible ne s'écoule si une tension non voulue provenant d'une source externe est connectée au patient, et de ce fait appliquée entre la CONNEXION PATIENT et la terre

NOTE Les PARTIES APPLIQUEES DU TYPE F sont soit des PARTIES APPLIQUEES DU TYPE BF soit des PARTIES APPLIQUEES DU TYPE CF.

3.30
FIXE
terme qui signifie assujetti ou fixé d'une autre manière à un emplacement spécifié soit de manière permanente soit en ne pouvant être enlevé qu'à l'aide d'un OUTIL

EXEMPLE 1 Fixé de manière permanente par soudage, etc.

EXEMPLE 2 Fixé au moyen de dispositifs (vis, écrous, etc.) rendant le retrait ou l'ouverture impossible sans l'aide d'un OUTIL.

NOTE Voir la taxinomie de la définition 3.63 dans les justifications.

3.31
MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'AIR
mélange de gaz anesthésiques inflammables et d'air d'une concentration telle qu'une inflammation peut avoir lieu dans des conditions spécifiées

3.32
MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'OXYGENE OU DU PROTOXYDE D'AZOTE
mélange de gaz anesthésiques inflammables et d'oxygène ou de protoxyde d'azote d'une concentration telle qu'une inflammation peut avoir lieu dans des conditions spécifiées

3.33
*** CONNEXION FONCTIONNELLE**
tout raccordement, électrique ou autre, y compris ceux qui sont destinés à transférer des signaux, des données, de l'énergie ou des substances

NOTE Le raccordement à un socle FIXE de prise de courant RESEAU, simple ou multiple, n'est pas considéré comme une CONNEXION FONCTIONNELLE.

3.34
CONDUCTEUR DE TERRE FONCTIONNELLE
conducteur à relier à une BORNE DE TERRE FONCTIONNELLE

NOTE Voir Figure 2.

3.35
*** BORNE DE TERRE FONCTIONNELLE**
borne directement reliée à un circuit ou à une partie servant d'écran destiné à être mis à la terre dans un but fonctionnel

NOTE Voir Figure 2, Figure 3 et Figure 4.

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3.36
BARRIERE
partie d'un appareil spécifiquement utilisée pour assurer la protection au moyen d'une barrière physique

NOTE Selon sa construction, une BARRIERE peut être désignée par le terme boîtier, couvercle, écran, porte, protection enveloppante, etc. Une BARRIERE peut agir:

– seule; elle n'est alors efficace que lorsqu'elle est en place ;

– avec un dispositif de verrouillage avec ou sans verrouillage de la BARRIERE; dans ce cas, la protection est assurée quelle que soit la position de la BARRIERE.

3.37
PORTATIF
terme faisant référence à un appareil ~~électrique~~ qui, une fois installé et mis en service, est destiné à être tenu à la main ~~pendant son UTILISATION NORMALE~~

NOTE 1 L'appareil peut se référer aux ACCESSOIRES ou aux parties de l'équipement.

NOTE 2 Voir la taxinomie de la définition 3.63 dans les justifications.

3.38
*** DOMMAGE**
blessure physique ou atteinte à la santé des personnes ou des animaux ou atteinte aux biens ou à l'environnement
[ISO 14971:~~2000~~ 2007, définition 2.2, modifiée]

3.39
DANGER
PHENOMENE DANGEREUX
source potentielle de DOMMAGE
[ISO 14971:~~2000~~ 2007, définition 2.3]

3.40
*** SITUATION DANGEREUSE**
circonstance dans laquelle les personnes, les biens ou l'environnement sont exposés à un ou plusieurs DANGER(S)
[~~ISO/IEC Guide 51:1999, définition 3.6~~ ISO 14971:2007, définition 2.4]

3.41
HAUTE TENSION
tension supérieure à 1 000 V en courant alternatif ou à 1 500 V en courant continu ou en valeur crête

3.42
PRESSION D'ESSAI HYDRAULIQUE
pression appliquée pour mettre à l'essai tout ou partie d'un réservoir

NOTE Voir 9.7.5.

3.43
COORDINATION DE L'ISOLEMENT
corrélation entre les caractéristiques d'isolement d'un appareil électrique tenant compte du micro-environnement attendu et d'autres contraintes exerçant une influence

NOTE Ceci inclut les types d'isolement, les LIGNES DE FUITE, les DISTANCES DANS L'AIR, les distances dans l'isolation, les revêtements, l'encapsulation, les aspects environnementaux, etc.

3.44
*** UTILISATION PREVUE**
USAGE PREVU
utilisation ~~d'un produit, d'un PROCESSUS ou service~~ pour laquelle un produit, un PROCESSUS ou un service est prévu conformément aux spécifications, aux instructions et aux informations fournies par le FABRICANT

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[ISO 14971:~~2000~~ 2007, définition 2.5 ~~modifiée~~]

NOTE Il convient de ne pas confondre UTILISATION PREVUE et UTILISATION NORMALE. Si les deux expressions intègrent le concept de l'utilisation telle qu'elle est prévue par le FABRICANT, l'UTILISATION PREVUE se concentre sur le but médical tandis que l'UTILISATION NORMALE ne se limite pas au but médical mais englobe aussi la maintenance, l'entretien, le transport, etc.

3.45
SOURCE D'ENERGIE ELECTRIQUE INTERNE
source d'énergie électrique qui fait partie de l'appareil, destinée au fonctionnement de celui-ci et qui produit le courant électrique à partir d'une autre forme d'énergie

EXEMPLE Chimique, mécanique, solaire ou nucléaire.

NOTE Une SOURCE D'ENERGIE ELECTRIQUE INTERNE peut se situer à l'intérieur de la partie principale de l'appareil, être fixée à l'extérieur ou être contenue dans une ENVELOPPE séparée.

3.46
ALIMENTE DE MANIERE INTERNE
terme faisant référence à un appareil électrique qui peut fonctionner à partir d'une SOURCE D'ENERGIE ELECTRIQUE INTERNE

3.47
COURANT DE FUITE
courant non fonctionnel

NOTE Les COURANTS DE FUITE suivants sont définis: COURANT DE FUITE A LA TERRE, COURANT DE CONTACT et COURANT DE FUITE PATIENT.

3.48
PRISE RESEAU
partie intégrante d'un CONNECTEUR ou prévue pour être fixée au câble souple destiné à être relié au RESEAU D'ALIMENTATION

NOTE Une PRISE RESEAU est destinée à être insérée dans le socle de CONNECTEUR de l'appareil électrique (voir Figure 1 et Figure 2).

3.49
*** PARTIE RELIEE AU RESEAU**
~~circuit électrique qui est destiné à être relié au RESEAU D'ALIMENTATION~~ partie d'un équipement électrique formant un circuit destiné à être connecté au RESEAU D'ALIMENTATION

NOTE 1 La PARTIE RELIEE AU RESEAU comprend toutes les parties conductrices qui ne sont pas séparées du RESEAU D'ALIMENTATION par au moins un MOYEN DE PROTECTION.

NOTE 2 Pour les besoins de cette définition, le CONDUCTEUR DE TERRE DE PROTECTION n'est pas considéré comme un élément de la PARTIE RELIEE AU RESEAU (voir Figure 2 et Figure 3).

3.50
*** FICHE RESEAU**
partie intégrante du CABLE D'ALIMENTATION ou destinée à être fixée au CABLE D'ALIMENTATION d'un appareil électrique, destinée à être insérée dans un socle de prise de courant réseau

NOTE 1 Voir Figure 1.

NOTE 2 Voir également l'IEC 60083 et l'IEC 60309-1 [8].

3.51
TRANSFORMATEUR D'ALIMENTATION RESEAU
partie statique d'un appareil avec au moins deux enroulements qui, par induction électro-magnétique, transforme une tension et un courant alternatif provenant du RESEAU D'ALIMENTATION en une autre tension et un autre courant généralement de différentes valeurs à la même fréquence

3.52
DISPOSITIF DE RACCORDEMENT AU RESEAU
DISPOSITIF DE RACCORDEMENT assurant la liaison électrique avec le RESEAU D'ALIMENTATION

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NOTE Voir Figure 2.

3.53
TENSION TRANSITOIRE RESEAU
tension crête la plus élevée attendue à l'entrée de puissance de l'appareil électrique, provenant des transitoires externes sur le RESEAU D'ALIMENTATION

3.54
TENSION RESEAU
tension d'un RESEAU D'ALIMENTATION entre deux conducteurs de phase d'un système polyphasé, ou tension entre le conducteur de phase et le conducteur neutre d'un système monophasé

3.55
FABRICANT
personne physique ou légale ayant une responsabilité dans la conception, la fabrication, l'emballage ou l'étiquetage des APPAREILS EM, qui assemble un APPAREIL EM ou qui adapte un APPAREIL EM ou un SYSTEME EM, que ces opérations soient réalisées par cette personne ou par délégation de celle-ci à un tiers

NOTE 1 L'ISO 13485 [30] définit l'"étiquetage" comme un élément écrit, imprimé ou graphique

– apposé sur un dispositif médical ou sur l'un de ses conteneurs ou emballages, ou

– qui accompagne un dispositif médical,

concernant l'identification, la description technique et l'utilisation du dispositif médical à l'exclusion des documents de transport. Dans la présente norme, ces éléments sont décrits comme des marquages et des DOCUMENTS D'ACCOMPAGNEMENT.

NOTE 2 "Adapter" inclut la réalisation de modifications substantielles sur les APPAREILS EM ou sur un SYSTEME EM déjà en utilisation.

NOTE 3 Dans certaines juridictions, l'ORGANISME RESPONSABLE peut être considéré comme un FABRICANT lorsque celui-ci est impliqué dans les activités décrites.

NOTE 4 Adapté de l'ISO 14971:~~2000~~ 2007, définition ~~2.6~~ 2.8.

3.56
*** TENSION RESEAU MAXIMALE**
tension utilisée dans le cadre des essais liés à la tension du RESEAU D'ALIMENTATION et reliée à certaines parties d'APPAREILS EM

NOTE La valeur de la TENSION RESEAU MAXIMALE est déterminée conformément à 8.5.3.

3.57
*** PRESSION MAXIMALE ADMISSIBLE DE FONCTIONNEMENT**
pression maximale admise sur un composant d'après la déclaration du FABRICANT de ce composant

3.58
*** MOYEN DE PROTECTION DE L'OPERATEUR**
MOOP

MOYEN DE PROTECTION destiné à réduire le RISQUE dû au choc électrique sur des personnes autres que le PATIENT

3.59
*** MOYEN DE PROTECTION DU PATIENT**
MOPP

MOYEN DE PROTECTION destiné à réduire le RISQUE dû au choc électrique sur le PATIENT

3.60
*** MOYENS DE PROTECTION**
MOP

moyen destiné à réduire le RISQUE dû au choc électrique conformément aux exigences de la présente norme

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NOTE Le MOYEN DE PROTECTION inclut l'isolation, les DISTANCES DANS L'AIR, les LIGNES DE FUITE, les impédances et les CONNEXIONS DE TERRE DE PROTECTION.

3.61
DANGER MECANIQUE
DANGER lié ou produit par une force physique

3.62
DISPOSITIF DE PROTECTION MECANIQUE
dispositif qui élimine ou réduit le RISQUE mécanique à un niveau acceptable et qui fonctionne en cas de CONDITION DE PREMIER DEFAUT

3.63
*** APPAREIL ELECTROMEDICAL (APPAREIL EM)**
appareil électrique qui possède une PARTIE APPLIQUEE ou qui transfère de l'énergie vers le PATIENT ou à partir de celui-ci ou qui détecte un tel transfert d'énergie vers le PATIENT ou à partir de celui-ci et qui est:

a) équipé au plus d'un moyen de raccordement à un RESEAU D'ALIMENTATION donné ; et

b) destiné par son FABRICANT à être utilisé:

1) pour le diagnostic, le traitement ou la surveillance d'un PATIENT ou

2) pour la compensation ou l'atténuation d'une maladie, d'une blessure ou d'une incapacité

NOTE 1 L'APPAREIL EM comprend les ACCESSOIRES tels qu'ils sont définis par le FABRICANT qui sont nécessaires pour permettre l'UTILISATION NORMALE de l'APPAREIL ELECTROMEDICAL.

NOTE 2 Tous les appareils électriques utilisés en pratique médicale n'entrent pas dans cette définition (par exemple certains appareils de diagnostic *in vitro).*

NOTE 3 Les parties implantables des dispositifs médicaux implantables actifs peuvent entrer dans le cadre de cette définition mais elles sont exclues du domaine d'application de la présente norme par le libellé approprié de l'Article 1.

NOTE 4 La présente norme utilise le terme "appareil électrique" dans le sens d'APPAREIL EM ou d'autre appareil électrique.

NOTE 5 Voir aussi 4.10.1, 8.2.1 et 16.3.

3.64
*** SYSTEME ELECTROMEDICAL (SYSTEME EM)**
combinaison, telle qu'elle est spécifiée par son FABRICANT, d'éléments d'appareils, dont au moins un est un APPAREIL EM, destinés à être interconnectés par une CONNEXION FONCTIONNELLE ou par l'utilisation d'un SOCLE A PRISES DE COURANT MULTIPLES

NOTE Il convient de considérer que les appareils mentionnés dans la présente norme incluent des APPAREILS EM.

3.65
MOBILE
terme faisant référence à un appareil TRANSPORTABLE qui, une fois installé et mis en service, est destiné à être déplacé d'un emplacement à un autre sur ses propres roues ou par un moyen équivalent

NOTE Voir la taxinomie de la définition 3.63 dans les justifications.

3.66
*** REFERENCE DU MODELE OU DU TYPE**
combinaison de chiffres, de lettres ou des deux, utilisée pour identifier un modèle particulier d'appareil ou d'ACCESSOIRE

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3.67
*** SOCLES DE PRISES MULTIPLES**
SPM (en anglais MSO)

un ou plusieurs socles ~~à~~ délivrant la tension du RESEAU D'ALIMENTATION ou ~~à~~ une tension équivalente, destinés à être reliés ou à être intégrés à des câbles souples ~~ou à~~, des cordons ou ~~à~~ des APPAREILS EM

NOTE Un SOCLE DE PRISES MULTIPLES peut être un élément séparé ou peut faire partie intégrante de l'appareil.

3.68
*** COUPLAGE DE RESEAU/DONNEES**
tout moyen pour émettre des informations vers d'autres appareils ou en recevoir conformément aux spécifications du FABRICANT

3.69
NOMINALE (valeur)
valeur citée comme référence et affectée de tolérances agréées

EXEMPLE TENSION RESEAU NOMINALE ou diamètre NOMINAL d'une vis.

3.70
CONDITION NORMALE
condition réalisée quand tous les moyens prévus de protection contre les DANGERS sont intacts

3.71
UTILISATION NORMALE
fonctionnement, y compris lors des vérifications périodiques et des réglages faits par un OPERATEUR, ainsi que dans l'état en attente, selon les instructions d'utilisation

NOTE Il convient de ne pas confondre UTILISATION PREVUE et UTILISATION NORMALE. Si les deux expressions intègrent le concept de l'utilisation telle qu'elle est prévue par le FABRICANT, L'UTILISATION PREVUE se concentre sur le but médical tandis que L'UTILISATION NORMALE ne se limite pas au but médical mais englobe aussi la maintenance~~, l'entretien~~, le transport etc.

3.72
PREUVE TANGIBLE
~~informations dont la véracité peut être démontrée, fondées sur des faits et obtenues par observation, mesurage, essai ou autres moyens~~ données démontrant l'existence ou la véracité de quelque chose

NOTE La preuve tangible est obtenue par observation, mesurage, essai ou un autre moyen.

[ISO 14971:~~2000~~ 2007, définition ~~2.8~~ 2.10]

3.73
*** OPERATEUR**
personne manipulant un appareil

NOTE Voir aussi 3.101.

3.74
DECLENCHEUR A MAXIMUM DE CURANT (DISJONCTEUR)
dispositif de protection interrompant un circuit avec ou sans temporisation, quand le courant y dépasse une valeur prédéterminée

[VEI 441-16-33, modifié]

3.75
*** ENVIRONNEMENT RICHE EN OXYGENE**
environnement dans lequel la concentration en oxygène est:

a) supérieure à 25 % pour les pressions ambiantes jusqu'à 110 kPa; ou

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b) la pression partielle de l'oxygène est supérieure à 27,5 kPa aux pressions ambiantes supérieures à 110 kPa

3.76
PATIENT
être vivant (personne ou animal) soumis à une PROCEDURE de nature médicale, chirurgicale ou dentaire

NOTE Un PATIENT peut être un OPERATEUR.

3.77
*** COURANT AUXILIAIRE PATIENT**
courant s'écoulant à travers le PATIENT en UTILISATION NORMALE entre toute CONNEXION PATIENT et toutes les autres CONNEXIONS PATIENT et qui n'est pas destiné à produire un effet physiologique

3.78
*** CONNEXION PATIENT**
point individuel sur la PARTIE APPLIQUEE à travers lequel le courant peut s'écouler entre le patient et L'APPAREIL EM en CONDITION NORMALE ou en CONDITION DE PREMIER DEFAUT

3.79
*** ENVIRONNEMENT DU PATIENT**
tout volume à l'intérieur duquel il peut se produire un contact intentionnel ou non intentionnel entre un PATIENT et des parties de l'APPAREIL EM ou du SYSTEME EM ou entre un PATIENT et d'autres personnes touchant des parties de l'APPAREIL EM ou du SYSTEME EM

3.80
COURANT DE FUITE PATIENT
courant:

– s'écoulant des CONNEXIONS PATIENT vers la terre à travers le PATIENT ou

– dû à l'apparition non voulue sur le PATIENT d'une tension provenant d'une source externe et courant s'écoulant du PATIENT vers la terre par l'intermédiaire des CONNEXIONS PATIENT d'une PARTIE APPLIQUEE DE TYPE F

3.81
*** TENSION DE SERVICE CRETE** valeur de crête ou continue la plus élevée d'une TENSION DE SERVICE, en prenant en compte les impulsions répétitives de crête générées dans l'appareil électrique, mais en excluant les perturbations transitoires provenant de l'extérieur

[IEC 60950-1:~~2001~~ 2005, définition 1.2.9.~~7~~8, modifiée]

3.82
CYCLE DE VIE DE DEVELOPPEMENT DU SEMP
activités nécessaires intervenant pendant la période qui commence à la phase de conception d'un projet et s'achève lorsque la VALIDATION du SEMP est terminée

NOTE Voir aussi 3.90.

3.83
VALIDATION DU SEMP
PROCESSUS d'évaluation d'un SEMP ou d'un de ses composants au cours ou à l'issue du PROCESSUS de développement, pour déterminer s'il satisfait aux exigences de son UTILISATION PREVUE

NOTE Voir aussi 3.90.

3.84
INSTALLE DE FAÇON PERMANENTE
terme qui signifie que l'appareil est relié électriquement au RESEAU D'ALIMENTATION au moyen d'une liaison permanente qui ne peut être supprimée qu'à l'aide d'un OUTIL

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3.85
PORTABLE
terme faisant référence à un appareil TRANSPORTABLE qui, une fois installé et mis en service, est destiné à être déplacé d'un emplacement à un autre en étant porté par une ou plusieurs personnes

NOTE 1 L'appareil peut se référer aux ACCESSOIRES ou aux parties de l'appareil.

NOTE 2 Voir la taxinomie de la définition 3.63 dans les justifications.

3.86
CONDUCTEUR D'EGALISATION DES POTENTIELS
conducteur autre qu'un CONDUCTEUR DE TERRE DE PROTECTION ou un conducteur neutre assurant une connexion directe entre l'appareil électrique et la barre d'égalisation des potentiels de l'installation électrique

NOTE Voir Figure 2.

3.87
CABLE D'ALIMENTATION
câble souple, FIXE à ou assemblé avec un appareil électrique pour la connexion au RESEAU D'ALIMENTATION

NOTE Voir Figure 1 à Figure 4 (incluse).

3.88
PROCEDURE
manière spécifique de mener à bien une activité ou un PROCESSUS

[ISO 14971:~~2000~~ 2007, définition ~~2.9, modifiée~~ 2.12]

3.89
PROCESSUS
ensemble ~~de ressources et d'activités en inter-relation qui transforme les éléments entrants en éléments sortants~~ d'activités corrélées ou interactives liées qui transforme des éléments d'entrée en éléments de sortie

[ISO 14971:~~2000~~ 2007, définition ~~2.10, modifiée~~ 2.13]

3.90
SYSTEME ELECTROMEDICAL PROGRAMMABLE
SEMP (en anglais PEMS)

APPAREIL EM ou SYSTEME EM comprenant un ou plusieurs SOUS-SYSTEMES ELECTRONIQUES PROGRAMMABLES (SSEP)

3.91
SOUS-SYSTEME ELECTRONIQUE PROGRAMMABLE
SSEP (en anglais PESS)

système basé sur une ou plusieurs unités centrales de traitement, y compris les logiciels et les interfaces

3.92
CORRECTEMENT INSTALLE

installé conformément aux DOCUMENTS D'ACCOMPAGNEMENT

3.93
CONDUCTEUR DE TERRE DE PROTECTION
conducteur destiné à être connecté entre la BORNE DE TERRE DE PROTECTION et un système de mise à la terre de protection externe

NOTE Voir Figure 2.

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3.94
CONNEXION DE TERRE DE PROTECTION
connexion à la BORNE DE TERRE DE PROTECTION dans un but de protection et conforme aux exigences de la présente norme

3.95
BORNE DE TERRE DE PROTECTION
borne connectée aux parties conductrices d'un appareil de CLASSE I à des fins de sécurité destinée à être connectée à un système de mise à la terre de protection extérieur par un CONDUCTEUR DE TERRE DE PROTECTION

NOTE Voir Figure 2.

3.96
PROTEGE PAR MISE A LA TERRE
connecté à la BORNE DE TERRE DE PROTECTION dans un but de protection par des moyens conformes aux exigences de la présente norme

3.97
ASSIGNEE (VALEUR)
terme qui fait référence à une valeur attribuée par le FABRICANT pour une condition de fonctionnement spécifiée

3.98
ENREGISTREMENT
document ~~qui fournit des PREUVES TANGIBLES des activités effectuées ou des résultats obtenus~~ faisant état de résultats obtenus ou apportant la preuve de la réalisation d'activités

[ISO 14971:~~2000~~ 2007, définition ~~2.11~~ 2.14]

3.99
*** ISOLATION RENFORCEE**
système d'isolation unique qui fournit deux MOYENS DE PROTECTION

3.100
RISQUE RESIDUEL
RISQUE subsistant après que des mesures de ~~prévention~~ MAITRISE DU RISQUE ont été prises

[ISO 14971:~~2000~~ 2007, définition ~~2.12~~ 2.15]

3.101
ORGANISME RESPONSABLE
entité responsable de l'utilisation et de la maintenance d'un APPAREIL EM ou d'un SYSTEME EM

NOTE 1 L'entité responsable peut être par exemple un hôpital, un clinicien à titre individuel ou une personne sans compétence médicale. Dans les applications utilisées à domicile, le PATIENT, l'OPERATEUR et l'ORGANISME RESPONSABLE peuvent être une seule et même personne.

NOTE 2 Les domaines de l'enseignement et de la formation sont inclus dans "utilisation".

3.102
RISQUE
combinaison de la probabilité d'apparition d'un DOMMAGE et de la GRAVITE de ce DOMMAGE

[ISO 14971:~~2000~~ 2007, définition ~~2.13, modifiée~~ 2.16]

3.103
ANALYSE DE RISQUE
usage systématique des informations disponibles pour identifier les DANGERS et estimer le RISQUE

[ISO 14971:~~2000~~ 2007, définition ~~2.14, modifiée~~ 2.17]

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3.104
APPRECIATION DU RISQUE
PROCESSUS englobant une ANALYSE DE RISQUE et une EVALUATION DU RISQUE

[ISO 14971:~~2000~~ 2007, définition ~~2.15~~ 2.18]

3.105
MAITRISE DU RISQUE
PROCESSUS ~~par lequel les décisions sont prises et des mesures de protection mises en place pour réduire les RISQUES ou les maintenir dans des limites spécifiées~~ au cours duquel les décisions sont prises et les mesures visant à réduire les RISQUES ou à les maintenir dans les limites spécifiées sont mises en place

[ISO 14971:~~2000~~ 2007, définition ~~2.16~~ 2.19]

3.106
EVALUATION DU RISQUE
~~jugement fondé sur l'ANALYSE DE RISQUE, indiquant si le niveau de RISQUE atteint est acceptable dans un certain contexte, sur la base des valeurs admises par la société~~

PROCESSUS de comparaison du RISQUE estimé avec les critères de RISQUE donnés afin de déterminer l'acceptabilité du RISQUE

[ISO 14971:~~2000~~ 2007, définition ~~2.17~~ 2.21]

3.107
GESTION DES RISQUES
application systématique des politiques de gestion, des PROCEDURES et des pratiques à des tâches d'analyse, d'évaluation et de maîtrise des RISQUES

NOTE Pour les besoins de la présente norme, la GESTION DES RISQUES n'inclut pas la planification ni la surveillance des informations de la production et post-production; tandis que celles-ci sont requises conformément à l'ISO 14971 (voir 4.2.2).

[ISO 14971:~~2000~~ 2007, définition ~~2.18~~ 2.22]

3.108
DOSSIER DE GESTION DES RISQUES
ensemble des ENREGISTREMENTS et d'autres documents~~, non nécessairement centralisés,~~ produits par ~~un PROCESSUS de~~ la GESTION DES RISQUES

[ISO 14971:~~2000~~ 2007, définition ~~2.19~~ 2.23]

NOTE Toutes les informations liées à la sécurité y compris les calculs du FABRICANT, les résultats d'essais etc. sont considérées comme faisant partie du DOSSIER DE GESTION DES RISQUES. Voir aussi 4.2.

3.109
CHARGE DE FONCTIONNEMENT EN SECURITE
charge (masse) mécanique extérieure maximale sur un appareil ou une partie d'un appareil qui est admise en UTILISATION NORMALE

3.110
*** CIRCUIT SECONDAIRE**
circuit qui est séparé de la PARTIE RELIEE AU RESEAU par au moins un MOYEN DE PROTECTION et qui tient sa puissance d'un transformateur, d'un convertisseur ou d'un dispositif d'isolation équivalent ou d'une SOURCE ELECTRIQUE INTERNE

NOTE Voir aussi 8.9.1.12.

3.111
COUPE-CIRCUIT THERMIQUE A REENCLENCHEMENT AUTOMATIQUE
COUPE-CIRCUIT THERMIQUE rétablissant automatiquement le courant lorsque la partie appropriée de l'appareil électrique s'est refroidie

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3.112
*** DISPOSITIF DE SEPARATION**
composant ou configuration de composants avec des entrées et des sorties qui, pour des raisons de sécurité, empêchent un transfert de tension non voulue ou de courant non voulu entre les parties d'un SYSTEME EM

3.113
PERSONNEL D'ENTRETIEN
individus ou entité rendant compte à l'ORGANISME RESPONSABLE qui installent, assemblent, entretiennent ou réparent l'APPAREIL EM, les SYSTEMES EM ou d'autres appareils

3.114
GRAVITE
mesure des conséquences possibles d'un DANGER

[ISO 14971:~~2000~~ 2007, définition ~~2.21, modifiée~~ 2.25]

3.115
*** ENTREE/SORTIE DE SIGNAL (en anglais SIP/SOP)**
partie d'un APPAREIL EM, qui n'est pas une PARTIE APPLIQUEE, destinée à envoyer des signaux à un appareil électrique ou à en recevoir de celui-ci, par exemple pour l'affichage, l'enregistrement ou le traitement de données

NOTE Voir Figure 2.

3.116
CONDITION DE PREMIER DEFAUT
condition d'un APPAREIL EM par laquelle un seul moyen de réduction d'un RISQUE est défectueux ou lorsqu'une seule condition anormale est présente

NOTE Voir 4.7 et 13.2.

3.117
SECURISE EN PREMIER DEFAUT
caractéristique d'un APPAREIL EM ou de ses parties par laquelle il n'y a pas de RISQUE inacceptable pendant la DUREE DE VIE PREVUE dans des CONDITIONS DE PREMIER DEFAUT

NOTE Voir 4.7.

3.118
STATIONNAIRE
terme ~~faisant référence~~ se référant à un appareil qui, une fois installé et mis en service, n'est pas destiné à être déplacé d'un endroit à un autre

NOTE Voir la taxinomie de la définition 3.63 dans les justifications.

3.119
ISOLATION SUPPLEMENTAIRE
isolation indépendante appliquée en plus de l'ISOLATION PRINCIPALE en vue d'assurer la protection contre les chocs électriques en cas de défaut de l'ISOLATION PRINCIPALE

[VEI 826-12-15, modifiée]

NOTE L'ISOLATION SUPPLEMENTAIRE fournit un MOYEN DE PROTECTION.

3.120
*** RESEAU D'ALIMENTATION**
source d'énergie électrique ne faisant pas partie d'un APPAREIL EM ou d'un SYSTEME EM

NOTE Ce terme englobe aussi les systèmes de batteries et de convertisseurs des ambulances et des installations similaires.

3.121
FACTEUR DE SECURITE EN TRACTION
rapport entre la RESISTANCE A LA TRACTION et la contrainte correspondant à la CHARGE TOTALE

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3.122
RESISTANCE A LA TRACTION
contrainte de traction maximale à laquelle une pièce en essai résiste avant de se rompre

3.123
DISPOSITIF DE RACCORDEMENT
partie d'un appareil électrique permettant de réaliser la connexion électrique

NOTE Un DISPOSITIF DE RACCORDEMENT peut contenir plusieurs contacts individuels.

3.124
COUPE-CIRCUIT THERMIQUE
dispositif qui, en condition anormale, limite la température d'un appareil électrique ou de parties de celui-ci en ouvrant automatiquement le circuit ou en réduisant le courant, et dont la construction ne permet une modification de son réglage que par un PERSONNEL D'ENTRETIEN qualifié

3.125
STABILITE THERMIQUE
condition dans laquelle la température d'un objet n'augmente pas de plus de 2 °C en 1 h

3.126
THERMOSTAT
dispositif de commande thermosensible, destiné à maintenir une température dans les limites d'une plage spécifique ou au-dessus/en dessous d'une valeur préréglée

3.127
OUTIL
objet extracorporel qui peut être utilisé pour serrer ou desserrer des moyens de fixation ou pour faire des réglages

NOTE Les pièces de monnaie et les clés sont considérées comme des OUTILS dans le cadre de la présente norme.

3.128
CHARGE TOTALE
charge totale maximale d'une partie incluant la CHARGE DE FONCTIONNEMENT EN SECURITE maximale, le cas échéant, et les forces statiques et dynamiques qui apparaissent en UTILISATION NORMALE

NOTE 1 Les forces causées par l'accélération ou la décélération des masses sont des exemples de forces dynamiques.

NOTE 2 Lorsqu'une charge est divisée sur plusieurs parties du support parallèles et que la répartition sur ces parties n'est pas déterminée sans équivoque, la possibilité la plus défavorable est prise en considération.

3.129
COURANT DE CONTACT
COURANT DE FUITE s'écoulant de l'ENVELOPPE ou de parties de celle-ci, à l'exclusion des CONNEXIONS PATIENT, accessibles à tout OPERATEUR ou au PATIENT en UTILISATION NORMALE, par un chemin externe autre que le CONDUCTEUR DE TERRE DE PROTECTION, vers la terre ou une autre partie de l'ENVELOPPE

NOTE La signification de ce terme est la même que celle de "COURANT DE FUITE A TRAVERS L'ENVELOPPE" dans la première et la deuxième édition de la présente norme. Le terme a été modifié pour s'aligner sur l'IEC 60950-1 et pour refléter le fait que la mesure s'applique maintenant également aux parties qui sont PROTEGEES PAR MISE A LA TERRE.

3.130
TRANSPORTABLE
~~terme faisant référence à des appareils destinés à être déplacés d'un lieu à un autre qu'ils soient ou non reliés à une alimentation et sans restriction notable de leur rayon d'utilisation~~

terme se référant à un appareil qui, une fois installé et mis en service, est destiné à être déplacé d'un endroit à un autre qu'il soit ou non relié à une alimentation et sans restriction notable de son rayon d'utilisation

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EXEMPLE Appareils MOBILES, appareils PORTABLES et appareil PORTE

NOTE Voir la taxinomie de la définition 3.63 dans les justifications.

3.131
ZONE DE PIEGEAGE
emplacement accessible sur ou à l'intérieur d'un APPAREIL EM ou d'un SYSTEME EM ou dans l'environnement de l'appareil où le corps d'une personne ou une partie du corps est exposé aux DANGERS de piégeage, d'écrasement, de cisaillement, d'impact, de coupures, d'embrouillement, d'étirage, de piqûre ou d'abrasion

3.132
*** PARTIE APPLIQUEE DE TYPE B**
PARTIE APPLIQUEE conforme aux exigences spécifiées de la présente norme pour assurer une protection contre les chocs électriques, en ce qui concerne particulièrement le COURANT DE FUITE PATIENT admissible et le COURANT AUXILIAIRE PATIENT

NOTE 1 Une PARTIE APPLIQUEE DE TYPE B est marquée avec le symbole IEC 60417-5840 (~~DB:~~2002-10) (voir Tableau D.1, symbole 19) ou, le cas échéant, avec le symbole IEC 60417-5841 (~~DB:~~ 2002-10) (Voir Tableau D.1, symbole 25). Voir aussi 3.20.

NOTE 2 Les PARTIES APPLIQUEES DE TYPE B ne sont pas adaptées à l'APPLICATION CARDIAQUE DIRECTE.

NOTE 3 Voir aussi 4.6 concernant le traitement des parties qui n'entrent pas dans la définition des PARTIES APPLIQUEES mais qui doivent être traitées comme de telles PARTIES APPLIQUEES lorsqu'on applique le PROCESSUS de GESTION DES RISQUES.

3.133
*** PARTIE APPLIQUEE DE TYPE BF**
PARTIE APPLIQUEE DE TYPE F conforme aux exigences spécifiées dans la présente norme pour assurer une protection contre les chocs électriques de degré plus élevé que celui procuré par les PARTIES APPLIQUEES DE TYPE B

NOTE 1 Une PARTIE APPLIQUEE DE TYPE BF est marquée avec le symbole IEC 60417-5333 (~~DB:~~2002-10) (voir Tableau D.1, symbole 20) ou, le cas échéant, avec le symbole IEC 60417-5334 (~~DB:~~2002-10) (voir Tableau D.1, symbole 26). Voir aussi 3.20.

NOTE 2 Les PARTIES APPLIQUEES DE TYPE BF ne sont pas adaptées à l'APPLICATION CARDIAQUE DIRECTE.

NOTE 3 Voir aussi 4.6 concernant le traitement des parties qui n'entrent pas dans la définition des PARTIES APPLIQUEES mais qui doivent être traitées comme de telles PARTIES APPLIQUEES lorsqu'on applique le PROCESSUS de GESTION DES RISQUES.

3.134
*** PARTIE APPLIQUEE DE TYPE CF**
PARTIE APPLIQUEE DE TYPE F conforme aux exigences spécifiées dans la présente norme pour assurer une protection contre les chocs électriques de degré plus élevé que celui procuré par les PARTIES APPLIQUEES DE TYPE BF

NOTE 1 Une PARTIE APPLIQUEE DE TYPE CF est marquée avec le symbole IEC 60417-5335 (~~DB:~~2002-10) (voir Tableau D.1, symbole 21) ou, le cas échéant, avec le symbole IEC 60417-5336 (~~DB:~~2002-10) (Voir Tableau D.1, symbole 27). Voir aussi 3.20.

NOTE 2 Voir aussi 4.6 concernant le traitement des parties qui n'entrent pas dans la définition des PARTIES APPLIQUEES mais qui doivent être traitées comme de telles PARTIES APPLIQUEES lorsqu'on applique le PROCESSUS de GESTION DES RISQUES.

NOTE 3 Voir les justifications pour la définition de l'APPLICATION CARDIAQUE DIRECTE (3.22) concernant les parties appliquées qui sont nécessairement des PARTIES APPLIQUEES DE TYPE CF.

3.135
ESSAI DE TYPE
essai sur un spécimen représentatif de l'appareil en vue de déterminer si celui-ci, tel qu'il est conçu et construit, peut satisfaire aux exigences de la présente norme

3.136
APTITUDE A L'UTILISATION
caractéristique~~ qui établit l'efficacité, le rendement et la simplicité d'apprentissage~~ de l'interface de l'OPERATEUR qui établit l'efficacité, le rendement, la simplicité d'apprentissage de l'OPERATEUR et la satisfaction de L'OPERATEUR

[~~IEC 60601-1-6:2004, définition 2.211~~ IEC 62366:2007, définition 3.17, modifiée]

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3.137
INGENIERIE DE L'APTITUDE A L'UTILISATION
application des connaissances concernant le comportement, les capacités, les limitations des personnes et d'autres caractéristiques liées à la conception des outils, ~~des machines, des APPAREILS,~~ des dispositifs, des systèmes, des tâches, des emplois et des environnements pour obtenir une APTITUDE A L'UTILISATION adéquate

[~~IEC 60601-1-6:2004, définition 2.212~~ IEC 62366:2007, définition 3.18]

3.138
VERIFICATION
confirmation, par ~~examen et par apport~~ des PREUVES TANGIBLES, que les exigences spécifiées ont été satisfaites

~~NOTE En conception et développement, la VERIFICATION concerne le PROCESSUS d'examen du résultat d'une activité en vue de déterminer la conformité aux exigences fixées pour ladite activité.~~

NOTE 1 Le terme "vérifié" désigne l'état correspondant.

NOTE 2 La confirmation peut couvrir des activités telles que:

– la réalisation d'autres calculs,
– la comparaison d'une spécification de conception nouvelle avec une spécification de conception similaire éprouvée,
– la réalisation d'essais et de démonstrations,
– la revue de documents avant diffusion.

[ISO 14971:~~2000~~ 2007, définition ~~2.22~~ 2.28]

3.139
*** TENSION DE SERVICE**
tension la plus élevée à laquelle se trouve, ou peut se trouver, l'isolation ou le composant étudié lorsque l'appareil électrique fonctionne dans les conditions D'UTILISATION NORMALE

[IEC 60950-1:~~2001~~ 2005, définition 1.2.9.6]

3.140
kérma dans l'air
K
quotient de dE_{tr} par dm, où dE_{tr} est la somme des énergies cinétiques initiales de toutes les particules chargées libérées par des particules non chargées dans une masse d'air dm, soit

$$K = \frac{dE_{tr}}{dm}$$

Unité: J kg^{-1}

Le nom spécial de l'unité de KERMA DANS L'AIR est le gray (Gy) (ICRU 60)

[IEC 60601-1-3:2008, définition 3.4]

3.141
condition d'alarme
état d'un SYSTEME D'ALARME lorsqu'il a déterminé qu'il existe une SITUATION DANGEREUSE potentielle ou réelle pour laquelle l'attention ou une réponse de l'OPERATEUR est requise

NOTE 1 Une CONDITION D'ALARME peut être invalide, c'est-à-dire qu'il peut s'agir d'une fausse CONDITION D'ALARME positive.

NOTE 2 Une CONDITION D'ALARME peut passer inaperçue, c'est-à-dire qu'il peut s'agir d'une fausse CONDITION D'ALARME négative.

[IEC 60601-1-8:2006 / Amendement 1(2012), définition 3.1]

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3.142
signal d'alarme
type de signal généré par le SYSTEME D'ALARME pour indiquer la présence (ou l'apparition) d'une CONDITION D'ALARME

[IEC 60601-1-8:2006, définition 3.9]

3.143
système d'alarme
parties d'un APPAREIL EM ou d'un SYSTEME EM qui détectent des CONDITIONS D'ALARME et, selon ce qui est approprié, génèrent des SIGNAUX D'ALARME

[IEC 60601-1-8:2006, définition 3.11]

3.144
porté sur le corps
terme faisant référence à un appareil TRANSPORTABLE dont l'UTILISATION PREVUE correspond à un fonctionnement pendant qu'il est porté par un PATIENT ou fixé au vêtement d'un PATIENT

NOTE 1 Un appareil TRANSPORTABLE peut être à la fois PORTE et PORTATIF.

[IEC 60601-1-11:2010, définition 3.1]

NOTE 2 Voir la taxinomie de la définition 3.63 dans les justifications.

3.145
réseau TI
réseau de technologies de l'information
un ou plusieurs systèmes composés de noeuds de communication et de liaisons de transmission afin de garantir une transmission à liaison physique ou sans fil entre au moins deux noeuds de communication précis

[IEC 80001-1:2010, définition 2.12]

3.146
fonction principale de service
fonction, qui implique une interaction avec l'OPERATEUR, qui est fréquemment utilisée ou liée à la sécurité de l'APPAREIL EM,

[IEC 62366:2007, définition 3.14, modifiée]

3.147
dossier d'ingenierie de l'aptitude a l'utilisation
ensemble des ENREGISTREMENTS et autres documents qui sont produits par le PROCESSUS D'INGENIERIE DE L'APTITUDE A L'UTILISATION

[IEC 62366:2007, définition 3.19]

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4 Exigences générales

4.1 * Conditions d'application aux APPAREILS EM ou aux SYSTEMES EM

Sauf spécification contraire, les exigences de la présente norme doivent s'appliquer en UTILISATION NORMALE et en cas de mauvais usage raisonnablement prévisible.

Lorsque la présente norme est appliquée à des APPAREILS EM ou SYSTEMES EM destinés à la compensation ou l'atténuation de maladie, de blessure ou d'incapacité, les définitions et les exigences qui utilisent le terme PATIENT doivent être considérées comme s'appliquant à la personne à laquelle L'APPAREIL EM ou le SYSTEME EM est destiné.

4.2 * PROCESSUS de GESTION DES RISQUES pour les APPAREILS EM ou SYSTEMES EM

~~Un PROCESSUS de GESTION DES RISQUES doit être réalisé conformément à l'ISO 14971.~~

~~Lorsqu'on applique l'ISO 14971:~~

- ~~Le terme "dispositif médical" doit avoir la même signification qu'APPAREIL EM ou SYSTEME EM.~~
- ~~Le terme "conditions de défaut" auquel il est fait référence dans l'ISO 14971 doit inclure mais sans s'y limiter, les CONDITIONS DE PREMIER DEFAUT identifiées dans la présente norme.~~
- ~~La politique de détermination du RISQUE acceptable et de l'acceptabilité des RISQUES RESIDUELS doit être établie par le FABRICANT.~~
- ~~Lorsque la présente norme, ou l'une de ses normes collatérales ou particulières, spécifie des exigences vérifiables couvrant des RISQUES spécifiques et que ces exigences sont satisfaites, les RISQUES RESIDUELS traités doivent être présumés acceptables sauf s'il existe une PREUVE TANGIBLE du contraire.~~

~~NOTE 1 La présente norme spécifie des exigences qui sont généralement applicables aux RISQUES associés aux APPAREILS EM ou aux SYSTEMES EM et elle est destinée à servir d'outil durant le PROCESSUS de GESTION DES RISQUES. Il convient que le PROCESSUS de GESTION DES RISQUES n'identifie pas seulement les DANGERS couverts par la présente norme mais tous les DANGERS, leurs RISQUES associés et les mesures de MAITRISE DU RISQUE.~~

~~NOTE 2 Les conditions ou les défauts qui peuvent donner lieu à des DANGERS sont identifiés dans les articles de la présente norme. Dans ces cas, il est souvent nécessaire de conduire un PROCESSUS de GESTION DES RISQUES pour déterminer quels sont les DANGERS réels et les essais qui doivent être réalisés pour montrer que les DANGERS identifiés n'apparaissent pas dans les circonstances spécifiées.~~

~~NOTE 3 Il est reconnu que le FABRICANT pourrait ne pas être en mesure de suivre tous les PROCESSUS identifiés dans la présente norme pour chaque composant constituant de l'APPAREIL EM ou du SYSTEME EM, tel que les composants propriétaires, les sous-systèmes d'origine non médicale et les dispositifs classiques. Dans ce cas, il convient que le FABRICANT tienne particulièrement compte des besoins en matière de mesures supplémentaires de MAITRISE DU RISQUE.~~

~~NOTE 4 Lorsque les exigences de la présente norme font référence à l'absence de RISQUE inacceptable, l'acceptabilité ou la non-acceptabilité de ce RISQUE est déterminée par le FABRICANT conformément à la politique du FABRICANT pour déterminer le RISQUE acceptable.~~

~~NOTE 5 Tous les RISQUES associés aux APPAREILS EM et aux SYSTEMES EM ne sont pas nécessairement couverts par des exigences particulières de la présente norme (voir 1.1).~~

~~*La conformité est vérifiée par inspection du DOSSIER DE GESTION DES RISQUES. Les exigences du présent article et toutes les exigences de la présente norme se référant à la vérification du DOSSIER DE GESTION DES RISQUES sont considérées comme satisfaites si le FABRICANT a:*~~

- ~~*établi un PROCESSUS de GESTION DES RISQUES ;*~~
- ~~*établi des niveaux acceptables de RISQUE ; et*~~
- ~~*démontré que le ou les RISQUES RESIDUELS sont acceptables (en accord avec sa politique de détermination du RISQUE acceptable)*~~

4.2.1 Introduction à la GESTION DES RISQUES

Le paragraphe 4.2 spécifie le processus de GESTION DES RISQUES requis pour la conformité avec la présente norme. Ce PROCESSUS de GESTION DES RISQUES est destiné à servir les objectifs suivants:

a) Identifier si les exigences normatives spécifiées aux Articles 5 à 17 de la présente norme, jointes aux exigences des normes collatérales et particulières applicables, couvrent tous les DANGERS associés à l'APPAREIL EM ou au SYSTEME EM considéré.

b) Identifier la manière dont il convient d'appliquer certains des essais particuliers spécifiés dans la présente norme à un APPAREIL EM ou à un SYSTEME EM particulier.

c) Identifier si des DANGERS particuliers ou des SITUATIONS DANGEREUSES particulières, pour lesquels la présente norme ne fournit pas de critères d'acceptation spécifiques, entraînent des RISQUES pour un APPAREIL EM ou un SYSTEME EM particulier et, si oui, établir des niveaux de RISQUE acceptables et évaluer les RISQUES RESIDUELS.

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d) Évaluer la possibilité de stratégies de MAITRISE DU RISQUE alternatives en comparant les RISQUES RESIDUELS à ceux qui existent en appliquant pleinement les exigences de la présente norme.

Bien que le PROCESSUS de GESTION DES RISQUES spécifié dans la présente norme doive être conforme aux exigences concernées de l'ISO 14971, il n'est pas aussi complet et n'inclut pas tous les éléments requis pour la conformité avec l'ISO 14971. Par exemple, le PROCESSUS de GESTION DES RISQUES requis pour la conformité avec la présente norme n'inclut pas la surveillance de la production et de la post-production requise dans l'ISO 14971. De plus, la vérification de la conformité avec les exigences de GESTION DES RISQUES de la présente norme peut être accomplie par l'examen des ENREGISTREMENTS et autres documents requis par la présente norme et l'évaluation des processus cités dans la présente norme et ne requiert pas l'audit du PROCESSUS de GESTION DES RISQUES.

4.2.2 Exigences générales pour la GESTION DES RISQUES

Un PROCESSUS de GESTION DES RISQUES conforme à l'ISO 14971 doit être exécuté. Pour la conformité avec la présente norme, tous les éléments du PROCESSUS de GESTION DES RISQUES de l'ISO 14971:2007 doivent s'appliquer, à l'exception:

– de la planification et de l'exécution de la surveillance de la production et de la post-production (paragraphe 3.1, quatrième tiret, paragraphe 3.4, point f), et Article 9 de l'ISO 14971:2007), et

– des revues périodiques de l'adéquation du PROCESSUS de GESTION DES RISQUES (paragraphe 3.2, quatrième tiret, de l'ISO 14971:2007).

Lors de l'application d'une exigence de l'ISO 14971:

– le terme "dispositif médical" doit avoir la même signification qu'APPAREIL EM ou SYSTEME EM; et

– le terme "conditions de défaut" auquel il est fait référence dans l'ISO 14971 doit inclure mais sans s'y limiter, les CONDITIONS DE PREMIER DEFAUT identifiées dans la présente norme.

NOTE 1 La présente norme spécifie des exigences qui sont généralement applicables aux RISQUES associés aux APPAREILS EM ou aux SYSTEMES EM. Ces exigences sont destinées à faciliter le PROCESSUS de GESTION DES RISQUES. Le PROCESSUS de GESTION DES RISQUES ne vise pas seulement à identifier les DANGERS couverts par la présente norme mais tous les DANGERS, leurs RISQUES associés et les mesures de MAITRISE DU RISQUE.

NOTE 2 Les conditions ou les défauts qui peuvent donner lieu à des SITUATIONS DANGEREUSES sont identifiés dans les articles de la présente norme. Dans ces cas, il est souvent nécessaire de conduire un PROCESSUS de GESTION DES RISQUES pour déterminer quelles sont les SITUATIONS DANGEREUSES réelles et les essais qui doivent être réalisés pour montrer que les SITUATIONS DANGEREUSES identifiées n'apparaissent pas dans les circonstances spécifiées.

NOTE 3 Il est reconnu que le FABRICANT pourrait ne pas être en mesure de suivre tous les PROCESSUS identifiés dans la présente norme pour chaque composant constituant de l'APPAREIL EM ou du SYSTEME EM tel que les composants propriétaires, les sous-systèmes d'origine non médicale et les dispositifs classiques. Dans ce cas, le FABRICANT pourrait tenir particulièrement compte des besoins en matière de mesures supplémentaires de MAITRISE DU RISQUE.

NOTE 4 Lorsque les exigences de la présente norme font référence à l'absence de RISQUE inacceptable, l'acceptabilité ou la non-acceptabilité de ce RISQUE est déterminée par le FABRICANT conformément à la politique du FABRICANT pour déterminer le RISQUE acceptable.

NOTE 5 Tous les RISQUES associés aux APPAREILS EM ou aux SYSTEMES EM ne sont pas nécessairement couverts par des exigences spécifiques de la présente norme (voir 1.1).

La conformité est vérifiée par:

– *l'inspection de la politique du FABRICANT en matière de détermination des critères d'acceptabilité du RISQUE;*

– *l'inspection du plan de GESTION DES RISQUES pour l'APPAREIL EM ou le SYSTEME EM particulier concerné; et*

– *la confirmation du fait que le FABRICANT a préparé un DOSSIER DE GESTION DES RISQUES contenant les ENREGISTREMENTS DE GESTION DES RISQUES et les autres documents requis par la présente norme pour l'APPAREIL EM ou le SYSTEME EM particulier concerné.*

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NOTE 6 Il est utile de garder un index contenant les références ou les indications relatives aux ENREGISTREMENTS DE GESTION DES RISQUES et les autres documents requis par la présente norme.

4.2.3 Évaluation du RISQUE

4.2.3.1 DANGERS identifiés dans la série IEC 60601

Les exigences de la présente norme doivent être appliquées de la manière suivante lors de l'évaluation du RISQUE:

a) Lorsque la présente norme ou ses normes collatérales ou particulières spécifient des exigences couvrant des DANGERS particuliers ou des SITUATIONS DANGEREUSES particulières, ainsi que des critères d'acceptation spécifiques, la conformité avec ces exigences est présumée établir le fait que les RISQUES RESIDUELS ont été réduits à des niveaux acceptables, sauf s'il existe des PREUVES TANGIBLES du contraire.

EXEMPLE 1 Paragraphe 8.5.1.2, MOYENS DE PROTECTION DU PATIENT (MOPP)

EXEMPLE 2 Paragraphe 9.4.2.1, Instabilité en position de transport

La conformité est vérifiée par la satisfaction des exigences concernées de la présente norme et de ses normes collatérales et particulières.

b) Lorsque la présente norme ou ses normes collatérales ou particulières spécifient des exigences couvrant des DANGERS particuliers ou des SITUATIONS DANGEREUSES particulières mais ne donnent pas de critères d'acceptation spécifiques, le FABRICANT doit fournir les critères d'acceptation définis dans le plan de GESTION DES RISQUES. Ces critères d'acceptation doivent garantir que le RISQUE RESIDUEL est acceptable selon les critères d'acceptabilité du RISQUE enregistrés dans le plan de GESTION DES RISQUES.

EXEMPLE 3 Paragraphe 9.8.3.3, Forces dynamiques dues à la charge des personnes

EXEMPLE 4 Paragraphe 11.6.3, Renversement sur un APPAREIL EM et sur un SYSTEME EM

La conformité est vérifiée en confirmant que les ENREGISTREMENTS du DOSSIER DE GESTION DES RISQUES démontrent que, après l'application des exigences spécifiques de la présente norme, les critères d'acceptation déterminés par le FABRICANT sont satisfaits. Seules les parties appropriées du DOSSIER DE GESTION DES RISQUES doivent être revues, par exemple les calculs ou résultats d'essais du FABRICANT, ou la détermination de l'acceptabilité du RISQUE.

c) Lorsque la présente norme ou ses normes collatérales ou particulières identifient des DANGERS particuliers ou des SITUATIONS DANGEREUSES particulières à examiner mais ne donnent pas d'exigences techniques spécifiques:

- le FABRICANT doit déterminer si ces DANGERS ou ces SITUATIONS DANGEREUSES existent pour l'APPAREIL EM ou le SYSTEME EM particulier, et
- lorsque de tels DANGERS ou SITUATIONS DANGEREUSES existent pour l'APPAREIL EM ou le SYSTEME EM particulier, le FABRICANT doit évaluer et (si nécessaire) maîtriser ces RISQUES à la suite du PROCESSUS de GESTION DES RISQUES spécifié en 4.2.2.

EXEMPLE 5 Paragraphe 10.2, Rayonnements alpha, bêta, gamma, neutroniques et d'autres particules

La conformité est vérifiée en confirmant que les ENREGISTREMENTS du DOSSIER DE GESTION DES RISQUES démontrent que le RISQUE RESIDUEL est acceptable en utilisant les critères d'acceptabilité du RISQUE enregistrés dans le plan de GESTION DES RISQUES , c'est-à-dire qu'il ne subsiste aucun RISQUE inacceptable. Seules les parties appropriées du DOSSIER DE GESTION DES RISQUES doivent être revues, par exemple les calculs ou résultats d'essais du FABRICANT, ou la détermination de l'acceptabilité du RISQUE.

NOTE Lorsqu'un APPAREIL EM ou un SYSTEME EM a été conçu de telle sorte que, pour un certain type de DANGER, il n'existe aucune SITUATION DANGEREUSE, aucune EVALUATION DU RISQUE supplémentaire n'est nécessaire pour ce DANGER. Ceci peut être vérifié au moyen d'essais ou d'inspections.

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4.2.3.2 DANGERS non identifiés dans la série IEC 60601

Pour les DANGERS ou les SITUATIONS DANGEREUSES qui sont identifiés pour l'APPAREIL EM ou le SYSTEME EM particulier mais qui ne sont pas spécifiquement couverts par la présente norme ou ses normes collatérales ou particulières, le FABRICANT doit traiter ces DANGERS dans le PROCESSUS de GESTION DES RISQUES comme spécifié en 4.2.2.

EXEMPLE APPAREIL EM ou SYSTEME EM pour lequel il existe des RISQUES particuliers mais aucune norme particulière.

La conformité est vérifiée par l'inspection du DOSSIER DE GESTION DES RISQUES.

4.3 * PERFORMANCE ESSENTIELLE

~~Le FABRICANT doit identifier quelles fonctions de l'APPAREIL EM et des SYSTEMES EM sont liées à des PERFORMANCES ESSENTIELLES. Lorsque la présente norme spécifie que les PERFORMANCES ESSENTIELLES doivent être maintenues à la suite d'un essai spécifique, ces fonctions doivent être utilisées et la conformité doit être vérifiée par vérification et, si nécessaire, par un essai fonctionnel.~~

~~NOTE Lorsque les exigences de la présente norme font référence aux PERFORMANCES ESSENTIELLES, ces PERFORMANCES ESSENTIELLES sont déterminées par le FABRICANT conformément à la politique du FABRICANT pour déterminer l'acceptabilité du RISQUE.~~

~~*La conformité est vérifiée par inspection du DOSSIER DE GESTION DES RISQUES.*~~

Durant l'ANALYSE DES RISQUES, le FABRICANT doit identifier les performances des fonctions cliniques de l'APPAREIL EM ou du SYSTEME EM, autres que celles relatives à la SECURITE DE BASE, qui sont nécessaires à l'exécution de l'UTILISATION PREVUE ou qui pourraient affecter la sécurité de l'APPAREIL EM ou du SYSTEME EM.

Le FABRICANT doit également spécifier les limites de la performance entre la fonctionnalité entière et la perte totale de la performance identifiée dans les CONDITIONS NORMALES comme dans les CONDITIONS DE PREMIER DEFAUT.

Le FABRICANT doit ensuite évaluer le RISQUE de perte ou de dégradation de la performance identifiée au-delà des limites spécifiées par le FABRICANT. Si le RISQUE résultant est inacceptable, alors la performance identifiée constitue une PERFORMANCE ESSENTIELLE de l'APPAREIL EM ou du SYSTEME EM.

Le FABRICANT doit mettre en œuvre des mesures de MAITRISE DU RISQUE afin de réduire le RISQUE de perte ou de dégradation des performances identifiées à un niveau acceptable.

NOTE 1 La performance de la mesure de MAITRISE DU RISQUE peut tout à fait devenir un aspect des PERFORMANCES ESSENTIELLES de l'APPAREIL EM ou du SYSTEME EM. Par exemple, la génération du SIGNAL D'ALARME indiquant la coupure du RESEAU D'ALIMENTATION peut être "essentielle" si une coupure du RESEAU D'ALIMENTATION peut entraîner un RISQUE inacceptable si le problème n'est pas résolu.

Le FABRICANT doit spécifier les méthodes utilisées pour vérifier l'efficacité des mesures de MAITRISE DU RISQUE. Celles-ci doivent inclure les évaluations réalisées pour déterminer si une vérification est nécessaire.

NOTE 2 Suivant les principes de la GESTION DES RISQUES, le FABRICANT a l'obligation de vérifier l'efficacité de chaque mesure de MAITRISE DU RISQUE. Ceci peut impliquer la démonstration de l'efficacité de la mesure de MAITRISE DU RISQUE en présence de conditions entraînant la perte ou la dégradation des performances identifiées.

EXEMPLE 1 Lorsqu'une PERFORMANCE ESSENTIELLE est perdue en raison d'une coupure du RESEAU D'ALIMENTATION, un système d'alarme destiné à signaler à l'OPERATEUR que le RESEAU D'ALIMENTATION est coupé devrait être équipé d'une source d'alimentation de secours, afin que la génération du SIGNAL D'ALARME ne dépende pas du RESEAU D'ALIMENTATION.

EXEMPLE 2 Si la défaillance d'un composant entraîne la perte d'une PERFORMANCE ESSENTIELLE, il serait nécessaire que la conception de l'APPAREIL EM ou du SYSTEME EM soit telle que la défaillance du composant ne compromette pas l'efficacité des mesures de MAITRISE DU RISQUE mises en place afin d'atténuer le RISQUE découlant de la perte de la PERFORMANCE ESSENTIELLE.

NOTE 3 Chaque norme collatérale ou particulière de la série IEC 60601 ou de la série IEC/ISO 80601 peut énumérer des PERFORMANCES ESSENTIELLES potentielles afin de guider le FABRICANT dans l'identification de PERFORMANCES ESSENTIELLES particulières conformes à 4.3.

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La conformité est vérifiée par l'inspection du DOSSIER DE GESTION DES RISQUES.

Lorsque la présente norme prescrit qu'une PERFORMANCE ESSENTIELLE doit être conservée à la suite d'un essai particulier, la conformité est vérifiée par inspection et, si nécessaire, par un(des) essai(s) fonctionnel(s) qui démontre(nt) que les limites spécifiées par le FABRICANT sont maintenues ou que l'APPAREIL EM ou le SYSTEME EM passe dans un état sûr tel que défini par le FABRICANT.

4.4 * DUREE DE VIE PREVUE

Le FABRICANT doit stipuler la DUREE DE VIE PREVUE de L'APPAREIL EM ou du SYSTEME EM dans le DOSSIER DE GESTION DES RISQUES.

La conformité est vérifiée par inspection du DOSSIER DE GESTION DES RISQUES.

4.5 * ~~Sécurité équivalente~~ Mesures de MAITRISE DU RISQUE ou méthodes d'essai alternatives pour les APPAREILS EM ou les SYSTEMES EM

~~Lorsque la présente norme spécifie des exigences couvrant des RISQUES particuliers, d'autres moyens de traitement de ces RISQUES sont acceptables sous réserve que le FABRICANT puisse justifier que les RISQUES RESIDUELS qui résultent de l'application de ces autres moyens sont inférieurs ou égaux aux RISQUES RESIDUELS qui résultent de l'application des exigences de la présente norme.~~

Lorsque la présente norme spécifie une mesure de MAITRISE DU RISQUE ou une méthode d'essai particulière, une mesure de MAITRISE DU RISQUE ou une méthode d'essai alternative est acceptable dès lors que le FABRICANT peut démontrer au moyen de données scientifiques, d'analyses cliniques ou d'études comparatives que le RISQUE RESIDUEL résultant de l'application de la mesure de MAITRISE DU RISQUE ou des méthodes d'essai alternatives reste acceptable et est comparable au RISQUE RESIDUEL résultant de l'application des exigences de la présente norme.

Dans ce contexte, les études comparatives signifient des études comparant l'effet de la mesure de MAITRISE DU RISQUE ou de la méthode d'essai alternative avec la mesure de MAITRISE DU RISQUE ou la méthode d'essai spécifiée dans la présente norme.

NOTE Des mesures de MAITRISE DU RISQUE alternatives peuvent permettre un dépassement des limites spécifiées dans la présente norme ou dans ses normes collatérales ou particulières si des mesures de compensation complémentaires sont prévues.

La conformité est vérifiée par l'inspection du DOSSIER DE GESTION DES RISQUES.

4.6 * Parties D'APPAREIL EM ou de SYSTEME EM en contact avec le PATIENT

Le PROCESSUS de GESTION DES RISQUES doit inclure une évaluation déterminant si des parties qui peuvent venir en contact avec le PATIENT mais qui n'entrent pas dans la définition des PARTIES APPLIQUEES doivent être soumises aux exigences applicables aux PARTIES APPLIQUEES. Pour les parties concernées, les exigences applicables à une PARTIE APPLIQUEE DE TYPE B doivent s'appliquer sauf si l'évaluation identifie le fait que les exigences applicables à une PARTIE APPLIQUEE DE TYPE BF ou à une PARTIE APPLIQUEE DE TYPE CF doivent s'appliquer.

Si le PROCESSUS de GESTION DES RISQUES détermine que de telles parties sont soumises aux exigences ~~pour les~~ applicables aux PARTIES APPLIQUEES, alors toutes les exigences et tous les essais appropriés de la présente norme et des normes collatérales et particulières appropriées doivent s'appliquer, ~~par contre~~ à l'exception de 7.2.10 qui ne s'applique pas à de telles parties.

La conformité est vérifiée par l'inspection du DOSSIER DE GESTION DES RISQUES.

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4.7 * CONDITION DE PREMIER DEFAUT pour APPAREILS EM

Les APPAREILS EM doivent être conçus et construits de manière à rester SECURISES EN PREMIER DEFAUT ou bien à ce que le RISQUE reste acceptable tel qu'il est déterminé en 4.2.

NOTE 1 Les CONDITIONS NORMALES identifiées en 8.1 a) sont prises en compte au cours de l'évaluation de la conformité avec toute exigence de la présente norme que ces conditions pourraient affecter.

Les APPAREILS EM sont considérés comme SECURISES EN PREMIER DEFAUT si:

a) ils emploient un seul moyen de réduction du RISQUE, moyen qui a une probabilité de défaillance négligeable (par exemple ISOLATION RENFORCEE, système de masses suspendues sans DISPOSITIFS DE PROTECTION MECANIQUE avec un FACTEUR DE SECURITE EN TRACTION de 8 X, COMPOSANT AUX CARACTERISTIQUES A HAUTE FIABILITE), ou

b) une condition de premier défaut apparaît mais:

   – le défaut initial est détecté au cours de la DUREE DE VIE PREVUE de L'APPAREIL EM et avant la défaillance d'un deuxième moyen de réduction du RISQUE (par exemple système de masses suspendues avec des DISPOSITIFS DE PROTECTION MECANIQUE) ; ou

   – la probabilité que le deuxième moyen de réduction du RISQUE soit défaillant au cours de la DUREE DE VIE PREVUE de L'APPAREIL EM est négligeable.

Lorsqu'une CONDITION DE PREMIER DEFAUT cause une autre CONDITION DE PREMIER DEFAUT, ces deux défaillances sont considérées comme une seule CONDITION DE PREMIER DEFAUT.

Au cours de tout essai dans des CONDITIONS DE PREMIER DEFAUT, un seul défaut doit être appliqué à la fois.

NOTE 2 Les défauts sont généralement divisés en 3 catégories de probabilités:

a) si improbables qu'ils peuvent être ignorés. Les RISQUES provenant des ces défauts sont considérés comme acceptables;

b) Suffisamment probables pour qu'il soit nécessaire de les prendre en compte, mais pas suffisamment pour qu'ils soient pris en compte un par un (défaut unique). Les défauts de cette catégorie englobent tous ceux qui sont identifiés comme CONDITIONS DE PREMIER DEFAUT dans la présente norme et tous les autres défauts identifiés en appliquant l'ISO 14971, qui satisfont aux critères des CONDITIONS DE PREMIER DEFAUT;

c) si probables, si imprévisibles ou indétectables qu'ils sont considérés comme une CONDITION NORMALE et sont pris en compte de manière individuelle et de manière collective.

Les résultats de l'ANALYSE DE RISQUE doivent être utilisés pour déterminer quelles défaillances doivent faire l'objet d'essais. La défaillance de tout composant à un moment qui causerait une SITUATION DANGEREUSE, y compris celles mentionnées en 13.1, doit être simulée, physiquement ou de manière théorique. L'évaluation destinée à déterminer si un composant est soumis à la simulation de défaillance doit tenir compte du RISQUE associé à la défaillance du composant au cours de la DUREE DE VIE PREVUE de L'APPAREIL EM. Cette évaluation doit être réalisée en appliquant les principes de la GESTION DES RISQUES. L'évaluation doit tenir compte des problèmes tels que la fiabilité, les FACTEURS DE SECURITE DE TRACTION et les caractéristiques des composants. De plus, au cours de la simulation des CONDITIONS DE PREMIER DEFAUT, les défaillances de composant qui sont très probables ou indétectables doivent être simulées.

NOTE 3 Voir aussi la Note 2 de 4.2.

Cette exigence et les essais correspondants ne doivent pas être appliqués aux défaillances de DOUBLE ISOLATION ou d'ISOLATION RENFORCEE ou aux COMPOSANTS AUX CARACTERISTIQUES A HAUTE FIABILITE.

La conformité est déterminée en appliquant les exigences spécifiques et les essais associés aux CONDITIONS DE PREMIER DEFAUT identifiées en 13.2 et aux essais pour les défaillances identifiées à partir de l'évaluation des résultats de L'ANALYSE DE RISQUES. La conformité est confirmée si l'introduction d'une des CONDITIONS DE PREMIER DEFAUT décrites en 13.2 une à la fois, ne conduit pas directement à des SITUATIONS DANGEREUSES décrites en 13.1, ou à toute autre situation donnant lieu à un RISQUE inacceptable.

4.8 * Composants des APPAREILS EM

Tous les composants y compris le câblage, dont la défaillance pourrait donner lieu à une SITUATION DANGEREUSE, doivent être utilisés conformément à leurs caractéristiques spécifiées

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à moins qu'une exception spécifique ne soit faite dans la présente norme ou dans le cadre du PROCESSUS de GESTION DES RISQUES. La fiabilité des composants qui sont utilisés comme MOYEN DE PROTECTION doit être évaluée pour les conditions d'utilisation dans les APPAREILS EM. Ils doivent être conformes avec un des éléments ci-dessous (voir aussi 4.5):

a) les exigences de sécurité applicables d'une norme IEC ou ISO pertinente.

NOTE 1 Pour les composants, il n'est pas nécessaire de réaliser des essais identiques ou équivalents déjà réalisés pour vérifier la conformité avec la norme de composant.

b) en l'absence de norme IEC ou ISO pertinente, les exigences de la présente norme doivent s'appliquer.

NOTE 2 En l'absence d'exigences à la fois dans la présente norme et dans les normes IEC ou ISO, toute autre source applicable (par exemple normes pour d'autres types d'appareils, normes nationales) pourrait être utilisée pour démontrer la conformité avec le PROCESSUS de GESTION DES RISQUES.

Voir Figure 5 pour un schéma fonctionnel de a) et b).

La conformité est vérifiée par examen et, si nécessaire par un essai. Les essais de la présente norme pour les moteurs (voir 13.2.8 et 13.2.13.3) et les transformateurs (voir 15.5.3) sont considérés comme complets et, avec l'évaluation du système d'isolation du moteur ou du système d'isolation du transformateur selon le Tableau 22, ils représentent tous les essais exigés par la présente norme. Les composants des SYSTEMES EM qui assurent une isolation par rapport aux APPAREILS non EM sont évalués selon l'Article 16.

4.9 * Utilisation de COMPOSANTS AUX CARACTERISTIQUES A HAUTE FIABILITE dans les APPAREILS EM

Un COMPOSANT AUX CARACTERISTIQUES A HAUTE FIABILITE doit être utilisé lorsqu'un défaut d'un composant particulier peut générer un RISQUE inacceptable. Les COMPOSANTS AUX CARACTERISTIQUES A HAUTE FIABILITE doivent être choisis et évalués de manière cohérente avec leurs conditions d'utilisation et de leurs mauvais usage raisonnablement prévisible au cours de la DUREE DE VIE PREVUE de l'APPAREIL EM.

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La conformité est vérifiée par inspection du DOSSIER DE GESTION DES RISQUES *et des critères de sélection pour les* COMPOSANTS AUX CARACTERISTIQUES A HAUTE FIABILITE.

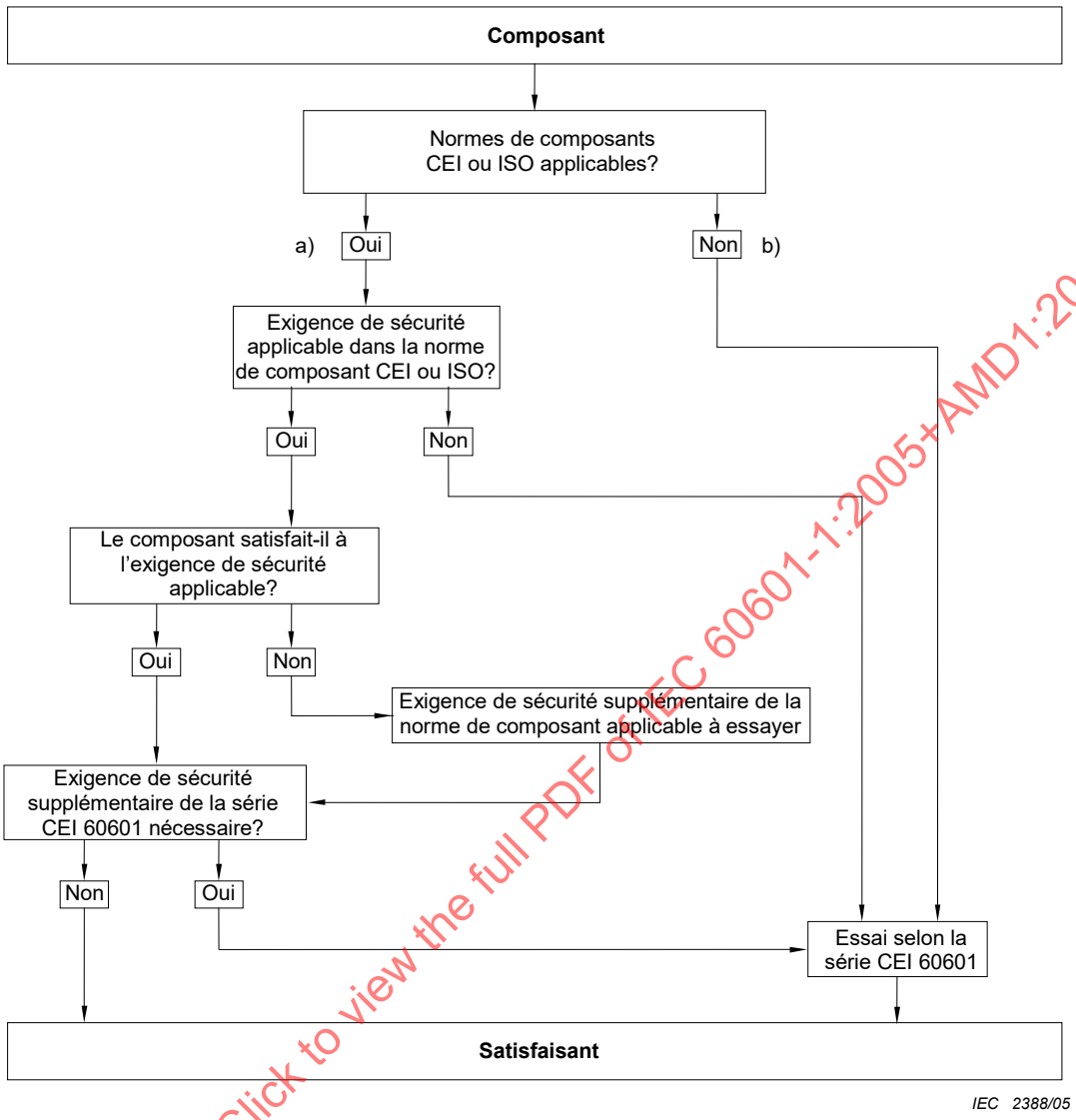


Figure 5 – Schéma fonctionnel pour la qualification des composants
(voir 4.8)

4.10 * Alimentation

4.10.1 Source d'alimentation pour APPAREIL EM

Les APPAREILS EM doivent être adaptés à une connexion au RESEAU, être spécifiés pour être reliés à une alimentation séparée ou pour être alimentés par une SOURCE ELECTRIQUE INTERNE. Sinon, une combinaison de ces sources peut être utilisée.

La conformité est vérifiée par inspection des DOCUMENTS D'ACCOMPAGNEMENT.

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4.10.2 RESEAU D'ALIMENTATION pour APPAREILS EM et SYSTEMES EM

Pour les APPAREILS EM destinés à être reliés au RESEAU D'ALIMENTATION, les tensions ASSIGNEES suivantes ne doivent pas être dépassées:

– 250 V pour les APPAREILS EM PORTATIFS ;

– 250 V courant continu ou courant alternatif monophasé ou 500 V courant alternatif polyphasé pour les APPAREILS EM et les SYSTEMES EM présentant une puissance absorbée ASSIGNEE ≤ 4 kVA ; ou

– 500 V pour tous les autres APPAREILS EM et SYSTEMES EM.

Dans la présente norme, le RESEAU D'ALIMENTATION doit être considéré comme présentant les caractéristiques suivantes:

– catégorie de surtension II pour les transitoires réseau sauf si une catégorie supérieure est spécifiée par le FABRICANT ;

– aucune tension supérieure à 110 % ou inférieure à 90 % de la tension NOMINALE entre chacun des conducteurs du système ou entre l'un de ces conducteurs et la terre (voir 7.9.3.1) ;

NOTE 1 L'IEC 60601-1-2 contient des exigences et des essais concernant les chutes de tension, les interruptions de courte durée et les variations de tension sur le RESEAU D'ALIMENTATION. Voir aussi 1.3.

– tensions pratiquement sinusoïdales et formant un réseau d'alimentation pratiquement symétrique en cas d'alimentation polyphasée ;

– une fréquence ≤ 1 kHz ;

– un écart de fréquence ≤ 1 Hz par rapport à la valeur NOMINALE jusqu'à 100 Hz et ≤ 1 % par rapport à la valeur NOMINALE entre 100 Hz et 1 kHz ;

– les mesures de protection décrites dans l'IEC 60364-4-41 ;

NOTE 2 Si un APPAREIL EM ou un SYSTEME EM est destiné à être alimenté par un RESEAU D'ALIMENTATION dont les caractéristiques diffèrent de celles du RESEAU D'ALIMENTATION décrit dans ce paragraphe, des mesures complémentaires de SECURITE pourraient être nécessaires.

– une tension en courant continu (telle que mesurée par un appareil de mesure à bobine mobile ou une méthode équivalente) présentant une ondulation crête à crête ne dépassant pas 10 % de la valeur moyenne.

Lorsque l'ondulation crête à crête dépasse 10 % de la valeur moyenne, la tension de crête doit être appliquée.

4.11 Puissance absorbée

La puissance, mesurée en régime stabilisé, des APPAREILS EM ou des SYSTEMES EM à la tension ASSIGNEE et avec les réglages de fonctionnement indiqués dans les instructions d'utilisation ne doit pas dépasser les valeurs indiquées de plus de 10 % (voir 7.2.7).

La conformité est vérifiée par inspection et par les essais suivants.

– *On fait fonctionner l'APPAREIL EM ou le SYSTEME EM comme spécifié dans les instructions d'utilisation jusqu'à ce que la puissance absorbée ait atteint une valeur stable. La puissance absorbée est mesurée et comparée avec les marquages et les indications de la description technique.*

– *L'APPAREIL EM ou le SYSTEME EM comportant un marquage avec une ou plusieurs plages de tensions ASSIGNEES est soumis aux essais à la fois aux limites supérieures et inférieures de la plage, sauf si chaque marquage de la puissance absorbée ASSIGNEE a trait à la valeur moyenne de la plage de tension correspondante, auquel cas l'essai est effectué à une tension égale à la valeur moyenne de cette plage.*

– *Le courant en régime stabilisé est mesuré à l'aide d'un instrument de mesure donnant une vraie valeur efficace.*

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Si la puissance absorbée, est exprimée en voltampères, elle est soit mesurée à l'aide d'un voltampèremètre soit déterminée par le produit du courant en régime stabilisé (mesuré comme indiqué ci-dessus) par la tension d'alimentation.

NOTE 1 Les détails techniques d'un compteur donnant une vraie valeur efficace peuvent être trouvés dans l'IEC 62354 [63].

~~Une certification fournisseur peut être utilisée à la place des mesures ci-dessus comme base pour la spécification du courant ou de la puissance absorbée en régime stabilisé.~~

NOTE 2 Des informations du fournisseur peuvent être utilisées pour compléter les mesures ci-dessus, telles qu'une indication de la puissance absorbée.

5 * Exigences générales relatives aux essais des APPAREILS EM

5.1 * ESSAIS DE TYPE

Les essais décrits dans la présente norme sont des ESSAIS DE TYPE. Les essais à réaliser sont déterminés en prenant en compte les exigences de l'Article 4 et en particulier celles de 4.2.

Il n'est pas nécessaire de réaliser un essai si l'analyse montre que la condition soumise aux essais a été correctement évaluée dans le cadre d'autres essais ou méthodes.

~~Les résultats de l'ANALYSE DE RISQUES sont utilisés pour déterminer quelle(s) combinaison(s) de défauts simultanés doit/doivent faire l'objet d'essais.~~

La combinaison de défauts indépendants simultanés, susceptibles de donner lieu à une SITUATION DANGEREUSE, doit être documentée dans le DOSSIER DE GESTION DES RISQUES (voir également 4.7). Lorsque des essais sont nécessaires pour démontrer que la SECURITE DE BASE et les PERFORMANCES ESSENTIELLLES sont conservées en présence de tels défauts indépendants simultanés, les essais concernés peuvent être limités aux situations les plus défavorables.

NOTE 1 Les résultats d'essais pourraient nécessiter une révision de l'ANALYSE DE RISQUES.

NOTE 2 Lorsque l'on considère l'utilisation des essais décrits dans la présente norme en tant qu'essais de routine, voir l'Annexe K de l'IEC/TR 62354 (essais de ligne de production) ou voir l'IEC 62353 (essais récurrents).

5.2 * Nombre de spécimens

Les ESSAIS DE TYPE sont effectués sur un spécimen représentatif du produit à vérifier.

NOTE Il est admis d'utiliser plusieurs spécimens simultanément si la validité des résultats n'est pas affectée de manière significative.

5.3 Température ambiante, humidité, pression atmosphérique

a) Après avoir mis l'APPAREIL EM à soumettre aux essais en condition d'UTILISATION NORMALE (conformément à 5.7), les essais sont effectués dans la plage des conditions d'environnement indiquées dans la description technique (voir 7.9.3.1).

b) Les APPAREILS EM sont protégés des autres influences (par exemple les courants d'air) qui pourraient affecter la validité des essais.

c) S'il n'est pas possible de maintenir la température ambiante, les conditions de l'essai doivent être modifiées et les résultats corrigés en conséquence.

5.4 Autres conditions

a) Sauf ~~spécification~~ indication contraire dans la présente norme, l'APPAREIL EM doit être essayé dans les conditions de ~~fonctionnement~~ service les moins favorables. Les conditions de service sont spécifiées dans les ~~instructions d'utilisation qui sont identifiées au cours de~~

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~~l'ANALYSE DE RISQUES~~ DOCUMENTS D'ACCOMPAGNEMENT. Les conditions de service les moins favorables doivent être documentées pour chaque essai où elles s'appliquent.

b) Les APPAREILS EM dont certains paramètres de fonctionnement peuvent être ajustés ou commandés par une personne n'appartenant pas au PERSONNEL D'ENTRETIEN doivent être ajustés, au cours des essais, aux valeurs les moins favorables pour l'essai correspondant, mais conformément aux instructions d'utilisation.

c) Si les résultats des essais sont affectés par la pression d'entrée et le débit ou par la composition chimique d'un liquide de refroidissement, l'essai est effectué dans les limites de ces caractéristiques telles qu'elles sont prescrites dans la description technique.

d) Lorsque de l'eau de refroidissement est nécessaire, de l'eau potable est utilisée.

5.5 Tensions d'alimentation, type de courant, nature de l'alimentation, fréquence

a) ~~Si les résultats des essais sont influencés par des fluctuations de la tension d'alimentation par rapport à sa valeur ASSIGNEE, les effets de ces fluctuations sont pris en considération.~~

~~La tension d'alimentation au cours des essais est conforme à 4.10 ou à celle marquée sur L'APPAREIL EM (voir 7.2.6), en prenant celle des deux qui est la moins favorable.~~

Si les résultats des essais sont influencés par des fluctuations des caractéristiques du RESEAU D'ALIMENTATION par rapport à leurs valeurs ASSIGNEES, l'effet de ces fluctuations est pris en considération.

Les valeurs utilisées durant les essais sont conformes à 4.10.2 ou conformes aux valeurs indiquées sur l'APPAREIL EM (voir 7.2.6), la moins favorable étant retenue.

NOTE 1 Pour la(les) valeur(s) ASSIGNEE(S) indiquée(s) sur l'APPAREIL EM, les fluctuations du RESEAU D'ALIMENTATION telles qu'indiquées en 4.10.2 n'ont à être soumises à l'essai que si les fluctuations ont un impact négatif sur la SECURITE DE BASE ou les PERFORMANCES ESSENTIELLES.

b) Les APPAREILS EM qui possèdent une PARTIE RELIEE AU RESEAU D'ALIMENTATION destinée à être raccordée à un RESEAU en courant alternatif sont seulement soumis aux essais avec le courant alternatif à la fréquence ASSIGNEE ~~(si celle-ci est marquée) ± 1 Hz jusqu'à 100 Hz inclus et ± 1 % au-delà 100 Hz~~. Les APPAREILS EM marqués d'une plage de fréquences ASSIGNEES sont soumis aux essais à la fréquence la moins favorable dans les limites de cette plage.

c) Les APPAREILS EM conçus pour fonctionner sous plus d'une tension ASSIGNEE~~, ou~~, à la fois en courant alternatif et en courant continu, ou à la fois avec une alimentation externe et une SOURCE ELECTRIQUE INTERNE, sont soumis à l'essai dans les conditions (décrites en 5.4) correspondant à la tension et à la nature de l'alimentation les moins favorables, par exemple nombre de phases (à l'exception de l'alimentation monophasée) et type de courant. Il pourrait être nécessaire d'effectuer certains essais plus d'une fois pour déterminer quelle est la configuration d'alimentation la moins favorable.

d) Les APPAREILS EM possédant une PARTIE RELIEE AU RESEAU D'ALIMENTATION destinés à être raccordés à un RESEAU en courant continu sont seulement soumis aux essais en courant continu. Au cours des essais, l'influence possible de la polarité sur leur fonctionnement est prise en compte, conformément aux instructions d'utilisation. Voir aussi 8.2.2.

e) Les APPAREILS EM pour lesquels des ACCESSOIRES ou des composants interchangeables spécifiés dans les DOCUMENTS D'ACCOMPAGNEMENT (voir 7.9.2.14 et 7.9.3.2) sont disponibles sont soumis à l'essai avec les ACCESSOIRES ou les composants qui créent les conditions les moins favorables.

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f) Si les instructions d'utilisation spécifient que l'APPAREIL EM est destiné à recevoir son énergie d'une alimentation séparée, il est connecté à une telle alimentation. Voir aussi 7.2.5 et 8.2.1.

NOTE 2 Ce qui était désigné dans la première et dans la deuxième édition de la présente norme comme une "alimentation spécifiée" est désormais considéré soit comme une autre partie du même APPAREIL EM soit comme un autre appareil dans un SYSTEME EM.

5.6 Réparations et modifications

Dans le cas de réparations ou de modifications rendues nécessaires à la suite d'une défaillance ou de la probabilité d'une défaillance future au cours de la séquence d'essais, le laboratoire d'essais et le fournisseur de l'APPAREIL EM peuvent se mettre d'accord, soit sur la présentation d'un nouveau spécimen sur lequel tous les essais influençant le résultat sont réalisés à nouveau, soit, de préférence, sur l'exécution de toutes les réparations ou modifications nécessaires, à la suite desquelles seuls les essais concernés sont répétés.

5.7 * Pré-conditionnement humide

Avant d'effecteur les essais de 8.7.4 et de 8.8.3, tous les APPAREILS EM ou leurs parties doivent être soumis à un pré-conditionnement humide.

LES APPAREILS EM ou leurs parties doivent être complètement montés (ou le cas échéant partiellement). Les protections utilisées pendant le transport et le stockage sont retirées.

Ce traitement n'est appliqué qu'aux parties des APPAREILS EM qui sont susceptibles d'être influencées par les conditions climatiques qui sont simulées par l'essai.

Les parties amovibles sans OUTIL sont détachées mais sont soumises au traitement en même temps que la partie principale.

Les CAPOTS D'ACCES dont l'ouverture ou l'enlèvement est possible sans OUTIL sont ouverts et détachés.

Le préconditionnement humide est effectué dans une ~~chambre~~ enceinte humide contenant de l'air à une humidité relative de 93 % ± 3 % dans laquelle sont placés l'APPAREIL EM ou ses parties. Les conditions d'humidité en d'autres endroits de la chambre peuvent varier de ± 6 %. La température de l'air dans ~~la chambre humide~~ l'enceinte, à tous les endroits où l'APPAREIL EM ~~peut~~ ou ses parties peuvent être placés, ~~est~~ doit être maintenue dans les limites de 2 °C de toute valeur *T* appropriée dans la plage de +20 °C à +~~32~~ 30 °C. Avant de ~~l'~~ les introduire dans ~~la chambre~~ l'enceinte humide, on amène l'APPAREIL EM ou ses parties à une température comprise entre *T* et *T* + 4 °C en le maintenant à cette température pendant au moins 4 h avant le début du traitement humide.

~~L'APPAREIL EM et ses parties sont maintenus dans la chambre humide pendant 48 h.~~

~~Lorsque le PROCESSUS de GESTION DES RISQUES suggère que l'APPAREIL EM peut être exposé à une humidité élevée pendant de longues périodes (comme dans le cas des APPAREILS EM destinés à une utilisation extérieure), la période est allongée en conséquence.~~

Conserver l'APPAREIL EM et ses parties, lorsque l'ENVELOPPE est de classe IPX0, dans l'enceinte humide pendant 48 h.

Conserver l'APPAREIL EM et ses parties, lorsque l'ENVELOPPE est conçue pour offrir une meilleure protection contre l'infiltration de liquides, dans l'enceinte humide pendant 168 h.

Après le traitement, l'APPAREIL EM est remonté, si nécessaire.

5.8 Ordre des essais

Sauf indication contraire, les essais de la présente norme sont réalisés dans un ordre tel que les résultats d'un essai n'influencent pas les résultats d'un essai effectué ensuite.

NOTE Il est recommandé que tous les essais soient réalisés selon l'ordre indiqué à l'Annexe B.

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5.9 * Détermination des PARTIES APPLIQUEES ET DES PARTIES ACCESSIBLES

5.9.1 PARTIES APPLIQUEES

Les PARTIES APPLIQUEES sont identifiées par inspection et en se référant aux DOCUMENTS D'ACCOMPAGNEMENT. Voir aussi 4.6.

5.9.2 PARTIE ACCESSIBLE

5.9.2.1 * Doigt d'essai

Les parties de l'APPAREIL EM qui doivent être considérées comme des PARTIES ACCESSIBLES sont identifiées par inspection et si cela est nécessaire par un essai. En cas de doute, l'accessibilité est déterminée par un essai avec le doigt d'essai normalisé représenté à la Figure 6 appliqué en position articulée ou rigide:

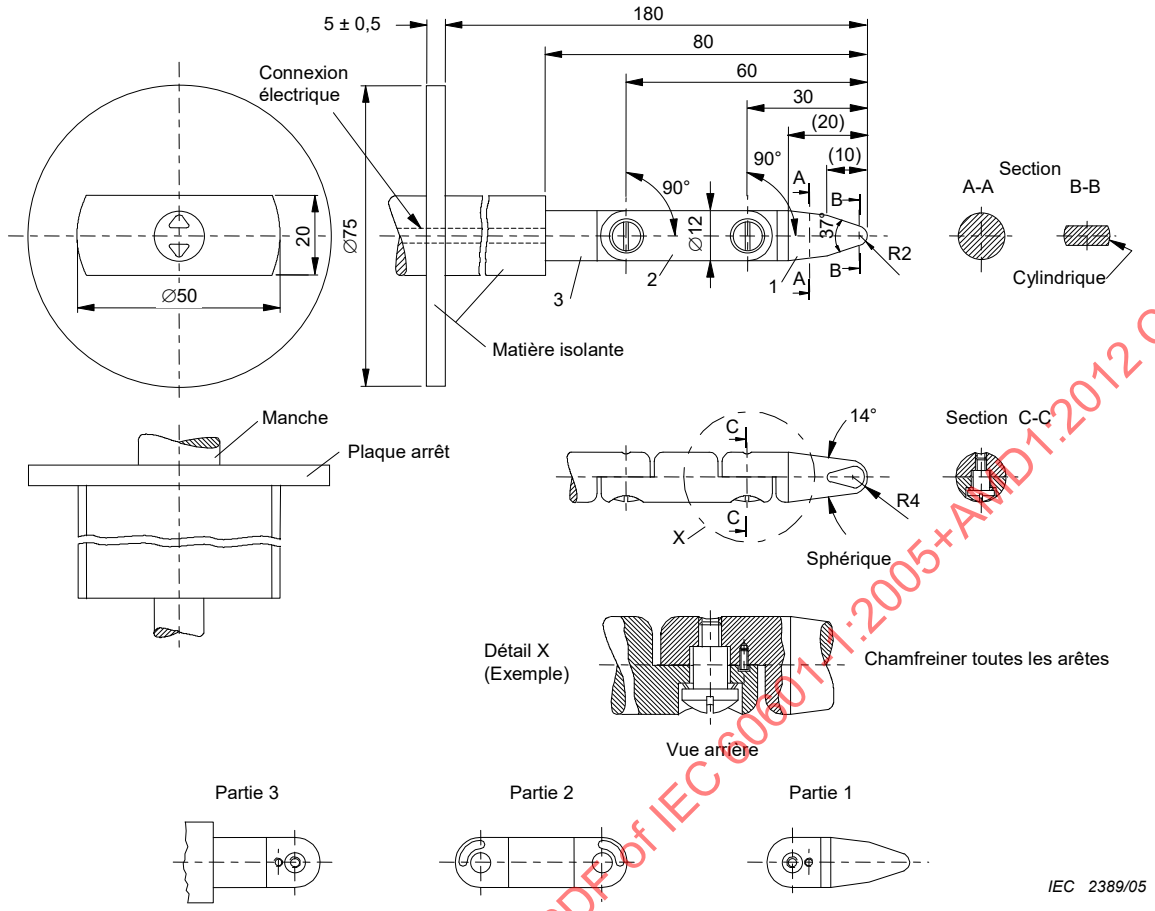
– pour toutes les positions de l'APPAREIL EM lorsqu'il fonctionne comme en UTILISATION NORMALE,

– même après ouverture des CAPOTS D'ACCES et retrait de parties, y compris les lampes, les fusibles et porte-fusibles sans l'utilisation d'un OUTIL ou selon les instructions d'utilisation.

Le doigt d'essai normalisé est appliqué sans force appréciable dans chaque position possible, à l'exception des APPAREILS EM destinés à être utilisés sur le sol et dont la masse dépasse 45 kg quelles que soient les conditions de fonctionnement, qui eux ne sont pas inclinés. Les APPAREILS EM qui, conformément à la description technique, sont destinés à être montés dans une armoire, sont soumis aux essais dans leur position de montage définitive.

Les ouvertures interdisant l'entrée du doigt d'essai normalisé de la Figure 6 sont soumises à l'essai mécanique avec un doigt d'essai rigide non articulé de mêmes dimensions, qui est appliqué avec une force de 30 N. Si ce doigt entre, l'essai avec le doigt d'essai normalisé de la Figure 6 est répété, le doigt étant poussé à travers l'ouverture si nécessaire.

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Dimensions linéaires en millimètres

Tolérances des dimensions sans tolérances spécifiées:

– angles de 14° et 37°: ±15′

– sur les rayons ± 0,1 mm

– sur les dimensions linéaires:

≤ 15 mm: $^{0}_{-0,1}$ mm

> 15 mm ≤ 25 mm: ± 0,1 mm

> 25 mm: ± 0,3 mm

Matériau du doigt: acier trempé à chaud par exemple.

Les deux articulations du doigt d'essai peuvent être pliées selon un angle de 90 $^{+10°}_{0°}$ mais dans une seule et même direction uniquement.

NOTE 1 L'utilisation de la solution pointe-rainure n'est qu'une des solutions possibles pour limiter l'angle de pliage à 90°. Pour cette raison, les dimensions et tolérances de ces détails ne sont pas indiquées sur le dessin. Il faut que la conception réelle assure un angle de pliage de 90° avec tolérance de 0° à +10°.

NOTE 2 Les dimensions entre parenthèses sont données à titre d'information seulement.

NOTE 3 Le doigt d'essai est pris de l'IEC 60950-1, Figure 2A. Ce doigt d'essai est basé sur l'IEC 61032[18)], Figure 2, calibre d'essai B. Dans certains cas, les tolérances sont différentes.

Figure 6 – Doigt d'essai normalisé (voir 5.9.2.1)

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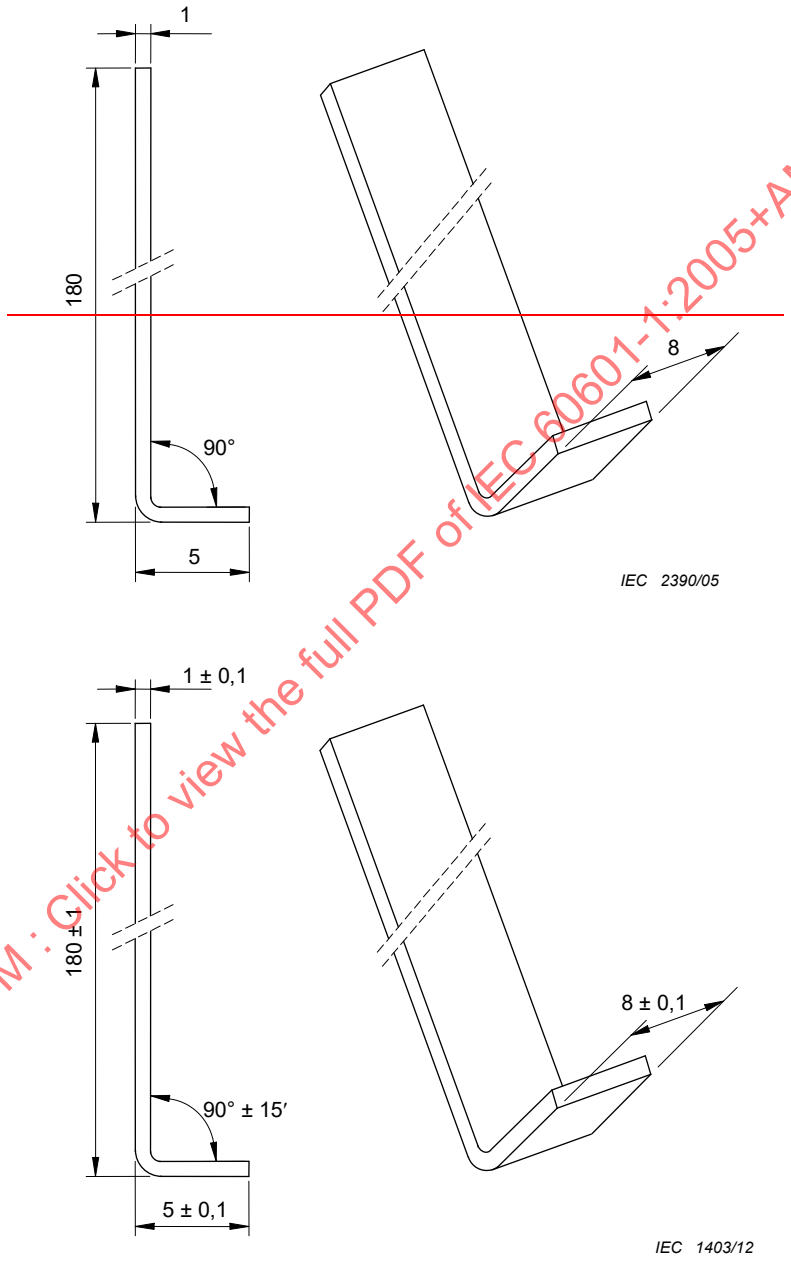
18) IEC 61032:1997, *Protection des personnes et des matériels par les enveloppes - Calibres d'essai pour la vérification*

5.9.2.2 Crochet d'essai

Les ouvertures des APPAREILS EM sont soumises à l'essai mécanique du crochet d'essai (voir Figure 7), si celui-ci peut être introduit.

Le crochet d'essai est introduit dans toutes les ouvertures concernées et il est ensuite tiré avec une force de 20 N pendant 10 s dans une direction sensiblement perpendiculaire à la surface comportant l'ouverture en cause. Toute partie complémentaire qui est devenue accessible est identifiée en utilisant le doigt d'essai normalisé de la Figure 6 et par inspection.

Dimensions en millimètres



Matériau: acier

Figure 7 – Crochet d'essai
(voir 5.9.2.2)

5.9.2.3 Mécanismes de manœuvre

Les parties conductrices des mécanismes de manœuvre des commandes électriques qui sont accessibles après enlèvement des poignées, des boutons, des leviers et pièces similaires

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sont considérées comme des PARTIES ASSESSIBLES. Les parties conductrices des mécanismes de manœuvre ne sont pas considérées comme des PARTIES ACCESSIBLES ~~si le retrait des~~ lorsque l'enlèvement des poignées, boutons, etc. ~~exige~~ nécessite l'utilisation d'un ~~OUTIL et que le contrôle du DOSSIER DE GESTION DES RISQUES montre que la partie concernée n'est pas susceptible d'être retirée involontairement au cours de la DUREE DE VIE PREVUE de L'APPAREIL EM. Voir aussi 15.4.6.1~~.

La conformité est vérifiée par des essais conformes à 5.9.2.1 et 15.4.6.1.

6 * Classification des APPAREILS EM ET DES SYSTEMES EM

6.1 Généralités

Pour les besoins de la présente norme, les APPAREILS EM ou les parties de ces appareils, y compris les PARTIES APPLIQUEES, doivent être classés comme suit.

6.2 * Protection contre les chocs électriques

Les APPAREILS EM alimentés par une source électrique externe doivent être classés APPAREILS EM DE LA CLASSE I ou APPAREILS EM DE LA CLASSE II (voir 7.2.6). Les autres APPAREILS EM doivent être classés comme APPAREILS EM A SOURCE ELECTRIQUE INTERNE.

Les APPAREILS EM A SOURCE ELECTRIQUE INTERNE ayant un moyen de raccordement au RESEAU D'ALIMENTATION doivent être conformes aux exigences pour les APPAREILS EM DE LA CLASSE I ou de la CLASSE II lorsqu'ils sont connectés, et aux exigences pour les APPAREILS EM à SOURCE ELECTRIQUE INTERNE lorsqu'ils ne sont pas connectés.

Les PARTIES APPLIQUEES doivent être classées comme PARTIES APPLIQUEES DE TYPE B comme PARTIES APPLIQUEES DE TYPE BF ou comme PARTIES APPLIQUEES DE TYPE CF (voir 7.2.10 et 8.3). Les PARTIES APPLIQUEES peuvent être classées comme PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION (voir 8.5.5).

6.3 * Protection contre les effets nuisibles de la pénétration d'eau ou de corps solides

Les ENVELOPPES doivent être classées en fonction du degré de protection contre les effets nuisibles de la pénétration d'eau et de corps solides comme détaillé dans l'IEC 60529 (voir 7.2.9 et 11.6.5).

NOTE 1 Cette classification est IPN_1N_2 où:

– N_1 est un nombre entier indiquant le degré de protection contre la pénétration de corps solides ou la lettre "X",

– N_2 est un nombre entier indiquant le degré de protection contre la pénétration d'eau ou la lettre "X".

NOTE 2 Voir aussi le Tableau D.3.

6.4 Méthode(s) de stérilisation

Les APPAREILS EM ou leurs parties qui sont destinés à être stérilisés doivent être classés selon la ou les méthodes de stérilisation indiquées dans les instructions d'utilisation (voir 7.9.2.12 et 11.6.7).

EXEMPLE 1 Au gaz d'oxyde d'éthylène.

EXEMPLE 2 Par rayonnement, comme le rayonnements gamma.

EXEMPLE 3 A la chaleur humide, comme avec un autoclave.

EXEMPLE 4 Par d'autres méthodes validées et décrites par le FABRICANT.

6.5 Adaptation à l'utilisation dans un ENVIRONNEMENT RICHE EN OXYGENE

Les APPAREILS EM et les SYSTEMES EM qui sont destinés à être utilisés dans un environnement riche en oxygène doivent être classés pour une telle utilisation (voir 11.2.2).

6.6 * Mode de fonctionnement

Les APPAREILS EM doivent être classés pour SERVICE CONTINU ou bien pour SERVICE NON CONTINU (voir 7.2.11).

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7 Identification, marquage et documentation des APPAREILS EM

NOTE L'Annexe C contient un guide pour aider le lecteur à localiser les exigences de marquage et d'étiquetage concernant les APPAREILS et les SYSTEMES EM traités dans d'autres articles de la présente norme.

7.1 Généralités

7.1.1 * APTITUDE A L'UTILISATION de l'identification, du marquage et de la documentation

~~Le FABRICANT doit, dans un PROCESSUS INGENIERIE DE L'APTITUDE A L'UTILISATION, traiter la question du RISQUE de mauvaise APTITUDE A L'UTILISATION associée à la conception de l'identification, du marquage et de la documentation des APPAREILS EM. Voir l'IEC 60601-1-6 et voir aussi 1.3 et 12.2.~~

~~*La conformité est vérifiée par inspection des résultats du PROCESSUS D'INGENIERIE DE L'APTITUDE A LA FONCTION.*~~

Voir 12.2.

7.1.2 * Lisibilité des marquages

Les marquages exigés par 7.2, 7.3, 7.4, 7.5 et 7.6 doivent être CLAIREMENT LISIBLES dans les conditions suivantes:

– pour les avertissements, les instructions, les signes de sécurité et les dessins situés sur l'extérieur de L'APPAREIL EM: à partir de l'emplacement prévu de la personne assurant la fonction associée;

– pour les APPAREILS EM INSTALLES A POSTE FIXE: lorsque L'APPAREIL EM est monté dans sa position d'UTILISATION NORMALE;

– pour les APPAREILS EM TRANSPORTABLES et pour les APPAREILS EM FIXES qui ne sont pas des APPAREILS EM INSTALLES A POSTE FIXE: en UTILISATION NORMALE ou après avoir écarté L'APPAREIL EM d'un mur contre lequel il était placé ou après rotation de L'APPAREIL EM par rapport à sa position en UTILISATION NORMALE et, dans le cas d'éléments modulaires amovibles, après retrait de ces derniers de l'ensemble;

– pour les marquages à l'intérieur des APPAREILS EM ou des parties D'APPAREILS EM: lorsqu'ils sont vus à partir de l'emplacement prévu de la personne assurant la fonction associée.

La conformité de bonne lisibilité est vérifiée par l'essai suivant:

~~*L'APPAREIL EM ou sa partie est positionné de manière que la position de vue soit la position prévue de l'OPERATEUR, ou bien la position de vue est située en tout point de la base d'un cône sous-tendu par un angle de 30° par rapport à l'axe perpendiculaire au centre du plan de marquage et à une distance de 1 m. L'éclairement ambiant est au niveau le moins favorable dans la plage comprise entre 100 lx et 1 500 lx. L'observateur a une acuité visuelle de 0 sur l'échelle log MAR (log (Angle Minimal de Résolution)) ou de 6/6 (20/20), corrigée si nécessaire.*~~

L'APPAREIL EM ou ses parties sont positionnés de sorte que la position de vue corresponde à la position prévue de l'OPERATEUR. Si la position prévue de l'OPERATEUR n'est pas spécifiée et si elle n'est pas claire, la position de vue se trouve en un point quelconque dans la base d'un cône sous-tendu par un angle de 30 ° par rapport à l'axe normal au centre du plan du marquage et à une distance de 1 m. L'éclairage ambiant est au niveau le moins favorable dans la plage comprise entre 100 lx et 1 500 lx.

L'observateur a une acuité visuelle, corrigée si nécessaire, de:

– *0 sur l'échelle d'Angle Minimal de Résolution (log MAR) ou de 6/6 (20/20); et*

– *est capable de lire le niveau N6 du test de Jaeger;*

dans des conditions d'éclairage normales (environ 500 lx).

L'observateur lit correctement le marquage depuis la position de vue.

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7.1.3 * Résistance des marquages

Les marquages exigés par 7.2, 7.3, 7.4, 7.5 et 7.6 ne doivent pouvoir être retirés qu'avec un OUTIL ou avec une force appréciable et ils doivent être suffisamment durables pour rester CLAIREMENT LISIBLES pendant la DUREE DE VIE PREVUE de L'APPAREIL EM. Lors de l'examen de la durabilité des marquages, l'effet de l'UTILISATION NORMALE doit être pris en compte.

La conformité est vérifiée par inspection et par les essais suivants:

a) *Après réalisation de tous les essais de la présente norme (voir l'ordre recommandé des essais à l'Annexe B):*

– *les marquages sont soumis aux essais des exigences de 7.1.2; et*

– *les étiquettes adhésives ne doivent pas être décollées, ou avoir roulé aux angles.*

b) Pour les marquages exigés par 7.2, 7.3, 7.4, 7.5 et 7.6, un essai supplémentaire de durabilité doit être réalisé. Les marquages sont frottés à la main, sans pression excessive, d'abord pendant 15 s avec un chiffon imbibé d'eau distillée, puis pendant 15 s avec un chiffon imbibé ~~d'alcool dénaturé~~ éthanol à 96 % à brûler à la température ambiante et enfin pendant 15 s avec un chiffon imbibé d'alcool isopropylique.

7.2 Marquage sur l'extérieur des APPAREILS EM ou parties d'APPAREILS EM (voir aussi Tableau C.1)

7.2.1 Exigences minimales pour le marquage sur les APPAREILS EM et sur les parties interchangeables

Si la taille de l'APPAREIL EM, d'une partie de l'APPAREIL EM ou d'un ACCESSOIRE D'APPAREIL EM ou la nature de son ENVELOPPE ne permet pas l'inscription de tous les marquages spécifiés de 7.2.2 à 7.2.20 (inclus), alors au minimum les marquages indiqués en 7.2.2, 7.2.5, 7.2.6 (à l'exception des APPAREILS EM INSTALLES DE FAÇON PERMANENTE), 7.2.10 et 7.2.13 (si applicable) doivent être apposés et les marquages restants doivent être mentionnés in extenso dans les DOCUMENTS D'ACCOMPAGNEMENT. Lorsque aucun marquage de L'APPAREIL EM n'est réalisable en pratique, il est admis que les marquages soient apposés sur l'emballage individuel.

Tout matériau, composant, ACCESSOIRE ou APPAREIL EM qui est destiné à un usage unique ou son emballage doit porter le marquage suivant "À usage unique", "Ne pas réutiliser" ou le symbole ISO 7000-1051 (~~DB:~~2004-01) (voir Tableau D.1, symbole 28).

NOTE Voir aussi 7.9.2.12.

7.2.2 * Identification

~~L'APPAREIL EM et ses composants amovibles doivent porter un marquage avec le nom ou la marque de fabrique du FABRICANT, et une REFERENCE DE MODELE OU DE TYPE sauf si une mauvaise identification ne présente pas un RISQUE inacceptable.~~

L'APPAREIL EM doit porter les marquages suivants:

– le nom ou la marque de fabrique et des informations permettant de contacter le FABRICANT;

– une REFERENCE DE MODELE OU DE TYPE;

– un numéro de série ou un identifiant de lot; et

– la date de construction ou la date limite d'utilisation, le cas échéant.

NOTE Voir l'ISO 15223-1 pour les symboles du FABRICANT, du numéro de série, du lot, de l'année de construction et de la date limite d'utilisation.

Le numéro de série, l'identifiant du lot et la date de construction peuvent être fournis sous forme de code lisible à l'œil humain ou par l'intermédiaire de technologies d'identification automatique telles que les codes barres ou la technologie RFID.

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Les composants non fixés à demeure de l'APPAREIL EM doivent indiquer:

– le nom ou la marque de fabrique du FABRICANT; et

– une REFERENCE DE MODELE OU DE TYPE;

sauf si une mauvaise identification n'entraîne aucun RISQUE INACCEPTABLE.

Un logiciel faisant partie d'un SYSTEME ELECTROMEDICAL PROGRAMMABLE (SEMP) doit être identifié de manière unique, par exemple par le niveau de révision ou la date de parution/d'édition. L'identification doit être à la disposition des personnes désignées, par exemple le PERSONNEL D'ENTRETIEN. Il n'est pas nécessaire que l'identification soit apposée sur l'extérieur de L'APPAREIL EM.

7.2.3 * Consultation des DOCUMENTS D'ACCOMPAGNEMENT

Lorsque cela est approprié, le symbole ISO 7000-1641 (~~DB:~~2004-01) (voir Tableau D.1, symbole 11) peut être utilisé pour engager L'OPERATEUR à consulter les DOCUMENTS D'ACCOMPAGNEMENT. Lorsque la consultation des DOCUMENTS D'ACCOMPAGNEMENT est une action obligatoire, le signe de sécurité ISO 7010-M002 (voir Tableau D.2, signe de sécurité 10) doit être utilisé à la place du symbole ISO 7000-1641.

7.2.4 * ACCESSOIRES

~~Les ACCESSOIRES doivent porter un marquage avec le nom ou la marque de fabrique de leur FABRICANT ou de leur fournisseur et avec une REFERENCE DE MODELE OU DE TYPE. Lorsque aucun marquage des ACCESSOIRES n'est réalisable en pratique, il est admis que les marquages soient apposés sur l'emballage individuel.~~

Les ACCESSOIRES doivent porter les marquages suivants:

– le nom ou la marque de fabrique et des informations permettant de contacter le FABRICANT;

– une REFERENCE DE MODELE OU DE TYPE;

– un numéro de série ou un identifiant de lot; et

– la date de construction ou la date limite d'utilisation, le cas échéant.

NOTE Voir l'ISO 15223-1 pour les symboles du FABRICANT, du numéro de série, du lot, de l'année de construction et de la date limite d'utilisation.

Le numéro de série, l'identifiant du lot et la date de construction peuvent être fournis sous forme de code lisible à l'œil humain ou par l'intermédiaire de technologies d'identification automatique telles les codes barres ou la technologie RFID.

Lorsqu'aucun marquage des ACCESSOIRES n'est réalisable en pratique, il est admis que les marquages soient apposés sur l'emballage individuel.

7.2.5 APPAREILS EM destinés à être alimentés par d'autres appareils

~~Si l'APPAREIL EM est destiné à être alimenté par d'autres appareils y compris d'autres APPAREILS EM d'un SYSTEME EM et que la connexion à une autre source pourrait donner lieu à un RISQUE inacceptable, la REFERENCE DE MODELE OU DE TYPE de l'autre appareil spécifié doit être marquée en permanence à proximité du point de connexion correspondant. Voir aussi 7.9.2.3, 8.2.1 et 16.3.~~

Si l'APPAREIL EM est destiné à être alimenté par d'autres appareils électriques dans un SYSTEME EM et si la conformité avec les exigences de la présente norme dépend de ces autres appareils, un des éléments ci-dessous doit être fourni:

– le nom ou la marque du FABRICANT des autres appareils électriques ainsi qu'une REFERENCE DE MODELE OU DE TYPE des autres appareils spécifiés à proximité du point de connexion concerné;

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– la mise en place d'un signe de sécurité ISO 7010-M002 (voir Tableau D.2, signe de sécurité 10) à proximité du point de connexion concerné et l'énumération des détails requis dans les instructions d'utilisation; ou

– l'utilisation d'un modèle spécial de connecteur, qui n'est pas couramment disponible sur le marché, et l'énumération des détails requis dans les instructions d'utilisation.

Voir aussi 7.9.2.3, 8.2.1 et 16.3.

7.2.6 Raccordement au RESEAU D'ALIMENTATION

Les APPAREILS EM doivent porter les marquages suivants:

– la ou les tensions d'alimentation ASSIGNEES ou la ou les plages de tensions ASSIGNEES auxquelles ils peuvent être reliés. Dans une plage de tensions d'alimentation ASSIGNEE, un trait d'union (-) doit séparer les tensions minimale et maximale. Lorsque plusieurs tensions d'alimentation ASSIGNEES ou plusieurs plages de tensions d'alimentation ASSIGNEES sont indiquées, elles doivent être séparées par une barre oblique (/) ;

  EXEMPLE 1 Plage de tensions d'alimentation ASSIGNEE 100-240 V. Cela signifie que l'APPAREIL EM est conçu pour être connecté à un RESEAU D'ALIMENTATION d'une tension NOMINALE comprise entre 100 V et 240 V.

  EXEMPLE 2 Tensions d'alimentation ASSIGNEES multiples: 120/220/240 V. Cela signifie que l'APPAREIL EM est conçu pour être commuté afin de permettre le raccordement à un RESEAU D'ALIMENTATION d'une tension NOMINALE de 120 V ou 220 V ou 240 V.

  NOTE 1 Le marquage de la tension ASSIGNEE d'alimentation est celui donné dans l'IEC 61293[19].

– nature de l'alimentation, par exemple nombre de phases (sauf pour l'alimentation monophasée) et type de courant. Il est admis d'utiliser les symboles IEC 60417-5032, 5032-1, 5032-2, 5031 et 5033 (tous ~~DB:~~2002-10) dans ce but (voir Tableau D.1, Symboles 1, 2, 3, 4 et 5);

  NOTE 2 Pour le courant alternatif, la fréquence ASSIGNEE en hertz est suffisante pour identifier le type de courant.

– la fréquence d'alimentation ASSIGNEE ou la plage de fréquences ASSIGNEE en hertz;

  EXEMPLE 3 Plage de fréquences d'alimentation ASSIGNEES: 50-60 Hz. Cela signifie que l'APPAREIL EM est conçu pour être raccordé à un RESEAU D'ALIMENTATION d'une fréquence NOMINALE comprise entre 50 Hz et 60 Hz.

– pour les APPAREILS EM DE LA CLASSE II, symbole IEC 60417-5172 (~~DB:~~2003-02) (voir Tableau D.1, symbole 9).

Sauf pour les APPAREILS EM INSTALLES DE FAÇON PERMANENTE, ces marquages doivent apparaître sur l'extérieur de la partie qui contient la connexion au RESEAU D'ALIMENTATION et de préférence près du point de connexion. Pour les APPAREILS EM INSTALLES DE FAÇON PERMANENTE, la tension d'alimentation ou la plage de tensions NOMINALE à laquelle ils peuvent être connectés peut être marquée à l'intérieur ou à l'extérieur de l'APPAREIL EM, de préférence à proximité ~~des bornes de connexion d'alimentation~~ de la connexion au RESEAU D'ALIMENTATION.

7.2.7 Puissance absorbée du RESEAU D'ALIMENTATION

La puissance absorbée ASSIGNEE du RESEAU D'ALIMENTATION doit être marquée sur l'APPAREIL EM. La puissance absorbée ASSIGNEE doit être donnée en:

– ampères ou volt-ampères, ou

– si le facteur de puissance ~~est supérieur à~~ dépasse 0,9, en ampères, volt-ampères ou watts.

Pour les APPAREILS EM qui ont une ou plusieurs plages de tensions ASSIGNEES, la puissance absorbée ASSIGNEE doit toujours être donnée pour les limites supérieures et inférieures de ces plages, lorsque l'étendue de celles-ci est supérieure à ±10 % de la valeur moyenne de la plage considérée.

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19) IEC 61293: 1994, *Marquage des matériels électriques avec des caractéristiques assignées relatives à l'alimentation électrique – Prescriptions de sécurité*

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Si les limites de la plage ne s'écartent pas de plus de 10 % de la valeur moyenne, le marquage de la puissance absorbée à la valeur moyenne de la plage est suffisant.

Si les caractéristiques d'un APPAREIL EM comprennent à la fois des niveaux permanents et des niveaux instantanés de courant et de volt-ampère, le marquage doit comporter à la fois le niveau de volt-ampère permanent et le niveau le plus approprié de puissance instantanée, chacun de ces niveaux étant distinctement identifié et indiqué dans les DOCUMENTS D'ACCOMPAGNEMENT.

La puissance absorbée marquée D'UN APPAREIL EM muni de sorties destinées au branchement de conducteurs d'alimentation d'autres appareils électriques doit comprendre la puissance de sortie ASSIGNEE (et marquée) de ces sorties.

7.2.8 Connecteurs de sortie

7.2.8.1 Sortie de puissance réseau

Pour les SOCLES DE PRISES MULTIPLES qui sont intégrés aux APPAREILS EM, voir 16.9.2.1 b).

7.2.8.2 Autres sources de puissance

A l'exception des SOCLES DE PRISES MULTIPLES ou des connecteurs destinés uniquement aux appareils, parties d'appareils ou ACCESSOIRES spécifiés, les connecteurs de sorties des APPAREILS EM destinés à fournir du courant doivent porter un marquage comportant les informations suivantes:

– tension de sortie ASSIGNEE;

– courant ou puissance ASSIGNES (si applicable);

– fréquence de sortie (si applicable).

7.2.9 Classification IP

Les APPAREILS EM ou les parties d'APPAREILS EM doivent être marqués avec un symbole, utilisant les lettres IP suivies par les désignations décrites dans l'IEC 60529, en fonction de la classification de 6.3 (voir Tableau D.3, Code 2).

Il n'est pas nécessaire que les APPAREILS EM classés IPX0 ou IP0X soient marqués comme tels.

7.2.10 * PARTIES APPLIQUEES

Cette exigence ne s'applique pas aux parties qui ont été identifiés conformément à 4.6.

Le degré de protection contre les chocs électriques selon 6.2 pour toutes les PARTIES APPLIQUEES doit être marqué avec le symbole pertinent, par exemple, PARTIES APPLIQUEES DE TYPE B, avec le symbole IEC 60417-5840 (~~DB:~~2002-10), PARTIES APPLIQUEES DE TYPE BF, avec le symbole IEC 60417-5333 (~~DB:~~2002-10) ou PARTIES APPLIQUEES DE TYPE CF avec le symbole IEC 60417-5335 (~~DB:~~2002-10) (voir Tableau D.1, symboles 19, 20 et 21).

Pour les PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION, les symboles IEC 60417-5841, IEC 60417-5334 ou IEC 60417-5336 (tous ~~DB:~~2002-10) doivent être utilisés selon celui qui est applicable (voir Tableau D.1, symboles 25, 26 et 27).

Le symbole pertinent doit être marqué à proximité ou sur le connecteur de la PARTIE APPLIQUEE, sauf:

– s'il n'y a pas un tel connecteur, auquel cas le marquage doit être placé sur la PARTIE APPLIQUEE ; ou

– si le connecteur est utilisé pour plus d'une PARTIE APPLIQUEE et si les différentes PARTIES APPLIQUEES ont des classifications différentes, auquel cas chaque PARTIE APPLIQUEE doit être marquée avec le symbole pertinent.

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Pour assurer une bonne différentiation avec le symbole IEC 60417-5333, le symbole IEC 60417-5840 ne doit pas être appliqué de manière à donner l'impression d'être inscrit à l'intérieur d'un carré. (voir Tableau D.1, symboles 19 et 20).

Si la protection contre l'effet de décharge d'un défibrillateur cardiaque est partiellement dans le câble PATIENT, le signe de sécurité ISO 7010-W001 doit être placé à proximité du socle concerné (voir Tableau D.2, signe de sécurité 2). Les instructions d'utilisation doivent expliquer que la protection des APPAREILS EM contre les effets de la décharge d'un défibrillateur cardiaque dépend de l'utilisation des câbles appropriés.

7.2.11 Mode de fonctionnement

En l'absence de marquage, on présume que l'APPAREIL EM est adapté au SERVICE CONTINU. Pour les APPAREILS EM destinés au SERVICE NON CONTINU, le TAUX D'UTILISATION doit être indiqué en utilisant un marquage approprié donnant la durée maximale de fonctionnement et la durée minimale d'arrêt.

7.2.12 * Fusibles

Lorsque le porte-fusible est une PARTIE ACCESSIBLE, le type et les caractéristiques complètes du fusible (tension, intensité, vitesse de fonctionnement et pouvoir de coupure) doivent être marqués à proximité du porte-fusible.

7.2.13 Effets physiologiques (signes de sécurité et avertissements)

Les APPAREILS EM qui produisent des effets physiologiques qui ne sont pas manifestes pour l'OPERATEUR et qui peuvent entraîner des DOMMAGES au PATIENT ou à l'OPERATEUR doivent porter un signe de sécurité approprié (voir 7.5). Le signe de sécurité doit apparaître à un emplacement en vue de manière à être CLAIREMENT LISIBLE en UTILISATION NORMALE après INSTALLATION CORRECTE de l'APPAREIL EM.

Les instructions d'utilisation doivent décrire la nature du DANGER et les précautions pour l'éviter ou en minimiser le RISQUE associé.

7.2.14 DISPOSITIFS DE RACCORDEMENT HAUTE TENSION

Les DISPOSITIFS DE RACCORDEMENT HAUTE TENSION sur l'extérieur des APPAREILS EM qui sont accessibles sans l'utilisation d'un OUTIL doivent être marqués avec le symbole IEC 60417-5036 (~~DB:~~2002-10) (voir Tableau D.1, symbole 24).

NOTE Les DISTANCES DANS L'AIR et les LIGNES DE FUITE entre les contacts haute tension et le doigt d'essai standard sont soumises aux exigences de 8.9.

7.2.15 Conditions de refroidissement

Les exigences relatives aux dispositions de refroidissement pour les APPAREILS EM (par exemple, alimentation en eau et en air) doivent être indiquées par marquage.

7.2.16 Stabilité mécanique

Pour les exigences concernant les APPAREILS EM à stabilité limitée, voir 9.4.

7.2.17 Emballage de protection

Si des mesures spéciales de manutention doivent être prises pendant le transport ou le stockage, l'emballage doit être marqué en conséquence (voir l'ISO 780).

Les conditions environnementales admissibles pour le transport et le stockage doivent être marquées sur l'extérieur de l'emballage (voir 7.9.3.1 et l'ISO 15223-1).

Si le déballage prématuré d'un APPAREIL EM ou des ses parties peut donner lieu à un RISQUE inacceptable, l'emballage doit porter un marquage avec le signe de sécurité approprié (voir 7.5).

EXEMPLE 1 APPAREILS EM sensibles à l'humidité.

EXEMPLE 2 APPAREILS EM contenant des substances et des matières dangereuses.

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L'emballage ~~d'un APPAREIL EM ou d'ACCESSOIRES~~ des APPAREILS EM ou des ACCESSOIRES fournis stériles doit être marqué comme étant stérile et indiquer la méthode de stérilisation (voir l'ISO 15223-1).

7.2.18 Source de pression externe

~~La pression d'alimentation maximale ASSIGNEE fournie par une source externe doit être indiquée par un marquage sur l'APPAREIL EM à proximité de chaque connecteur d'entrée.~~

A proximité de chaque connecteur d'entrée, l'APPAREIL EM doit être marqué avec:

– la pression d'alimentation maximale ASSIGNEE fournie par une source externe, et

– la vitesse d'écoulement ASSIGNEE, si nécessaire pour maintenir la SECURITE DE BASE ou les PERFORMANCES ESSENTIELLES.

7.2.19 BORNES DE TERRE FONCTIONNELLE

Une BORNE DE TERRE FONCTIONNELLE doit être marquée avec le symbole IEC 60417-5017 (~~DB:2002-10~~ 2006-08) (voir Tableau D.1, symbole 7).

7.2.20 Moyens de protection amovibles

Si un APPAREIL EM a différentes applications qui exigent le retrait d'un moyen de protection pour utiliser une fonction particulière, ce moyen de protection doit porter un marquage indiquant la nécessité de sa remise en place lorsque la fonction concernée n'est plus nécessaire. Aucun marquage n'est exigé lorsqu'il existe un verrouillage.

La conformité avec les exigences de 7.2 est vérifiée par examen et par l'application des essais et des critères de 7.1.2 et 7.1.3.

7.2.21 * Masse de l'APPAREIL EM MOBILE

UN APPAREIL EM MOBILE doit porter un marquage indiquant sa masse et comprenant sa CHARGE DE FONCTIONNEMENT EN SECURITE en kilogrammes. Le marquage doit être réalisé de manière à s'appliquer de manière évidente à l'APPAREIL EM MOBILE dans son entier lorsqu'il est chargé à sa CHARGE DE FONCTIONNEMENT EN SECURITE, et est séparé et distinct de tout marquage relatif aux exigences applicables à la charge maximale des coffres, des tablettes ou des tiroirs.

7.3 Marquage à l'intérieur des APPAREILS EM ou parties d'APPAREILS EM (voir aussi Tableau C.2)

7.3.1 Eléments chauffants ou douilles

La puissance consommée maximale des éléments chauffants ou des douilles des lampes chauffantes doit être marquée à proximité du corps chauffant ou dans le corps chauffant lui-même.

Pour les éléments chauffants ou les douilles qui sont conçus pour être utilisés avec des lampes chauffantes qui ne peuvent être remplacées que par le PERSONNEL D'ENTRETIEN avec utilisation d'un OUTIL, un marquage d'identification se référant à une information indiquée dans les DOCUMENTS D'ACCOMPAGNEMENT est suffisant.

7.3.2 * Parties à HAUTE TENSION

La présence de parties à HAUTE TENSION doit être marquée avec le symbole IEC 60417-5036 (~~DB:~~2002-10) (voir Tableau D.1, symbole 24) ou avec le signe de sécurité 3 (voir Tableau D.2, signe de sécurité 3). Voir aussi 7.5.

7.3.3 Batteries d'accumulateurs

Le type de batterie d'accumulateurs et le mode de montage (si applicable) doivent être indiqués (voir 15.4.3.2).

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Pour les batteries d'accumulateurs qui sont prévues pour être remplacées uniquement par le PERSONNEL D'ENTRETIEN à l'aide d'un OUTIL, un marquage d'identification se référant à une information indiquée dans les DOCUMENTS D'ACCOMPAGNEMENT est suffisant.

Lorsque des batteries d'accumulateurs au lithium ou des piles à combustible sont incorporées et qu'un remplacement incorrect pourrait entraîner un RISQUE inacceptable, un avertissement indiquant que le remplacement par un personnel sans formation appropriée pourrait entraîner un DANGER (par exemple températures excessives, incendie, explosion) doit être donné en plus du marquage d'identification faisant référence aux informations contenues dans les DOCUMENTS D'ACCOMPAGNEMENT.

7.3.4 * Fusibles, COUPE-CIRCUIT THERMIQUES et DISJONCTEURS

Les fusibles et les COUPE-CIRCUIT THERMIQUES remplaçables et les DISJONCTEURS qui sont accessibles uniquement à l'aide d'un OUTIL doivent être identifiés soit par le type et les caractéristiques complètes placés près du composant (tension, intensité, vitesse de fonctionnement et pouvoir de coupure) soit par une référence à l'information donnée dans les DOCUMENTS D'ACCOMPAGNEMENT.

Les fusibles et les COUPE-CIRCUIT THERMIQUES remplaçables ~~et~~ ainsi que les DISJONCTEURS qui sont accessibles uniquement à l'aide d'un OUTIL doivent être identifiés soit par ~~le type et les caractéristiques complètes placés près du composant~~ une spécification (tension, ~~intensité~~ courant, vitesse de fonctionnement ~~et~~, taille, pouvoir de coupure) située à proximité du composant, soit par une référence ~~à l'information donnée~~ aux informations données dans les DOCUMENTS D'ACCOMPAGNEMENT.

La nomenclature de l'IEC 60127-1 peut être utilisée.

7.3.5 * BORNES DE TERRE DE PROTECTION

Les BORNES DE TERRE DE PROTECTION doivent être marquées avec le symbole IEC 60417-5019 (~~DB:2002-10~~ 2006-08) (voir Tableau D.1, symbole 6) sauf si la BORNE DE TERRE DE PROTECTION se trouve dans un SOCLE DE CONNECTEUR conformément à l'IEC 60320-1.

Les marquages qui se trouvent sur ou à proximité des BORNES DE TERRE DE PROTECTION ne doivent pas être apposés sur des parties qui doivent être retirées pour réaliser la connexion. Ils doivent rester visibles à l'issue de la connexion.

7.3.6 BORNES DE TERRE FONCTIONNELLE

Les BORNES DE TERRE FONCTIONNELLE doivent être marquées avec le symbole IEC 60417-5017 (~~DB:2002-10~~ 2006-08) (voir Tableau D.1, symbole 7).

7.3.7 Bornes d'alimentation

Les bornes pour les conducteurs d'alimentation doivent être marquées à proximité des bornes sauf s'il peut être démontré qu'aucun~~e SITUATION DANGEREUSE~~ RISQUE inacceptable ne peut résulter d'une inversion lors du branchement.

Si l'APPAREIL EM est petit au point que les marquages de borne ne puissent être indiqués, ceux-ci doivent être inclus dans les DOCUMENTS D'ACCOMPAGNEMENT.

Les bornes qui sont prévues exclusivement pour le raccordement du conducteur neutre dans un APPAREIL EM INSTALLE DE FAÇON PERMANENTE doivent être marquées avec le code approprié de l'IEC 60445 (voir Tableau D.3, Code 1).

Si le marquage pour raccordement à une alimentation triphasée est nécessaire, celui-ci doit être conforme à l'IEC 60445.

Les marquages qui sont situés sur ou à proximité des points de raccordement électrique ne doivent pas être apposés sur des parties devant être retirées pour réaliser le raccordement. Ils doivent rester visibles après réalisation du raccordement.

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7.3.8 Température des bornes d'alimentation

Si un point quelconque à l'intérieur d'un boîtier ou d'un compartiment de raccordement des conducteurs d'alimentation pour APPAREILS EM INSTALLES DE FAÇON PERMANENTE (y compris ces conducteurs eux-mêmes) peut atteindre une température supérieure à 75 °C en UTILISATION NORMALE et en CONDITION NORMALE à la température ambiante de fonctionnement maximale indiquée dans la description technique (voir 7.9.3.1), alors l'APPAREIL EM doit être marqué comme suit ou avec une indication équivalente:

> "Pour le raccordement à l'alimentation, utiliser des câbles et conducteurs adaptés à une température d'au moins X °C".

où "X" est supérieur à la température maximale mesurée dans le boîtier ou dans le compartiment de raccordement en UTILISATION NORMALE et en CONDITION NORMALE.

Cette indication doit être placée sur ou à proximité du point où doit être réalisé le raccordement. Cette indication ne doit pas être apposée sur des parties qui doivent être retirées pour réaliser le raccordement. Elle doit être CLAIREMENT LISIBLE après la réalisation du raccordement.

La conformité avec les exigences de 7.3 est vérifiée par inspection et par l'application des essais et des critères de 7.1.2 et 7.1.3.

7.4 Marquage des organes de commande et des instruments (voir aussi Tableau C.3)

7.4.1 * Interrupteurs

Les positions "marche" et "arrêt" des interrupteurs utilisés pour commander l'alimentation des APPAREILS EM ou de leurs parties, y compris les interrupteurs réseau, doivent être indiquées comme suit:

– marquage avec les symboles IEC 60417-5007 (~~DB:~~2002-10) et IEC 60417-5008 (~~DB:~~2002-10) (voir Tableau D.1, symboles 12 et 13) ; ou
– par un voyant lumineux placé à proximité ; ou
– par tout autre moyen non ambigu.

Si un bouton poussoir à positions bistables est utilisé:

– il doit être marqué avec le symbole IEC 60417-5010 (~~DB:~~2002-10) (voir Tableau D.1, symbole 14) ; et
– le statut doit être indiqué par un voyant lumineux placé à proximité ou par tout autre moyen non ambigu.

Si un bouton poussoir à position "marche" par action maintenue est utilisé:

– il doit être marqué avec le symbole IEC 60417-5011 (~~DB:~~2002-10) (voir Tableau D.1, symbole 15) ; ou
– le statut doit être indiqué par un voyant lumineux placé à proximité ; ou
– le statut doit être indiqué par tout autre moyen non ambigu.

7.4.2 * Dispositifs de commande

Les différentes positions des dispositifs de commande et des interrupteurs placés sur les APPAREILS EM doivent être indiquées par des chiffres, des lettres ou d'autres moyens visuels, par exemple par l'utilisation des symboles IEC 60417-5264 (~~DB:~~2002-10) et IEC 60417-5265 (~~DB:~~2002-10) (voir Tableau D.1, symboles 16 et 17).

Si en UTILISATION NORMALE la modification du réglage d'un organe de commande peut entraîner un RISQUE inacceptable pour le PATIENT, ces organes doivent être équipés:

– soit d'un dispositif indicateur associé, par exemple appareils de mesure ou échelle, soit
– d'une indication donnant le sens dans lequel la grandeur de la fonction varie. Voir aussi 15.4.6.2.

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Un dispositif de commande ou un interrupteur qui amène l'APPAREIL EM dans l'état "d'attente" peut être indiqué au moyen du symbole IEC 60417-5009 (2002-10) (voir Tableau D.1, Symbole 29).

7.4.3 Unités de ~~mesure~~ mesurage

Les indications numériques des paramètres des APPAREILS EM doivent être exprimées en unités du système SI conformément à l'~~ISO 31~~ ISO 80000-1 sauf pour les grandeurs de base données dans le Tableau 1, qui peuvent être exprimées dans les unités indiquées qui ne font pas partie du système SI.

Pour l'application des unités du SI, de leurs multiples et de certaines autres unités, c'est l'~~ISO 1000~~ ISO 80000-1 qui s'applique.

La conformité avec les exigences de 7.4 est vérifiée par examen et par l'application des essais et des critères de 7.1.2 et 7.1.3.

Tableau 1 – Unités n'appartenant pas au système SI qui peuvent être utilisées sur les APPAREILS EM

Grandeur de base	Unité	
	Nom	Symbole
Angle plan	tour	r
	gon	gon ou grade
	degré	°
	minute d'angle	′
	seconde d'angle	″
Durée	minute	min
	heure	h
	jour	j
Energie	électron volt	eV
Volume	litre	l [a]
Pression des gaz du sang, du sang et d'autres fluides corporels:	millimètres de mercure	mmHg
	Centimètres d'eau	cmH_2O
Pression des gaz	bar	bar
	millibar	mbar

[a] Pour des raisons de cohérence, seul le symbole "l" est utilisé dans les normes internationales pour désigner le litre, bien que le symbole "L" soit également donné dans l'~~ISO 31~~ ISO 80000-1.

7.5 Signes de sécurité

Pour les besoins de cet article, les marquages utilisés pour indiquer un avertissement, une interdiction ou une action obligatoire qui permettent de réduire un RISQUE qui n'est pas manifeste pour l'OPERATEUR doivent être des signes de sécurité tirés de l'ISO 7010. Si un signe de sécurité ayant une signification établie est utilisé de manière appropriée, l'utilisation du signe d'avertissement général ISO 7010:2003-W001 (voir Tableau D.2, signe de sécurité 2) n'est pas requise.

NOTE 1 Dans ce contexte, un avertissement est utilisé pour indiquer "il existe un certain danger" ; une interdiction est utilisée pour indiquer "Vous ne devez pas..." ; une action obligatoire est utilisée pour indiquer "Vous devez...".

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En l'absence de signe de sécurité pour la signification particulière souhaitée, celle-ci peut être obtenue par l'une des méthodes suivantes.

a) En construisant un signe de sécurité conforme à l'ISO 3864-1:2002, Article 7 (pour les modèles correspondants, voir le Tableau D.2, signes de sécurité 1,4 et 8).

b) En utilisant le signe d'avertissement général ISO 7010:2003-W001(voir Tableau D.2, signe de sécurité 2) placé avec un symbole ou un texte supplémentai Le texte associé au signe d'avertissement général doit être une indication affirmative (c'est-à-dire une indication de sécurité) décrivant le ou les RISQUES principaux prévus (par exemple “Cause des brûlures”, “Risque d'explosion”, etc.).

c) En utilisant le signe d'interdiction général ISO 7010:2003-P001(voir Tableau D.2, signe de sécurité 4) placé avec un symbole ou un texte supplémentaire. Le texte associé au signe d'interdiction général doit être une indication (c'est-à-dire une indication de sécurité) décrivant ce qui est interdit (par exemple “Ne pas ouvrir”, “Ne pas laisser tomber”, etc.).

d) En utilisant le signe d'action obligatoire général ISO 7010:2003-M001(voir Tableau D.2, signe de sécurité 9) placé avec un symbole ou un texte supplémentaire. Le texte associé au signe d'action obligatoire général doit être une indication (c'est-à-dire une indication de sécurité) décrivant l'action exigée (par exemple “Porter des lunettes de protection”, “Frotter avant d'entrer”, etc.).

S'il n'y a pas assez d'espace pour placer l'indication affirmative avec le signe de sécurité sur L'APPAREIL EM, il est admis de la placer dans les instructions d'utilisation.

NOTE 2 Les couleurs utilisées pour les signes de sécurité sont spécifiées dans l'ISO 3864-1 et il est important d'utiliser la couleur spécifiée.

NOTE 3 Il convient qu'une indication de sécurité mentionne les précautions appropriées ou des instructions sur la manière de réduire le RISQUE (par exemple “Ne pas utiliser pour...” “Tenir à l'écart de...”, etc.).

Les signes de sécurité, y compris tout symbole ou texte supplémentaire, doivent faire l'objet d'une explication dans les instructions d'utilisation (voir 7.9.2).

Lorsqu'un texte complémentaire accompagne les signes de sécurité, le texte complémentaire doit être dans une langue compréhensible par l'OPERATEUR prévu.

NOTE 4 Dans certains pays, plusieurs langues sont requises.

La conformité est vérifiée par inspection.

7.6 Symboles

7.6.1 Explication des symboles

La signification des symboles utilisés pour le marquage doit être donnée dans les instructions d'utilisation.

7.6.2 Symboles de l'Annexe D

Les symboles exigés par la présente norme doivent être conformes aux exigences des publications IEC et ISO citées en référence. L'Annexe D donne les symboles graphiques accompagnés de leur description sous forme de référence rapide.

7.6.3 Symboles pour les organes de commande et les performances

Les symboles utilisés pour les organes de commande et les performances doivent être conformes aux exigences de la publication ISO ou IEC dans laquelle le symbole est défini, lorsque cela est applicable. Voir aussi 7.2.13.

NOTE L'IEC 60878 [60] donne une liste des titres, des descriptions et des représentations graphiques des symboles pour les appareils électriques utilisés dans la pratique médicale.

La conformité aux exigences de 7.6 est vérifiée par inspection.

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7.7 Couleurs de l'isolation des conducteurs

7.7.1 CONDUCTEUR DE TERRE DE PROTECTION

Un CONDUCTEUR DE TERRE DE PROTECTION doit être identifié sur toute sa longueur par une isolation de couleur vert-jaune.

7.7.2 CONNEXIONS DE TERRE PROTECTION

Toute isolation de conducteurs à l'intérieur d'APPAREILS EM qui forment des CONNEXIONS DE TERRE DE PROTECTION doit être identifiée par les couleurs verte et jaune au moins à l'extrémité des conducteurs.

EXEMPLE Les conducteurs d'un cordon multibrins qui sont connectés en parallèle, lorsque la résistance maximale autorisée des CONNEXIONS DE TERRE DE PROTECTION est dépassée si seul le conducteur vert et jaune était utilisé.

7.7.3 Isolation vert-jaune

L'identification par une isolation vert-jaune ne doit être utilisée que pour:

– les CONDUCTEURS DE TERRE DE PROTECTION (voir 8.6.2) ;

– les conducteurs spécifiés en 7.7.2 ;

NOTE Dans d'autres normes de sécurité telles que l'IEC 60950-1, des connexions internes entre des parties conductrices et la terre de protection principale sont appelées des conducteurs de liaison de protection.

– les CONDUCTEURS D'EGALISATION DES POTENTIELS (voir 8.6.7) ;

– les CONDUCTEURS DE TERRE FONCTIONNELLE (voir 8.6.9).

7.7.4 Conducteur neutre

Les conducteurs des CABLES D'ALIMENTATION destinés à être raccordés au conducteur neutre du système d'alimentation doivent être de couleur “bleu clair” comme spécifié dans la IEC 60227-1 ou l'IEC 60245-1.

7.7.5 Conducteurs de CABLES D'ALIMENTATION

Les couleurs des conducteurs dans les CABLES D'ALIMENTATION doivent être conformes à l'IEC 60227-1 ou à l'IEC 60245-1.

La conformité aux exigences de 7.7 est vérifiée par inspection.

7.8 * Voyants lumineux et organes de commande

7.8.1 Couleurs des voyants lumineux

Les couleurs des voyants lumineux et leur signification doivent être conformes au Tableau 2.

NOTE L'IEC 60601-1-8 contient des exigences spécifiques pour la couleur, la fréquence de clignotement et le TAUX D'UTILISATION des voyants lumineux d'alarme.

Les affichages par matrice et les affichages alphanumériques ne sont pas considérés comme des voyants lumineux.

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Tableau 2 – Couleurs des voyants lumineux et leur signification pour les APPAREILS EM

Couleur	Signification
Rouge	Avertissement – réponse immédiate de l'OPERATEUR exigée
Jaune	Prudence – réponse rapide de L'OPERATEUR exigée
Vert	Prêt à fonctionner
Toute autre couleur	Signification autre que rouge, jaune ou vert

7.8.2 Couleurs des organes de commande

La couleur rouge doit être utilisée exclusivement pour une commande interrompant une fonction en cas d'urgence.

La conformité aux exigences de 7.8 est vérifiée par inspection. Voir aussi 15.4.4.

7.9 DOCUMENTS D'ACCOMPAGNEMENT

7.9.1 * Généralités (voir aussi Tableau C.4)

LES APPAREILS EM doivent être accompagnés de documents comprenant au moins des instructions d'utilisation et une description technique. Les DOCUMENTS D'ACCOMPAGNEMENT doivent être considérés comme faisant partie des APPAREILS EM.

NOTE Le but des DOCUMENTS D'ACCOMPAGNEMENT est de promouvoir l'usage en toute sécurité des APPAREILS EM au cours de leur DUREE DE VIE PREVUE.

Les DOCUMENTS D'ACCOMPAGNEMENT doivent identifier les APPAREILS EM en incluant, lorsque applicable, les éléments suivants:

– le nom ou la marque de fabrique du FABRICANT, et une ~~adresse~~ information de contact à laquelle l'ORGANISME RESPONSABLE peut s'adresser;

– la REFERENCE DU MODELE OU DU TYPE (voir 7.2.2).

Les DOCUMENTS D'ACCOMPAGNEMENT ~~des APPAREILS EM~~ peuvent être fournis sur support électronique, par exemple fichier électronique sur CD-ROM. Si les DOCUMENTS D'ACCOMPAGNEMENT sont fournis ~~sous forme~~ sur support électronique, le PROCESSUS ~~de GESTION DES RISQUES~~ D'INGENIERIE D'APTITUDE A L'UTILISATION doit définir quelles informations doivent également être fournies sur papier ou sous forme de marquages sur les APPAREILS EM~~, par exemple pour couvrir le fonctionnement d'urgence~~ (voir 12.2).

EXEMPLE Informations pour couvrir un fonctionnement d'urgence.

NOTE Les DOCUMENTS D'ACCOMPAGNEMENT fournis sur support électronique pourraient ne pas être acceptables dans toutes les juridictions.

Les DOCUMENTS D'ACCOMPAGNEMENT doivent spécifier toute aptitude, formation et connaissances spéciales requises de l'OPERATEUR prévu ou de l'ORGANISME RESPONSABLE et toute restriction concernant les emplacements ou les environnements dans lesquels les APPAREILS EM peuvent être utilisés.

Les DOCUMENTS D'ACCOMPAGNEMENT doivent être rédigés pour un niveau correspondant au niveau scolaire, à la formation et à tout besoin spécifique de la ou des personnes auxquelles ils sont destinés.

La conformité est vérifiée par l'inspection des DOCUMENTS D'ACCOMPAGNEMENT, et, lorsqu'ils sont fournis sous forme électronique, comme spécifié dans l'IEC 60601-1-6.

7.9.2 Instructions d'utilisation (voir aussi Tableau C.5)

7.9.2.1 * Généralités

Les instructions d'utilisation doivent indiquer:

– l'utilisation de L'APPAREIL EM comme prévu par le FABRICANT;

– les fonctions utilisées fréquemment~~, et~~;

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– toute(s) contre-indication(s) connue(s) liée(s) à l'utilisation de L'APPAREIL EM; et

– les parties de l'APPAREIL EM qui ne doivent subir ni entretien ni maintenance lorsqu'elles sont utilisées avec un PATIENT.

Lorsque le PATIENT est un OPERATEUR prévu, les instructions d'utilisation doivent indiquer:

– que le PATIENT est un OPERATEUR prévu;

– un avertissement contre tout entretien et toute maintenance pendant que l'APPAREIL EM est en cours d'utilisation;

– quelles fonctions le PATIENT peut utiliser en toute sécurité et, le cas échéant, les fonctions que le PATIENT ne peut pas utiliser en toute sécurité; et

– quelle maintenance le PATIENT peut effectuer (changer les piles, par exemple).

NOTE 1 Pour un APPAREIL EM dont l'UTILISATION PREVUE inclut l'activation totale ou partielle de l'APPAREIL EM par le PATIENT, le PATIENT devient un OPERATEUR.

NOTE 2 Pour un APPAREIL EM pour lequel le PATIENT est autorisé à effectuer une maintenance restreinte, le PATIENT devient un PERSONNEL D'ENTRETIEN.

Les instructions d'utilisation doivent indiquer:

– le nom ou la marque de fabrique et l'adresse du FABRICANT;

– une REFERENCE DE MODELE OU DE TYPE.

Les instructions d'utilisation doivent inclure toutes les classifications applicables spécifiées à l'Article 6, tous les marquages spécifiés en 7.2 et l'explication des signes de sécurité et des symboles (figurant comme marquage sur L'APPAREIL EM).

NOTE ~~1~~ 3 Les instructions d'utilisation sont destinées à L'OPERATEUR et à L'ORGANISME RESPONSABLE. et il convient qu'elles contiennent uniquement les informations les plus susceptibles d'être utiles à L'OPERATEUR et à L'ORGANISME RESPONSABLE. Des détails complémentaires peuvent être contenus dans la description technique. Voir aussi 7.9.3.

NOTE ~~2~~ 4 Le guide pour la préparation des instructions d'utilisation se trouve dans l'IEC 62079 [25]. Un guide sur la préparation des supports de formation pour les APPAREILS EM se trouve dans le TR 61258 de l'IEC [24].

Les instructions d'utilisation doivent être dans une langue compréhensible par l'OPERATEUR prévu.

NOTE 5 Dans certains pays, plusieurs langues sont requises.

7.9.2.2 * Avertissement et consignes de sécurité

Les instructions d'utilisation doivent inclure tous les avertissements et toutes les consignes de sécurité.

NOTE Il convient que les avertissements et les consignes de sécurité d'ordre général soient placés dans une section spécialement identifiée des instructions d'utilisation. Il convient qu'un avertissement ou une consigne de sécurité qui s'applique uniquement à une instruction ou une action spécifique précède l'instruction à laquelle elle s'applique.

Pour les APPAREILS EM de la CLASSE I, un avertissement comme celui ci-après doit être inclus dans les instructions d'utilisation: "AVERTISSEMENT: Pour éviter tout risque de choc électrique, cet appareil doit être raccordé uniquement à un réseau d'alimentation équipé d'une terre de protection."

Les instructions d'utilisation doivent fournir à l'OPERATEUR ou à l'ORGANISME RESPONSABLE les avertissements concernant tout RISQUE significatif d'interférence réciproque se posant en présence de l'APPAREIL EM au cours d'examens ou de traitements spécifiques.

Les instructions d'utilisation doivent inclure des informations sur les interférences potentielles qu'elles soient d'origine électromagnétique ou autre entre L'APPAREIL EM et d'autres appareils avec des conseils sur la manière d'éviter ou de minimiser de telles interférences.

Si L'APPAREIL EM intègre un SOCLE A PRISES MULTIPLES, les instructions d'utilisation doivent contenir un avertissement indiquant que le fait de raccorder l'appareil électrique au SOCLE A PRISES MULTIPLES conduit effectivement à créer un SYSTEME EM et que cela peut entraîner un niveau réduit de sécurité. Pour les exigences qui sont applicables à un SYSTEME EM, L'ORGANISME RESPONSABLE doit être renvoyé à la présente norme.

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7.9.2.3 APPAREILS EM spécifiés pour être raccordés à une alimentation séparée

Si l'APPAREIL EM est destiné à être raccordé à une alimentation séparée, soit l'alimentation doit être spécifiée comme partie de l'APPAREIL EM soit la combinaison doit être spécifiée comme un SYSTEME EM. Les instructions d'utilisation doivent indiquer cette spécification.

7.9.2.4 Source d'alimentation électrique

Pour les APPAREILS EM alimentés par le réseau qui possèdent une source d'alimentation complémentaire qui n'est pas maintenue automatiquement en charge totale, les instructions d'utilisation doivent inclure un avertissement indiquant la nécessité de vérification ou de remplacement périodiques de ces sources complémentaires.

Si une fuite provenant d'une batterie peut entraîner un RISQUE inacceptable, les instructions d'utilisation doivent inclure un avertissement demandant de retirer la batterie si l'APPAREIL EM est susceptible de rester inutilisé pendant un certain temps.

Si une ALIMENTATION ELECTRIQUE INTERNE est remplaçable, les instructions d'utilisation doivent indiquer ses spécifications.

Si la perte de la source d'alimentation peut entraîner un RISQUE inacceptable, les instructions d'utilisation doivent contenir un avertissement indiquant que L'APPAREIL EM doit être raccordé à une source d'alimentation appropriée.

EXEMPLE Batteries d'accumulateurs internes ou externes, alimentations sans interruption (ASI) ou générateur de secours institutionnel.

7.9.2.5 Description de l'APPAREIL EM

Les instructions d'utilisation doivent inclure:

– une brève description de l'APPAREIL EM;

– la manière dont l'APPAREIL EM fonctionne ; et

– les caractéristiques physiques et de performances les plus importantes de l'APPAREIL EM.

Si cela est applicable, cette description doit inclure les positions attendues de l'OPERATEUR, du PATIENT et des autres personnes à proximité de l'APPAREIL EM en UTILISATION NORMALE (voir 9.2.2.3).

Les instructions d'utilisation doivent inclure des informations sur les matériaux ou les substances auxquels le PATIENT ou l'OPERATEUR est exposé si une telle exposition peut constituer un RISQUE inacceptable (voir 11.7).

Les instructions d'utilisation doivent spécifier toute restriction concernant un autre appareil ou des COUPLAGE DE RESEAUX / DONNEES, autres que ceux faisant partie d'un SYSTEME EM, auxquels une ENTREE/SORTIE DE SIGNAL peut être connectée.

Les instructions d'utilisation doivent indiquer toute PARTIE APPLIQUEE existante.

7.9.2.6 * Installation

Si l'installation de l'APPAREIL EM ou de ses parties est requise, les instructions d'utilisation doivent contenir:

– une référence de l'endroit où les instructions d'installation peuvent être trouvées (par exemple dans la description technique), ou

– des informations permettant de contacter les personnes désignées par le FABRICANT comme qualifiées pour réaliser l'installation.

7.9.2.7 * Isolation avec le RESEAU D'ALIMENTATION

Si un CONNECTEUR ou une FICHE RESEAU ou une autre fiche séparable est utilisé comme moyen d'isolation pour satisfaire à 8.11.1 a), les instructions d'utilisation doivent contenir une

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instruction demandant de ne pas positionner l'APPAREIL EM de telle manière qu'il soit difficile d'utiliser le dispositif de déconnexion.

7.9.2.8 PROCEDURE de démarrage

Les instructions d'utilisation doivent contenir les informations nécessaires, comprenant les éléments tels que les réglages de commande initiaux, le raccordement au PATIENT, ou le positionnement de celui-ci, etc., pour que l'OPERATEUR mette l'APPAREIL EM en fonctionnement.

Les instructions d'utilisation doivent détailler tout traitement ou toute manipulation nécessaire avant que l'APPAREIL EM, ses parties ou ACCESSOIRES puissent être utilisés.

EXEMPLE Une liste de contrôle avant utilisation.

7.9.2.9 Instructions de fonctionnement

Les instructions d'utilisation doivent contenir toutes les informations nécessaires au fonctionnement de l'APPAREIL EM conformément à sa spécification. Elles doivent comporter des explications concernant les fonctions des commandes, affichages et signaux, la séquence de fonctionnement, la connexion et la déconnexion des parties amovibles et des ACCESSOIRES, et le remplacement des matières qui sont consommées au cours de l'utilisation.

La signification des chiffres, des symboles, des avertissements, des abréviations et des voyants sur les APPAREILS EM doit être expliquée dans les instructions d'utilisation.

7.9.2.10 Messages

Les instructions d'utilisation doivent donner la liste de tous les messages système, messages d'erreur et messages de défaut qui sont générés, sauf si ces messages sont compréhensibles par eux-mêmes.

NOTE 1 Ces listes peuvent être identifiées par groupes.

La liste doit inclure une explication des messages y compris les causes importantes et l'action possible de L'OPERATEUR, le cas échéant, nécessaires pour apporter une solution à la situation révélée par le message.

NOTE 2 Les exigences et les lignes directrices concernant les messages générés par un système d'alarme sont données dans l'IEC 60601-1-8.

7.9.2.11 PROCEDURE d'arrêt

Les instructions d'utilisation doivent contenir les informations nécessaires à l'OPERATEUR pour arrêter en toute sécurité le fonctionnement de l'APPAREIL EM.

7.9.2.12 Nettoyage, désinfection et stérilisation

Pour les APPAREILS EM dont des parties ou des ACCESSOIRES peuvent être contaminés en UTILISATION NORMALE par contact avec le PATIENT, par des fluides corporels ou des gaz expirés, les instructions d'utilisation doivent contenir:

– des informations détaillées concernant le nettoyage et les méthodes de désinfection ou de stérilisation qu'il est admis d'utiliser; et

– la liste des paramètres applicables comme les limites de température, de pression, d'humidité, de temps et de nombre de cycles que de telles parties D'APPAREILS EM ou ACCESSOIRES peuvent tolérer.

Voir aussi 11.6.6 et 11.6.7.

Cette exigence ne s'applique pas aux matériaux, composants, ACCESSOIRES ou APPAREILS EM marqués comme étant à usage unique sauf si le FABRICANT spécifie que le matériau, le composant, L'ACCESSOIRE ou L'APPAREIL EM concerné doit être nettoyé, désinfecté ou stérilisé avant utilisation (voir 7.2.1).

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7.9.2.13 Maintenance

Les instructions d'utilisation doivent instruire de manière suffisamment détaillée L'OPERATEUR ou L'ORGANISME RESPONSABLE sur les opérations d'inspection préventive, de maintenance et d'étalonnage qu'ils doivent réaliser, y compris sur la fréquence d'une telle maintenance.

Les instructions d'utilisation doivent fournir des informations permettant la réalisation en toute sécurité d'une telle maintenance de routine qui est nécessaire pour assurer une utilisation continuelle en toute sécurité de l'APPAREIL EM.

De plus, les instructions d'utilisation doivent identifier les parties sur lesquelles une inspection et une maintenance préventives doivent être réalisées par le PERSONNEL D'ENTRETIEN, y compris les périodicités à appliquer, mais pas nécessairement avec les informations détaillées concernant la réalisation réelle de cette maintenance.

Dans le cas D'APPAREILS EM contenant des batteries rechargeables dont la maintenance incombe à toute personne n'appartenant pas au PERSONNEL D'ENTRETIEN, les instructions d'utilisation doivent contenir des instructions pour assurer une maintenance adéquate.

7.9.2.14 ACCESSOIRES, équipements supplémentaires, fournitures utilisées

Les instructions d'utilisation doivent inclure une liste des ACCESSOIRES, des pièces détachées et des fournitures dont le FABRICANT a déterminé qu'ils étaient destinés à être utilisés avec l'APPAREIL EM.

Si l'APPAREIL EM est prévu pour être alimenté par un autre appareil inclus dans un SYSTEME EM, les instructions d'utilisation doivent spécifier cet autre appareil de manière suffisante afin d'assurer la conformité avec les exigences de la présente norme (par exemple référence de pièce, tension ASSIGNEE, puissances maximale ou minimale, classe de protection, ~~service~~ tâche intermittente ou continue).

NOTE Ce qui était désigné dans la première et dans la deuxième édition de cette norme comme une "alimentation spécifiée" est désormais considéré soit comme une autre partie du même APPAREIL EM soit comme un autre appareil dans un SYSTEME EM. De même, un chargeur de batterie est considéré soit comme une partie d'un APPAREIL EM soit comme un autre appareil dans un SYSTEME EM.

7.9.2.15 Protection de l'environnement

~~Les instructions d'utilisation doivent:~~

~~– identifier tout RISQUE associé à la mise au rebut des déchets, des résidus, etc. de L'APPAREIL EM et de ses ACCESSOIRES à la fin de leur DUREE DE VIE PREVUE ; et~~

~~– donner des conseils pour minimiser ces RISQUES.~~

Les instructions d'utilisation doivent donner des avis sur l'évacuation appropriée des déchets, résidus, etc. et sur celle de l'APPAREIL EM et des ACCESSOIRES à la fin de leur DUREE DE VIE PREVUE.

7.9.2.16 Référence à la description technique

Les instructions d'utilisation doivent contenir les informations spécifiées en 7.9.3 ou une référence à l'endroit où les éléments spécifiés en 7.9.3 peuvent être trouvés (par exemple dans un manuel d'entretien).

7.9.2.17 APPAREIL EM émettant des rayonnements

Pour les APPAREILS EM émettant des rayonnements à des fins médicales, le cas échéant, les instructions d'utilisation doivent indiquer la nature, le type, l'intensité et la distribution de ces rayonnements.

7.9.2.18 APPAREIL EM et ACCESSOIRES fournis stériles

Les instructions d'utilisation pour les APPAREILS EM ou les ACCESSOIRES fournis stériles doivent indiquer qu'ils ont été stérilisés et donner la méthode de stérilisation.

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Les instructions d'utilisation doivent donner les instructions nécessaires en cas de détérioration de l'emballage stérile et le cas échéant, détailler les méthodes de re-stérilisation appropriées (voir aussi 7.9.2.12).

7.9.2.19 * Identifiant unique

Les instructions d'utilisation doivent contenir un identifiant unique, par exemple leur date de publication.

EXEMPLE Mois et année.

La conformité aux exigences de 7.9.2 est vérifiée par examen des instructions d'utilisation dans une langue d'un OPERATEUR prévu.

7.9.3 Description technique (voir aussi Tableau C.6)

7.9.3.1 * Généralités

La description technique doit fournir toutes les données qui sont essentielles à un fonctionnement, un transport et un stockage en toute sécurité ainsi que les mesures ou conditions nécessaires à l'installation d'un APPAREIL EM et à sa préparation pour son utilisation. Ces données doivent comprendre:

– les conditions environnementales d'utilisation admissibles y compris les conditions pour le transport et le stockage. Voir aussi 7.2.17;

– toutes les caractéristiques de l'APPAREIL EM, y compris la ou les plages de réglage, l'exactitude et la précision des valeurs affichées ou l'indication où l'on peut les trouver;

– toute exigence particulière d'installation comme l'impédance apparente maximale admissible du RESEAU D'ALIMENTATION;

NOTE 1 L'impédance apparente du RESEAU D'ALIMENTATION est la somme de l'impédance du réseau de distribution plus l'impédance de la source d'alimentation.

– si un liquide est utilisé pour le refroidissement, la plage admissible des valeurs de pression et de flux d'entrée ainsi que la composition chimique de ce liquide de refroidissement;

– une description des moyens d'isolation de l'APPAREIL EM, du RESEAU D'ALIMENTATION, si de tels moyens ne sont pas incorporés à l'APPAREIL EM (voir 8.11.1 b));

– le cas échéant, une description des moyens de vérification du niveau d'huile dans les APPAREILS EM ou leurs parties qui sont remplis d'huile et partiellement scellés (voir 15.4.9);

– un avertissement mettant en garde contre les DANGERS qui peuvent résulter d'une modification non autorisée de L'APPAREIL EM, par exemple un avertissement comme suit:

- " AVERTISSEMENT: Modification de L'APPAREIL EM interdite."
- " AVERTISSEMENT: Interdiction de modification de cet appareil sans l'autorisation du fabricant."
- " AVERTISSEMENT: Si l'APPAREIL EM est modifié, un contrôle et un essai appropriés doivent être réalisés pour s'assurer que l'APPAREIL EM est toujours utilisable en toute sécurité."

– informations relatives aux PERFORMANCES ESSENTIELLES et à tout essai récurrent nécessaire concernant les PERFORMANCES ESSENTIELLES et la SECURITE DE BASE, y compris les détails des moyens, les méthodes et la fréquence recommandée.

NOTE 2 Ces informations sont directement dérivées des PERFORMANCES ESSENTIELLES identifiées par le FABRICANT en 4.3.

Si la description technique est séparable des instructions d'utilisation, elle doit contenir:

– toutes les classifications applicables spécifiées à l'Article 6, tout avertissement et toute consigne de sécurité ainsi que l'explication des signes de sécurité (marqués sur l'APPAREIL EM);

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– une brève description de l'APPAREIL EM, de la manière dont ~~il~~ l'APPAREIL EM fonctionne ainsi que ses caractéristiques physiques et de performances significatives; et

– un identifiant unique tel que la date de publication.

NOTE ~~2~~ 3 La description technique est destinée à l'ORGANISME RESPONSABLE et au PERSONNEL D'ENTRETIEN.

Le FABRICANT peut donner les qualifications minimales pour le PERSONNEL D'ENTRETIEN. Dans ce cas, ces exigences doivent être documentées dans la description technique.

NOTE ~~3~~ 4 Certaines autorités de tutelle imposent des exigences supplémentaires pour la qualification du PERSONNEL D'ENTRETIEN.

7.9.3.2 Remplacement des fusibles, des CABLES D'ALIMENTATION et d'autres parties

La description technique doit contenir les éléments suivants, lorsque applicables:

– le type exigé et le calibre précis des fusibles utilisés dans le circuit d'alimentation externe d'un APPAREIL EM INSTALLE DE FAÇON PERMANENTE si le type et le calibre de ces fusibles ne se déduisent pas du courant ASSIGNE et du mode de fonctionnement de l'APPAREIL EM;

– une mention indiquant, pour les APPAREILS EM équipés d'un CABLE D'ALIMENTATION FIXE A DEMEURE, si le CABLE D'ALIMENTATION peut être ou non remplacé par le PERSONNEL D'ENTRETIEN, et, s'il peut l'être, les instructions pour un raccordement et une fixation corrects qui assurent que les exigences de 8.11.3 sont toujours satisfaites;

– des instructions pour le remplacement correct des parties interchangeables ou amovibles spécifiées par le FABRICANT comme remplaçables par le PERSONNEL D'ENTRETIEN; et

– lorsque le remplacement d'un composant pourrait engendrer un RISQUE inacceptable, des avertissements appropriés identifiant la nature du danger et, si le FABRICANT spécifie que le composant est remplacé par le PERSONNEL D'ENTRETIEN, toutes les informations nécessaires au remplacement en toute sécurité du composant concerné.

7.9.3.3 Schémas des circuits, listes de composants, etc.

La description technique doit comporter une mention indiquant que le FABRICANT met à disposition, sur demande, les schémas de circuits, les listes de composants, les descriptions, les consignes d'étalonnage ou toute autre information utile au PERSONNEL D'ENTRETIEN pour réparer les parties des APPAREILS EM que le FABRICANT a désignées comme réparables par le PERSONNEL D'ENTRETIEN.

7.9.3.4 * Interrupteur d'isolation réseau

La description technique doit identifier clairement tout dispositif utilisé pour être conforme aux exigences de 8.11.1.

La conformité aux exigences de 7.9.3 est vérifiée par inspection de la description technique.

8 * Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM

8.1 Règle fondamentale de protection contre les chocs électriques

Les limites spécifiées en 8.4 ne doivent pas être dépassées pour les PARTIES ACCESSIBLES, y compris les PARTIES APPLIQUEES, en CONDITION NORMALE ou en CONDITION DE PREMIER DEFAUT. Pour les autres SITUATIONS DANGEREUSES en CONDITION DE PREMIER DEFAUT, voir 13.1.

a) * La CONDITION NORMALE comprend simultanément toutes les situations suivantes:

– la présence de toute ENTREE/SORTIE DE SIGNAL quels que soient la tension et le courant provenant d'un autre appareil électrique qu'il est permis de raccorder d'après les DOCUMENTS D'ACCOMPAGNEMENT comme spécifié en 7.9 ou, si les DOCUMENTS D'ACCOMPAGNEMENT ne prévoient aucune restriction concernant un tel autre appareil électrique, la présence de la TENSION RESEAU MAXIMALE telle qu'elle est spécifiée en 8.5.3;

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– la transposition des connexions d'alimentation, pour APPAREIL EM destinées à être raccordées au RESEAU D'ALIMENTATION au moyen d'une FICHE RESEAU ;

– le court-circuit de toute ou partie de l'isolation qui n'est pas conforme aux exigences de 8.8;

– le court-circuit d'une ou de toutes les LIGNES DE FUITE ou DISTANCES DANS L'AIR qui ne sont pas conformes aux exigences de 8.9;

– la rupture d'une ou de toutes les liaisons à la terre qui ne sont pas conformes aux exigences de 8.6, y compris la liaison de terre fonctionnelle.

b) * Les CONDITIONS DE PREMIER DEFAUT comprennent:

– le court-circuit de toute isolation qui est conforme aux exigences pour un MOYEN DE PROTECTION comme spécifié en 8.8;

NOTE Cela comprend le court-circuit de tout élément constituant d'une DOUBLE ISOLATION conforme à 8.8.

– le court-circuit de toute LIGNE DE FUITE ou de toute DISTANCE DANS L'AIR qui est conforme aux exigences pour un MOYEN DE PROTECTION comme spécifié en 8.9;

– le court-circuit et l'ouverture du circuit de tout composant, autre qu'un COMPOSANT AUX CARACTERISTIQUES A HAUTE FIABILITE, connecté en parallèle avec l'isolation avec une DISTANCE DANS L'AIR ou avec une LIGNE DE FUITE à moins qu'il puisse être montré que le court-circuit n'est pas un mode de défaillance pour le composant (voir aussi 4.8 et 4.9);

– la rupture de tout CONDUCTEUR DE TERRE DE PROTECTION ou de toute CONNEXION DE TERRE DE PROTECTION qui est conforme aux exigences de 8.6: cela ne s'applique pas au CONDUCTEUR DE TERRE DE PROTECTION des APPAREILS EM INSTALLES DE FAÇON PERMANENTE, considéré comme peu susceptible d'être déconnecté;

– l'interruption de tout conducteur d'alimentation, à l'exception du conducteur neutre d'un APPAREIL EM polyphasé ou INSTALLE DE FAÇON PERMANENTE;

– l'interruption de tout conducteur d'alimentation entre ~~les parties séparées des enveloppes de l'APPAREIL EM, si l'ANALYSE DE RISQUE indique que cette condition pourrait causer le dépassement des limites autorisées~~ des parties de l'APPAREIL EM situées dans des ENVELOPPES séparées, si cette condition peut causer le dépassement des limites autorisées;

– le mouvement non désiré d'un composant ~~; mais seulement si le composant n'est pas monté de manière suffisamment sécurisée pour assurer qu'un tel mouvement soit très peu probable au cours de la DUREE DE VIE PREVUE de l'APPAREIL EM, comme cela est déterminé par le PROCESSUS de GESTION DES RISQUES~~ (voir ~~aussi~~ 8.10.1);

– le détachement accidentel de conducteurs et de connecteurs lorsqu'il pourrait donner lieu à une SITUATION DANGEREUSE. Voir aussi 8.10.2.

La détermination des PARTIES ACCESSIBLES est réalisée conformément à 5.9.

Les COURANTS DE FUITE sont mesurés conformément à 8.7.

8.2 Exigences liées aux sources d'énergie électrique

8.2.1 Connexion à une source électrique séparée

Si l'APPAREIL EM est spécifié pour être connecté à une source électrique séparée, autre que le RESEAU, soit la source électrique séparée doit être considérée comme une partie de l'APPAREIL EM et toutes les exigences de la présente norme doivent s'appliquer, soit la combinaison doit être considérée comme un SYSTEME EM. Voir aussi 7.2.5, 7.9.2.14, 5.5 f) et l'Article 16.

NOTE Ce qui était désigné dans la première et dans la deuxième édition de la présente norme comme une "alimentation spécifiée" est désormais considéré soit comme une autre partie du même APPAREIL EM soit comme un autre appareil dans un SYSTEME EM.

La conformité est vérifiée par inspection et par les essais spécifiés en 5.5 f). Si une alimentation séparée spécifique est indiquée, les essais applicables sont réalisés, l'APPAREIL EM étant connecté à celle-ci. Si une alimentation séparée générique est indiquée, la spécification dans les DOCUMENTS D'ACCOMPAGNEMENT fait l'objet d'un examen.

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8.2.2 Connexion à une source externe en courant continu

~~Si L'APPAREIL EM est spécifié pour une alimentation à partir d'une source externe en courant continu, aucune SITUATION DANGEREUSE autre que l'absence de sa fonction prévue, ne doit apparaître si une connexion est réalisée avec la mauvaise polarité. Lorsque la connexion est réalisée ensuite avec la polarité correcte, L'APPAREIL EM doit assurer l'absence de tout RISQUE inacceptable. Les dispositifs de protection qui peuvent être remis en place sans l'aide d'un OUTIL sont acceptables sous réserve qu'ils restaurent un fonctionnement correct à leur remise en place.~~

Si l'APPAREIL EM est spécifié comme étant alimenté par une source externe en courant continu, alors une connexion sur la mauvaise polarité ne doit pas conduire aux SITUATIONS DANGEREUSES décrites en 13.1. L'APPAREIL EM, lorsque la connexion est ensuite effectuée sur la bonne polarité, doit maintenir la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES.

Les dispositifs de protection qui peuvent être remis en service par quiconque sans utiliser un OUTIL sont acceptables, si l'APPAREIL EM retourne à la CONDITION NORMALE à la remise en service.

NOTE 1 Voir aussi 11.8.

NOTE 2 La source externe en courant continu peut être constituée par un RESEAU D'ALIMENTATION ou par un autre élément d'appareil électrique. Dans ce dernier cas, la combinaison est considérée comme étant un SYSTEME EM tel que spécifié en 8.2.1.

~~*La conformité est vérifiée par examen et, si nécessaire, par des essais fonctionnels.*~~

8.3 Classification des PARTIES APPLIQUEES

a) * Une PARTIE APPLIQUEE qui est spécifiée dans les DOCUMENTS D'ACCOMPAGNEMENT comme adaptée à une application cardiaque directe doit être une PARTIE APPLIQUEE DE TYPE CF.

NOTE Voir les justifications pour la définition de l'APPLICATION CARDIAQUE DIRECTE (3.22) concernant les PARTIES APPLIQUEES qui doivent être des PARTIES APPLIQUEES DE TYPE CF. D'autres restrictions peuvent exister pour les applications cardiaques.

La conformité est vérifiée par inspection.

b) * Une PARTIE APPLIQUEE qui comprend une CONNEXION PATIENT destinée à fournir de l'énergie électrique ou un signal électrophysiologique vers ou provenant du PATIENT doit être une PARTIE APPLIQUEE DE TYPE BF ou une PARTIE APPLIQUEE DE TYPE CF.

La vérification est effectuée par inspection.

c) Une PARTIE APPLIQUEE qui n'est pas couverte par a) ou b) doit être une PARTIE APPLIQUEE DE TYPE B , une PARTIE APPLIQUEE DE TYPE BF ou une PARTIE APPLIQUEE DE TYPE CF.

La conformité est vérifiée par inspection.

~~d) * Pour une partie qui est identifiée selon 4.6 comme devant être soumise aux exigences d'une PARTIE APPLIQUEE (à l'exception du marquage), les exigences pour une PARTIE APPLIQUEE DE TYPE B doivent s'appliquer sauf si le PROCESSUS de GESTION DES RISQUES identifie la nécessité d'utiliser les exigences pour une PARTIE APPLIQUEE DE TYPE BF ou d`une PARTIE APPLIQUEE DE TYPE CF.~~

8.4 Limitation de la tension, du courant ou de l'énergie

8.4.1 * CONNEXIONS PATIENT destinées à fournir du courant

Les limites spécifiées en 8.4.2 ne s'appliquent pas aux courants qui sont destinés à traverser le corps du PATIENT pour produire un effet physiologique en UTILISATION NORMALE.

8.4.2 PARTIES ACCESSIBLES ~~incluant des~~ et PARTIES APPLIQUEES

a) Les courants en provenance, vers ou entre des CONNEXIONS PATIENT ne doivent pas dépasser les limites du COURANT DE FUITE PATIENT et du COURANT AUXILIAIRE PATIENT spécifiées au Tableau 3 et au Tableau 4 lorsqu'ils sont mesurés comme spécifié en 8.7.4.

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La conformité est vérifiée par des mesures selon 8.7.4.

b) * Les ~~courants de fuite~~ COURANTS DE FUITE en provenance, vers ou entre des PARTIES ACCESSIBLES~~, autres que les CONNEXIONS PATIENT,~~ ne doivent pas dépasser les limites pour le COURANT DE CONTACT spécifiées en 8.7.3 c) lorsqu'ils sont mesurés comme spécifié en 8.7.4.

La conformité est vérifiée par des mesures selon 8.7.4.

c) * Les limites spécifiées en b) ci-dessus ne s'appliquent pas aux parties suivantes si la probabilité d'une connexion vers le PATIENT, soit directement soit par l'intermédiaire du corps de l'OPERATEUR, au travers duquel un courant dépassant le COURANT DE CONTACT admissible pourrait s'écouler, est négligeable en UTILISATION NORMALE, et que les instructions d'utilisation indiquent à l'OPERATEUR de ne pas toucher la partie correspondante et le PATIENT simultanément:

– contacts accessibles des connecteurs;

– contacts des portes fusibles qui sont accessibles au cours du remplacement du fusible;

– contacts des douilles qui sont accessibles après enlèvement de la lampe;

– parties sous un CAPOT D'ACCES qui peut être ouvert sans l'utilisation d'un OUTIL, ou lorsqu'un OUTIL est nécessaire mais que les instructions d'utilisation indiquent à tout OPERATEUR qui ne fait pas partie du PERSONNEL D'ENTRETIEN comment ouvrir le CAPOT D'ACCES.

EXEMPLE 1 Boutons poussoirs lumineux.

EXEMPLE 2 Voyants lumineux.

EXEMPLE 3 Plumes d'enregistreur.

EXEMPLE 4 Parties de modules enfichables.

EXEMPLE 5 Batteries d'accumulateurs.

Pour de telles parties, la tension par rapport à la terre ou par rapport à d'autres PARTIES ACCESSIBLES ne doit pas dépasser 42,4 V en valeur de crête en courant alternatif ou 60 V en courant continu en CONDITION NORMALE ou en CONDITION DE PREMIER DEFAUT. La limite de 60 V en courant continu s'applique à un courant continu avec 10 % d'ondulation crête à crête au maximum. Si l'ondulation dépasse cette grandeur, la limite de 42,4 V de crête s'applique. L'énergie ne doit pas dépasser 240 VA pendant plus de 60 s ou l'énergie stockée disponible ne doit pas dépasser 20 J à une valeur de potentiel ~~jusqu'à~~ de 2 V ou plus.

NOTE En présence de tensions supérieures aux limites spécifiées en 8.4.2 c), les limites du COURANT DE FUITE données en 8.4.2 b) s'appliquent.

La conformité est vérifiée par l'inspection ~~du DOSSIER DE GESTION DES RISQUES, par référence aux~~ des instructions d'utilisation et par des mesures.

d) * Les limites de tension et d'énergie spécifiées en c) ci-dessus s'appliquent également:

– aux parties internes, autres que les contacts des fiches, des connecteurs et des socles qui peuvent être touchés par la broche d'essai représentée à la Figure 8, insérée par une ouverture dans une ENVELOPPE ; et

– aux parties internes qui peuvent être touchées par une tige d'essai métallique d'un diamètre de $4\ ^{0}_{-0,05}$ mm et d'une longueur de $100\ ^{+0,5}_{0}$ mm, insérée à travers une ouverture au sommet d'une ENVELOPPE ou à travers une ouverture prévue pour l'ajustement de commandes préréglées qui peuvent être ajustées par l'ORGANISME RESPONSABLE en UTILISATION NORMALE en utilisant un OUTIL.

Voir aussi 8.9.4 pour la mesure des LIGNES DE FUITE et des DISTANCES DANS L'AIR à travers les fentes ou les ouvertures dans les parties externes par rapport au doigt d'essai normalisé.

La conformité est vérifiée en insérant la broche d'essai ou la tige d'essai dans les ouvertures correspondantes. La broche d'essai est insérée dans chaque position possible avec une force minimale (1 N maximum).

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*La tige d'essai est insérée dans chaque position possible dans les ouvertures prévues pour l'ajustement des commandes préréglées qui peuvent être ajustées par l'*ORGANISME RESPONSABLE *en* UTILISATION NORMALE*, en cas de doute avec une force de 10 N.*

Si les instructions d'utilisation spécifient qu'un OUTIL *particulier doit être utilisé, l'essai est répété avec cet* OUTIL*.*

*La tige d'essai est également suspendue librement et verticalement à travers toute ouverture au sommet de l'*ENVELOPPE*.*

Dimensions en millimètres

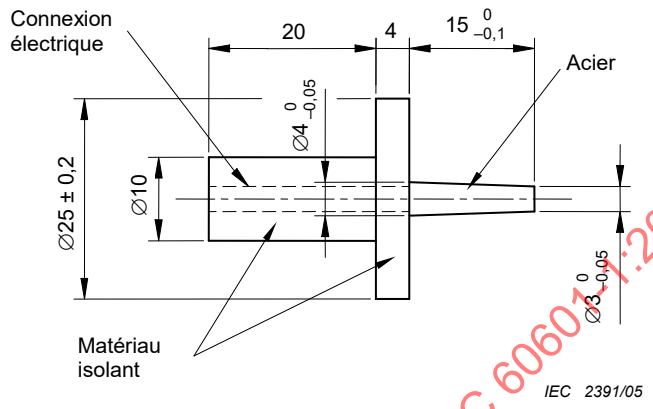


Figure 8 – Broche d'essai
(voir 8.4.2 d))

e) Lorsqu'un CAPOT D'ACCES qui peut être ouvert sans l'utilisation d'un OUTIL donne accès aux parties sous tensions autorisées par ce paragraphe, mais que ces parties sont automatiquement mises hors tension lorsque le CAPOT D'ACCES est ouvert, le ou les dispositifs utilisés pour mettre les parties hors tension doivent satisfaire aux exigences spécifiées en 8.11.1 pour les interrupteurs d'isolement du réseau et doivent rester efficaces en CONDITION DE PREMIER DEFAUT. S'il est possible d'empêcher ces dispositifs de fonctionner, un OUTIL doit être exigé.

La vérification est effectuée par inspection.

8.4.3 * APPAREILS EM destinés à être connectés à une source de puissance par une fiche

LES APPAREILS EM ou leurs parties destinés à être connectés à une source de puissance par une fiche doivent être conçus de telle manière qu' 1 s après le retrait de la fiche, la tension entre les broches de la fiche et entre chaque broche de l'ENVELOPPE ne dépasse pas 60 V ou, si cette valeur est dépassée, la charge stockée ne dépasse pas 45 µC.

La vérification est effectuée par l'essai suivant:

On fait fonctionner les APPAREILS EM *à la tension* ASSIGNEE *ou à la limite supérieure de la plage de tension* ASSIGNEE*.*

*L'*APPAREIL EM *est déconnecté de la source de puissance avec tout interrupteur correspondant en position "En circuit" et "Hors circuit".*

*Soit l'*APPAREIL EM *est déconnecté de la source de puissance par retrait de la fiche, auquel cas l'essai est réalisé aussi souvent que nécessaire pour permettre de mesurer le cas le plus défavorable, soit un circuit de déclenchement est utilisé pour s'assurer que la déconnexion intervient à la crête de l'onde de la tension d'alimentation.*

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La tension entre les broches de la fiche et entre toute broche et l'ENVELOPPE est mesurée 1 s après déconnexion avec un appareil dont l'impédance interne n'affecte pas significativement l'essai.

NOTE Un exemple de dispositif de mesure qui est considéré comme acceptable est un oscilloscope et une sonde ayant une impédance d'entrée qui consiste en une résistance de 100 MΩ ± 5 MΩ en parallèle avec un condensateur de capacité 20 pF ± 5 pF.

La charge restante peut être mesurée ou calculée par toute méthode adaptée.

Le cas échéant, une tension d'entrée en courant continu égale à la valeur de crête de la tension du RESEAU D'ALIMENTATION ASSIGNE peut être utilisée.

8.4.4 * Circuits capacitifs internes

Les parties conductrices des circuits capacitifs qui deviennent accessibles après la mise hors tension des APPAREILS EM et après le retrait immédiatement après des CAPOTS D'ACCES présents en UTILISATION NORMALE ne doivent pas présenter de tension résiduelle dépassant 60 V ou, si cette valeur est dépassée, ne doivent pas présenter une charge restante de plus de 45 µC.

Si la décharge automatique n'est raisonnablement pas possible et si les CAPOTS D'ACCES ne peuvent être enlevés qu'avec l'aide d'un OUTIL, un dispositif incorporé permettant une décharge manuelle est acceptable. Le ou les condensateurs ou les circuits qui leur sont reliés doivent alors être marqués avec le symbole IEC 60417-5036 (~~DB:~~2002-10) (voir Tableau D.1, symbole 24) et le dispositif de décharge non automatique doit être spécifié dans la description technique.

La vérification est effectuée par l'essai suivant:

L'APPAREIL EM est mis en fonctionnement à la tension ASSIGNEE puis il est mis hors tension. Tout CAPOT D'ACCES présent en UTILISATION NORMALE est retiré aussi rapidement que possible. Immédiatement après, la tension résiduelle de tous les condensateurs ou des parties de circuits accessibles est mesurée et la charge stockée est calculée.

Si un dispositif de décharge non automatique est spécifié dans la description technique, son inclusion et son marquage doivent être vérifiés par examen.

8.5 Séparation des parties

8.5.1 * MOYENS DE PROTECTION

8.5.1.1 Généralités

Un APPAREIL EM doit posséder deux MOYENS DE PROTECTION pour empêcher les PARTIES APPLIQUEES et d'autres PARTIES ACCESSIBLES de dépasser les limites spécifiées en 8.4.

Chaque MOYEN DE PROTECTION doit être classé comme MOYEN DE PROTECTION DU PATIENT ou MOYEN DE PROTECTION DE L'OPERATEUR, en se référant à 4.6. Voir aussi la Figure A.12.

Les vernissages, émaillages, oxydations et autres finitions de protection similaires, ainsi que les revêtements avec des mélanges d'étanchéité qui peuvent se ramollir à des températures prévisibles en fonctionnement (y compris au cours de la stérilisation), ne doivent pas être considérés comme un MOYEN DE PROTECTION.

NOTE ~~Les revêtements et les autres isolations qui sont destinés à constituer un MOYEN DE PROTECTION et qui sont conformes à l'IEC 60950-1:2001 sont acceptables comme MOYEN DE PROTECTION DE L'OPERATEUR mais pas automatiquement comme MOYEN DE PROTECTION DU PATIENT.~~ Les revêtements et les autres isolations qui sont destinés à constituer un MOYEN DE PROTECTION et qui satisfont à l'IEC 60950-1:2005 peuvent être utilisés comme MOYEN DE PROTECTION DE L'OPERATEUR mais pas automatiquement comme MOYEN DE PROTECTION DU PATIENT. Pour le MOYEN DE PROTECTION DU PATIENT, des éléments peuvent apparaître à la suite du PROCESSUS de GESTION DES RISQUES.

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Les composants et les câblages formant un MOYEN DE PROTECTION doivent être conformes aux exigences de 8.10.

Toute isolation, LIGNE DE FUITE, DISTANCE DANS L'AIR, tout composant ou toute connexion à la terre qui ne sont pas conformes aux exigences de 8.5.1.2 et de 8.5.1.3 ne doit pas être considéré comme un MOYEN DE PROTECTION. La défaillance de l'une ou de toutes ces parties doit être considérée comme une CONDITION NORMALE.

La conformité est vérifiée par l'essai de 8.5.1.3.

8.5.1.2 * MOYENS DE PROTECTION DU PATIENT

L'isolation solide constituant un MOYEN DE PROTECTION DU PATIENT doit être conforme à l'essai de tension de tenue de 8.8 à la tension d'essai spécifiée au Tableau 6.

LES LIGNES DE FUITE et les DISTANCES DANS L'AIR constituant un MOYEN DE PROTECTION pour le PATIENT doivent être conformes aux limites spécifiées dans le Tableau 12.

Les CONNEXIONS DE TERRE DE PROTECTION constituant un MOYEN DE PROTECTION du PATIENT doivent être conformes aux exigences et aux essais de 8.6.

~~Un condensateur Y1conforme à l'IEC 60384-14 est considéré comme étant équivalent à un MOYEN DE PROTECTION du PATIENT sous réserve qu'il passe avec succès l'essai de tension de tenue correspondant à deux MOYENS DE PROTECTION du PATIENT. Lorsque deux condensateurs sont utilisés en série, ils doivent chacun présenter les caractéristiques ASSIGNEES pour la TENSION DE SERVICE totale à travers la paire et ils doivent présenter la même capacité NOMINALE.~~

Un condensateur Y (Y1 ou Y2 seulement) conforme à l'IEC 60384-14 est considéré comme étant équivalent à un MOYEN DE PROTECTION DU PATIENT. Lorsque deux condensateurs sont utilisés en série, ils doivent être de type identique (soit tous les deux Y1, soit tous les deux Y2) et ils doivent présenter la même capacité NOMINALE. Le(les) condensateur(s) doi(ven)t satisfaire à la tension de tenue pour le type de protection pour lequel ils sont utilisés (c'est-à-dire un ou deux MOYENS DE PROTECTION DU PATIENT).

Lorsque la tension de service dans une barrière formant un MOYEN DE PROTECTION DU PATIENT est inférieure à 42,4 V en valeur de crête en courant alternatif ou 60 V en courant continu, un seul condensateur Y1 est acceptable pour deux MOYENS DE PROTECTION DU PATIENT.

La conformité est vérifiée par l'essai de 8.5.1.3.

8.5.1.3 MOYENS DE PROTECTION DE L'OPERATEUR

Une isolation solide constituant un MOYEN DE PROTECTION DE L'OPERATEUR doit:

– être conforme à l'essai de tension de tenue selon 8.8 à la tension d'essai spécifiée dans le Tableau 6 ; ou

– être conforme aux exigences de l'IEC 60950-1 pour la COORDINATION DE L'ISOLEMENT.

Les LIGNES DE FUITE et les DISTANCES DANS L'AIR constituant un MOYEN DE PROTECTION DE L'OPERATEUR doivent:

– être conformes aux limites spécifiées du Tableau 13 au Tableau 16 (inclus) ; ou

– être conformes aux exigences de l'IEC 60950-1 pour la COORDINATION DE L'ISOLEMENT.

Les CONNEXIONS DE TERRE DE PROTECTION formant des MOYENS DE PROTECTION DE L'OPERATEUR doivent soit:

– être conformes aux exigences de 8.6 ; ou

– être conformes aux exigences et aux essais de l'IEC 60950-1 pour la mise à la terre de protection.

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~~Un condensateur Y2 conforme à l'IEC 60384-14 est considéré comme étant équivalent à un MOYEN DE PROTECTION DE L'OPERATEUR sous réserve qu'il passe avec succès l'essai de tension de tenue correspondant à un MOYEN DE PROTECTION DE L'OPERATEUR. Un condensateur Y1 conforme à l'IEC 60384-14 est considéré comme étant équivalent à deux MOYENS DE PROTECTION DE L'OPERATEUR sous réserve qu'il passe avec succès l'essai de tension de tenue correspondant à deux MOYENS DE PROTECTION DE L'OPERATEUR. Lorsque deux condensateurs sont utilisés en série, ils doivent chacun présenter les caractéristiques ASSIGNEES pour la TENSION DE SERVICE totale à travers la paire et ils doivent présenter la même capacité NOMINALE.~~

Un condensateur Y (Y1 ou Y2 seulement) conforme à l'IEC 60384-14 est considéré comme étant équivalent à un MOYEN DE PROTECTION DE L'OPERATEUR. Lorsque deux condensateurs sont utilisés en série, ils doivent être de type identique (soit tous les deux Y1, soit tous les deux Y2) et ils doivent présenter la même capacité NOMINALE. Le(les) condensateur(s) doi(ven)t satisfaire à la tension de tenue pour le type de protection pour lequel ils sont utilisés (c'est-à-dire un ou deux MOYENS DE PROTECTION DE L'OPERATEUR). Un condensateur Y1 peut être utilisé pour deux MOYENS DE PROTECTION DE L'OPERATEUR.

La conformité ~~aux Paragraphes 8.5.1.1 à 8.5.1.3 (inclus)~~ est vérifiée par l'examen de la configuration physique et électrique ~~des~~ de l'APPAREIL~~S~~ EM afin d'identifier les points auxquels l'isolation, les LIGNES DE FUITE, les DISTANCES DANS L'AIR, les impédances des composants ou les CONNEXIONS DE TERRE DE PROTECTION empêchent les PARTIES ACCESSIBLES ou les PARTIES APPLIQUEES de dépasser les limites spécifiées en 8.4.

NOTE De tels points comprennent généralement l'isolation entre les parties qui ne sont pas au potentiel de terre et les PARTIES ACCESSIBLES ou les PARTIES APPLIQUEES mais ils peuvent également inclure, par exemple, l'isolation entre un circuit flottant et la terre ou d'autres circuits. ~~Un relevé~~ Une étude des chemins d'isolation est ~~donné~~ présentée à l'Annexe J.

Pour chacun de ces points, on détermine si:

- *l'isolation solide est conforme à l'essai de tension de tenue selon 8.8 ou, pour un MOYEN DE PROTECTION DE L'OPERATEUR, avec les exigences de l'IEC 60950-1 pour la COORDINATION DE L'ISOLEMENT;*
- *les LIGNES DE FUITE et les DISTANCES DANS L'AIR sont celles spécifiées en 8.9 ou, pour un MOYEN DE PROTECTION DE L'OPERATEUR, avec les exigences de l'IEC 60950-1 pour la COORDINATION DE L'ISOLEMENT;*
- *les composants qui sont connectés en parallèle avec une isolation, avec une DISTANCE DANS L'AIR ou une LIGNE DE FUITE sont conformes à 4.8 et à 8.10.1;*
- *les CONNEXIONS DE TERRE DE PROTECTION sont conformes aux exigences de 8.6 ou, pour un MOYEN DE PROTECTION DE L'OPERATEUR, aux exigences de l'IEC 60950-1 pour la mise à la terre de protection*;

et ainsi si une défaillance au niveau de ces points doit être considérée comme une CONDITION NORMALE ou comme une CONDITION DE PREMIER DEFAUT.

Chaque MOYEN DE PROTECTION est classifié en fonction des parties de l'APPAREIL EM qu'il protège sans dépasser les limites autorisées. Il s'agit d'un MOYEN DE PROTECTION DU PATIENT s'il protège les PARTIES APPLIQUEES ou des parties qui sont identifiées conformément à 4.6 comme devant être soumises aux mêmes exigences que les PARTIES APPLIQUEES. Sinon, il s'agit d'un MOYEN DE PROTECTION DE L'OPERATEUR.

La TENSION DE SERVICE est déterminée par inspection, calcul ou mesure, conformément à 8.5.4.

La tension, le courant ou l'énergie qui peuvent apparaître entre ~~toute~~ une PARTIE ACCESSIBLE ou une PARTIE APPLIQUEE et toute autre PARTIE ACCESSIBLE, PARTIE APPLIQUEE ou ~~la~~ terre ~~en~~ dans des CONDITIONS NORMALES et en CONDITION DE PREMIER DEFAUT ~~doivent être~~ sont déterminés par inspection ou calcul ou, ~~si nécessaire~~ le cas échéant, par des ~~mesures~~ mesurages dans les conditions appropriées.

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8.5.2 Séparation des CONNEXIONS PATIENT

8.5.2.1 * PARTIES APPLIQUEES DE TYPE F

La ou les CONNEXIONS PATIENT de toute PARTIE APPLIQUEE DE TYPE F doivent être séparées de toutes les autres parties, y compris la ou les CONNEXIONS PATIENT d'autres PARTIES APPLIQUEES, par des moyens équivalents à un MOYEN DE PROTECTION DU PATIENT pour une TENSION DE SERVICE égale à la TENSION RESEAU MAXIMALE et doivent être conformes à la limite spécifiée pour le COURANT DE FUITE PATIENT avec application de 110 % de la TENSION RESEAU MAXIMALE.

Une seule PARTIE APPLIQUEE DE TYPE F peut intégrer plusieurs fonctions, auquel cas une séparation entre ces fonctions n'est pas exigée.

En l'absence de séparation électrique entre la ou les CONNEXIONS PATIENT de la même fonction ou d'une autre fonction (par exemple entre électrode d'électrocardiogramme et cathéter de pression), ces CONNEXIONS PATIENT sont traitées comme une (1) PARTIE APPLIQUEE.

C'est le FABRICANT qui définit si plusieurs fonctions doivent être considérées comme faisant partie d'une seule PARTIE APPLIQUEE ou comme plusieurs parties appliquées.

La classification en TYPE BF, TYPE CF ou PROTEGE CONTRE LES CHOCS DE DEFIBRILLATION s'applique à l'ensemble d'une PARTIE APPLIQUEE.

La conformité est vérifiée par inspection, par les essais de COURANT DE FUITE de 8.7.4, par l'essai de tension de tenue de 8.8.3 et par la mesure des LIGNES DE FUITE et des DISTANCES DANS L'AIR correspondantes.

NOTE Les moyens de séparation entre une PARTIE APPLIQUEE DE TYPE F et d'autres parties sont soumis à la fois à ces essais, liés à la TENSION RESEAU MAXIMALE, et aux essais liés aux tensions présentes dans les circuits respectifs spécifiés en 8.5.4. Selon l'amplitude de ces dernières tensions, un des ensembles d'essais peut être plus sévère.

Tout dispositif de protection connecté entre les CONNEXIONS PATIENT d'une PARTIE APPLIQUEE DE TYPE F et l'ENVELOPPE pour assurer une protection contre les tensions excessives ne doit pas fonctionner en dessous de 500 V en valeur efficace.

La conformité est vérifiée en testant la tension de fonctionnement du dispositif de protection.

8.5.2.2 * PARTIES APPLIQUEES DE TYPE B

La ou les CONNEXIONS PATIENT d'une PARTIE APPLIQUEE DE TYPE B qui ne sont pas PROTEGEES PAR MISE A LA TERRE doivent être séparées des PARTIES METALLIQUES ACCESSIBLES qui ne sont pas PROTEGEES PAR MISE A LA TERRE par un MOYEN DE PROTECTION DU PATIENT, sauf:

– si la PARTIE METALLIQUE ACCESSIBLE est physiquement contiguë de la PARTIE APPLIQUEE et qu'elle peut être considérée comme une partie de la PARTIE APPLIQUEE ; et

– si le RISQUE que la PARTIE METALLIQUE ACCESSIBLE entre en contact avec une source de tension ou que le COURANT DE FUITE dépassant des limites autorisées est suffisamment faible pour être acceptable.

La conformité est vérifiée par inspection, par les essais de COURANT DE FUITE de 8.7.4, par l'essai de tension de tenue de 8.8.3 et par la mesure des LIGNES DE FUITE et des DISTANCES DANS L'AIR et en se référant au DOSSIER DE GESTION DES RISQUES.

8.5.2.3 * ~~Conducteurs PATIENT~~ Conducteurs PATIENT ou câbles PATIENT

Tout connecteur destiné à assurer des connexions électriques sur un conducteur PATIENT ou un câble PATIENT qui

– se situe à l'extrémité du conducteur ou du câble qui est éloigné~~e~~ du PATIENT; et

– qui contient une partie conductrice qui n'est pas séparée de toutes les CONNEXIONS PATIENT par un MOYEN DE PROTECTION DU PATIENT pour une TENSION DE SERVICE égale à la TENSION RESEAU MAXIMALE

doit être construit de telle manière que ladite partie ne puisse pas être reliée à la terre ou à une tension potentiellement dangereuse lorsque les CONNEXIONS PATIENT sont en contact avec le PATIENT.

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NOTE Lorsque l'expression "ladite partie" apparaît dans ce paragraphe, elle fait référence à la "partie conductrice du connecteur qui n'est pas séparée de l'ensemble des CONNEXIONS PATIENT " de la première phrase du présent paragraphe.

En particulier:

– ladite partie ne doit pas entrer en contact avec une plaque conductrice plate d'un diamètre inférieur à 100 mm;

– la DISTANCE DANS L'AIR entre les broches du connecteur et une surface plate doit être d'au moins 0,5 mm;

– s'il est possible d'introduire ladite partie dans un socle de prise de courant réseau, celle-ci doit être protégée contre l'établissement d'un contact avec les parties à la TENSION RESEAU par des moyens d'isolation fournissant une LIGNE DE FUITE d'au moins 1,0 mm et une tension de tenue de 1 500 V et conforme à 8.8.4.1.

– Le doigt d'essai droit et rigide de mêmes dimensions que le doigt d'essai normalisé de la Figure 6 ne doit pas établir de contact électrique avec ladite partie s'il est appliqué dans la position la moins favorable contre les ouvertures d'accès avec une force de 10 N, à moins que le PROCESSUS de GESTION DES RISQUES montre qu'il n'existe pas de risque inacceptable de contact avec des objets autres qu'un socle réseau ou une surface plate (par exemple coins et bords).

La vérification est effectuée par inspection et par les essais appropriés.

8.5.3 * TENSION RESEAU MAXIMALE

La TENSION RESEAU MAXIMALE doit être déterminée comme suit:

– pour les APPAREILS EM monophasés ou en courant continu ALIMENTES PAR LE RESEAU D'ALIMENTATION, y compris les APPAREILS EM A SOURCE ELECTRIQUE INTERNE qui ont également un moyen de raccordement au RESEAU, la TENSION MAXIMALE RESEAU est la tension d'alimentation ASSIGNEE la plus élevée ; sauf pour une valeur inférieure à 100 V, auquel cas la TENSION MAXIMALE RESEAU est 250 V;

– pour les APPAREILS EM polyphasés, la TENSION MAXIMALE RESEAU est la tension d'alimentation ASSIGNEE la plus élevée entre phase et neutre;

– pour les autres APPAREILS EM A SOURCE ELECTRIQUE INTERNE, la TENSION MAXIMALE RESEAU est 250 V.

8.5.4 * TENSION DE SERVICE

La TENSION DE SERVICE pour chaque MOYEN DE PROTECTION doit être déterminée comme suit:

– La tension d'alimentation à l'entrée de L'APPAREIL EM doit être la tension ASSIGNEE ou la tension dans la plage des tensions ASSIGNEES qui résulte de la valeur mesurée la plus élevée.

– Pour les tensions en courant continu à ondulation superposée, la TENSION DE SERVICE est la valeur moyenne si l'ondulation crête à crête ne dépasse pas 10 % de la valeur moyenne ou la tension de crête si l'ondulation crête à crête dépasse 10 % de la valeur moyenne.

– La TENSION DE SERVICE pour chaque MOYEN DE PROTECTION formant une DOUBLE ISOLATION est la tension à laquelle est soumise la DOUBLE ISOLATION dans son ensemble.

– Pour les TENSIONS DE SERVICE concernant une CONNEXION PATIENT non reliée à la terre, la situation dans laquelle le PATIENT est relié à la terre (intentionnellement ou accidentellement) est considérée comme une CONDITION NORMALE.

– La TENSION DE SERVICE entre les CONNEXIONS PATIENT d'une PARTIE APPLIQUEE DE TYPE F et l'ENVELOPPE est prise égale à la tension la plus élevée apparaissant à travers l'isolation en UTILISATION NORMALE, y compris la mise à la terre de toute partie de la PARTIE APPLIQUEE. Voir aussi 8.5.2.1.

– Pour les PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION, la TENSION DE SERVICE est déterminée sans tenir compte de la présence potentielle de tensions de défibrillation. Voir aussi 8.5.5 et 8.9.1.15.

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– Pour les moteurs équipés de condensateurs dans lesquels une tension de résonance entre le point où un enroulement et un condensateur sont reliés ensemble d'une part et toute borne pour conducteurs externes d'autre part, la TENSION DE SERVICE doit être égale à la tension de résonance.

8.5.5 PARTIE APPLIQUEE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION

8.5.5.1 * Protection contre la défibrillation

La classification PARTIE APPLIQUE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION doit s'appliquer à l'ensemble d'une PARTIE APPLIQUEE.

~~NOTE 1 Cette exigence ne s'applique pas aux fonctions séparées de la même PARTIE APPLIQUEE mais il convient de tenir compte dans le PROCESSUS de GESTION DES RISQUES de la possibilité qu'un OPERATEUR reçoive un choc provenant de telles parties.~~

Voir 8.9.1.15 pour les exigences concernant les LIGNES DE FUITE et les DISTANCES DANS L'AIR associées à une PARTIE APPLIQUEE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION.

Les arrangements utilisés pour isoler les CONNEXIONS PATIENT d'une PARTIE APPLIQUEE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION des autres parties des APPAREILS EM doivent être conçus de telle manière que:

a) Pendant une décharge d'un défibrillateur cardiaque appliquée à un PATIENT connecté à une PARTIE APPLIQUEE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION, des énergies électriques dangereuses, telles que celles déterminées par la tension de crête mesurée entre les points Y_1 et Y_2 de la Figure 9 et de la Figure 10 au-delà de 1 V, n'apparaissent pas sur:

   – l'ENVELOPPE, y compris les connecteurs des conducteurs PATIENT et les câbles lorsqu'ils sont connectés à l'APPAREIL EM;

     NOTE ~~2~~ 1 Cette exigence ne s'applique pas à un conducteur provenant d'une PARTIE APPLIQUEE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION ou son connecteur lorsqu'il est déconnecté de l'APPAREIL EM.

   – toute ENTREE/SORTIE DE SIGNAL;

   – la feuille métallique pour les essais sur laquelle l'APPAREIL EM est placé et qui a une superficie au moins égale à celle de la base de l'APPAREIL EM; ~~ou~~

   – les CONNEXIONS PATIENT de toute autre PARTIE APPLIQUEE (classée ou non PARTIE APPLIQUEE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION); ou

   – toute connexion inutilisée ou non connectée de la PARTIE APPLIQUEE soumise à l'essai ou toute fonction de la même PARTIE APPLIQUEE. UN APPAREIL EM qui est totalement PORTE (par exemple un moniteur Holter) est exempt de cette exigence.

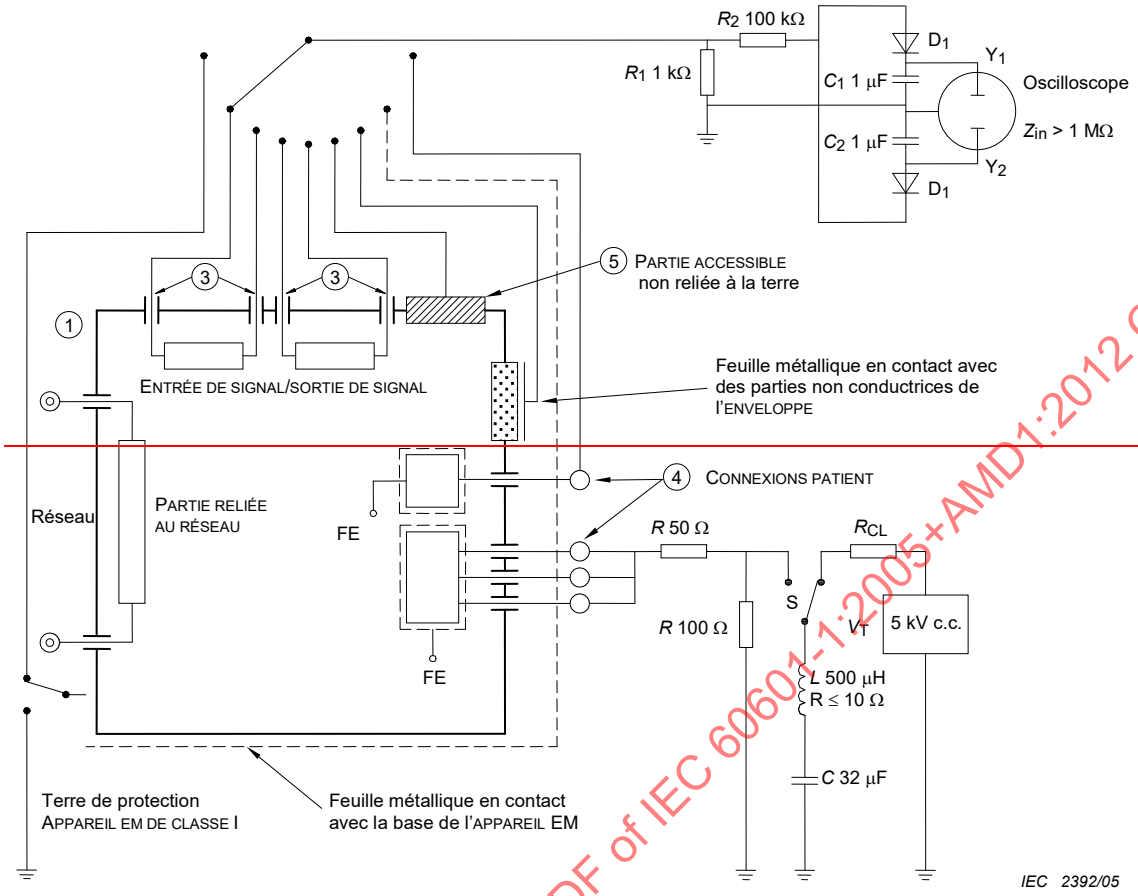
b) Après exposition à la tension de défibrillation et à toute période nécessaire de récupération indiquée dans les DOCUMENTS D'ACCOMPAGNEMENT, l'APPAREIL EM doit être conforme aux exigences applicables de la présente norme et doit continuer à assurer la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES.

La conformité est vérifiée par les essais suivants, pour chaque PARTIE APPLIQUEE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION successivement:

- ***Essai en mode commun***

L'APPAREIL EM est connecté au circuit d'essai comme représenté à la Figure 9. La tension d'essai est appliquée à toutes les CONNEXIONS PATIENT de la PARTIE APPLIQUEE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION connectées ensemble, à l'exclusion de celles qui sont PROTEGEES PAR MISE A LA TERRE ou mises à la terre de façon fonctionnelle. Si une PARTIE APPLIQUEE a de multiples fonctions, la tension d'essai est appliquée à toutes les CONNEXIONS PATIENT d'une fonction à la fois, les autres fonctions étant déconnectées.

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~~Pour les légendes, voir le Tableau 5.~~

~~Composants~~

~~V_T Tension d'essai~~

~~S Interrupteur pour appliquer la tension d'essai~~

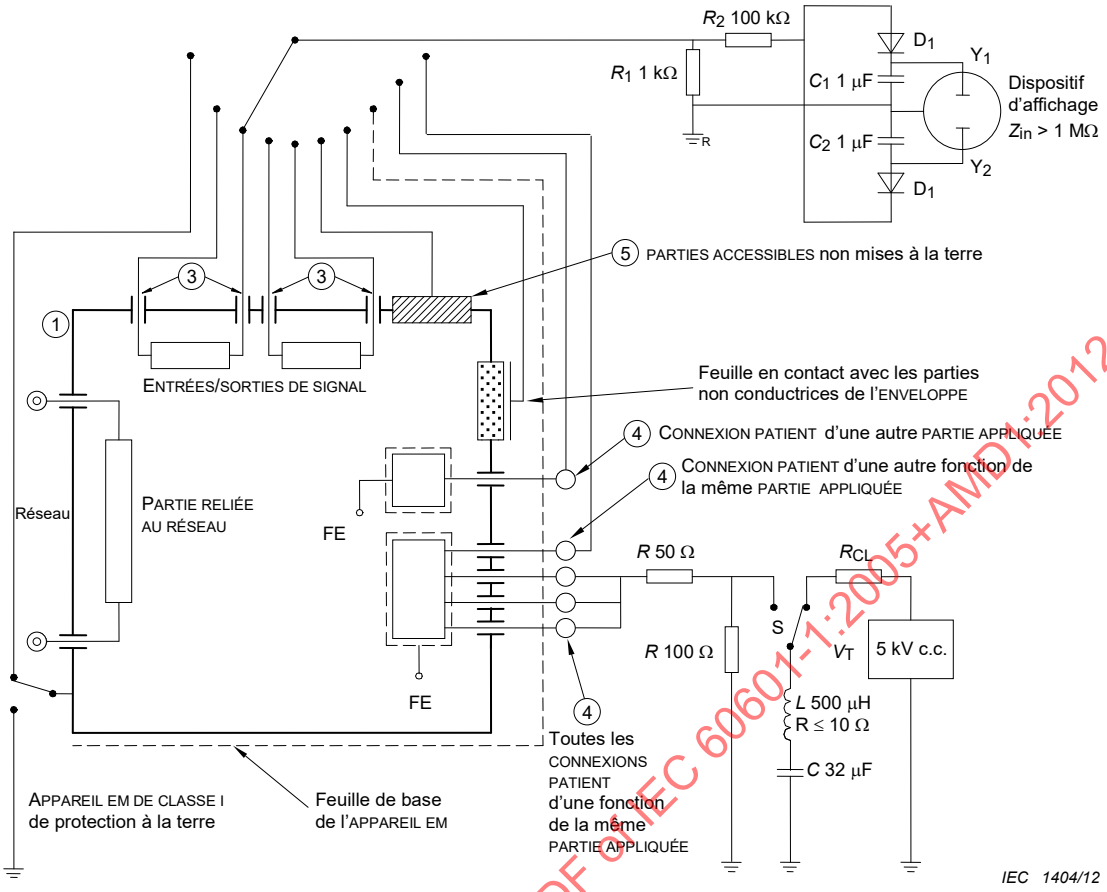
~~R_1, R_2 Tolérance à ± 2 %, Tension d'utilisation pas inférieure à 2 kV~~

~~R_{CL} Résistance de limitation du courant~~

~~D_1, D_2 Diodes au silicium pour petits signaux~~

~~Autres composants avec tolérance à ± 5 %~~

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Pour les légendes, voir Tableau 5.

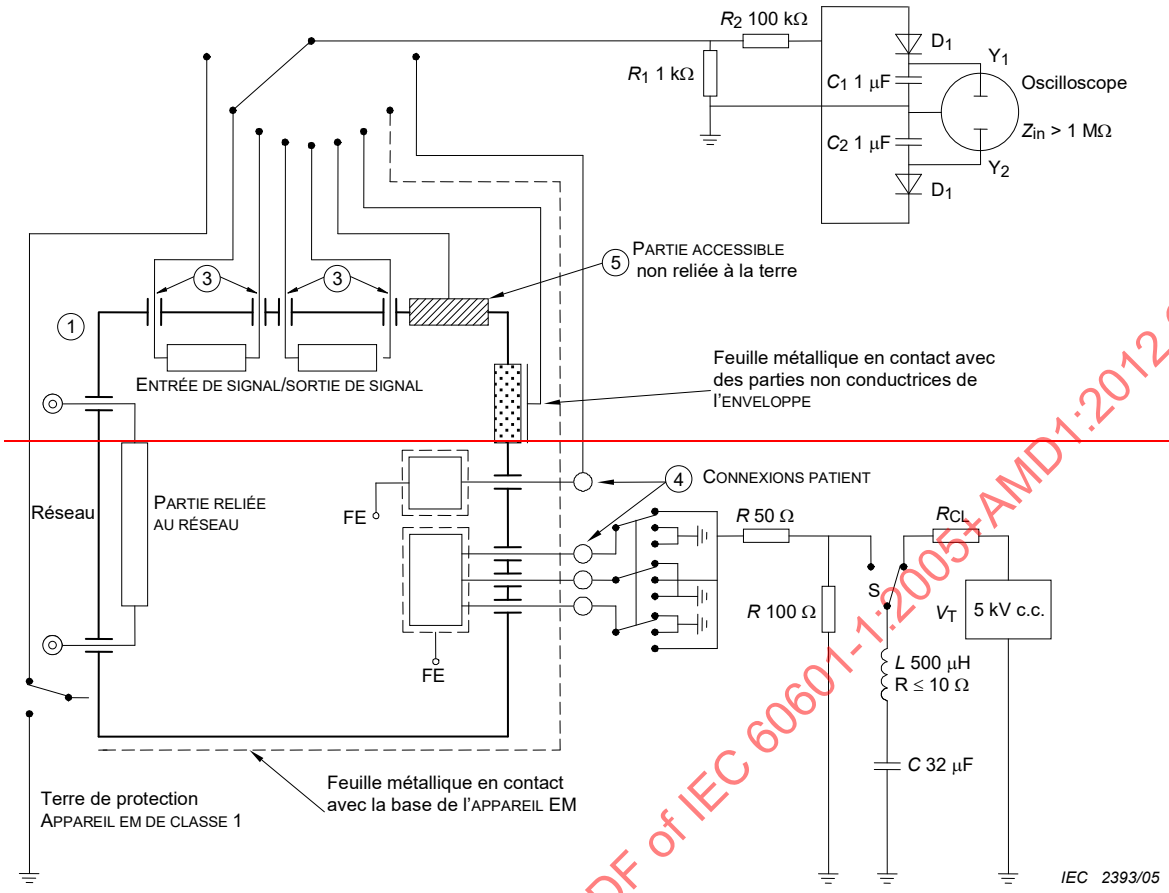
Composants

V_T	Tension d'essai
S	Interrupteur pour appliquer la tension d'essai
R_1, R_2	Tolérance à ± 2 %, non inférieur à 2 kV
R_{CL}	Résistance de limitation du courant
D_1, D_2	Diodes au silicium pour petits signaux

Autres composants avec tolérance à ± 5 %

Figure 9 – Application de la tension d'essai ~~aux~~ à des CONNEXIONS PATIENT reliées entre elles pour les PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION
(voir 8.5.5.1)

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~~Pour les légendes, voir le Tableau 5.~~

~~**Composants**~~

~~V_T Tension d'essai~~

~~S Interrupteur pour appliquer la tension d'essai~~

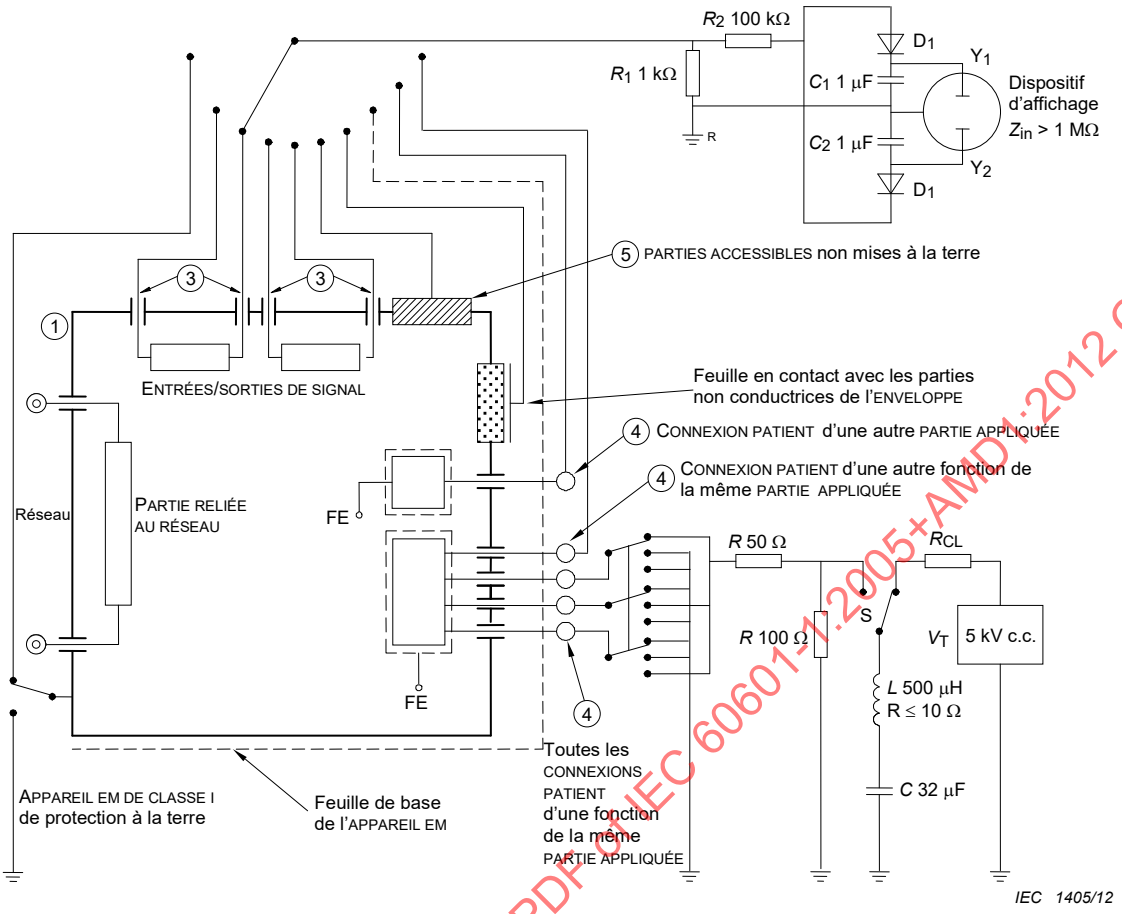
~~R_1, R_2 Tolérance à ± 2 %. Tension d'utilisation pas inférieure à 2 kV~~

~~R_{CL} Résistance de limitation du courant~~

~~D_1, D_2 Diodes au silicium pour petits signaux~~

~~Autres composants avec tolérance à ± 5 %~~

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Pour les légendes, voir Tableau 5.

Composants

V_T	Tension d'essai
S	Interrupteur pour appliquer la tension d'essai
R_1, R_2	Tolérance à ± 2 %, non inférieur à 2 kV
R_{CL}	Résistance de limitation du courant
D_1, D_2	Diodes au silicium pour petits signaux

Autres composants avec tolérance à ± 5 %

Figure 10 – Application de la tension d'essai ~~aux~~ à des CONNEXIONS PATIENT individuelles pour les PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION
(voir 8.5.5.1)

- ***Essai en mode différentiel***

L'APPAREIL EM est connecté au circuit d'essai comme représenté à la Figure 10. La tension d'essai est appliquée tour à tour à chaque CONNEXION PATIENT de la PARTIE APPLIQUEE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION, toutes les autres CONNEXIONS PATIENT restantes de la même PARTIE APPLIQUEE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION étant reliées à la terre.

NOTE 2 L'essai en mode différentiel n'est pas utilisé lorsque la PARTIE APPLIQUEE se compose d'une CONNEXION PATIENT unique.

Au cours de chaque essai:

– *les APPAREILS EM, à l'exception des APPAREILS EM INSTALLES DE FAÇON PERMANENTE, doivent être soumis aux essais avec et sans CONDUCTEUR DE TERRE DE PROTECTION connecté (c'est-à-dire deux essais séparés);*

– *les surfaces isolantes des PARTIES APPLIQUEES sont recouvertes d'une feuille métallique ou, le cas échéant, plongées dans une solution saline à 0,9 %;*

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– *toute connexion externe à une BORNE DE TERRE FONCTIONNELLE est débranchée;*

– *les parties spécifiées en 8.5.5.1 a) qui ne sont pas PROTEGEES PAR MISE A LA TERRE sont successivement connectées à un oscilloscope;*

– *l'APPAREIL EM est raccordé au RESEAU D'ALIMENTATION et il est mis en marche conformément aux instructions d'utilisation.*

Après la fermeture de S, la tension de crête est mesurée entre les points Y_1 et Y_2. Chaque essai est répété en inversant V_T.

A l'issue de toute période de récupération indiquée dans les DOCUMENTS D'ACCOMPAGNEMENT, déterminer que L'APPAREIL EM continue à assurer la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES.

8.5.5.2 Essai de réduction de l'énergie

Les PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION ou les CONNEXIONS PATIENT doivent intégrer un ou plusieurs moyens de telle sorte que l'énergie du défibrillateur délivrée sur une charge de 100 Ω soit égale à au moins 90 % de l'énergie délivrée sur cette charge, l'APPAREIL EM étant déconnecté.

La vérification de la conformité est effectuée par l'essai suivant:

Le circuit d'essai est représenté à la Figure 11. Pour cet essai, les ACCESSOIRES tels que les câbles, les électrodes et les transducteurs qui sont recommandés dans les instructions d'utilisation (voir 7.9.2.14) doivent être utilisés. La tension d'essai est appliquée à chaque CONNEXION PATIENT ou PARTIE APPLIQUEE successivement, toutes les CONNEXIONS PATIENT restantes de la même PARTIE APPLIQUEE étant reliées à la terre (mode différentiel). Les autres PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION, le cas échéant, sont soumises à l'essai séparément, successivement.

La PROCEDURE est la suivante.

a) Connecter la PARTIE APPLIQUEE ou la CONNEXION PATIENT au circuit d'essai. Les parties décrites en 8.5.5.1 a) sont connectées à la terre.

b) Charger le condensateur C jusqu'à 5 kV en courant continu, l'interrupteur S étant en position A.

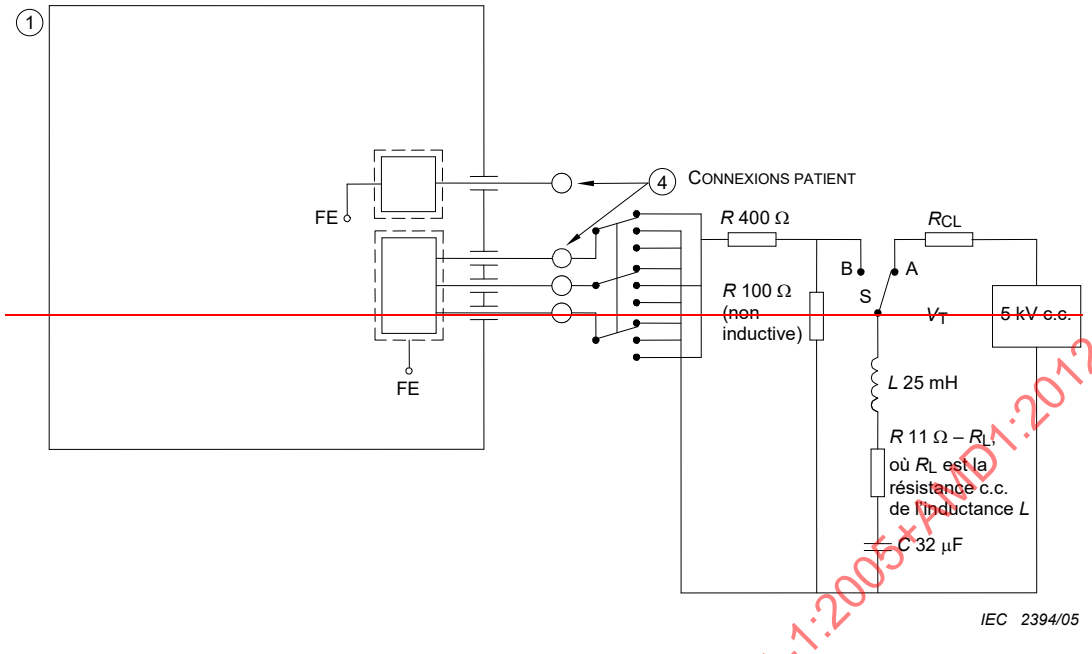
c) Décharger le condensateur C en manœuvrant l'interrupteur S en position B, et mesurer l'énergie E_1 délivrée aux bornes de la charge de 100 Ω.

d) Retirer l'APPAREIL EM en essai du circuit d'essai et répéter les étapes b) et c) ci-dessus en mesurant l'énergie E_2 délivrée (en réponse à) aux bornes de la charge de 100 Ω.

e) Vérifier que l'énergie E_1 représente au moins 90 % de E_2.

f) Répéter l'essai avec V_T inverse.

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~~Pour les légendes, voir le Tableau 5.~~

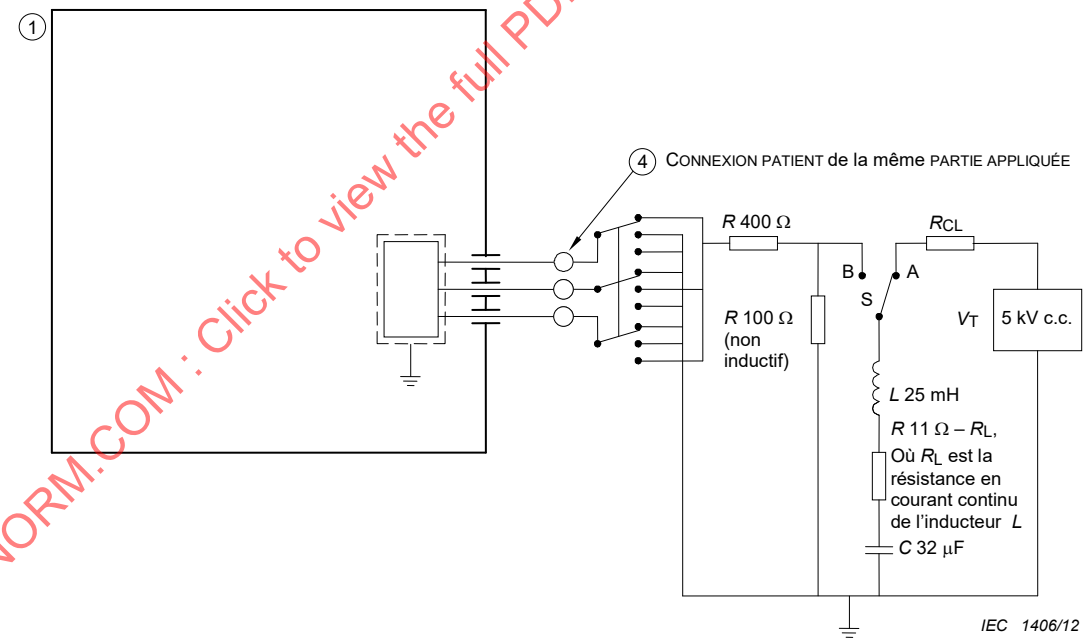
~~**Composants**~~

~~S Interrupteur pour appliquer la tension d'essai~~

~~A, B Positions de l'interrupteur~~

~~R_{CL} Résistance de limitation du courant~~

~~Composants avec tolérance à ± 5 %~~



Pour les légendes, voir Tableau 5.

Composants

S Interrupteur pour appliquer la tension d'essai

A, B Positions de l'interrupteur

R_{CL} Résistance de limitation du courant

Composants avec tolérance à ± 5 %

Figure 11 – Application de la tension d'essai pour tester l'énergie de défibrillation délivrée
(voir 8.5.5.2)

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8.6 * Mise à la terre de protection, mise à la terre fonctionnelle et égalisation des potentiels des APPAREILS EM

8.6.1 * Applicabilité des exigences

Les exigences de 8.6.2 à 8.6.8 (inclus) s'appliquent, sauf si les parties concernées sont conformes aux exigences et aux essais de l'IEC 60950-1 pour la mise à la terre de protection et servent de MOYENS DE PROTECTION DE L'OPERATEUR mais pas de MOYENS DE PROTECTION DU PATIENT.

8.6.2 * BORNE DE TERRE DE PROTECTION

La BORNE DE TERRE DE PROTECTION des APPAREILS EM doit être adaptée à un système de mise à la terre de protection extérieur soit par un CONDUCTEUR DE TERRE DE PROTECTION dans un CABLE D'ALIMENTATION et, lorsque cela est approprié, par une fiche adaptée, soit par un CONDUCTEUR DE TERRE DE PROTECTION FIXE A DEMEURE.

Les moyens de serrage des BORNES DE TERRE DE PROTECTION des APPAREILS EM pour les conducteurs d'alimentation ou les CABLES D'ALIMENTATION FIXES A DEMEURE doivent être conformes aux exigences de 8.11.4.3. Il ne doit pas être possible de les desserrer sans l'aide d'un OUTIL.

Les vis destinées aux CONNEXIONS DE TERRE DE PROTECTION internes doivent être complètement recouvertes ou protégées contre un desserrement accidentel depuis l'extérieur de l'APPAREIL EM.

Lorsqu'un SOCLE DE CONNECTEUR constitue le raccordement d'alimentation vers l'APPAREIL EM, la broche de terre de ce SOCLE doit être considérée comme une BORNE DE TERRE DE PROTECTION.

La BORNE DE TERRE DE PROTECTION ne doit pas servir à relier mécaniquement différentes parties de l'APPAREIL EM ou à fixer un composant sans rapport avec la mise à la terre de protection ou la mise à la terre fonctionnelle.

La conformité est vérifiée par inspection des matériaux et de la construction, par des essais manuels et par l'essai de 8.11.4.3.

8.6.3 * Mise à la terre de protection des parties en mouvement

Une CONNEXION DE TERRE DE PROTECTION ne doit pas être utilisée pour une partie en mouvement sauf si le FABRICANT montre que la connexion restera fiable pendant la DUREE DE SERVICE ATTENDUE des APPAREILS EM.

La conformité est vérifiée par inspection de L'APPAREIL EM et, si nécessaire, par inspection du DOSSIER DE GESTION DES RISQUES.

8.6.4 Impédance et courant admissible

a) * Les CONNEXIONS DE TERRE DE PROTECTION doivent pouvoir transporter des courants de défaut de manière fiable et sans chute de tension excessive.

Pour les APPAREILS EM INSTALLES DE FAÇON PERMANENTE, l'impédance entre la BORNE DE TERRE DE PROTECTION et toute partie qui est PROTEGEE PAR MISE A LA TERRE ne doit pas dépasser 100 mΩ, sauf dans les cas autorisés en 8.6.4 b).

Pour les APPAREILS EM équipés d'un SOCLE DE CONNECTEUR, l'impédance entre la broche de terre dans le SOCLE DE CONNECTEUR et toute partie qui est PROTEGEE PAR MISE A LA TERRE ne doit pas dépasser 100 mΩ, sauf dans les cas autorisés en 8.6.4 b).

Pour les APPAREILS EM équipés d'un CABLE D'ALIMENTATION NON FIXE A DEMEURE, l'impédance entre la broche de terre de protection dans la FICHE RESEAU et toute partie qui est PROTEGEE PAR MISE A LA TERRE ne doit pas dépasser 200 mΩ, sauf dans les cas autorisés en 8.6.4 b).

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De plus, l'impédance entre la broche de terre de protection de la FICHE RESEAU de tout CABLE D'ALIMENTATION NON FIXE A DEMEURE fourni ou spécifié par le FABRICANT, lorsqu'il est fixé à l'APPAREIL EM, et toute partie de l'APPAREIL EM qui est PROTEGEE PAR MISE A LA TERRE ne doit pas dépasser 200 mΩ, à l'exception des autorisations en 8.6.4 b).

Lorsqu'un CABLE D'ALIMENTATION NON FIXE A DEMEURE n'est ni fourni ni spécifié, l'essai doit être réalisé au moyen d'un câble de 3 m de long de section appropriée selon 8.11.3.3 et le Tableau 17.

La vérification de la conformité est effectuée par l'essai suivant:

On fait passer durant 5 s à 10 s un courant de 25 A ou de 1,5 fois le courant ASSIGNE le plus élevé du ou des circuits correspondants, en retenant le plus élevé (± 10 %), provenant d'une source d'une fréquence de 50 Hz ou 60 Hz et dont la tension à vide ne dépasse pas 6 V, entre la BORNE DE TERRE DE PROTECTION ou le contact de terre de protection dans le SOCLE DE CONNECTEUR ou la broche de terre de protection de la FICHE RESEAU et chaque partie PROTEGEE PAR MISE A LA TERRE.

Sinon, un courant continu peut être utilisé pour cet essai.

La chute de tension entre les parties décrites est mesurée et l'impédance est déterminée à partir de l'intensité et de la chute de tension.

Lorsque le produit du courant d'essai tel qu'il est spécifié ci-dessus et de l'impédance totale (c'est-à-dire l'impédance mesurée plus l'impédance des conducteurs d'essai et les impédances de contact) dépasse 6 V, l'impédance est d'abord mesurée avec une tension à vide ne dépassant pas 6 V.

Si l'impédance mesurée se situe dans la limite autorisée, soit la mesure d'impédance est répétée en utilisant une source de courant avec une tension à vide suffisante pour fournir le courant spécifié dans l'impédance totale, soit le courant admissible du conducteur de terre de protection concerné et de la connexion de terre de protection est confirmé en vérifiant que leur section est au moins égale à celle des conducteurs de courant admissible concernés.

b) * Il est autorisé que l'impédance des CONNEXIONS DE TERRE DE PROTECTION dépasse les valeurs spécifiées ci-dessus si les circuits correspondants ont un courant admissible limité tel qu'en cas de court-circuit d'isolation, les valeurs admissibles du COURANT DE CONTACT et du COURANT DE FUITE PATIENT en CONDITION DE PREMIER DEFAUT ne sont pas dépassées.

La conformité est vérifiée par inspection et, si nécessaire, par la mesure du COURANT DE FUITE dans la CONDITION DE PREMIER DEFAUT correspondante. Les courants transitoires qui apparaissent au cours des premières 50 ms qui suivent le court-circuit sont ignorés.

8.6.5 Revêtements de surface

Les éléments conducteurs d'APPAREIL EM dont les revêtements de surface sont en matériaux peu conducteurs comme la peinture et entre lesquels le contact électrique est essentiel à une CONNEXION DE TERRE DE PROTECTION doivent être débarrassés de leur revêtement au point de contact à moins qu'un examen de la construction du joint et le PROCESSUS de construction ne montrent que les exigences d'impédance et de courant admissible sont satisfaites sans retrait du revêtement de surface.

La conformité est effectuée par inspection.

8.6.6 Fiches et socles

Lorsque le raccordement entre le RESEAU D'ALIMENTATION et l'APPAREIL EM ou entre des parties séparées d'APPAREILS EM qui peuvent être actionnées par des personnes autres que celles appartenant au PERSONNEL D'ENTRETIEN est réalisé via une fiche et un socle, la CONNEXION DE TERRE DE PROTECTION doit être réalisée avant et interrompue après que le raccordement à

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l'alimentation soit réalisé ou interrompu. Cela s'applique également lorsque des parties interchangeables sont PROTEGEES PAR MISE A LA TERRE.

La conformité est vérifiée par inspection.

8.6.7 * CONDUCTEUR D'EGALISATION DES POTENTIELS

Si l'APPAREIL EM est pourvu d'une borne pour le raccordement d'un CONDUCTEUR D'EGALISATION DES POTENTIELS, les exigences suivantes s'appliquent:

– cette borne doit être accessible à l'OPERATEUR lorsque l'APPAREIL EM est dans une position d'UTILISATION NORMALE;

~~– le RISQUE de déconnexion accidentelle doit être réduit en UTILISATION NORMALE;~~

– Une déconnexion accidentelle doit être évitée en UTILISATION NORMALE.

– la borne doit permettre le débranchement du conducteur sans utiliser d'OUTIL;

– la borne ne doit pas être utilisée pour une CONNEXION DE TERRE DE PROTECTION;

– la borne doit être marquée avec le symbole IEC 60417-5021 (~~DB:~~2002-10) (voir Tableau D.1, symbole 8);

– les instructions d'utilisation doivent contenir des informations concernant la fonction et l'utilisation du CONDUCTEUR D'EGALISATION DES POTENTIELS avec une référence aux exigences de la présente norme pour les SYSTEMES EM.

Le CABLE D'ALIMENTATION ne doit pas incorporer un CONDUCTEUR D'EGALISATION DES POTENTIELS.

La conformité est vérifiée par inspection.

8.6.8 BORNE DE TERRE FONCTIONNELLE

Une BORNE DE TERRE FONCTIONNELLE d'un APPAREIL EM ne doit pas être utilisée comme CONNEXION A LA TERRE DE PROTECTION.

La conformité est vérifiée par inspection.

8.6.9 * APPAREILS EM de CLASSE II

Si un APPAREIL EM de la CLASSE II comportant des écrans internes isolés est alimenté par un CABLE D'ALIMENTATION à trois conducteurs, le troisième conducteur (relié au contact de terre de protection de la FICHE RESEAU) doit être utilisé uniquement comme connexion de terre fonctionnelle vers une BORNE DE TERRE FONCTIONNELLE pour ces écrans et doit être de couleur vert-jaune. Dans ce cas, les DOCUMENTS D'ACCOMPAGNEMENT doivent indiquer que le troisième conducteur dans le CABLE D'ALIMENTATION est seulement une terre fonctionnelle.

~~L'isolation de ces écrans internes et de tous les câblages internes qui leur sont reliés doivent fournir deux MOYENS DE PROTECTION. Si tel est le cas, il doit y avoir une explication dans la description technique.~~

L'isolation entre les écrans internes, y compris les câblages internes qui leur sont connectés, et les PARTIES ACCESSIBLES, doit fournir deux MOYENS DE PROTECTION.

La conformité est vérifiée par inspection et mesure. L'isolation est soumise aux essais décrits en 8.8.

8.7 COURANTS DE FUITE et COURANTS AUXILIAIRES PATIENT

8.7.1 Exigences générales

a) L'isolation électrique assurant la protection contre les chocs électriques doit être d'une qualité telle que les courants la traversant soient limités aux valeurs spécifiées en 8.7.3.

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b) Les valeurs spécifiées du COURANT DE FUITE A LA TERRE, du COURANT DE CONTACT, du COURANT DE FUITE PATIENT et du COURANT AUXILIAIRE PATIENT s'appliquent pour toute combinaison des conditions suivantes:

- à la température de fonctionnement et après le traitement de pré-conditionnement humide décrit en 5.7;
- après toute PROCEDURE de stérilisation exigée (voir 11.6.7);
- en CONDITION NORMALE et en CONDITION DE PREMIER DEFAUT spécifiées en 8.7.2;
- avec l'APPAREIL EM alimenté en attente et en fonctionnement et avec tout interrupteur des PARTIES RELIEES AU RESEAU quelle que soit leur position;
- avec la fréquence d'alimentation ASSIGNEE la plus élevée;
- avec une alimentation de valeur égale à 110 % de la TENSION RESEAU ASSIGNEE la plus élevée.

8.7.2 * CONDITIONS DE PREMIER DEFAUT

Les valeurs admissibles spécifiées en 8.7.3 s'appliquent aux CONDITIONS DE PREMIER DEFAUT spécifiées en 8.1 b), excepté que:

- lorsque l'isolation est utilisée conjointement à une CONNEXION DE TERRE DE PROTECTION, le court-circuit de l'isolation ne s'applique que dans les circonstances spécifiées en 8.6.4 b);
- la seule CONDITION DE PREMIER DEFAUT pour le COURANT DE FUITE A LA TERRE soit l'interruption d'un conducteur d'alimentation à la fois;
- les COURANTS DE FUITE et le COURANT AUXILIAIRE PATIENT ne soient pas mesurés en CONDITION DE PREMIER DEFAUT durant la mise en court-circuit d'un élément constituant la DOUBLE ISOLATION.

Les CONDITIONS DE PREMIER DEFAUT ne doivent pas être appliquées en même temps que les conditions particulières d'essai de la TENSION RESEAU MAXIMALE sur les PARTIES APPLIQUEES (8.7.4.7 b)) et sur les parties NON PROTEGEES PAR MISE A LA TERRE de L'ENVELOPPE (8.7.4.7 d)).

8.7.3 * Valeurs admissibles

a) Les valeurs admissibles spécifiées en 8.7.3 b), c) et d) s'appliquent aux courants circulant dans le circuit de la Figure 12 a) et mesurés comme indiqué dans cette figure (ou par un dispositif mesurant la forme et la fréquence des courants tel que défini à la Figure 12 b)). Les valeurs s'appliquent aux formes d'ondes en courant continu et en courant alternatif ainsi qu'aux formes d'ondes complexes. Sauf indication contraire, elles peuvent être en courant continu ou en valeur efficace.

b) Les valeurs admissibles des COURANTS DE FUITE PATIENT et des COURANTS AUXILIAIRES PATIENT sont indiquées au Tableau 3 et au Tableau 4. Les valeurs du courant alternatif s'appliquent aux courants dont la fréquence n'est pas inférieure à 0,1 Hz.

c) Les valeurs admissibles du COURANT DE CONTACT sont de 100 µA en CONDITION NORMALE et de 500 µA en CONDITION DE PREMIER DEFAUT.

d) Les valeurs admissibles du COURANT DE FUITE A LA TERRE sont de 5 mA en CONDITION NORMALE et de 10 mA en CONDITION DE PREMIER DEFAUT. Pour les APPAREILS EM INSTALLES DE FAÇON PERMANENTE connectés à des circuits d'alimentation qui alimentent uniquement ces APPAREILS EM, une valeur plus élevée de COURANT DE FUITE A LA TERRE est admise.

NOTE 1 Les règlements locaux peuvent fixer des limites pour les courants de protection à la terre pour l'installation. Voir aussi l'IEC 60364-7-710 [10].

NOTE 2 Le COURANT DE FUITE A LA TERRE en CONDITION NORMALE peut devenir un COURANT DE CONTACT en CONDITION DE PREMIER DEFAUT, à moins que l'APPAREIL EM soit INSTALLE EN PERMANENCE ou que la terre de protection ne soit pas accessible de l'extérieur de l'APPAREIL EM.

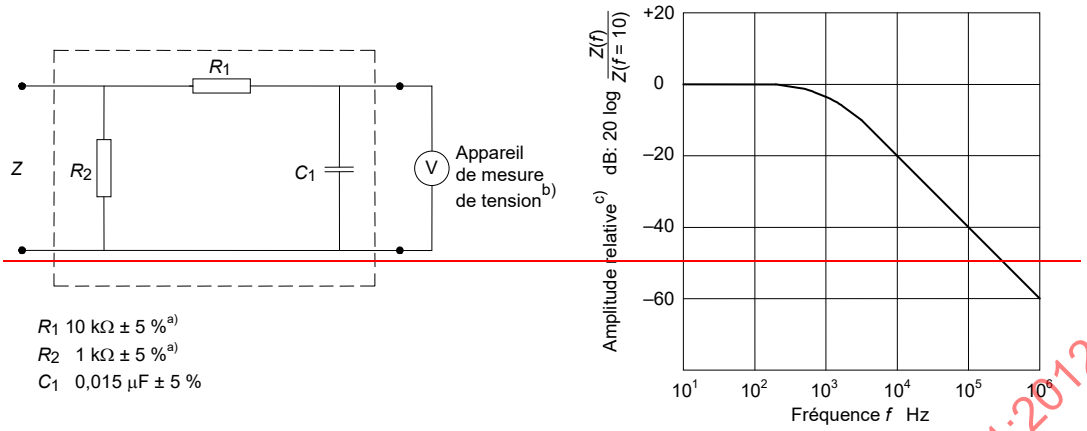
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e) En outre, sans tenir compte de la forme d'onde ni de la fréquence, aucun COURANT DE FUITE ne doit dépasser 10 mA efficaces en CONDITION NORMALE ou en CONDITION DE PREMIER DEFAUT lorsque les mesures sont réalisées avec un dispositif non pondéré en fréquence.

f) * Les valeurs autorisées des COURANTS DE FUITE qui peuvent circuler dans un CONDUCTEUR DE TERRE FONCTIONNELLE dans un APPAREIL EM non INSTALLE EN PERMANENCE sont de 5 mA dans des CONDITIONS NORMALES et de 10 mA dans des CONDITIONS DE PREMIER DEFAUT.

NOTE 3 Le paragraphe 16.6.1 exige que lorsqu'un APPAREIL EM est inclus dans un SYSTEME EM, les COURANTS DE CONTACT provenant d'une partie quelconque du SYSTEME EM ne puissent pas dépasser 100 µA en CONDITION NORMALE et 500 µA en CONDITION DE PREMIER DEFAUT.

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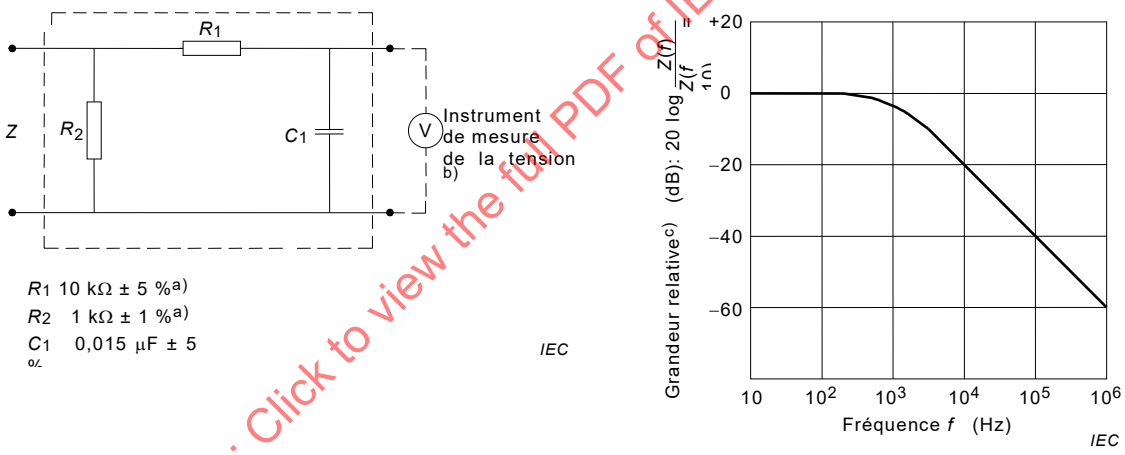
a) Dispositif de mesure

b) Caractéristiques de fréquence

NOTE L'appareil de mesure du circuit et de la tension ci-dessus est remplacé par le symbole 

dans les Figures suivantes.

a) Composants non inductifs
b) Impédance >> impédance de mesure Z
c) $Z(f)$ est l'impédance de transfert du circuit, i.e. $V_{E/S}$, pour un courant de fréquence f



a) Appareil de mesure

b) Caractéristiques de fréquence

NOTE Le réseau de l'instrument de mesure de la tension ci-dessus sont remplacés par le symbole 

dans les figures qui suivent

a) Composants non inductifs
b) Résistance ≥ 1 MΩ et capacité ≤ 150 pF
c) $Z(f)$ est l'impédance de transfert du réseau; c.-à-d. Vout/in, pour un courant fréquence f

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Figure 12 – Exemple de dispositif de mesure et de ses caractéristiques de fréquence
(voir 8.7.3)

Tableau 3 – * Valeurs admissibles des COURANTS DE FUITE PATIENT et des COURANTS AUXILIAIRES PATIENT EN CONDITION NORMALE ET EN CONDITION DE PREMIER DEFAUT

Courant en µA

Courant	Description	Référence	Circuit de mesure		PARTIE APPLIQUEE DE TYPE B		PARTIE APPLIQUEE DE TYPE BF		PARTIE APPLIQUEE DE TYPE CF	
					NC	SFC	NC	SFC	NC	SFC
COURANT AUXILIAIRE PATIENT		8.7.4.8	Figure 19	c.c.	10	50	10	50	10	50
				c.a.	100	500	100	500	10	50
COURANT DE FUITE PATIENT	Entre la CONNEXION PATIENT et la terre	8.7.4.7 a)	Figure 15	c.c.	10	50	10	50	10	50
				c.a.	100	500	100	500	10	50
	Causé par une tension externe sur un SIP/SOP	8.7.4.7 c)	Figure 17	c.c.	10	50	10	50	10	50
				c.a.	100	500	100	500	10	50
COURANT DE FUITE PATIENT total [a]	Avec les mêmes types de PARTIES APPLIQUEES connectés ensemble	8.7.4.7 a) et 8.7.4.7 h)	Figure 15 et Figure 20	c.c.	50	100	50	100	50	100
				c.a.	500	1 000	500	1 000	50	100
	Causé par une tension externe sur un SIP/SOP	8.7.4.7 c) et 8.7.4.7 h)	Figure 17 et Figure 20	c.c.	50	100	50	100	50	100
				c.a.	500	1 000	500	1 000	50	100

Légende
CN = CONDITION NORMALE
CPD = CONDITION DE PREMIER DEFAUT

NOTE 1 Pour le COURANT DE FUITE A LA TERRE, voir 8.7.3 d).

NOTE 2 Pour le COURANT DE CONTACT, voir 8.7.3 c).

[a] Les valeurs du COURANT DE FUITE PATIENT total ne sont applicables qu'aux appareils qui ont des PARTIES APPLIQUEES multiples. Voir 8.7.4.7 h). Les PARTIES APPLIQUEES individuelles doivent être conformes aux valeurs du COURANT DE FUITE PATIENT.

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Tableau 4 – * Valeurs admissibles des COURANTS DE FUITE PATIENT dans les conditions d'essais particulières identifiées en 8.7.4.7

Courant en µA

Courant	Description [a]	Référence	Circuit de mesure	PARTIE APPLIQUEE DE TYPE B	PARTIE APPLIQUEE DE TYPE BF	PARTIE APPLIQUEE DE TYPE CF
COURANT DE FUITE PATIENT	Causé par une tension externe sur la CONNEXION PATIENT d'une PARTIE APPLIQUEE DE TYPE F	8.7.4.7 b)	Figure 16	Pas applicable	5 000	50
	Causé par une tension externe sur une PARTIE ACCESSIBLE métallique NON PROTEGEE PAR MISE A LA TERRE	8.7.4.7 d)	Figure 18	500	500	– [c]
COURANT DE FUITE PATIENT total [b]	Causé par une tension externe sur la CONNEXION PATIENT d'une PARTIE APPLIQUEE DE TYPE F	8.7.4.7 b) et 8.7.4.7 h)	Figure 16 et Figure 20	Pas applicable	5 000	100
	Causé par une tension externe sur a une PARTIE ACCESSIBLE métallique NON PROTEGEE PAR MISE A LA TERRE	8.7.4.7 d) et 8.7.4.7 h)	Figure 18 et Figure 20	1 000	1 000	– [c]

[a] La condition indiquée au Table IV de la seconde édition comme "TENSION RESEAU sur PARTIE APPLIQUEE ", et traitée dans cette édition comme une CONDITION DE PREMIER DEFAUT , est traitée dans la présente édition comme une condition d'essai particulière. L'essai avec TENSION RESEAU MAXIMALE sur une PARTIE ACCESSIBLE non PROTEGEE PAR MISE A LA TERRE est également une condition d'essai particulière, mais les valeurs admissibles sont les mêmes que pour les CONDITIONS DE PREMIER DEFAUT. Voir aussi les justifications de 8.5.2.2 et 8.7.4.7 d).

[b] Les valeurs du COURANT DE FUITE PATIENT total ne sont applicables qu'aux appareils qui ont des PARTIES APPLIQUEES multiples. Voir 8.7.4.7 h). Les PARTIES APPLIQUEES individuelles doivent être conformes aux valeurs du COURANT DE FUITE PATIENT.

[c] Cette condition ne fait pas l'objet d'essais avec les PARTIES APPLIQUEES DE TYPE CF parce qu'elle est couverte par l'essai avec la TENSION RESEAU MAXIMAL sur la PARTIE APPLIQUEE. Voir aussi la justification pour 8.7.4.7 d).

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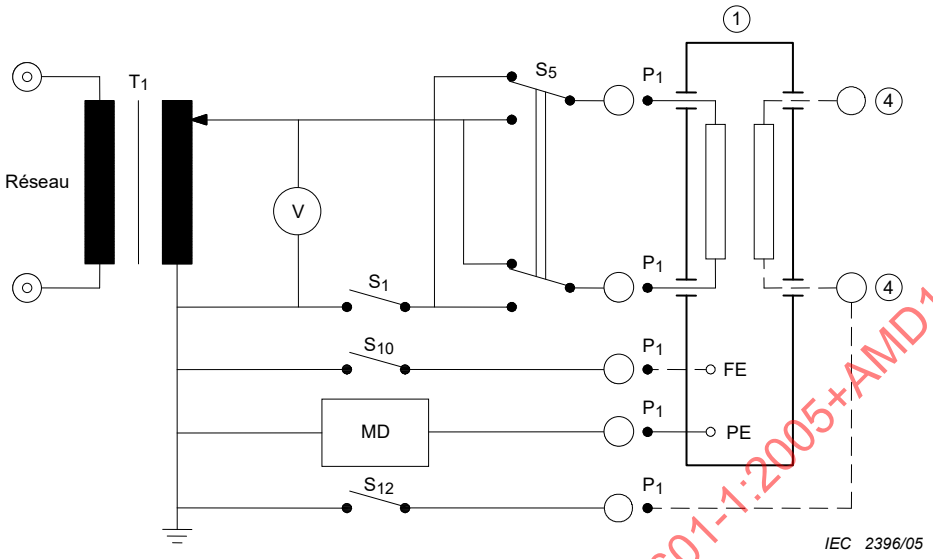
8.7.4 Mesures

8.7.4.1 Généralités

Les figures des essais de mesure du COURANT DE FUITE PATIENT et COURANT DE FUITE AUXILIAIRE PATIENT référencées de 8.7.4.5 à 8.7.4.8 (Figure 13 à Figure 19 incluse) montrent des configurations d'essai adaptées à l'utilisation conjointement aux PROCEDURES D'ESSAI spécifiées dans ces paragraphes. Il est reconnu que d'autres figures d'essai peuvent donner des résultats précis. Cependant, si les résultats d'essai sont proches des valeurs autorisées ou s'il y a un doute quelconque en ce qui concerne la validité des résultats d'essai, la figure d'essai applicable doit être utilisée comme facteur de décision.

a) Le COURANT DE FUITE A LA TERRE, le COURANT DE CONTACT, le COURANT DE FUITE PATIENT et le COURANT AUXILIAIRE PATIENT sont mesurés après avoir amené l'APPAREIL EM à sa température de fonctionnement conformément aux exigences de 11.1.3 c).

b) Quand l'examen de la disposition des circuits et de la disposition des composants et matériaux de l'APPAREIL EM montre qu'il n'y a aucune possibilité de SITUATION DANGEREUSE décrite en 13.1, quel qu'il soit, le nombre d'essais peut être réduit.



Pour les légendes, voir le Tableau 5.

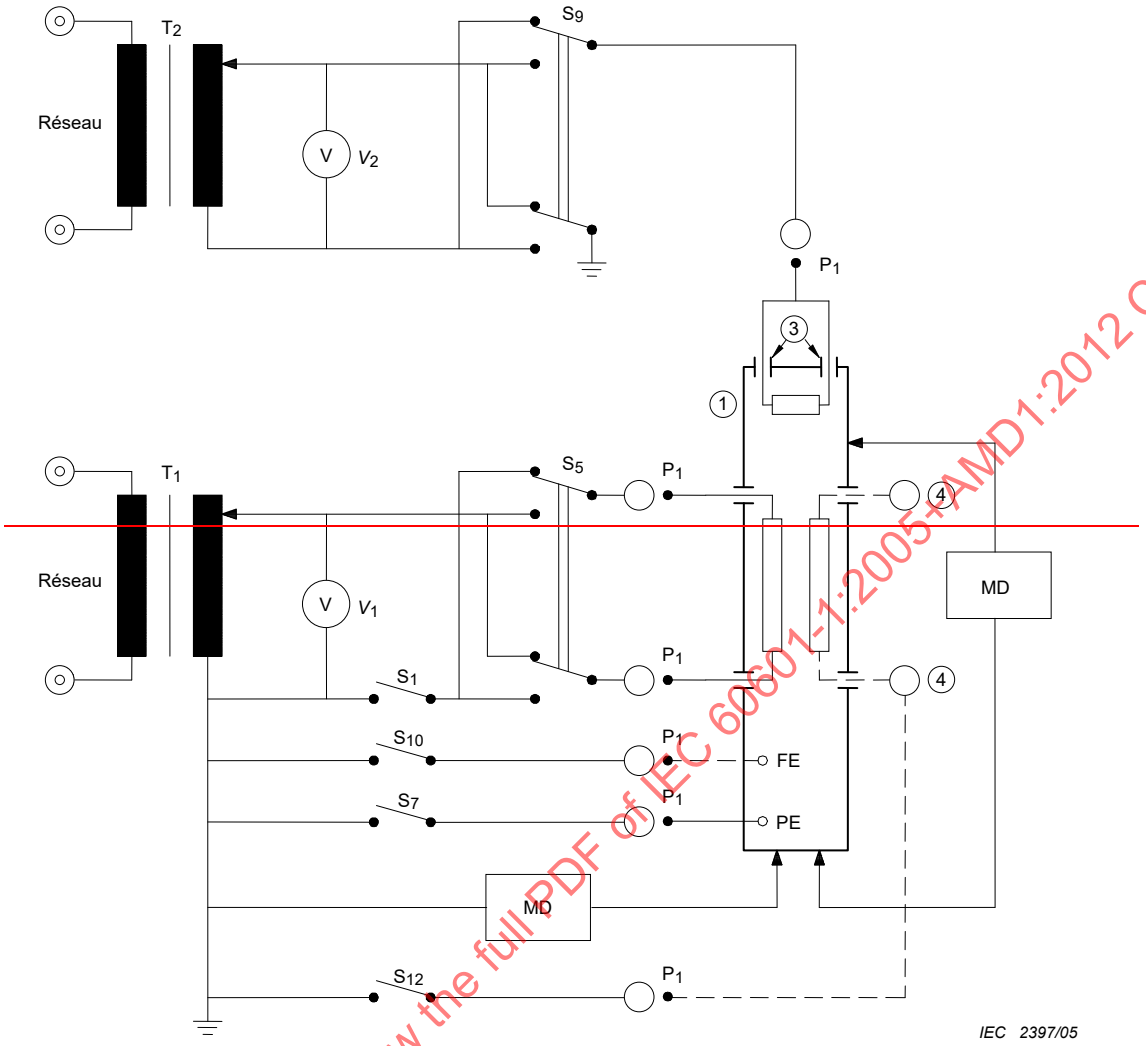
Indication

Mesure dans toutes les combinaisons possibles des positions de S_5, S_{10} et S_{12} avec :
S_1 fermé (CONDITION NORMALE), et
S_1 ouvert (CONDITION DE PREMIER DEFAUT).

Exemple avec le circuit d'alimentation de mesure de la Figure F.1

Figure 13 – Circuit de mesure pour le COURANT DE FUITE A LA TERRE des APPAREILS EM de la CLASSE I, avec ou sans PARTIE APPLIQUEE (voir 8.7.4.5)

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Pour les légendes, voir le Tableau 5.

Indication

Mesure (avec S_7 fermé si appareil(s) de la CLASSE I) dans toutes les combinaisons possibles des positions de S_1, S_5, S_9, S_{10}, et S_{12},
S_1 ouvert est une CONDITION DE PREMIER DEFAUT.

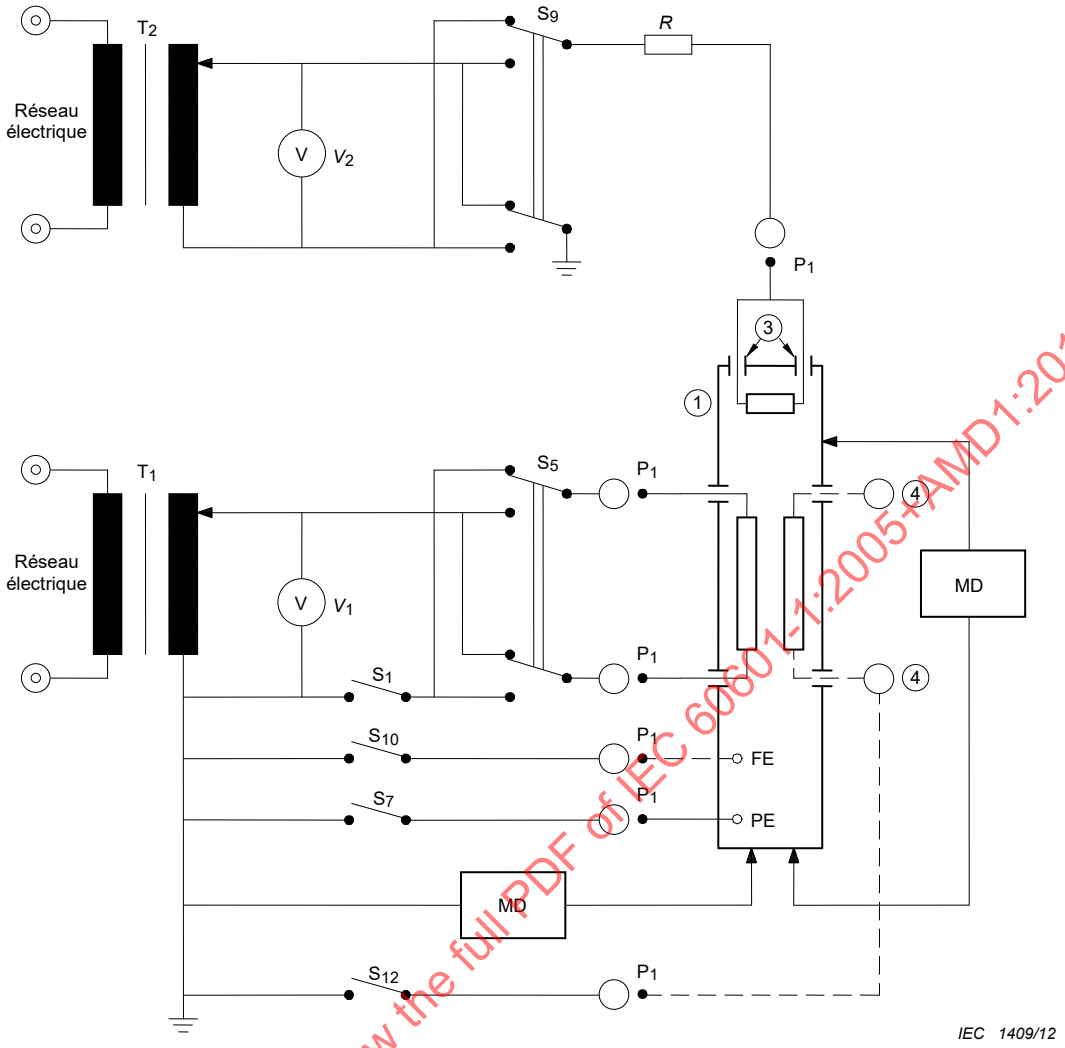
Appareils de la CLASSE I uniquement :
Mesure avec S_7 ouvert (CONDITION DE PREMIER DEFAUT) et avec S_1 fermé dans toutes les combinaisons possibles de S_5, S_9, S_{10} et S_{12}.

Pour les appareils de la CLASSE II, la CONNEXION DE TERRE DE PROTECTION et S_7 ne sont pas utilisés.

Le transformateur T_2 est utilisé si nécessaire (voir 8.1 a))

Exemple avec le circuit d'alimentation de mesure de la Figure F.1

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Pour les légendes, voir Tableau 5.

Légende

Mesure (avec S_7 fermé si APPAREIL EM de classe I) dans toutes les combinaisons possibles de positions de S_1, S_5, S_9, S_{10} et S_{12}.

S_1 ouvert est une CONDITION DE PREMIER DEFAUT.

APPAREIL EM de classe I uniquement:
Mesure avec S_7 ouvert (CONDITION DE PREMIER DEFAUT) et avec S_1 fermé dans toutes les combinaisons possibles de S_5, S_9, S_{10} et S_{12}.

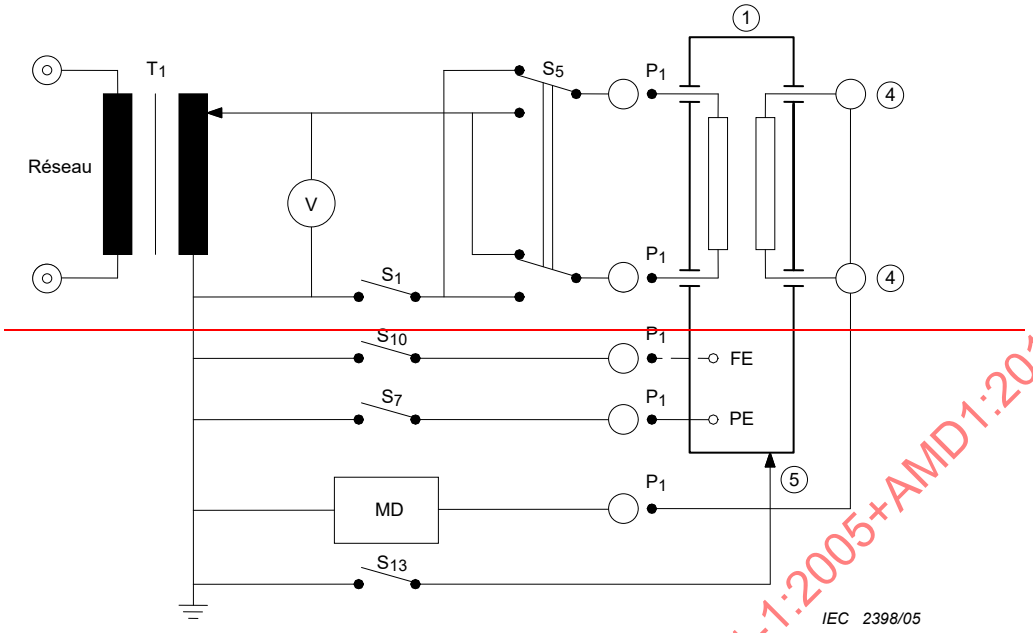
Pour les APPAREILS EM DE CLASSE II, la CONNEXION DE TERRE DE PROTECTION et S_7 ne sont pas utilisés.

Transformateur T_2 utilisé si nécessaire (voir 8.1 a)

Exemple de circuit d'alimentation de mesure de la Figure F.1.

Figure 14 – Circuit de mesure pour le COURANT DE CONTACT
(voir 8.7.4.6)

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~~Pour les légendes, voir le Tableau 5.~~

~~**Indication**~~

~~Mesure (avec S_7 fermé si APPAREILS EM de la CLASSE I) dans toutes les combinaisons possibles des positions de S_1, S_5, S_{10} et S_{13}~~

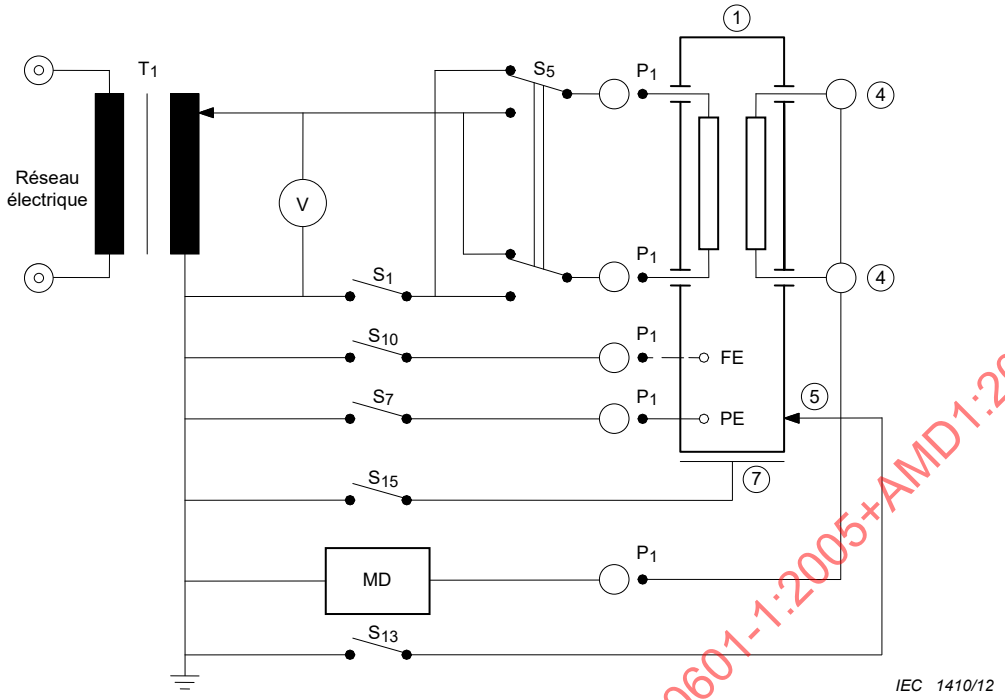
~~S_1 ouvert est une CONDITION DE PREMIER DEFAUT~~

~~APPAREILS EM de la CLASSE I uniquement :~~
~~Mesure avec S_7 ouvert (CONDITION DE PREMIER DEFAUT) et avec S_1 fermé dans toutes les combinaisons possibles de S_5, S_{10} et S_{13}.~~

~~Pour LES APPAREILS EM de la CLASSE II, la CONNEXION DE TERRE DE PROTECTION et S_7 ne sont pas utilisés.~~

~~Exemple avec le circuit d'alimentation de mesure de la Figure F.1~~

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Pour les légendes, voir Tableau 5.

Légende

Mesure (avec S_7 fermé si APPAREIL EM DE CLASSE I) dans toutes les combinaisons possibles des positions de S_1, S_5, S_{10}, S_{13} et S_{15}.

S_1 ouvert est une CONDITION DE PREMIER DEFAUT.

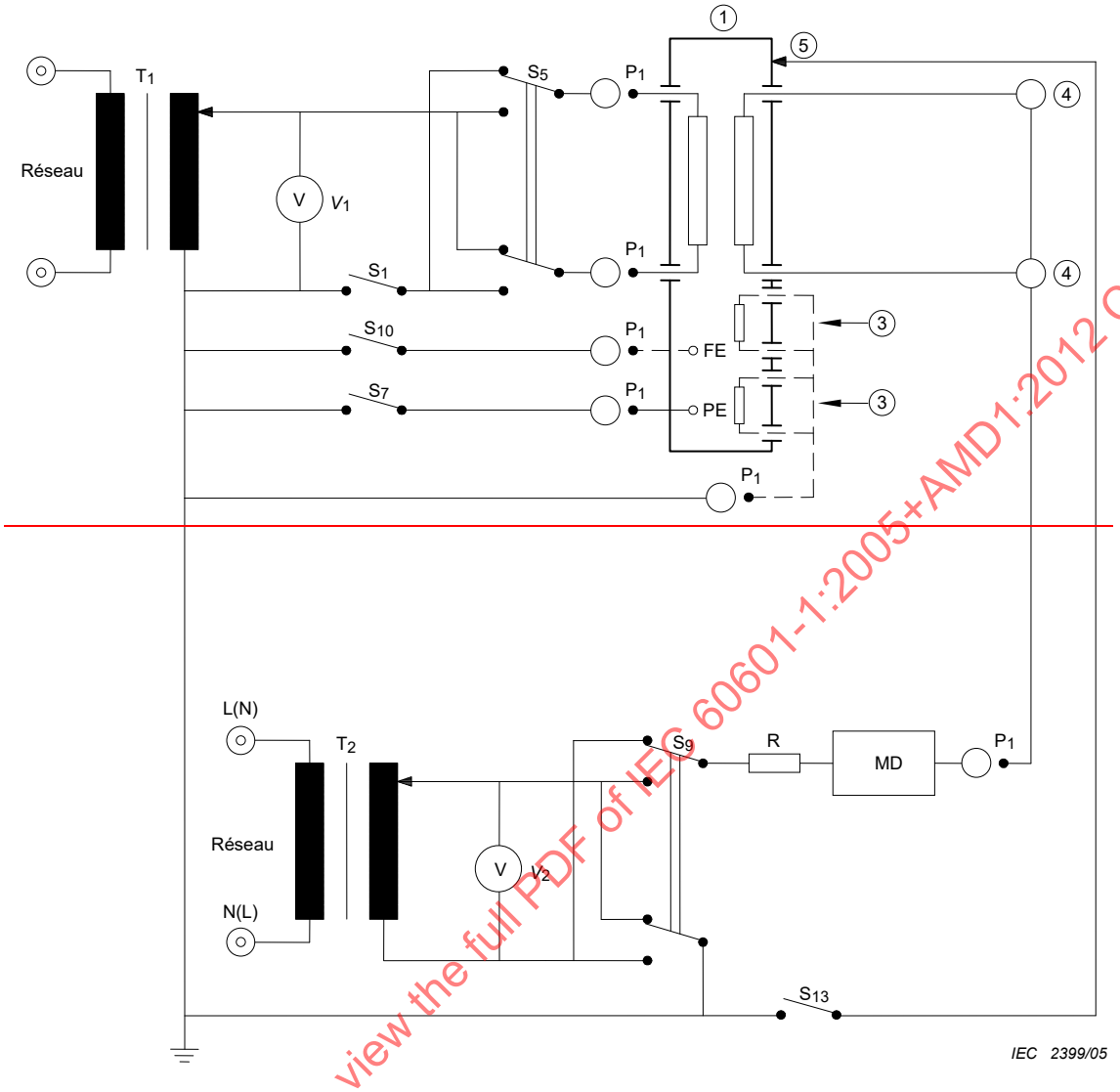
APPAREIL EM DE CLASSE I uniquement:
Mesure avec S_7 ouvert (CONDITION DE PREMIER DEFAUT) et avec S_1 fermé dans toutes les combinaisons possibles de S_5, S_{10}, S_{13} et S_{15}.

Pour les APPAREILS EM DE CLASSE II, la CONNEXION DE TERRE DE PROTECTION et S_7 ne sont pas utilisés.

Exemple de circuit d'alimentation de mesure de la Figure F.1.

Figure 15 – Circuit de mesure pour le COURANT DE FUITE PATIENT provenant de la CONNEXION PATIENT à la terre
(voir 8.7.4.7 a))

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~~Pour les légendes, voir le Tableau 5.~~

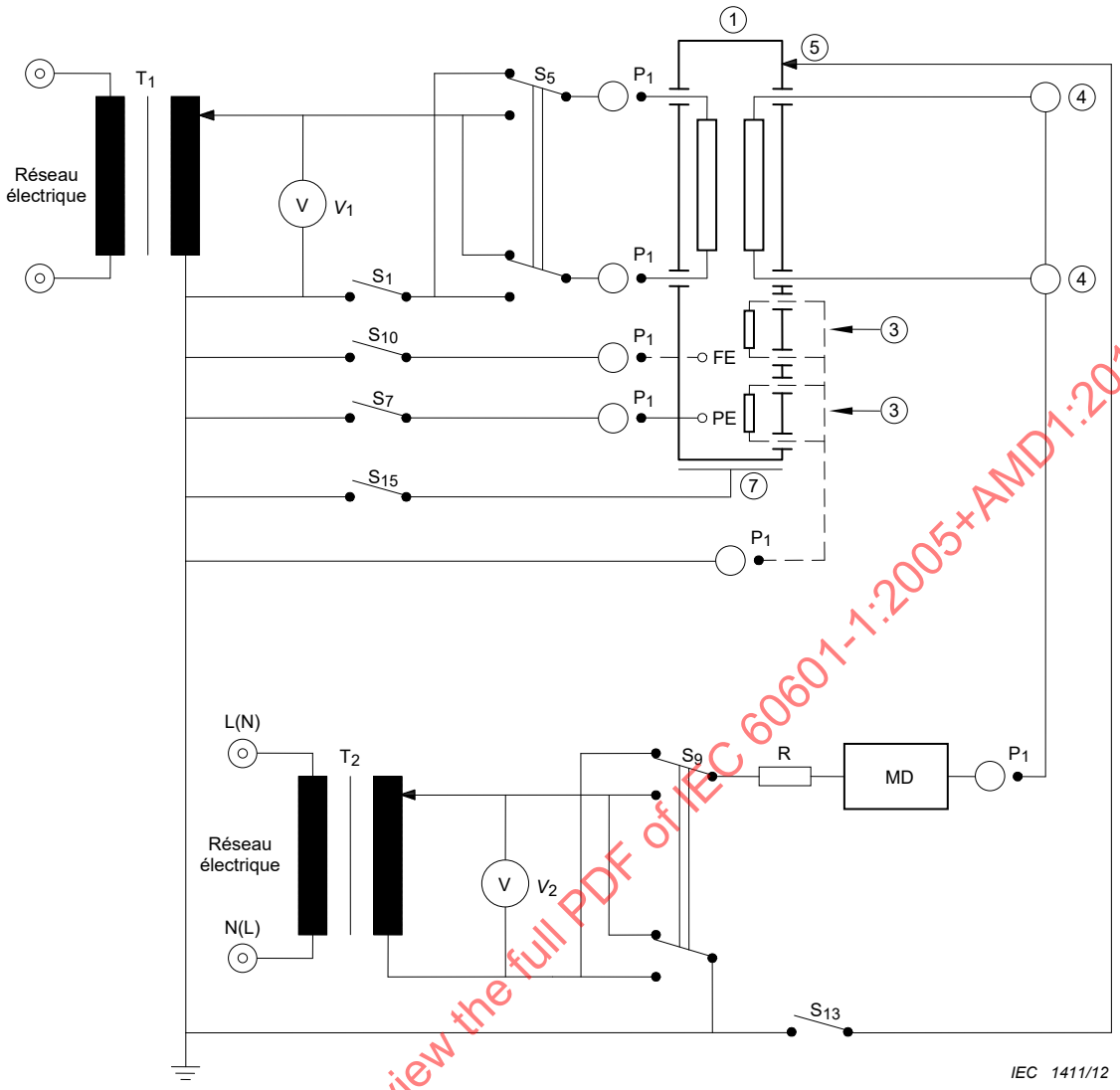
~~Indication~~

~~Mesure (avec S_9 fermé si APPAREILS EM de la CLASSE I) avec S_1 fermé dans toutes les combinaisons possibles des positions de S_5, S_9, S_{10} et S_{13}.~~

~~Pour les APPAREILS EM de la CLASSE II, la CONNEXION DE TERRE DE PROTECTION et S_7 ne sont pas utilisés.~~

~~Exemple avec le circuit d'alimentation de mesure de la Figure F.1~~

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Pour les légendes, voir Tableau 5.

Légende

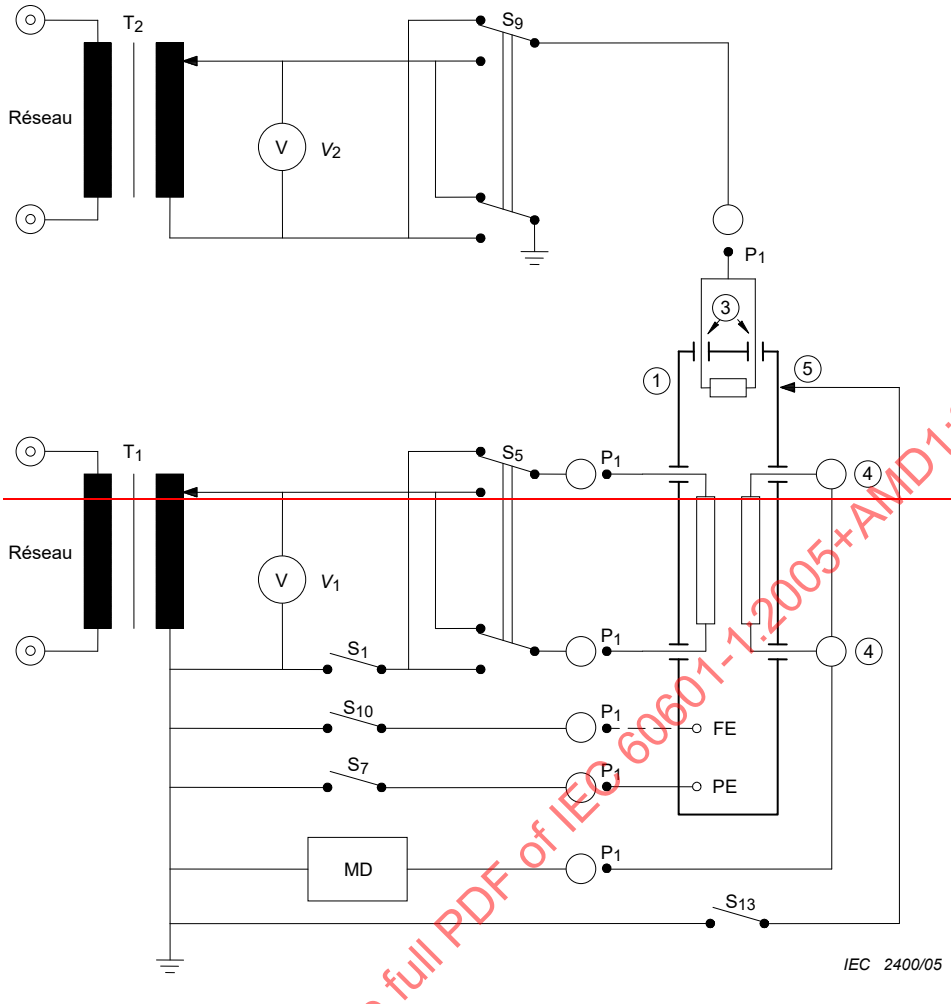
Mesure (avec S_7 fermé si APPAREIL EM DE CLASSE I) avec S_1 fermé dans toutes les combinaisons possibles des positions de S_5, S_9, S_{10} et S_{13}.

Pour les APPAREILS EM DE CLASSE II, la CONNEXION DE TERRE DE PROTECTION et S_7 ne sont pas utilisés.

Exemple de circuit d'alimentation de mesure de la Figure F.1.

Figure 16 – Circuit de mesure pour le COURANT DE FUITE PATIENT ~~à travers~~ via la ~~ou~~ (les) CONNEXION(S) PATIENT d'une PARTIE APPLIQUEE DE TYPE F ~~vers~~ à la terre, ~~causé~~ provoqué par une tension externe sur la ~~ou~~ (les) CONNEXION(S) PATIENT
(voir 8.7.4.7 b))

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~~Pour les légendes, voir le Tableau 5.~~

~~**Indication**~~

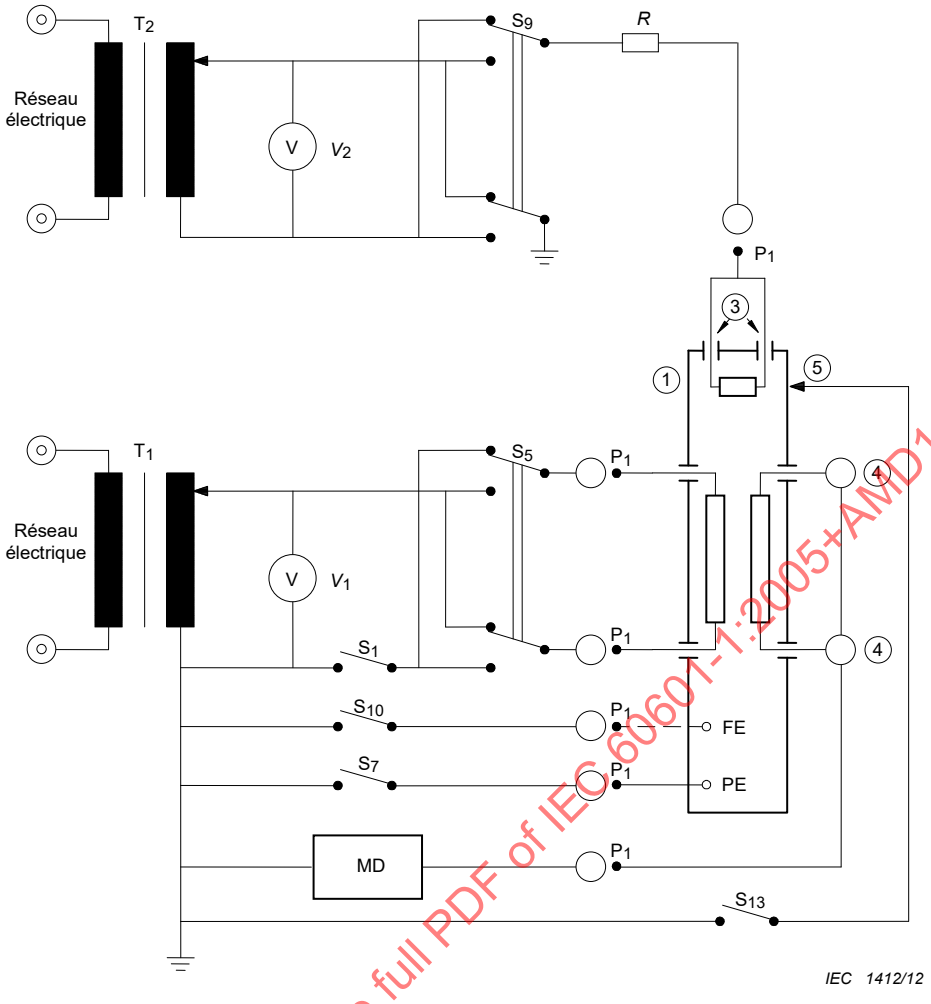
~~Mesure (avec S_7 fermé si appareils de la CLASSE I) dans toutes les combinaisons possibles des positions de S_1, S_5, S_9, S_{10}, et S_{13} (S_1 ouvert si CONDITION DE PREMIER DEFAUT).~~

~~APPAREILS EM de la CLASSE I uniquement :~~
~~Mesure avec S_7 ouvert (CONDITION DE PREMIER DEFAUT) et avec S_1 fermé dans toutes les combinaisons possibles de S_5, S_9, S_{10} et S_{13}.~~

~~Pour les APPAREILS EM de la CLASSE II, la CONNEXION DE TERRE DE PROTECTION et S_7 ne sont pas utilisés.~~

~~Exemple avec le circuit d'alimentation de mesure de la Figure F.1~~

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Pour les légendes, voir Tableau 5.

Légende

Mesure (avec S_7 fermé si APPAREIL EM de classe I) dans toutes les combinaisons possibles de positions de S_1, S_5, S_9, S_{10} et S_{13}(S_1 ouvert est une CONDITION DE PREMIER DEFAUT).

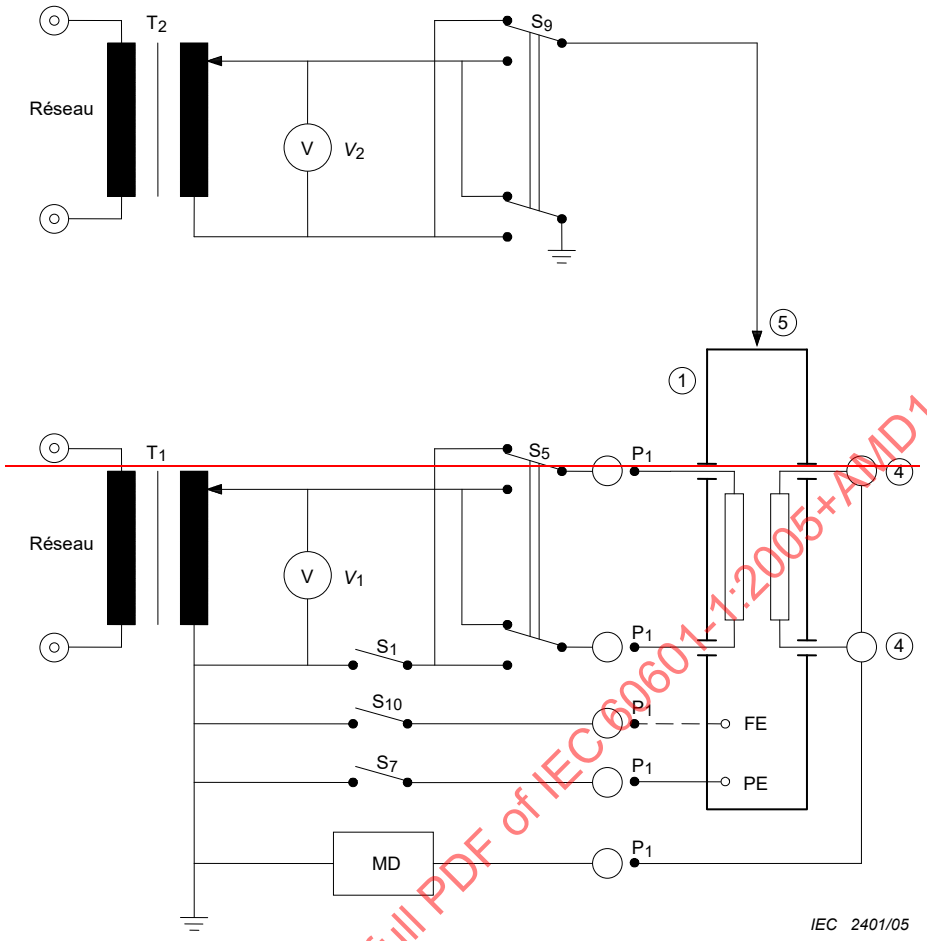
APPAREIL EM DE CLASSE I uniquement:
Mesure avec S_7 ouvert (CONDITION DE PREMIER DEFAUT) et avec S_1 fermé dans toutes les combinaisons possibles de S_5, S_9, S_{10} et S_{13}.

Pour les APPAREILS EM DE CLASSE II, la CONNEXION DE TERRE DE PROTECTION et S_7 ne sont pas utilisés.

Exemple de circuit d'alimentation de mesure de la Figure F.1.

Figure 17 – Circuit de mesure pour le COURANT DE FUITE PATIENT ~~provenant~~ de la ou des CONNEXION(S) PATIENT ~~vers~~ à la terre, ~~causé~~ provoqué par une tension externe sur une ENTREE/SORTIE DE SIGNAL
(voir 8.7.4.7 c))

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Pour les légendes, voir le Tableau 5.

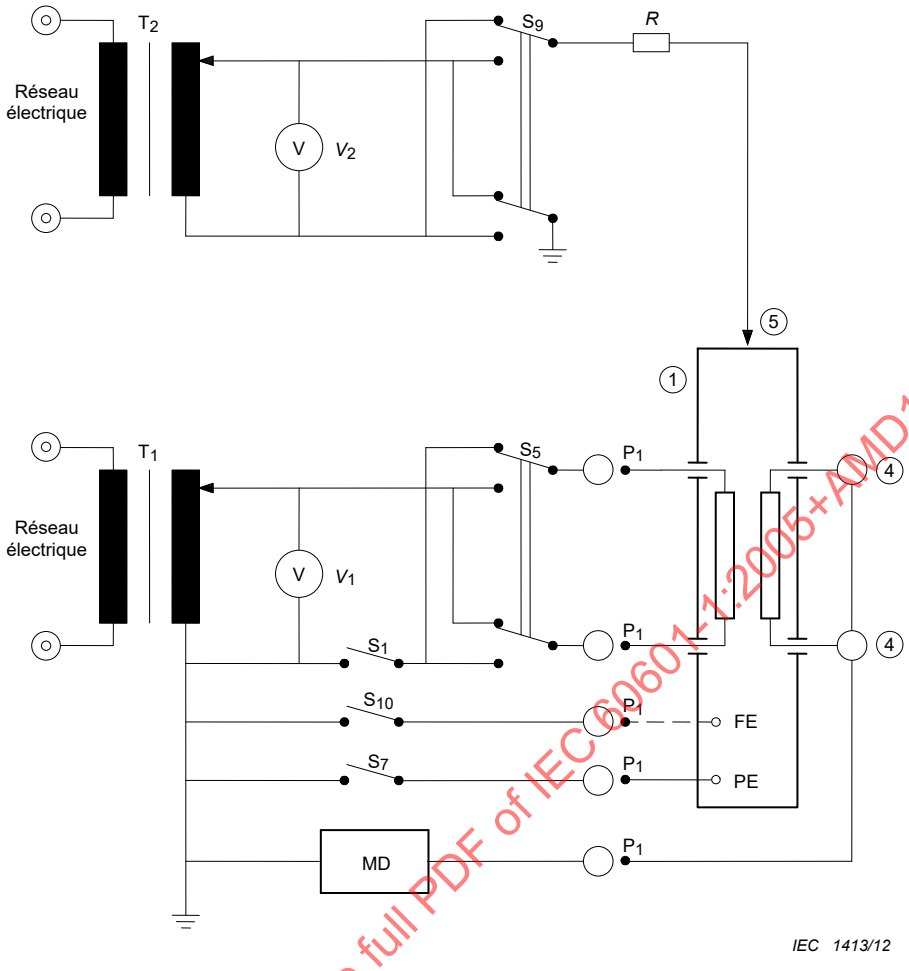
Indication

Mesure avec S_1 fermé (et avec S_7 fermé si APPAREILS EM de la CLASSE I) dans toutes les combinaisons possibles des positions de S_5, S_9 et S_{10}

Pour les APPAREILS EM de la CLASSE II, la CONNEXION DE TERRE DE PROTECTION et S_7 ne sont pas utilisés.

Exemple avec le circuit d'alimentation de mesure de la Figure F.1

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Pour les légendes, voir Tableau 5.

Légende

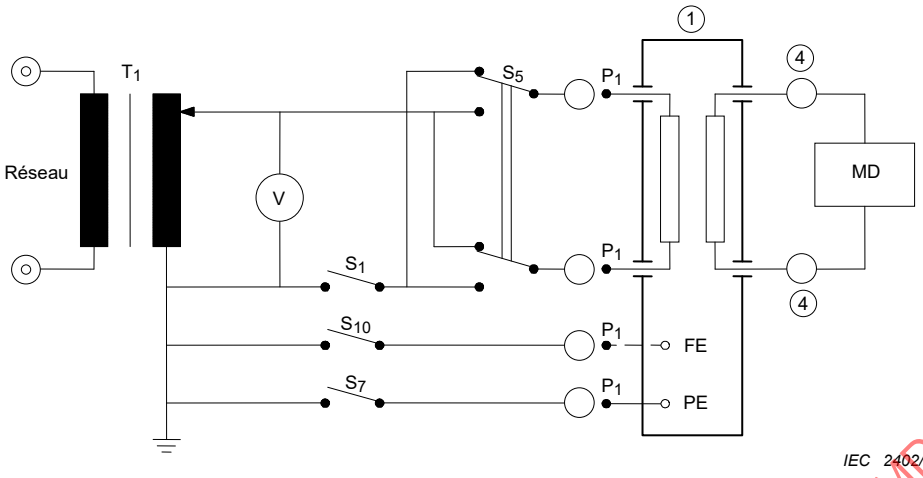
Mesure avec S_1 fermé (et avec S_7 fermé si APPAREIL EM DE CLASSE I) dans toutes les combinaisons possibles des positions de S_5, S_9 et S_{10}

Pour les APPAREILS EM DE CLASSE II, la CONNEXION DE TERRE DE PROTECTION et S_7 ne sont pas utilisés.

Exemple de circuit d'alimentation de mesure de la Figure F.1.

Figure 18 – Circuit de mesure pour le COURANT DE FUITE PATIENT ~~provenant~~ de la ou des CONNEXION(S) PATIENT ~~vers~~ à la terre, ~~causé~~ provoqué par une tension externe sur une PARTIE ACCESSIBLE métallique qui n'est pas PROTEGEE PAR MISE A LA TERRE)
(voir 8.7.4.7d))

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Pour les légendes, voir le Tableau 5.

Indication

Mesure (avec S_7 fermé si APPAREILS EM de la CLASSE I) dans toutes les combinaisons possibles des positions de S_1, S_5 et S_{10}

S_1 ouvert est une CONDITION DE PREMIER DEFAUT

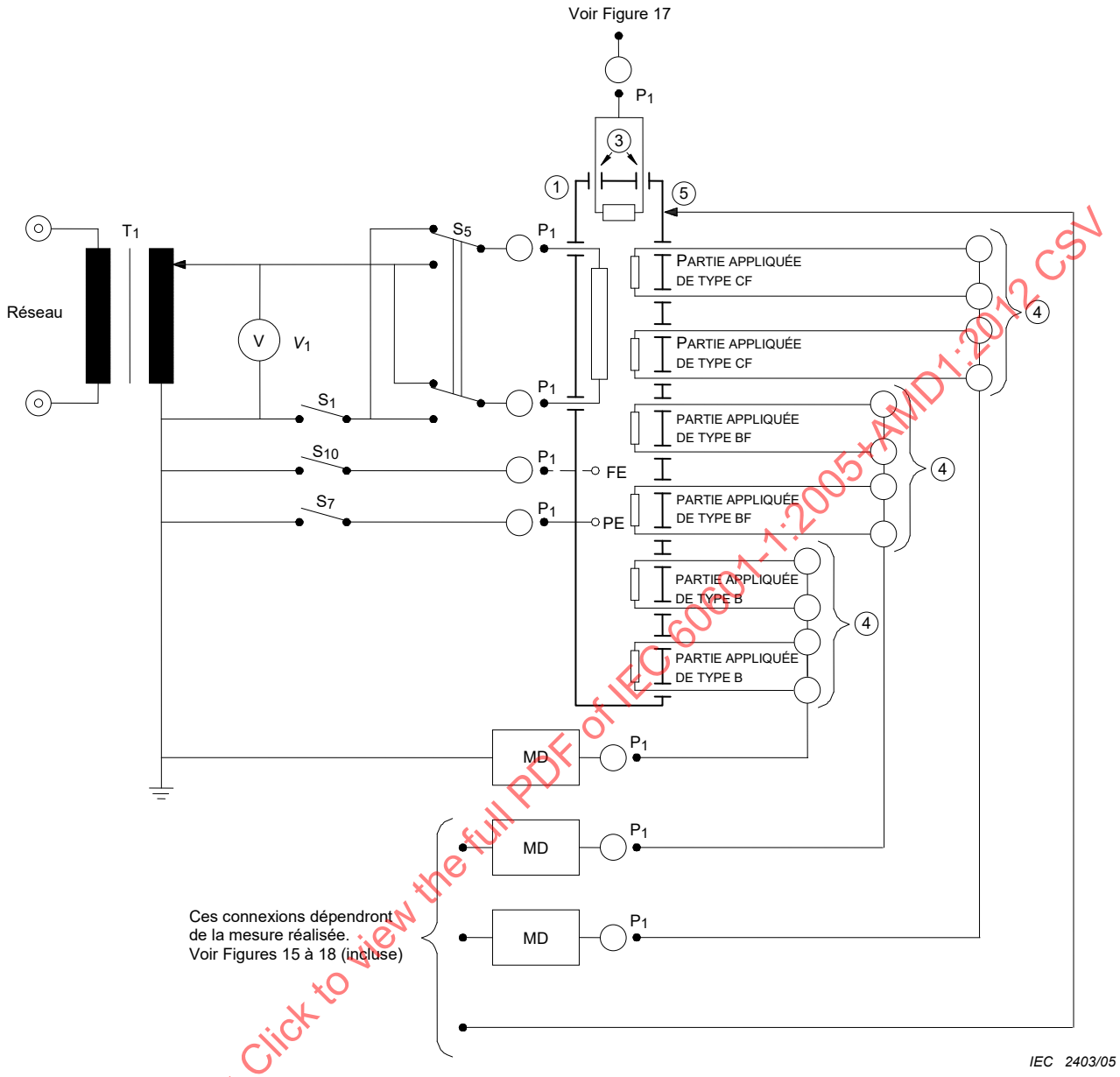
APPAREIL EM de la CLASSE I seulement
Mesure avec S_7 ouvert (CONDITION DE PREMIER DEFAUT) et avec S_1 fermé dans toutes les combinaisons possibles de S_5 et S_{10}.

Pour les APPAREILS EM de la CLASSE II, la CONNEXION DE TERRE DE PROTECTION et S_7 ne sont pas utilisés.

Exemple avec le circuit d'alimentation de mesure de la Figure F.1

Figure 19 – Circuit de mesure pour le COURANT AUXILIAIRE PATIENT
(voir 8.7.4.8)

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Pour les légendes, voir le Tableau 5.

Indication

Pour la position de S_1, S_5 et S_7 et S_{10} voir Figure 15, 16, 17 ou 18

Figure 20 – Circuit de mesure pour le COURANT DE FUITE PATIENT total avec toutes les CONNEXIONS PATIENT de toutes les PARTIES APPLIQUEES du même type (PARTIES APPLIQUEES DE TYPE B, BF ou TYPE CF) connectées ensemble
(voir 8.7.4.7 h))

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Tableau 5 – Légendes des symboles pour les Figures 9 à 11 et 13 à 20, Figure A.15, Annexes E et F

(1)	ENVELOPPE D'APPAREIL EM
(2)	Alimentation séparée ou autre appareil électrique dans un SYSTEME EM qui alimente l'APPAREIL EM (voir 5.5 ~~g~~ *f)* et Annexe F)
(3)	ENTREE/SORTIE DE SIGNAL court-circuitée ou chargée
(4)	CONNEXIONS PATIENT
(5)	PARTIES ACCESSIBLES métalliques non PROTEGEES PAR MISE A LA TERRE En cas d'ENVELOPPE non conductrice et de mesure du COURANT DE FUITE PATIENT, la connexion est remplacée par une feuille métallique de dimensions maximales 20 cm × 10 cm en contact étroit avec l'ENVELOPPE ou des parties pertinentes de l'ENVELOPPE et connectée à la terre de référence.
(6)	Circuit PATIENT
(7)	Plaque métallique sous une ENVELOPPE non conductrice de dimensions au moins égales à la projection du plan de l'ENVELOPPE connectée à la terre de référence
T_1, T_2	Transformateurs de séparation monophasés ou polyphasés ayant une puissance suffisante et une tension secondaire réglable (Voir aussi la justification de 8.7.4.2 et 8.7.4.3)
V(1,2,3)	Voltmètre indiquant la valeur efficace, en utilisant, le cas échéant et si possible, un seul appareil avec un commutateur
S_1, S_2, S_3	Interrupteurs monopolaires, simulant la coupure sur un conducteur d'alimentation (CONDITION DE PREMIER DEFAUT) (Voir Annexe F)
S_5, S_9	Inverseurs de polarité de la TENSION RESEAU
S_7	Interrupteurs monopolaires, simulant la coupure sur un seul CONDUCTEUR DE TERRE DE PROTECTION vers L'APPAREIL EM (CONDITION DE PREMIER DEFAUT)
S_8	Interrupteur monopolaire, simulant la coupure sur un seul CONDUCTEUR DE TERRE DE PROTECTION vers une unité d'alimentation séparée ou un autre appareil électrique dans un SYSTEME EM (CONDITION DE PREMIER DEFAUT) qui alimente L'APPAREIL EM (CONDITION DE PREMIER DEFAUT) (voir Figure F.5)
S_{10}	Interrupteur pour le raccordement d'une BORNE DE TERRE FONCTIONNELLE au point de mise à la terre du circuit d'alimentation de mesure
S_{12}	Interrupteur pour le raccordement d'une CONNEXION PATIENT au point de mise à la terre du circuit d'alimentation de mesure
S_{13}	Interrupteur pour le raccordement à la terre d'une PARTIE ACCESSIBLE métallique NON PROTEGEE PAR MISE A LA TERRE
S_{14}	Interrupteur pour le raccordement/la coupure de la CONNEXIONS PATIENT de/vers la terre
S_{15}	Interrupteur pour connexion à la terre d'une plaque métallique sous une ENVELOPPE non conductrice
P_1	Socles, fiches ou bornes pour le raccordement d'alimentation des APPAREILS EM
P_2	Socles, fiches ou bornes pour le raccordement à une alimentation séparée ou à un autre appareil électrique dans un SYSTEME EM qui alimente l'APPAREIL EM (voir Figure F.5)
MD	Dispositif de mesure (voir Figure 12)
FE	BORNE DE TERRE FONCTIONNELLE
PE	BORNE DE TERRE DE PROTECTION
R	Impédance pour protéger les circuits et la personne réalisant l'essai, mais suffisamment faible pour accepter des courants supérieurs aux valeurs admissibles du COURANT DE FUITE à mesurer (facultatif)
- - - -	Connexion optionnelle
 ~~R~~	Terre de référence (pour les mesures du COURANT DE FUITE et du COURANT AUXILIAIRE PATIENT et pour les essais des PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION, non raccordées à la terre de protection du RESEAU D'ALIMENTATION)
	Source de tension RESEAU D'ALIMENTATION

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8.7.4.2 * Circuits d'alimentation de mesure

LES APPAREILS EM spécifiés pour être reliés à un RESEAU D'ALIMENTATION sont reliés à une source de puissance appropriée. Pour les APPAREILS EM monophasés, la polarité de l'alimentation peut être inversée et les essais sont réalisés pour chacune des polarités. Les APPAREILS EM ALIMENTES DE MANIERE INTERNE sont soumis aux essais sans connexion à un circuit d'alimentation de mesure.

NOTE Les Figures F.1 à Figure F.5 (incluse) montrent plusieurs montages appropriés mais ne couvrent pas toutes les possibilités, par exemple les alimentations triphasées en delta.

8.7.4.3 * Raccordement au circuit d'alimentation de mesure

a) LES APPAREILS EM équipés d'un CABLE D'ALIMENTATION sont soumis aux essais avec ce câble.

b) LES APPAREILS EM équipés d'un SOCLE DE CONNECTEUR sont essayés alors qu'ils sont reliés au circuit d'alimentation de mesure avec un CABLE D'ALIMENTATION NON FIXE A DEMEURE d'une longueur de 3 m ou d'une longueur et d'un type spécifié dans les instructions d'utilisation.

c) Les APPAREILS EM INSTALLES DE FAÇON PERMANENTE sont essayés en les reliant avec le raccordement le plus court possible au circuit d'alimentation de mesure.

d) Dispositions de mesure

1) Les PARTIES APPLIQUEES, y compris les câbles PATIENT (le cas échéant), sont placées sur une surface isolante ayant une constante diélectrique d'environ 1 (par exemple, polystyrène expansé) et environ 200 mm au-dessus de la surface métallique reliée à la terre.

NOTE 1 Il convient que le circuit d'alimentation de mesure et le circuit de mesure soient positionnés aussi loin que possible des conducteurs non connectés à l'écran de la source de puissance. Il convient d'éviter de placer l'APPAREIL EM sur ou à proximité d'une surface métallique de grande taille reliée à la terre.

NOTE 2 Lorsque les PARTIES APPLIQUEES sont telles que les résultats d'essai peuvent dépendre de la manière dont elles sont placées sur la surface isolante, l'essai est répété autant que nécessaire pour déterminer le positionnement le plus défavorable possible.

2) Si un transformateur de séparation n'est pas utilisé pour les mesures de COURANT DE FUITE (par exemple pour la mesure du COURANT DE FUITE D'APPAREILS EM à très forte puissance), la terre de référence des circuits de mesure est raccordée à la terre de protection du RESEAU D'ALIMENTATION.

8.7.4.4 Dispositif de mesure (DM)

a) Le dispositif de mesure charge la source de COURANT DE FUITE ou du COURANT AUXILIAIRE PATIENT avec une impédance résistive d'environ 1 000 Ω en courant continu, en courant alternatif et en courant de formes composites avec des fréquences inférieures ou égales à 1 MHz.

b) L'évaluation du courant ou des composantes du courant selon 8.7.3 a) est obtenue automatiquement lorsqu'on utilise un dispositif de mesure selon la Figure 12 a) ou un circuit similaire avec la même caractéristique de fréquence. Cela permet le mesurage en tenant totalement compte de l'effet produit par toutes les fréquences avec un seul instrument.

Lorsque des courants ou des composantes du courant ayant des fréquences supérieures à 1 kHz pourraient dépasser la limite de 10 mA spécifiée en 8.7.3 e), ils sont mesurés en utilisant d'autres moyens appropriés comme une résistance non inductive de 1 kΩ et un appareil de mesure adapté.

c) Le dispositif de mesure de la tension tel qu'il est représenté à la Figure 12 a) a une résistance d'entrée d'au moins 1 MΩ et une capacité d'entrée au plus égale à 150 pF. Il est sensible à la valeur efficace vraie de la tension soit en courant continu soit en courant alternatif ou en courant de forme composite ayant des composantes avec des fréquences comprises de 0,1 Hz à 1 MHz inclus, avec une erreur de lecture ne dépassant pas ± 5 % de la valeur indiquée.

L'échelle peut indiquer le courant passant par le dispositif de mesure, y compris l'évaluation automatique des composantes avec des fréquences supérieures à 1 kHz de

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façon à permettre une comparaison directe de lecture avec les valeurs limites spécifiées en 8.7.3.

Ces exigences peuvent être limitées à une gamme de fréquences dont la limite supérieure est inférieure à 1 MHz, s'il peut être établi (par exemple à l'aide d'un oscilloscope) que des fréquences au-dessus d'une telle limite supérieure n'existent pas dans le courant mesuré.

8.7.4.5 * Mesure du COURANT DE FUITE A LA TERRE et du courant dans la connexion de terre fonctionnelle

a) Les APPAREILS EM de la CLASSE I sont soumis ~~aux~~ à l'essai~~s~~ conformément à la Figure 13. Les APPAREILS EM DE CLASSE II avec une connexion de terre fonctionnelle conforme à 8.6.9 sont soumis à l'essai comme s'ils étaient des APPAREILS EM DE CLASSE I.

b) Si L'APPAREIL EM possède plus d'un CONDUCTEUR DE TERRE DE PROTECTION (par exemple, un relié à L'ENVELOPPE principale et un à une alimentation séparée), alors le courant à mesurer est le courant total qui s'écoulerait vers le système de terre de protection de l'installation.

c) Pour les APPAREILS EM FIXES qui peuvent être reliés à la terre par l'intermédiaire de la structure du bâtiment, le FABRICANT spécifie une PROCEDURE d'essai adaptée et la configuration de mesure du COURANT DE FUITE A LA TERRE.

8.7.4.6 * Mesure du COURANT DE CONTACT

a) LES APPAREILS EM sont soumis aux essais conformément à la Figure 14, en utilisant un circuit d'alimentation de mesure approprié.

Mesure avec le DM entre la terre et chaque partie de la ou des ENVELOPPES qui n'est pas PROTEGEE PAR MISE A LA TERRE.

Mesure avec le DM entre les parties de la ou des ENVELOPPES qui ne sont pas PROTEGEES PAR MISE A LA TERRE.

En CONDITION DE PREMIER DEFAUT avec coupure d'un des CONDUCTEURS DE TERRE DE PROTECTION (selon le cas, voir 8.1 b)), mesure avec le DM entre la terre et toute partie de l'ENVELOPPE qui est normalement PROTEGEE PAR MISE A LA TERRE.

NOTE Il n'est pas nécessaire de réaliser des mesures séparées à partir de plus d'une partie qui est PROTEGEE PAR MISE A LA TERRE.

Les APPAREILS EM A SOURCE ELECTRIQUE INTERNE sont examinés pour rechercher le COURANT DE CONTACT mais uniquement entre les parties de l'ENVELOPPE, pas entre l'ENVELOPPE et la terre sauf si 8.7.4.6 c) s'applique.

b) Si l'APPAREIL EM a une ENVELOPPE ou une partie de cette ENVELOPPE constituée par un matériau isolant, une feuille métallique de 20 cm x 10 cm au maximum est appliquée en contact étroit avec l'ENVELOPPE ou la partie appropriée de l'ENVELOPPE.

La feuille métallique est déplacée, si possible, pour déterminer la valeur la plus élevée du courant de contact. Il convient que la feuille métallique n'entre en contact avec aucune partie métallique de l'ENVELOPPE qui pourrait être PROTEGEE PAR UNE MISE A LA TERRE ; cependant, les parties métalliques de l'ENVELOPPE qui ne sont pas PROTEGEES PAR MISE A LA TERRE peuvent être recouvertes partiellement ou totalement par la feuille métallique.

Lorsqu'on désire mesurer le COURANT DE CONTACT en CONDITION DE PREMIER DEFAUT avec coupure d'un CONDUCTEUR DE TERRE DE PROTECTION, la feuille métallique est disposée pour être en contact avec des parties de l'ENVELOPPE qui sont NORMALEMENT PROTEGEES PAR MISE A LA TERRE.

Lorsque la surface de l'ENVELOPPE en contact avec le PATIENT ou l'OPERATEUR est d'une taille supérieure à 20 cm x 10 cm, la taille de la feuille est augmentée en proportion de la surface de contact.

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c) Les APPAREILS EM avec ENTREE/SORTIE DE SIGNAL sont, si cela est exigé (voir 8.1 a)), soumis en plus à des essais en utilisant le transformateur T_2.

La valeur de la tension réglée au transformateur T_2 est égale à 110 % de la TENSION RESEAU MAXIMALE. La configuration spécifique des broches utilisées, lorsque la tension externe est appliquée, est déterminée comme étant le cas le plus défavorable d'essais ou d'analyse de circuit.

8.7.4.7 Mesure du COURANT DE FUITE PATIENT

Voir l'Annexe K, qui contient des schémas simplifiés du COURANT DE FUITE PATIENT pour plus d'explications détaillées.

a) Les APPAREILS EM qui possèdent une PARTIE APPLIQUEE sont essayés conformément à la Figure 15.

Une ENVELOPPE autre qu'une PARTRIE APPLIQUEE réalisée en matériau isolant est placée dans une position d'UTILISATION NORMALE quelconque sur une surface métallique plate reliée à la terre dont les dimensions sont au moins égales à celles de la projection du plan de l'ENVELOPPE.

*b) * Les APPAREILS EM qui possèdent une PARTIE APPLIQUEE DE TYPE F sont essayés en plus conformément à la Figure 16.*

Les ENTREES/SORTIES DE SIGNAL sont reliées à la terre, si elles ne sont pas déjà reliées à la terre de manière permanente à l'intérieur de l'APPAREIL EM.

La valeur de la tension à régler sur le transformateur T_2 à la Figure 16 est égale à 110 % de la TENSION RESEAU MAXIMALE.

Pour cette mesure, les PARTIES ACCESSIBLES métalliques non PROTEGEES PAR MISE A LA TERRE y compris les CONNEXIONS PATIENT des autres PARTIES APPLIQUEES (s'il y en a) sont reliées à la terre.

*c) * Les APPAREILS EM comportant une PARTIE APPLIQUEE et une ENTREE/SORTIE DE SIGNAL sont, si nécessaire (voir 8.1 a)), soumis en plus aux essais selon la Figure 17.*

La valeur de la tension réglée au transformateur T_2 est égale à 110 % de la TENSION RESEAU MAXIMALE. La configuration spécifique des broches utilisées, lorsque la tension externe est appliquée, doit être fondée sur le cas le plus défavorable des essais ou de l'analyse de circuit.

*d) * Les APPAREILS EM avec une CONNEXION PATIENT ayant une PARTIE APPLIQUEE DE TYPE B qui n'est pas PROTEGEE PAR MISE A LA TERRE, ou ayant une PARTIE APPLIQUEE DE TYPE BF et avec des PARTIES ACCESSIBLES métalliques qui ne sont pas PROTEGEES PAR MISE A LA TERRE sont en outre essayés selon la Figure 18.*

La valeur de la tension réglée au transformateur T_2 est égale à 110 % de la TENSION RESEAU MAXIMALE.

Il n'est pas nécessaire de réaliser cet essai s'il peut être démontré qu'il existe une séparation adéquate.

e) Une PARTIE APPLIQUEE constituée par une surface en matière isolante est essayée en utilisant une feuille métallique comme celle décrite en 8.7.4.6. Une autre possibilité consiste à utiliser une solution saline à 0,9 % dans laquelle on immerge la PARTIE APPLIQUEE.

Lorsque la surface de la PARTIE APPLIQUEE destinée à entrer en contact avec le PATIENT est d'une taille considérablement plus grande que celle d'une feuille de 20 cm x 10 cm, la taille de la feuille est augmentée en proportion de la surface de contact.

Une telle feuille métallique ou une telle solution saline est considérée comme l'unique CONNEXION PATIENT pour la PARTIE APPLIQUEE concernée.

f) Lorsque la CONNEXION PATIENT est formée par un fluide qui entre en contact avec le PATIENT, ce fluide est remplacé par une solution saline à 0,9 %, une électrode est placée

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dans la solution saline et cette électrode est considérée comme la CONNEXION PATIENT pour la PARTIE APPLIQUEE concernée.

g) *Le COURANT DE FUITE PATIENT est mesuré (voir aussi Annexe E)*

~~– pour les PARTIES APPLIQUEES DE TYPE B et les PARTIES APPLIQUEES DE TYPE BF, à partir de et vers toutes les CONNEXIONS PATIENT d'une fonction unique, soit reliées ensemble, soit chargées comme en UTILISATION NORMALE;~~

~~– dans les PARTIES APPLIQUEES DE TYPE CF, à partir de et vers toutes les CONNEXIONS PATIENT à tour de rôle.~~

– *pour les PARTIES APPLIQUEES DE TYPE B, depuis toutes les CONNEXIONS PATIENT connectées ensemble directement.*

– *pour les PARTIES APPLIQUEES DE TYPE BF, depuis et vers toutes les CONNEXIONS PATIENT d'une fonction unique soit connectées directement ensemble, soit chargées en UTILISATION NORMALE.*

– *pour les PARTIES APPLIQUEES DE TYPE CF, depuis et vers chaque CONNEXION PATIENT tour à tour.*

Si les instructions d'utilisation spécifient plusieurs alternatives pour une partie amovible d'une PARTIE APPLIQUEE (par exemple, câbles et électrodes PATIENT), des mesures du COURANT DE FUITE PATIENT sont effectuées avec la partie amovible spécifiée la plus défavorable. Voir aussi 7.9.2.14.

h) * *Le COURANT DE FUITE PATIENT total est mesuré à partir de et vers toutes les CONNEXIONS PATIENT de toutes les PARTIES APPLIQUEES du même type (PARTIES APPLIQUEES DE TYPE B, PARTIES APPLIQUEES DE TYPE BF ou PARTIES APPLIQUEES DE TYPE CF reliées ensemble. Voir la Figure 20. Si nécessaire, une terre fonctionnelle peut être déconnectée avant de réaliser cet essai.*

NOTE La mesure du COURANT DE FUITE PATIENT total des PARTIES APPLIQUEES DE TYPE B est seulement nécessaire si au moins deux CONNEXIONS PATIENT appartiennent à différentes fonctions et ne sont pas directement connectées électriquement ensemble.

i) *Si les CONNEXIONS PATIENT de la PARTIE APPLIQUEE sont chargées en UTILISATION NORMALE, le dispositif de mesure est tour à tour relié à chaque CONNEXION PATIENT.*

8.7.4.8 Mesure du COURANT AUXILIAIRE PATIENT

Les APPAREILS EM qui possèdent une PARTIE APPLIQUEE sont essayés conformément à la Figure 19 en utilisant un circuit d'alimentation de mesure approprié, à moins que L'APPAREIL EM n'aie qu'une seule CONNEXION PATIENT.

Le COURANT AUXILIAIRE PATIENT est mesuré entre toute CONNEXION PATIENT unique et toutes les autres CONNEXIONS PATIENT, soit reliées directement ensemble soit chargées comme en UTILISATION NORMALE (voir aussi Annexe E).

8.7.4.9 * APPAREILS EM avec plusieurs CONNEXIONS PATIENT

Les APPAREILS EM avec plusieurs CONNEXIONS PATIENT sont examinés pour s'assurer que le COURANT DE FUITE PATIENT et le COURANT AUXILIAIRE PATIENT ne dépassent pas les valeurs admissibles pour la CONDITION NORMALE lorsqu'une ou plusieurs CONNEXIONS PATIENT sont:

– *déconnectées du PATIENT ; et*

– *déconnectées du PATIENT et reliées à la terre.*

L'essai est réalisé si un examen du circuit de l'APPAREIL EM indique que le COURANT DE FUITE PATIENT ou le COURANT AUXILIAIRE PATIENT peut atteindre des niveaux excessifs dans les conditions indiquées ci-dessus. Il convient que les mesures réelles soient limitées à un nombre représentatif de combinaisons.

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8.8 Isolation

8.8.1 * Généralités

~~Seule l'isolation suivante doit être soumise aux essais:~~

~~– isolation assurant le rôle de MOYEN DE PROTECTION, y compris d'ISOLATION RENFORCEE ;~~

~~– isolation entre parties de polarité opposée de la PARTIE RELIEE AU RESEAU du côté RESEAU D'ALIMENTATION de tout fusible ou DISJONCTEUR réseau, qui doit être essayée comme un MOYEN DE PROTECTION.~~

Seule l'isolation qui assure le rôle de MOYEN DE PROTECTION, y compris d'ISOLATION RENFORCEE, doit être soumise à l'essai.

L'isolation qui fait partie d'un composant est exemptée sous réserve que le composant soit conforme à 4.8.

L'isolation qui constitue un MOYEN DE PROTECTION OPERATEUR est exemptée des essais de 8.8 si elle est conforme aux exigences et aux essais de l'IEC 60950-1 pour la COORDINATION DE L'ISOLEMENT.

8.8.2 * Distance à travers une isolation solide ou utilisation d'une feuille mince comme matériau d'isolation

L'isolation solide qui forme une ISOLATION SUPPLEMENTAIRE ou une ISOLATION RENFORCEE pour une TENSION DE SERVICE CRETE supérieure à 71 V doit soit:

a) avoir une distance à travers l'isolation d'au moins 0,4 mm, soit

b) ne pas faire partie d'une ENVELOPPE et ne pas être manipulée ou ne pas subir d'abrasion en UTILISATION NORMALE, et comprendre:

   – au moins deux couches de matériau, dont chacune passe avec succès l'essai de tension de tenue approprié; ou

   – trois couches de matériau, auquel cas toutes les combinaisons de deux couches ensemble passent avec succès l'essai de tension de tenue approprié.

L'essai de tension de tenue approprié pour une ou deux couches de matériau correspond à l'essai pour un MOYEN DE PROTECTION dans le cas de l'ISOLATION SUPPLEMENTAIRE ou à l'essai correspondant à deux MOYENS DE PROTECTION dans le cas de L'ISOLATION RENFORCEE.

NOTE 1 Il n'existe pas d'exigence d'épaisseur minimale pour l'ISOLATION PRINCIPALE, ni pour une isolation soumise à une TENSION DE SERVICE jusqu'à 71 V.

NOTE 2 Il n'y a pas d'exigence imposant que toutes les couches d'isolation soient du même matériau.

La conformité est vérifiée par inspection, par mesure de l'épaisseur et par l'essai de tension de tenue de 8.8.3.

Pour les composants toriques dans lesquels une ISOLATION PRINCIPALE, une ISOLATION SUPPLEMENTAIRE ou une ISOLATION RENFORCEE est exigée entre les enroulements, ceux-ci doivent être séparés par une isolation intercalée conforme aux points a) ou b) ci-dessus ou au deux à moins qu'une des constructions suivantes ne soit utilisée:

c) fil possédant une isolation solide qui n'est pas de l'émail à base de solvant conforme au point a) ci-dessus;

d) fil qui possède une isolation extrudée multi-couches ou enroulée en spirale (cas dans lequel les couches peuvent être soumises à l'essai de tension de tenue individuellement) conforme au point b) ci-dessus et qui passe avec succès les essais de l'Annexe L;

e) fil qui possède une isolation extrudée multi-couches ou enroulée en spirale (dans lequel seul le fil fini peut être soumis à l'essai) et qui passe avec succès les essais de l'Annexe L. Le nombre minimal de couches de construction appliquées au conducteur doit être comme suit:

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– ISOLATION DE BASE: deux couches enroulées ou une couche extrudée;

– ISOLATION SUPPLEMENTAIRE: deux couches, enroulées ou extrudées;

– ISOLATION RENFORCEE: trois couches, enroulées ou extrudées.

A la fois en d) et e), pour l'isolation enroulée en spirale où les LIGNES DE FUITE entre couches, telles qu'elles sont enroulées, sont inférieures à celles données au Tableau 12 ou au Tableau 16 (pour le degré de pollution 1) en fonction du type d'isolation considéré, le chemin entre les couches doit être hermétique comme un joint collé décrit en 8.9.3.3 et les tensions d'essai des ESSAIS DE TYPE de l'Article L.3 sont portées à 1,6 fois leurs valeurs normales.

NOTE 3 On considère qu'une couche de matériau enroulée avec plus de 50 % de chevauchement constitue deux couches.

Lorsque deux fils isolés ou un fil nu et un fil isolé sont en contact à l'intérieur du composant enroulé et se croisent selon un angle compris entre 45° et 90° et sont soumis à une tension d'enroulement, une protection contre les contraintes mécaniques doit être prévue. Cette protection peut être obtenue, par exemple, en assurant une séparation physique sous la forme d'un gainage ou d'un matériau constitué de feuilles ou en utilisant le double du nombre exigé de couches d'isolation.

Le composant fini doit passer avec succès les essais de tension de tenue de série en utilisant les tensions d'essai appropriées de 8.8.3.

La conformité est vérifiée par examen et par des mesures et, si cela est applicable, comme spécifié à l'Annexe L. Toutefois, les essais de l'Annexe L ne sont pas répétés si les fiches techniques du matériau confirment la conformité.

8.8.3 * Tension de tenue

La tension de tenue de l'isolation électrique solide des APPAREILS EM doit être capable de résister aux tensions d'essai spécifiées au Tableau 6. L'essai n'est requis que pour les isolations ayant une fonction de sécurité (voir 8.8.1).

La conformité est vérifiée par l'application de la tension d'essai spécifiée au Tableau 6 pendant 1 min:

– *immédiatement après le traitement de pré-conditionnement humide (comme décrit en 5.7) avec l'APPAREIL EM hors tension au cours de l'essai, et*

– *après toute PROCEDURE de stérilisation exigée (voir 11.6.7, 7.9.2.12, et les instructions d'utilisation) avec l'APPAREIL EM hors tension, et*

– *après avoir atteint une température équivalente à la température stabilisée de fonctionnement atteinte au cours de l'essai d'échauffement de 11.1.1.*

Au départ, pas plus de la moitié de la tension d'essai est appliquée et ensuite elle est progressivement augmentée sur une période de 10 s pour atteindre sa pleine valeur, qui est maintenue pendant 1 min, après quoi elle est progressivement abaissée sur une période de 10 s à moins de la moitié de la valeur pleine.

Les conditions d'essai sont les suivantes:

*a) * La tension d'essai a une forme d'onde et une fréquence telles que la contrainte diélectrique de l'isolation soit au moins égale à celle qui apparaît en UTILISATION NORMALE. Si la forme d'onde et la fréquence de la tension d'essai peuvent différer de la tension appliquée en UTILISATION NORMALE s'il peut être démontré que la contrainte diélectrique sur l'isolation soumise à l'essai ne sera pas diminuée.*

Lorsque la tension à laquelle l'isolation correspondante est soumise en UTILISATION NORMALE n'est pas sinusoïdale en courant alternatif, l'essai peut être réalisé en utilisant une tension d'essai sinusoïdale de 50 Hz ou 60 Hz.

Une tension d'essai en courant continu égale à la valeur de crête de la tension d'essai en courant alternatif peut être utilisée à la place.

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La tension d'essai pour la TENSION DE SERVICE à laquelle l'isolation est soumise est supérieure ou égale à la valeur spécifiée au Tableau 6.

b) *Au cours de l'essai, un claquage constitue une défaillance. On considère qu'il y a claquage de l'isolation lorsque le courant qui s'écoule suite à l'application de la tension d'essai augmente rapidement de manière incontrôlée, c'est-à-dire que l'isolation ne restreint pas l'écoulement du courant. Une décharge de couronne ou un contournement momentané unique ne sont pas considérés comme un claquage de l'isolation.*

c) *S'il n'est pas possible de soumettre les isolations solides à l'essai individuellement, il est nécessaire de soumettre une grande partie de L'APPAREIL EM ou même L'APPAREIL EM dans son ensemble à l'essai. Dans ce cas, il est important de ne pas appliquer de contraintes excessives à différents types et niveaux d'isolation et on doit prendre en compte ce qui suit.*

   – *Lorsqu'une enveloppe ou une partie D'ENVELOPPE se compose de surfaces non conductrices, une feuille métallique est appliquée. On veille à ce que la feuille métallique soit positionnée de manière à ce qu'il ne se produise pas de contournement sur les bords des revêtements isolants. Si cela est applicable, la feuille métallique est déplacée de manière à pouvoir soumettre toutes les parties de la surface concernée aux essais.*
   – *Il convient que les circuits de chaque côté de l'isolation en essai soient connectés ou court-circuités de manière à ce qu'ils ne subissent pas de contrainte au cours de l'essai. Par exemple, les bornes de la PARTIE RELIEE AU RESEAU, les ENTREES/SORTIES DE SIGNAL et la ou les CONNEXIONS PATIENT (le cas échéant) sont respectivement court-circuitées au cours de l'essai.*
   – *Les condensateurs éventuellement présents à travers l'isolation en essai (par exemple condensateur de filtrage radioélectrique) peuvent être débranchés au cours de l'essai, s'ils sont certifiés selon l'IEC 60384-14.*

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Tableau 6 – Tensions d'essai pour l'isolation solide formant un MOYEN DE PROTECTION

TENSION DE SERVICE DE CRETE (*U*) V crête	TENSION DE SERVICE DE CRETE (*U*) V c.c.	Tensions d'essai en courant alternatif en V, valeur efficace							
		MOYEN DE PROTECTION DE L'OPERATEUR				MOYEN DE PROTECTION DU PATIENT			
		Protection vis à vis de la PARTIE RELIEE AU RESEAU		Protection vis à vis DES CIRCUITS SECONDAIRES		Protection vis à vis de la PARTIE RELIEE AU RESEAU		Protection vis à vis des CIRCUITS SECONDAIRES	
		Un MOOP	Deux MOOP	Un MOOP	Deux MOOP	Un MOPP	Deux MOPP	Un MOPP	Deux MOPP
U < 42,4	*U* < 60	1 000	2 000	Pas d'essai	Pas d'essai	1 500	3 000	500	1 000
42,4 < *U* ≤ 71	60 < *U* ≤ 71	1 000	2 000	Voir Tableau 7	Voir Tableau 7	1 500	3 000	750	1 500
71 < *U* ≤ 184	71 < *U* ≤ 184	1 000	2 000	Voir Tableau 7	Voir Tableau 7	1 500	3 000	1 000	2 000
184 < *U* ≤ 212	184 < *U* ≤ 212	1 500	3 000	Voir Tableau 7	Voir Tableau 7	1 500	3 000	1 000	2 000
212 < *U* ≤ 354	212 < *U* ≤ 354	1 500	3 000	Voir Tableau 7	Voir Tableau 7	1 500	4 000	1 500	3 000
354 < *U* ≤ 848	354 < *U* ≤ 848	Voir Tableau 7	3 000	Voir Tableau 7	Voir Tableau 7	√2*U* + 1 000	2 x (√2*U* + 1 500)	√2*U* + 1 000	2 x (√2*U* + 1 500)
848 < *U* ≤ 1 414	848 < *U* ≤ 1 414	Voir Tableau 7	3 000	Voir Tableau 7	Voir Tableau 7	√2*U* + 1 000	2 x (√2*U* + 1 500)	√2*U* + 1 000	2 x (√2*U* + 1 500)
1 414 < *U* ≤ 10 000	1 414 < *U* ≤ 10 000	Voir Tableau 7	Voir Tableau 7	Voir Tableau 7	Voir Tableau 7	*U*/√2 + 2 000	√2*U* + 5 000	*U*/√2 + 2 000	√2*U* + 5 000
10 000 < *U* ≤ 14 140	10 000 < *U* ≤ 14 140	1,06 x *U*/√2	1,06 x *U*/√2	1,06 x *U*/√2	1,06 x *U*/√2	*U*/√2 + 2 000	√2*U* + 5 000	*U*/√2 + 2 000	√2*U* + 5 000
U > 14 140	*U* > 14 140	Si nécessaire, doit être prescrit par les normes particulières.							

NOTE 1 Pour une barrière selon:

– la Figure J.6, utiliser la colonne MOYEN DE PROTECTION DU PATIENT – Protection vis-à-vis des CIRCUITS SECONDAIRES – Deux MOPP.

– 8.5.2.1 et la Figure J.7, utiliser la colonne MOYEN DE PROTECTION DU PATIENT – Protection vis-à-vis de la PARTIE RELIEE AU RESEAU – Un MOPP.

NOTE 2 Voir la justification de 8.8.3.

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Tableau 7 – Tensions d'essai pour les MOYENS DE PROTECTION DE L'OPERATEUR

Tension d'essai en V, valeur efficace

TENSION DE SERVICE DE CRETE (*U*) V crête ou V c.c.	Un MOOP	Deux MOOP	TENSION DE SERVICE DE CRETE (*U*) V crête ou V c.c.	Un MOOP	Deux MOOP	TENSION DE SERVICE DE CRETE (*U*) V crête ou V c.c.	Un MOOP	Deux MOOP
34	500	800	250	1 261	2 018	1 750	3 257	3 257
35	507	811	260	1 285	2 055	1 800	3 320	3 320
36	513	821	270	1 307	2 092	1 900	3 444	3 444
38	526	842	280	1 330	2 127	2 000	3 566	3 566
40	539	863	290	1 351	2 162	2 100	3 685	3 685
42	551	882	300	1 373	2 196	2 200	3 803	3 803
44	564	902	310	1 394	2 230	2 300	3 920	3 920
46	575	920	320	1 414	2 263	2 400	4 034	4 034
48	587	939	330	1 435	2 296	2 500	4 147	4 147
50	598	957	340	1 455	2 328	2 600	4 259	4 259
52	609	974	350	1 474	2 359	2 700	4 369	4 369
54	620	991	360	1 494	2 390	2 800	4 478	4 478
56	630	1 008	380	1 532	2 451	2 900	4 586	4 586
58	641	1 025	400	1 569	2 510	3 000	4 693	4 693
60	651	1 041	420	1 605	2 567	3 100	4 798	4 798
62	661	1 057	440	1 640	2 623	3 200	4 902	4 902
64	670	1 073	460	1 674	2 678	3 300	5 006	5 006
66	680	1 088	480	1 707	2 731	3 400	5 108	5 108
68	690	1 103	500	1 740	2 784	3 500	5 209	5 209
70	699	1 118	520	1 772	2 835	3 600	5 309	5 309
72	708	1 133	540	1 803	2 885	3 800	5 507	5 507
74	717	1 147	560	1 834	2 934	4 000	5 702	5 702
76	726	1 162	580	1 864	2 982	4 200	5 894	5 894
78	735	1 176	588	1 875	3 000	4 400	6 082	6 082
80	744	1 190	600	1 893	3 000	4 600	6 268	6 268
85	765	1 224	620	1 922	3 000	4 800	6 452	6 452
90	785	1 257	640	1 951	3 000	5 000	6 633	6 633
95	805	1 288	660	1 979	3 000	5 200	6 811	6 811
100	825	1 319	680	2 006	3 000	5 400	6 987	6 987
105	844	1 350	700	2 034	3 000	5 600	7 162	7 162
110	862	1 379	720	2 060	3 000	5 800	7 334	7 334
115	880	1 408	740	2 087	3 000	6 000	7 504	7 504
120	897	1 436	760	2 113	3 000	6 200	7 673	7 673
125	915	1 463	780	2 138	3 000	6 400	7 840	7 840
130	931	1 490	800	2 164	3 000	6 600	8 005	8 005
135	948	1 517	850	2 225	3 000	6 800	8 168	8 168
140	964	1 542	900	2 285	3 000	7 000	8 330	8 330
145	980	1 568	950	2 343	3 000	7 200	8 491	8 491
150	995	1 593	1 000	2 399	3 000	7 400	8 650	8 650
152	1 000	1 600	1 050	2 454	3 000	7 600	8 807	8 807
155	1 000	1 617	1 100	2 508	3 000	7 800	8 964	8 964
160	1 000	1 641	1 150	2 560	3 000	8 000	9 119	9 119
165	1 000	1 664	1 200	2 611	3 000	8 200	9 273	9 273
170	1 000	1 688	1 250	2 661	3 000	8 400	9 425	9 425
175	1 000	1 711	1 300	2 710	3 000	8 600	9 577	9 577
180	1 000	1 733	1 350	2 758	3 000	8 800	9 727	9 727
184	1 000	1 751	1 400	2 805	3 000	9 000	9 876	9 876
185	1 097	1 755	1 410	2 814	3 000	9 200	10 024	10 024
190	1 111	1 777	1 450	2 868	3 000	9 400	10 171	10 171
200	1 137	1 820	1 500	2 934	3 000	9 600	10 317	10 317
210	1 163	1 861	1 550	3 000	3 000	9 800	10 463	10 463
220	1 189	1 902	1 600	3 065	3 065	10 000	10 607	10 607
230	1 214	1 942	1 650	3 130	3 130			
240	1 238	1 980	1 700	3 194	3 194			

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8.8.4 Isolation autre que l'isolation du câblage

8.8.4.1 * Résistance mécanique et résistance à la chaleur

La résistance à la chaleur doit être conservée pour tous les types d'isolation, y compris les cloisons de séparation isolantes, au cours de la DUREE DE VIE PREVUE de L'APPAREIL EM.

La conformité est vérifiée par ~~examen~~ inspection de l'APPAREIL EM et de la documentation de conception, et si nécessaire, inspection du DOSSIER DE GESTION DES RISQUES ~~et, si nécessaire~~, ~~conjointement~~ en conjonction avec les essais suivants:

– *résistance à l'humidité, etc. (voir 11.6);*

– *tension de tenue (voir 8.8.3);*

– *résistance mécanique (voir 15.3).*

La résistance à la chaleur est vérifiée par les essais ci-dessous, qui n'ont pas à être effectués si la conformité peut être démontrée de façon satisfaisante.

a) *Pour les parties de L'ENVELOPPE et d'autres parties isolantes extérieures dont la détérioration pourrait donner lieu à un RISQUE inacceptable, par l'essai à la bille:*

Les ENVELOPPES et autres parties extérieures en matériau isolant, à l'exception de l'isolation des câbles souples et des parties en matériau céramique, sont soumises à l'essai à la bille à l'aide de l'appareillage d'essai indiqué à la Figure 21. La surface de la partie soumise à l'essai est placée en position horizontale et une bille d'acier de 5 mm de diamètre est pressée contre cette surface avec une force de 20 N. L'essai est effectué en chambre chauffante, à une température de 75 °C ± 2 °C ou à la température ambiante indiquée dans la description technique (voir 7.9.3.1) ± 2 °C majorée de l'échauffement de la partie concernée du matériau isolant, mesuré lors de l'essai mentionné en 11.1, la valeur la plus élevée étant retenue.

Après 1 h, on retire la bille et on mesure le diamètre de son empreinte. Une empreinte supérieure à 2 mm en diamètre constitue une défaillance.

b) *Pour les parties en matériau isolant servant de support à des parties non isolées de la PARTIE RELIEE AU RESEAU, dont la détérioration pourrait influer sur la sécurité de l'APPAREIL EM, par l'essai à la bille:*

On procède à l'essai mentionné au point a) ci-dessus, mais à une température de 125 °C ± 2 °C ou à la température ambiante indiquée dans la description technique (voir 7.9.3.1) ± 2 °C majorée de l'échauffement de la partie concernée du matériau isolant, mesuré lors de l'essai mentionné en 11.1 pour la partie concernée, la valeur la plus élevée étant retenue.

L'essai n'est pas effectué sur les parties en matière céramique, les parties isolantes des commutateurs, les porte-balais ou les pièces analogues, et sur les carcasses de bobines non utilisées comme ISOLATION RENFORCEE.

NOTE Pour l'ISOLATION SUPPLEMENTAIRE et l'ISOLATION RENFORCEE des matériaux thermoplastiques, voir aussi 13.1.2.

8.8.4.2 Résistance aux contraintes environnementales

Les caractéristiques isolantes et la résistance mécanique des MOYENS DE PROTECTION doivent être conçues ou protégées de façon à ne pas être altérées par les contraintes environnementales comme les dépôts de saletés ou de poussière provenant de l'usure de pièces à l'intérieur des APPAREILS EM en quantité telle que les LIGNES DE FUITE et les DISTANCES DANS L'AIR soient réduites à des valeurs inférieures à celles spécifiées en 8.9.

Les matériaux céramiques non fortement agglomérés, les matériaux analogues et les perles seules ne doivent pas être utilisés comme ISOLATION SUPPLEMENTAIRE ou ISOLATION RENFORCEE.

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Les matériaux isolants dans lesquels sont encastrés des conducteurs chauffants sont considérés comme constituant un MOYEN DE PROTECTION mais ils ne doivent pas être utilisés comme deux MOYENS DE PROTECTION.

La conformité est vérifiée par examen, par mesurage et pour le caoutchouc naturel par l'essai suivant:

Les pièces en caoutchouc naturel sont vieillies dans une atmosphère d'oxygène sous pression. Les spécimens sont suspendus librement dans un cylindre rempli d'oxygène dont la capacité réelle est égale à au moins 10 fois le volume des spécimens. Le cylindre est rempli d'oxygène, dont la pureté est supérieure ou égale à 97 %, à une pression de 2,1 MPa ± 70 kPa.

Les spécimens sont maintenus pendant 96 h dans le cylindre à une température de 70 °C ± 2 °C. Immédiatement après, ils sont sortis du cylindre et laissés pendant au moins 16 h à la température ambiante. A l'issue de l'essai, les spécimens sont examinés. Les fissurations visibles à l'œil nu constituent des défaillances.

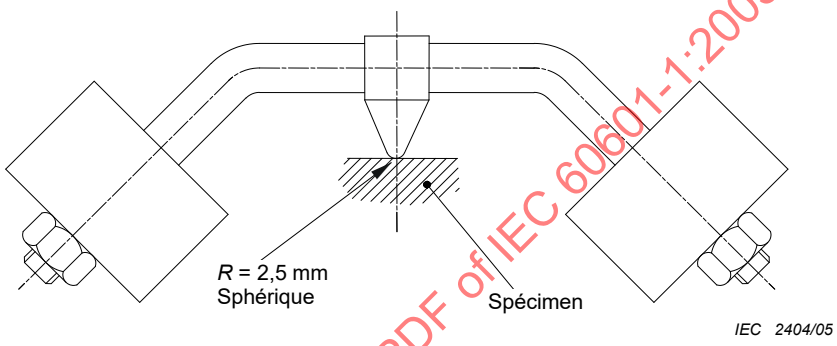


Figure 21 – Appareillage pour l'essai à la bille
(voir 8.8.4.1)

8.9 * LIGNES DE FUITE ET DISTANCES DANS L'AIR

8.9.1 * Valeurs

8.9.1.1 Généralités

Les LIGNES DE FUITE et les DISTANCES DANS L'AIR des APPAREILS EM doivent être supérieures ou égales aux valeurs ~~des Tableaux 11 à 16 (inclus) sauf pour ce qui est spécifié en 8.9.1.2 à 8.9.1.15. Voir aussi 8.9.2 à 8.9.4.~~:

– pour l'isolation entre parties de polarité opposée de la PARTIE RELIEE AU RESEAU du côté RESEAU D'ALIMENTATION de tout fusible ou DISJONCTEUR réseau, un MOYEN DE PROTECTION DE L'OPERATEUR conformément au Tableau 13, au Tableau 14 et au Tableau 16; et

– pour l'isolation constituant au moins un MOYEN DE PROTECTION, conformément aux Tableaux 12 à 16 (inclus) sauf pour ce qui est spécifié en 8.9.1.2 à 8.9.1.15. Voir aussi 8.9.2 à 8.9.4.

8.9.1.2 LIGNES DE FUITE et DISTANCES DANS L'AIR conformes à l'IEC 60950-1

Les valeurs des Tableaux ~~11~~ 12 à 16 (inclus) ne s'appliquent pas aux LIGNES DE FUITE et aux DISTANCES DANS L'AIR qui constituent un MOYEN DE PROTECTION DE L'OPERATEUR conforme aux exigences de l'IEC 60950-1 pour la COORDINATION DE L'ISOLEMENT mais sont utilisées dans les conditions (par exemple catégorie de surtensions, degré de pollution) dans lesquelles la conformité a été soumise aux essais.

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8.9.1.3 LIGNES DE FUITE à travers le verre, le mica, la céramique et des matériaux analogues

Pour les LIGNES DE FUITE à travers le verre, le mica, la céramique et d'autres matériaux isolants inorganiques présentant des caractéristiques de cheminement similaires, la valeur minimale spécifiée pour la DISTANCE DANS L'AIR doit être appliquée comme la LIGNE DE FUITE minimale.

8.9.1.4 LIGNE DE FUITE minimale

Si la LIGNE DE FUITE minimale provenant des Tableaux ~~11~~ 12 à 16 (inclus) est inférieure à la DISTANCE DANS L'AIR minimale applicable, cette valeur de DISTANCE DANS L'AIR minimale doit être appliquée comme LIGNE DE FUITE minimale.

8.9.1.5 APPAREILS EM de caractéristiques ASSIGNEES pour altitudes élevées

Sauf déclaration contraire du FABRICANT, les APPAREILS EM ont des caractéristiques ASSIGNEES pour fonctionner à une altitude ≤ 2 000 m. Lorsque les APPAREILS EM sont destinés à fonctionner dans un environnement pressurisé, par exemple un aéronef, l'altitude de fonctionnement correspondant à la pression de l'air concernée doit être utilisée pour la détermination du facteur de multiplication du Tableau 8. La DISTANCE DANS L'AIR est ensuite multipliée par ce facteur. Les LIGNES DE FUITE ne sont pas soumises aux facteurs de multiplication mais elles doivent toujours être au moins aussi élevées que la valeur obtenue pour la DISTANCE DANS L'AIR.

Tableau 8 – Facteurs de multiplication pour les distances dans l'air pour des altitudes jusqu'à 5 000 m

Altitude de fonctionnement ASSIGNEE (*a*) m	Pression barométrique normale kPa	Facteur de multiplication pour MOOP	Facteur de multiplication pour MOPP
a ≤ 2 000	80,0	1,00	1,00
2 000 < *a* ≤ 3 000	70,0	1,14	1,00
3 000 < *a* ≤ 4 000	62,0	1,29	1,14
4 000 < *a* ≤ 5 000	54,0	1,48	1,29

NOTE 1 Les facteurs de multiplication pour les MOYENS DE PROTECTION DE L'OPERATEUR font référence à l'IEC 60950-1, qui spécifie les DISTANCES DANS L'AIR pour des altitudes jusqu'à 2 000 m.

NOTE 2 Les facteurs de multiplication pour les MOYENS DE PROTECTION DU PATIENT font référence à la deuxième édition de l'IEC 60601-1, qui spécifiait des DISTANCES DANS L'AIR pour les altitudes jusqu'à 3 000 m.

NOTE 3 Les facteurs de multiplication pour MOOP (colonne 3) sont tirés de l'IEC 60664-1:~~1992~~2007~~, modifiée~~.

8.9.1.6 * Interpolation

Si la TENSION DE SERVICE a une valeur comprise entre celles données aux Tableaux ~~11~~ 12 à 16 (inclus):

– pour déterminer les LIGNES DE FUITE, l'interpolation linéaire est autorisée entre les deux valeurs les plus proches, l'espacement calculé étant arrondi au 0,1 mm immédiatement supérieur;

– pour déterminer les DISTANCES DANS L'AIR pour les TENSIONS DE SERVICE CRETE supérieures à 2 800 V en valeur de crête ou en courant continu, l'interpolation linéaire est autorisée entre les deux valeurs les plus proches, l'espacement calculé étant arrondi au 0,1 mm immédiatement supérieur;

– pour déterminer les DISTANCES DANS L'AIR pour les TENSIONS DE SERVICE CRETE jusqu'à 2 800 V en valeur crête ou en courant continu, la plus élevée des deux valeurs doit être appliquée.

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8.9.1.7 Classification des groupes de matériaux

Les groupes de matériaux sont classés comme représenté au Tableau 9.

Tableau 9 – Classification des groupes de matériaux

Groupe de matériau	Indice de résistance au cheminement (IRC)
I	600 ≤ IRC
II	400 ≤ IRC < 600
IIIa	175 ≤ IRC < 400
IIIb	100 ≤ IRC < 175

Le groupe de matériau est vérifié par l'évaluation des données d'essai pour le matériau selon l'IEC 60112 en utilisant 50 gouttes de la solution A.

Si le groupe de matériau n'est pas connu, on doit utiliser le groupe de matériau IIIb.

8.9.1.8 Classification du degré de pollution

Les degrés de pollution sont classés comme suit.

– Le degré de pollution 1 est utilisé pour un micro-environnement qui est scellé de manière à exclure les poussières et l'humidité.

NOTE 1 Un exemple d'un tel micro-environnement est un composant ou un assemblage scellé ou encapsulé.

– Le degré de pollution 2 est utilisé pour décrire un micro-environnement dans lequel il ne se produit qu'une pollution non conductrice à l'exception d'une conductivité temporaire occasionnelle prévisible due à la condensation.

– Le degré de pollution 3 est utilisé pour décrire un micro-environnement qui est soumis à une pollution conductrice ou à une pollution non conductrice sèche qui pourrait devenir conductrice en raison de la condensation prévisible.

– Le degré de pollution 4 est utilisé pour décrire un micro-environnement dans lequel il se produit une conductivité continue due à des poussières conductrices, à la pluie ou à d'autres conditions humides.

NOTE 2 Ce type d'environnement peut apparaître à l'intérieur de moteurs en train de commuter dont les balais génèrent de la poussière de carbone.

Le degré de pollution 4 n'est pas acceptable pour l'isolation assurant un MOYEN DE PROTECTION. Toutefois, lorsque l'isolation entre la PARTIE RELIEE AU RESEAU et la terre pourraient être compromise, il est nécessaire de prévoir des mesures comme la maintenance planifiée pour assurer que le micro-environnement est ramené à un degré de pollution inférieur.

L'Annexe M spécifie les mesures pouvant être utilisées pour réduire le degré de pollution.

8.9.1.9 Classification des catégories de surtension

La valeur applicable de la TENSION TRANSITOIRE RESEAU doit être déterminée à partir de la catégorie de surtension conformément à l'IEC 60664-1 et à la TENSION RESEAU NOMINALE en courant alternatif en utilisant le Tableau 10.

8.9.1.10 DISTANCE DANS L'AIR pour PARTIES RELIEES AU RESEAU

Pour les PARTIES RELIEES AU RESEAU qui fonctionnent à des TENSIONS RESEAU ASSIGNEES jusqu'à 300 V, la DISTANCE DANS L'AIR exigée doit être la valeur indiquée dans le Tableau 13 pour la TENSION RESEAU ASSIGNEE en valeur efficace ou en courant continu à laquelle on ajoute la DISTANCE DANS L'AIR supplémentaire indiquée dans le Tableau 14 pour la TENSION DE SERVICE CRETE.

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8.9.1.11 Surtension du RESEAU D'ALIMENTATION

La présente norme fait référence à la catégorie de surtension II conformément à la IEC 60664-1. Si l'APPAREIL EM est destiné à être utilisé dans des lieux où le RESEAU D'ALIMENTATION correspond à la catégorie de surtension III, les valeurs spécifiées du Tableau 13 au Tableau 15 (inclus) seront inappropriées comme espacement. C'est pourquoi les valeurs données dans la colonne suivante de TENSION TRANSITOIRE RESEAU au dessus doivent être utilisées. Bien qu'il ne soit pas envisagé d'exiger une protection du PATIENT (Tableau 12) pour l'utilisation des APPAREILS EM sur des réseaux de catégorie de surtension III, au cas où cela serait nécessaire, des lignes directrices sont données, pour les valeurs exigées, au Paragraphe 8.9.

Tableau 10 – TENSION TRANSITOIRE RESEAU

TENSION NOMINALE du RESEAU D'ALIMENTATION en courant alternatif entre phase et neutre jusqu'à inclus V valeur efficace	TENSION TRANSITOIRE RESEAU V crête			
	Catégorie de surtension			
	I	II	III	IV
50	330	500	800	1 500
100	500	800	1 500	2 500
150 [a]	800	1 500	2 500	4 000
300 [b]	1 500	2 500	4 000	6 000
600 [c]	2 500	4 000	6 000	8 000
NOTE 1 En Norvège, compte tenu du schéma IT utilisé, la tension du RESEAU D'ALIMENTATION en courant alternatif est considérée comme égale à la tension entre phases et restera 203 V en cas de défaut simple à la terre. NOTE 2 Au Japon, la valeur des TENSIONS TRANSITOIRES RESEAU pour la TENSION NOMINALE RESEAU en courant alternatif de 100 V est déterminée à partir des colonnes applicables à la TENSION NOMINALE RESEAU en courant alternatif applicable de 150 V.				
[a] y compris 120/208 ou 120/240 V. [b] y compris 230/400 ou 277/480 V. [c] Y compris 400/690 V.				

8.9.1.12 CIRCUITS SECONDAIRES

Un CIRCUIT SECONDAIRE issu du RESEAU D'ALIMENTATION sera normalement de la catégorie de surtension I selon l'IEC 60664-1 si la PARTIE RELIEE AU RESEAU D'ALIMENTATION appartient à la catégorie de surtension II; les transitoires maximales pour diverses tensions du RESEAU D'ALIMENTATION dans la catégorie de surtension I sont indiquées dans les en-têtes de colonnes du Tableau 15.

Lorsque le CIRCUIT SECONDAIRE est à la terre ou que l'APPAREIL EM est ALIMENTE DE MANIERE INTERNE, le Tableau 15 s'applique.

Lorsque le CIRCUIT SECONDAIRE n'est pas relié à la terre et qu'il est issu d'un RESEAU D'ALIMENTATION, le circuit doit être soumis aux exigences pour les circuits primaires du Tableau 13 et du Tableau 14.

Si le CIRCUIT SECONDAIRE est séparé de la PARTIE RELIEE AU RESEAU par un écran métallique relié à la terre de manière fonctionnelle ou PROTEGE PAR MISE A LA TERRE ou si les transitoires dans le CIRCUIT SECONDAIRE sont inférieures aux niveaux attendus pour la catégorie de surtension I (par exemple parce qu'elles sont atténuées en connectant un composant, comme un condensateur, entre le CIRCUIT SECONDAIRE et la terre), les valeurs du Tableau 15 s'appliquent.

La colonne pour les circuits qui ne sont pas soumis aux surtensions transitoires s'applique:

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– aux CIRCUITS SECONDAIRES en courant continu qui sont reliés de manière fiable à la terre et qui possèdent un filtrage capacitif qui limite l'ondulation crête à crête à 10 % de la tension en courant continu ; et

– aux circuits des APPAREILS EM ALIMENTES DE MANIERE INTERNE.

8.9.1.13 TENSIONS DE SERVICE CRETE au-delà de 1 400 V en valeur crête ou continue

Les valeurs du Tableau 15 pour la TENSION DE SERVICE CRETE au-delà de 1 400 V crête ou continue ne s'appliquent pas si toutes les conditions suivantes sont satisfaites:

– la DISTANCE DANS L'AIR est d'au moins 5 mm;

– l'isolation concernée passe avec succès un essai de tension de tenue selon 8.8.3 en utilisant:

  - une tension d'essai en courant alternatif dont la valeur efficace est égale à 1,06 fois la TENSION DE SERVICE CRETE ou
  - une tension d'essai en courant continu égale à la valeur de crête de la tension d'essai en courant alternatif prescrite ci-dessus.

  et

– le cheminement de la DISTANCE DANS L'AIR est partiellement ou complètement dans l'air et/ou le long de la surface d'un matériau isolant du groupe de matériau I.

Si le cheminement de la DISTANCE DANS L'AIR est également partiellement le long de la surface d'un matériau qui n'est pas du groupe de matériau I, l'essai de tension de tenue est conduit uniquement à travers la ou les parties du cheminement qui traversent l'air.

8.9.1.14 LIGNES DE FUITE minimales pour deux MOYENS DE PROTECTION DE L'OPERATEUR

Les LIGNES DE FUITE minimales pour deux MOYENS DE PROTECTION DE L'OPERATEUR sont obtenues en doublant les valeurs données au Tableau 16 pour un MOYEN DE PROTECTION DE L'OPERATEUR.

8.9.1.15 * LIGNES DE FUITE et DISTANCES DANS L'AIR pour PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION

Les LIGNES DE FUITE et les DISTANCES DANS L'AIR nécessaires pour satisfaire à 8.5.5.1 pour les PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION ne doivent pas être inférieures à 4 mm.

NOTE Dans les Tableaux ~~11 et~~ 12 qui détaillent l'espacement pour la protection du PATIENT, la LIGNE DE FUITE et la DISTANCE DANS L'AIR sont toutes les deux liées aux TENSIONS DE SERVICE efficaces ou en courant continu. Dans les Tableaux 13, 14 et 15, où sont détaillés l'espacement pour la protection de L'OPERATEUR, la DISTANCE DANS L'AIR est liée à la TENSION DE SERVICE de crête ou en courant continu et la LIGNE DE FUITE est liée à la TENSION DE SERVICE en valeur efficace ou en courant continu.

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Tableau 11 – ~~LIGNES DE FUITE et DISTANCES DANS L'AIR minimales entre parties de polarité opposée de la PARTIE RELIEE AU RESEAU~~ Non utilisé

~~TENSION DE SERVICE V courant continu jusqu'à et inclus~~	~~TENSION DE SERVICE V Valeur efficace jusqu'à et inclus~~	~~LIGNE DE FUITE~~ mm	~~DISTANCE DANS L'AIR~~ mm
~~17~~	~~12~~	~~0,8~~	~~0,4~~
~~43~~	~~30~~	~~1~~	~~0,5~~
~~85~~	~~60~~	~~1,3~~	~~0,7~~
~~177~~	~~125~~	~~2~~	~~1~~
~~354~~	~~250~~	~~3~~	~~1,6~~
~~566~~	~~400~~	~~4~~	~~2,4~~
~~707~~	~~500~~	~~5,5~~	~~3~~
~~934~~	~~660~~	~~7~~	~~4~~
~~1 061~~	~~750~~	~~8~~	~~4,5~~
~~1 414~~	~~1 000~~	~~11~~	~~6~~

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Tableau 12 – LIGNES DE FUITE et DISTANCES DANS L'AIR minimales assurant des MOYENS DE PROTECTION DU PATIENT

TENSION DE SERVICE V courant continu jusqu'à et inclus	TENSION DE SERVICE V courant continu jusqu'à et inclus	Espacement assurant un MOYEN DE PROTECTION AU PATIENT		Espacement assurant deux MOYENS DE PROTECTION AU PATIENT	
		LIGNE DE FUITE mm	DISTANCE DANS L'AIR mm	LIGNE DE FUITE mm	DISTANCE DANS L'AIR mm
17	12	1,7	0,8	3,4	1,6
43	30	2	1	4	2
85	60	2,3	1,2	4,6	2,4
177	125	3	1,6	6	3,2
354	250	4	2,5	8	5
566	400	6	3,5	12	7
707	500	8	4,5	16	9
934	660	10,5	6	21	12
1 061	750	12	6,5	24	13
1 414	1 000	16	9	32	18
1 768	1 250	20	11,4	40	22,8
2 263	1 600	25	14,3	50	28,6
2 828	2 000	32	18,3	64	36,6
3 535	2 500	40	22,9	80	45,8
4 525	3 200	50	28,6	100	57,2
5 656	4 000	63	36,0	126	72,0
7 070	5 000	80	45,7	160	91,4
8 909	6 300	100	57,1	200	114,2
11 312	8 000	125	71,4	250	142,8
14 140	10 000	160	91,4	320	182,8

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Tableau 13 – DISTANCES DANS L'AIR minimales assurant un MOYEN DE PROTECTION à L'OPERATEUR vis à vis de la PARTIE RELIEE AU RESEAU

DISTANCE DANS L'AIR mm

TENSION DE SERVICE jusqu'à et inclus		TENSION NOMINALE du RESEAU ≤ 150 V (TENSION TRANSITOIRE RESEAU 1 500 V)				150 V < tension NOMINALE du RESEAU ≤ 300 V (TENSION TRANSITOIRE RESEAU 2 500 V)		300 V < tension NOMINALE du RESEAU ≤ 600 V (TENSION TRANSITOIRE RESEAU 4 000 V)	
Tension de crête ou courant continu	Tension valeur efficace (sinusoïdale)	Degrés de pollution 1 et 2		Degré de pollution 3		Degrés de pollution 1, 2 et 3		Degrés de pollution 1, 2 et 3	
V	V	Un MOOP	Deux MOOP	Un MOOP	Deux MOOP	Un MOOP	Deux MOOP	Un MOOP	Deux MOOP
210	150	1,0	2,0	1,3	2,6	2,0	4,0	3,2	6,4
420	300	1 MOOP 2,0 2 MOOP 4,0						3,2	6,4
840	600	1 MOOP 3,2 2 MOOP 6,4							
1 400	1 000	1 MOOP 4,2 2 MOOP 6,4							
2 800	2 000	1 or 2 MOOP 8,4							
7 000	5 000	1 or 2 MOOP 17,5							
9 800	7 000	1 or 2 MOOP 25							
14 000	10 000	1 or 2 MOOP 37							
28 000	20 000	1 or 2 MOOP 80							
Les DISTANCES DANS L'AIR pour les TENSIONS DE SERVICE au-delà de 20 kV en valeur efficace ou 28 kV en courant continu peuvent être prescrites par les normes particulières, si nécessaire.									
NOTE Les DISTANCES DANS L'AIR sont une fonction de la tension de crête dans le circuit. La colonne de la tension efficace est donnée pour le cas particulier où la tension a une forme sinusoïdale.									

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Tableau 14 – DISTANCES DANS L'AIR complémentaires pour l'isolation dans les PARTIES RELIEES AU RESEAU avec des TENSIONS DE SERVICE CRETE dépassant la valeur de crête de la TENSION RESEAU NOMINALE [a]

(voir 8.9.1.10)

TENSION RESEAU NOMINALE ≤ 150 V valeur efficace ou 210 V courant continu		150 V valeur efficace ou 210 V courant continu < Tension RESEAU NOMINALE ≤ 300 V valeur efficace ou 420 V courant continu	DISTANCE DANS L'AIR complémentaire mm	
Degrés de pollution 1 et 2	Degré de pollution 3	Degrés de pollution 1, 2 et 3		
TENSION DE SERVICE CRETE V	TENSION DE SERVICE CRETE V	TENSION DE SERVICE CRETE V	Un MOOP	Deux MOOP
210	210	420	0	0
298	294	493	0,1	0,2
386	379	567	0,2	0,4
474	463	640	0,3	0,6
562	547	713	0,4	0,8
650	632	787	0,5	1,0
738	715	860	0,6	1,2
826	800	933	0,7	1,4
914		1 006	0,8	1,6
1 002		1 080	0,9	1,8
1 090		1 153	1,0	2,0
		1 226	1,1	2,2
		1 300	1,2	2,4

[a] Lors de l'utilisation de ce tableau, choisir la colonne appropriée pour la TENSION ASSIGNEE DU RESEAU et le degré de pollution et choisir la ligne dans la colonne qui correspond à la TENSION DE SERVICE CRETE réelle. Lire la DISTANCE DANS L'AIR complémentaire exigée dans la colonne de droite correspondante (pour un ou deux MOYENS DE PROTECTION DE L'OPERATEUR) et l'ajouter à la DISTANCE DANS L'AIR minimale du Tableau 13 pour obtenir la DISTANCE DANS l'air minimale totale.

NOTE Pour les valeurs de tension supérieures aux valeurs de la TENSION DE SERVICE CRETE données dans le tableau, l'extrapolation linéaire est autorisée.

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Tableau 15 – DISTANCES DANS L'AIR minimales pour MOYENS DE PROTECTION DE L'OPERATEUR dans des CIRCUITS SECONDAIRES
(voir 8.9.1.12)

DISTANCE DANS L'AIR mm

TENSION DE SERVICE jusqu'à et inclus		Valeur transitoire pour CIRCUIT SECONDAIRE ≤ 800 V (TENSION RESEAU NOMINALE ≤ 150 V)				Valeur transitoire pour CIRCUIT SECONDAIRE ≤ 1 500 V (150 V < TENSION RESEAU NOMINALE ≤ 300 V)				Valeur transitoire pour CIRCUIT SECONDAIRE ≤ 2 500 V (300 V < TENSION RESEAU NOMINALE ≤ 600 V)		Circuit non soumis aux surtensions transitoires	
Tension V crête ou V courant continu	Tension V valeur efficace (sinu-soïdale)	Degrés de pollution 1 et 2		Degré de pollution 3		Degrés de pollution 1 et 2		Degré de pollution 3		Degrés de pollution 1, 2 et 3		Degrés de pollution 1 et 2 seulement	
		Un MOOP	Deux MOOP	Un MOOP	Deux MOOP	Un MOOP	Deux MOOP	Un MOOP	Deux MOOP	Un MOOP	Deux MOOP	Un MOOP	Deux MOOP
71	50	0,7	1,4	1,3	2,6	1,0	2,0	1,3	2,6	2,0	4,0	0,4	0,8
140	100	0,7	1,4	1,3	2,6	1,0	2,0	1,3	2,6	2,0	4,0	0,7	1,4
210	150	0,9	1,8	1,3	2,6	1,0	2,0	1,3	2,6	2,0	4,0	0,7	1,4
280	200	Un MOOP 1,4 ; Deux MOOP 2,8								2,0	4,0	1,1	2,2
420	300	Un MOOP 1,9 ; Deux MOOP 3,8								2,0	4,0	1,4	2,8
700	500	Un MOOP 2,5 ; Deux MOOP 5,0											
840	600	Un MOOP 3,2 ; Deux MOOP 5,0											
1 400	1 000	Un MOOP 4,2 ; Deux MOOP 5,0											
2 800	2 000	Un ou deux MOOP 8,4, mais voir 8.9.1.13											
7 000	5 000	Un ou deux MOOP 17,5, mais voir8.9.1.13											
9 800	7 000	Un ou deux MOOP 25, mais voir 8.9.1.13											
14 000	10 000	Un ou deux MOOP 37, mais voir 8.9.1.13											
28 000	20 000	Un ou deux MOOP 80, mais voir 8.9.1.13											
42 000	30 000	Un ou deux MOOP 130, mais voir 8.9.1.13											

NOTE Les DISTANCES DANS L'AIR sont une fonction de la tension de crête dans le circuit. La colonne de la tension efficace est donnée pour le cas particulier où la tension a une forme sinusoïdale.

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Tableau 16 – LIGNES DE FUITE minimales assurant un MOYEN DE PROTECTION DE L'OPERATEUR [a]

LIGNE DE FUITE EN mm

TENSION DE SERVICE V valeur efficace ou courant continu	Espacement assurant un MOYEN DE PROTECTION DE L'OPERATEUR						
	Degré de pollution 1	Degré de pollution 2			Degré de pollution 3		
	Groupe de matériau	Groupe de matériau			Groupe de matériau		
	I, II, IIIa, IIIb	I	II	IIIa ou IIIb	I	II	IIIa ou IIIb
25	Utiliser la DISTANCE DANS L'AIR du tableau approprié	0,5	0.5	0,5	1,3	1,3	1,3
50		0,6	0,9	1,2	1,5	1,7	1,9
100		0,7	1,0	1,4	1,8	2,0	2,2
125		0,8	1,1	1,5	1,9	2,1	2,4
150		0,8	1,1	1,6	2,0	2,2	2,5
200		1,0	1,4	2,0	2,5	2,8	3,2
250		1,3	1,8	2,5	3,2	3,6	4,0
300		1,6	2,2	3,2	4,0	4,5	5,0
400		2,0	2,8	4,0	5,0	5,6	6,3
600		3,2	4,5	6,3	8,0	9,6	10,0
800		4,0	5,6	8,0	10,0	11,0	12,5
1 000		5,0	7,1	10,0	12,5	14,0	16,0

NOTE 1 Les LIGNES DE FUITE minimales pour deux MOYENS DE PROTECTION DE L'OPERATEUR sont obtenues en doublant les valeurs du présent tableau.

NOTE 2 Une LIGNE DE FUITE ne peut pas être inférieure à la distance dans l'air requise. Voir 8.9.1.4.

NOTE 3 Pour les valeurs de la TENSION DE SERVICE supérieures à 1 000 V, voir Tableau A.2.

[a] Les LIGNES DE FUITE de ce tableau s'appliquent à toutes les situations.

8.9.2 * Application

a) * En ce qui concerne l'isolation de la PARTIE RELIEE AU RESEAU entre des parties de polarité opposée, les LIGNES DE FUITE minimales et les DISTANCES DANS L'AIR ne sont pas exigées si une mise en court-circuit de chacune de ces LIGNES DE FUITE et DISTANCES DANS L'AIR à tour de rôle n'entraîne pas de SITUATION DANGEREUSE décrite en 13.1.

b) La contribution aux LIGNES DE FUITE de toute rainure ou de tout espace inférieur à 1 mm en largeur doit être limitée à sa largeur (voir Figure 23 à Figure 31 [incluse]).

c) Si la DISTANCE DANS L'AIR fournit un MOYEN DE PROTECTION, le positionnement relatif doit être tel que les parties correspondantes soient rigides et fixées par moulage ou la conception doit être telle qu'il n'y ait pas de réduction d'une distance en dessous de la valeur spécifiée par déformation ou mouvement des parties.

Lorsqu'un mouvement limité de l'une des parties concernées est normal ou probable, cela doit être pris en compte lors du calcul de la DISTANCE DANS L'AIR minimale.

8.9.3 * Espaces remplis par un mélange isolant

8.9.3.1 Généralités

Lorsque les distances entre les parties conductrices sont remplies par un mélange isolant, y compris lorsque l'isolation est collée de manière fiable avec un mélange isolant, de telle

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manière qu'il n'y pas de DISTANCES DANS L'AIR ni de LIGNES DE FUITE, seules les exigences pour l'isolation solide s'appliquent.

NOTE On peut citer comme exemples de tels traitements l'empotage, l'encapsulation et l'imprégnation sous vide, les composants ou sous-ensembles qui sont traités avec un mélange isolant qui remplit les vides et l'isolation interne entre pistes adjacentes d'une carte imprimée multi-couches.

La vérification est effectuée par examen, par des mesures et par l'essai des spécimens. Les exigences concernant les LIGNES DE FUITE et les DISTANCES DANS L'AIR ne s'appliquent pas si les spécimens passent avec succès les essais de cycle thermique, de pré-conditionnement humide et de tension de tenue spécifiés soit en 8.9.3.2 et 8.9.3.4 soit en 8.9.3.3 et 8.9.3.4.

8.9.3.2 Mélange isolant formant une isolation solide entre parties conductrices

Dans les situations où le mélange isolant constitue une isolation solide entre des parties conductrices, un seul spécimen fini est soumis aux essais. Le spécimen est soumis à la PROCEDURE du cycle thermique comme spécifié en 8.9.3.4, suivi du pré-conditionnement humide selon 5.7 mais seulement pendant 48 h, puis à l'essai de tension de tenue selon 8.8.3 avec comme seule différence que la tension d'essai soit multipliée par 1,6. Les essais sont suivis par examen, comprenant le sectionnement et la mesure. Des fissures ou des vides dans le mélange isolant de nature à affecter l'homogénéité du matériau constituent une défaillance.

8.9.3.3 Mélange isolant formant un joint collé avec d'autres parties isolantes

Dans les situations où le mélange isolant constitue un joint collé avec d'autres parties isolantes, la fiabilité du joint est vérifiée en soumettant trois spécimens aux essais. Si un bobinage en fil émaillé à base de solvant est utilisé, il est remplacé pour les essais par une feuille métallique ou par plusieurs tours de fil nu placés à proximité du joint collé. Les trois spécimens sont ensuite soumis aux essais comme suit.

- *Un des spécimens est soumis à la PROCEDURE de cycle thermique telle qu'elle est spécifiée en 8.9.3.4. Immédiatement après la dernière période à la température la plus élevée au cours du cycle thermique, il est soumis à un essai de tension de tenue selon 8.8.3 avec comme seule différence que la tension d'essai est multipliée par 1,6;*
- *Les deux autres spécimens sont soumis au pré-conditionnement humide selon 5.7 mais seulement pendant 48 h, puis à l'essai de tension de tenue selon 8.8.3 avec comme seule différence que la tension d'essai est multipliée par 1,6.*

8.9.3.4 Cycle thermique

Le spécimen est soumis 10 fois à la séquence suivante de cycles de température:

68 h à T_1 ± 2 °C ;
1 h à 25 °C ± 2 °C ;
2 h à 0 °C ± 2 °C ;
pas moins de 1 h à 25 °C ± 2 °C ;

où T_1 est supérieur à

- *10 °C au-dessus de la température maximale de la partie concernée selon 11.1.1 ; ou*
- *85 °C.*

Cependant, la marge de 10 °C n'est pas ajoutée si la température est mesurée par un thermocouple encastré.

Le temps de transition d'une température à une autre n'est pas spécifié mais il est autorisé que la transition soit progressive.

8.9.4 * Mesure des LIGNES DE FUITE ET DES DISTANCES DANS L'AIR

La conformité est vérifiée par des mesures prenant en compte les règles des Figures 22 à 31 (incluse). Dans chaque figure, la ligne en pointillés (— — —) représente la DISTANCE DANS L'AIR et la ligne pleine (▒▒▒▒▒▒▒▒▒▒▒▒▒▒▒▒) représente la LIGNE DE FUITE .

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L'espacement minimal (X) pour les encoches transversales par rapport à la LIGNE DE FUITE sur les Figures 23 à 25 et les Figures 27 à 31 (incluse) qui sont considérées comme un MOYEN DE PROTECTION DE L'OPERATEUR peut être ajusté en fonction du degré de pollution si la DISTANCE DANS L'AIR minimale est de 3 mm ou plus. La largeur minimale de l'encoche est égale à:

- *0,25 mm pour le degré de pollution 1*
- *1,0 mm pour le degré de pollution 2*
- *1,5 mm pour le degré de pollution 3.*

Si la DISTANCE DANS L'AIR minimale spécifiée est inférieure à 3 mm, l'espacement minimal (X) pour les encoches transversales à la LIGNE DE FUITE est la plus petite des deux valeurs suivantes:

- *la valeur pertinente spécifiée à l'alinéa précédent, ou*
- *un tiers de la DISTANCE DANS L'AIR minimale spécifiée.*

L'espacement minimal (X) pour une encoche transversale à une LIGNE DE FUITE qui est considérée comme un MOYEN DE PROTECTION DU PATIENT est de 1 mm pour le degré de pollution 1 et le degré de pollution 2 et de 1,5 mm pour le degré de pollution 3.

Tout coin dont l'angle d'ouverture est inférieur à 80° est considéré comme mis en dérivation par un tronçon isolant de 1 mm placé dans la position la moins favorable (voir Figure 25).

Lorsque la distance au sommet d'une encoche est supérieure ou égale à 1 mm, il n'y a aucune LIGNE DE FUITE traversant l'espace dans l'air (voir Figure 24).

Les LIGNES DE FUITE et les DISTANCES DANS L'AIR entre des parties mobiles l'une par rapport à l'autre sont mesurées avec ces parties dans leurs positions les moins favorables.

La LIGNE DE FUITE calculée n'est jamais inférieure à la DISTANCE DANS L'AIR mesurée.

Les revêtements en vernis, en émail ou en oxyde sont ignorés. Des revêtements en matériau isolant sont cependant considérés comme constituant une isolation si le revêtement est équivalent à une feuille de matériau isolant d'une épaisseur égale eu égard à ses propriétés électriques, thermiques et mécaniques.

Si les LIGNES DE FUITE ou les DISTANCES DANS L'AIR pour un ou deux moyens de protection sont interrompues par une ou plusieurs parties conductrices flottantes, la valeur minimale spécifiée dans les Tableaux ~~11~~ 12 à 16 (inclus) s'applique à la somme des sections, mais les distances inférieures à 1 mm ne sont pas prises en compte.

S'il y a des encoches transversales par rapport à la LIGNE DE FUITE, la paroi de l'encoche n'est comptée comme LIGNE DE FUITE que si la largeur de l'encoche est supérieure à 1 mm (voir Figure 24). Dans tous les autres cas, l'encoche est négligée.

Dans le cas d'une barrière placée sur la surface de l'isolation encastrée, les LIGNES DE FUITE sont mesurées au dessus de la barrière uniquement si celle-ci est fixée de telle manière que ni la poussière, ni l'humidité ne puissent pénétrer dans le joint ou dans la partie en renfoncement.

Pour les APPAREILS EM équipés d'un SOCLE DE CONNECTEUR, les mesures sont effectuées avec un connecteur approprié inséré. Pour les autres APPAREILS EM incorporant des CABLES D'ALIMENTATION, elles sont réalisées avec des conducteurs d'alimentation de la section la plus importante spécifiée par le FABRICANT et également sans conducteurs.

Les parties mobiles sont placées dans la position la moins favorable ; les écrous et les vis à tête non circulaire sont serrés dans la position la moins favorable.

Les LIGNES DE FUITE et les DISTANCES DANS L'AIR à travers les fentes ou les ouvertures des parties externes sont mesurées par rapport au doigt d'essai normalisé de la Figure 6. Si nécessaire, une force est appliquée en tout point des conducteurs nus et à l'extérieur des

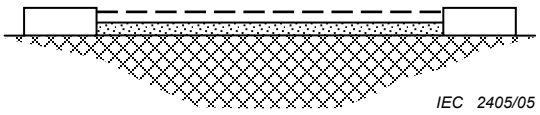
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ENVELOPPES métalliques afin d'essayer de réduire les LIGNES DE FUITE et les DISTANCES DANS L'AIR pendant qu'on les mesure.

La force est appliquée au moyen d'un doigt d'essai normalisé dont l'extrémité est celle représentée à la Figure 6 et qui a une valeur de:

2 N pour les conducteurs nus ;
30 N pour les ENVELOPPES.

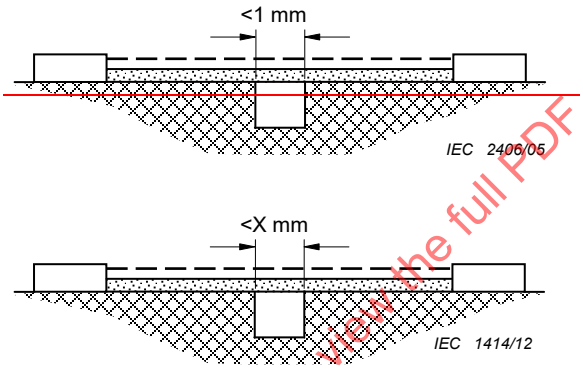
Les LIGNES DE FUITE et les DISTANCES DANS L'AIR sont mesurées après l'utilisation du crochet d'essai selon 5.9.2.2, si cela est applicable.



Condition : Le cheminement considéré est une surface plate.

Règle : La LIGNE DE FUITE et la DISTANCE DANS L'AIR sont mesurées en ligne droite au-dessus de la surface.

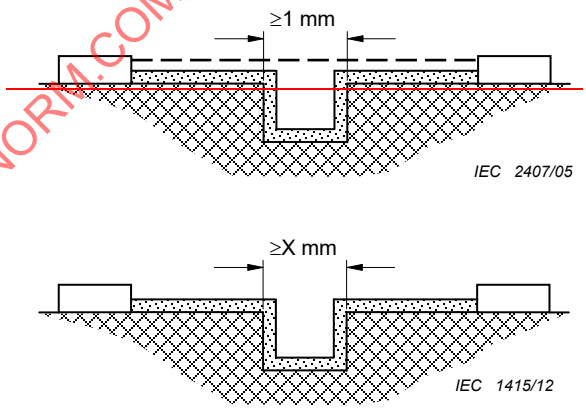
Figure 22 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 1



Condition : Le cheminement considéré comprend une encoche à flancs parallèles ou convergents de profondeur quelconque et de largeur inférieure à ~~1~~ X mm.

Règle : La LIGNE DE FUITE et la DISTANCE DANS L'AIR sont mesurées en ligne droite au-dessus de l'encoche comme indiqué dans la figure.

Figure 23 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 2

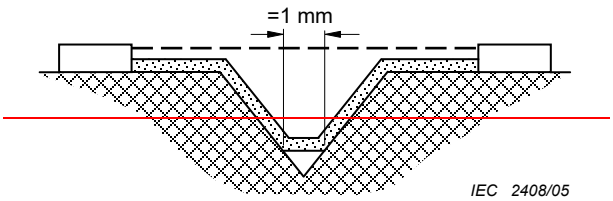


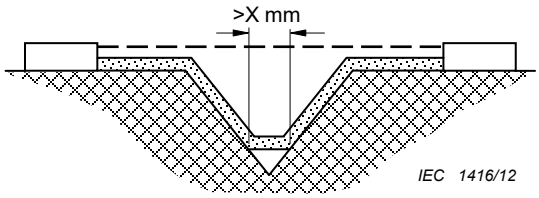
Condition : Le cheminement considéré comprend une encoche à flancs parallèles de profondeur quelconque et de largeur supérieure ou égale à ~~1~~ X mm.

Règle : La DISTANCE DANS L'AIR est la distance “en ligne droite”. Le cheminement de LIGNE DE FUITE longe le profil de l'encoche.

Figure 24 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 3

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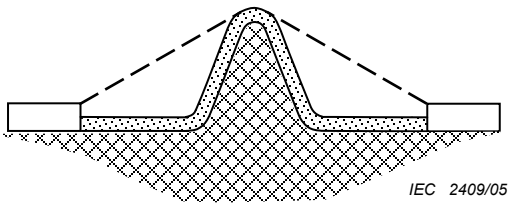




Condition : Le cheminement considéré comprend une encoche en V dont la largeur est supérieure à ~~1~~ X mm et un angle interne de moins de 80 °.

Règle : La DISTANCE DANS L'AIR est la distance “en ligne droite”. Le cheminement de la LIGNE DE FUITE longe le profil de l'encoche mais “court-circuite” le bas de l'encoche par un tronçon de ~~1~~ X mm.

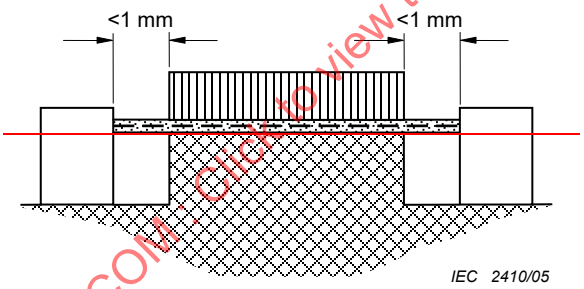
Figure 25 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 4

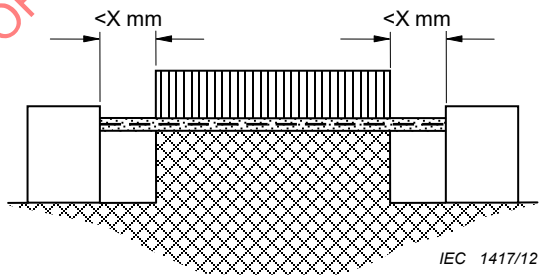


Condition : Le cheminement considéré comprend une nervure.

Règle : La DISTANCE DANS L'AIR est le cheminement dans l'air le plus court par dessus le sommet de la nervure. Le cheminement de LIGNE DE FUITE longe le profil de la nervure.

Figure 26 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 5



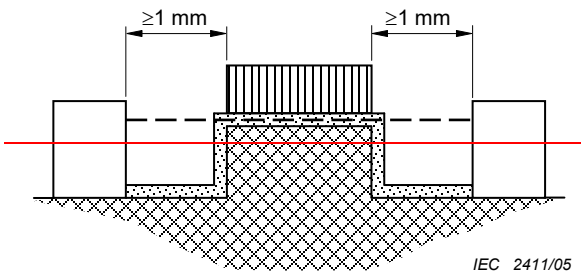


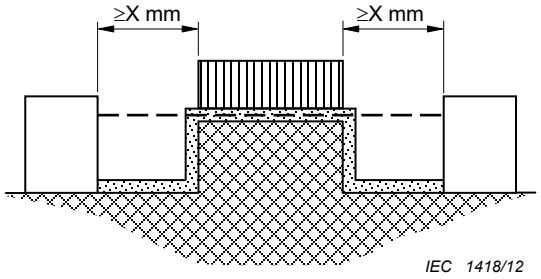
Condition : Le cheminement considéré comprend un joint non collé (voir 8.9.3) avec des encoches de largeur inférieure à ~~1~~ X mm de chaque côté.

Règle : Le cheminement de la LIGNE DE FUITE et de la DISTANCE DANS L'AIR est «la distance en ligne droite» indiquée.

Figure 27 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 6

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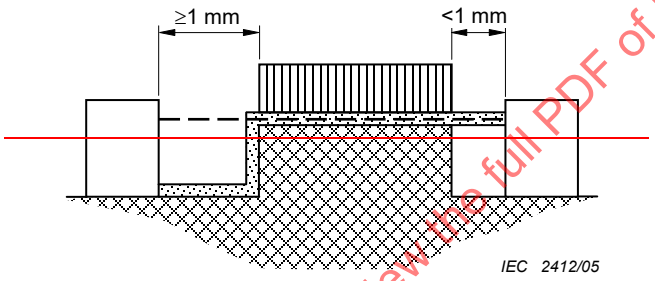


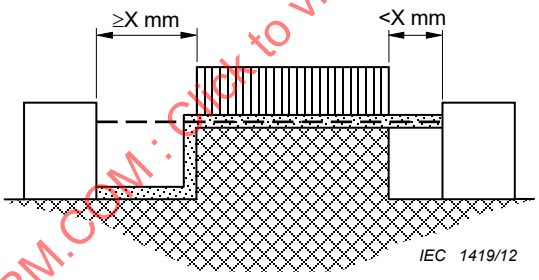


Condition : Le cheminement considéré comprend un joint non collé (voir 8.9.3) avec des encoches de largeur supérieure ou égale à ~~1~~ X mm de chaque côté.

Règle : La DISTANCE DANS L'AIR est la distance “en ligne droite”. Le cheminement de LIGNE DE FUITE longe le profil de l'encoche.

Figure 28 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 7



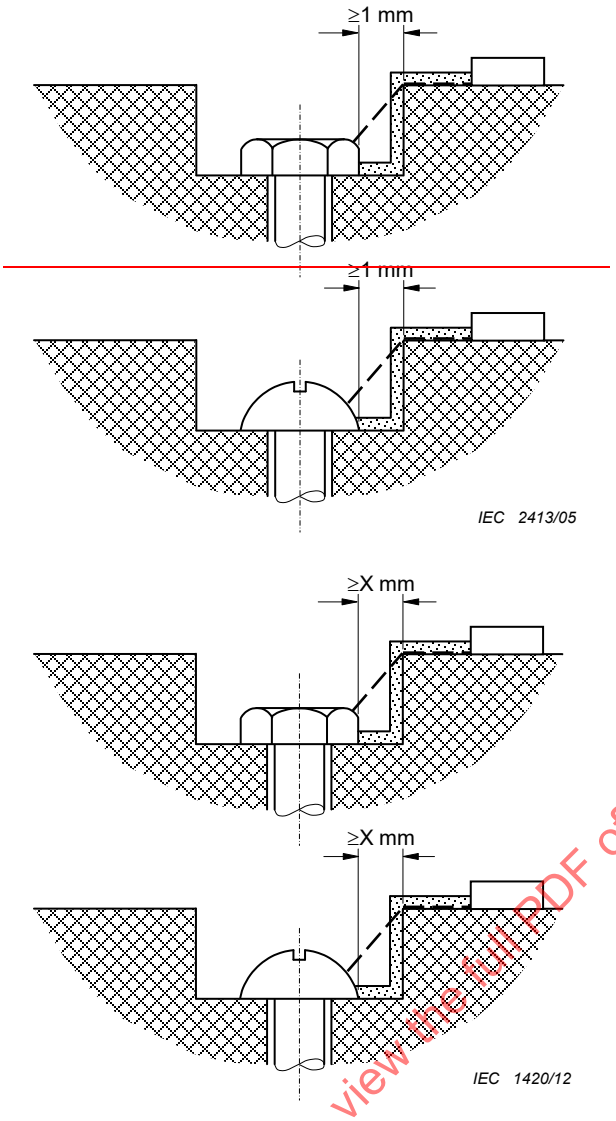


Condition : Le cheminement considéré comprend un joint non collé (voir 8.9.3) avec, d'un côté, une encoche de largeur inférieure à ~~1~~ X mm et, de l'autre côté, une encoche de largeur supérieure ou égale *à* ~~1~~ X mm.

Règle : La DISTANCE DANS L'AIR et la LIGNE DE FUITE sont telles qu'indiquées.

Figure 29 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 8

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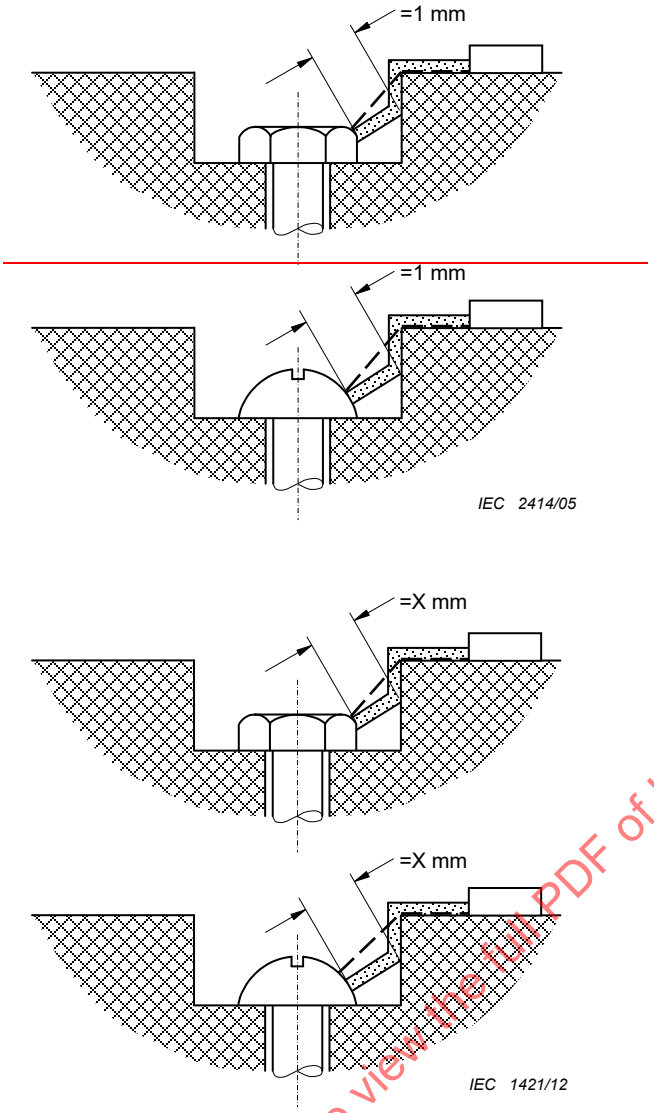


Condition : L'espace entre la tête de la vis et la paroi de l'évidement est assez large pour être pris en compte.

Règle : La DISTANCE DANS L'AIR est la distance la plus courte vers tout point de la tête de vis. Le cheminement de la LIGNE DE FUITE suit la surface.

Figure 30 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 9

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Condition : L'espace entre la tête de la vis et la paroi de l'évidement est trop faible pour être pris en compte.

Règle : Le mesurage de la LIGNE DE FUITE se fait entre la vis et la paroi en tout point où la distance est égale à ~~1~~ X mm. La DISTANCE DANS L'AIR est la distance la plus courte avec tout point de la tête de la vis.

Figure 31 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 10

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8.10 Composants et câblage

8.10.1 * Fixation des composants

Les composants des APPAREILS EM, dont le déplacement involontaire pourrait donner lieu à un RISQUE inacceptable, doivent être correctement fixés pour empêcher de tels déplacements.

La conformité est vérifiée par inspection de l'APPAREIL EM et du DOSSIER DE GESTION DES RISQUES.

8.10.2 * Fixation du câblage

Les conducteurs et les connecteurs des APPAREILS EM doivent être fixés ou isolés de telle manière que leur détachement accidentel n'entraîne pas de SITUATION DANGEREUSE. Ils ne sont pas considérés comme étant fixés de façon adéquate si, se détachant à leur point de raccordement et se déplaçant par rapport à leur point d'ancrage, ils peuvent entrer en contact avec des ~~points du circuit~~ parties et donner lieu à une SITUATION DANGEREUSE décrite en 13.1.

Le détachement d'un moyen de retenue mécanique doit être considéré comme une CONDITION DE PREMIER DEFAUT.

Les conducteurs multibrins ne doivent pas être étamés s'ils sont fixés par un collier quelconque et un contact de mauvaise qualité peut donner lieu à une SITUATION DANGEREUSE décrite en 13.1.

La conformité est vérifiée par ~~examen~~ l'inspection de l'APPAREIL EM ~~et du DOSSIER DE GESTION DES RISQUES~~.

8.10.3 Connexions entre différentes parties de l'APPAREIL EM

Les câbles souples qui peuvent être détachés sans l'aide d'un OUTIL qui sont destinés à l'interconnexion de différentes parties de l'APPAREIL EM doivent être équipés d'organes de raccordement tels que la conformité des PARTIES métalliques ACCESSIBLES avec 8.4 ne soit pas remise en cause lorsqu'un branchement est desserré ou rompu à la suite du retrait de l'un des organes de raccordement.

La conformité est vérifiée par examen et mesurage et, si nécessaire, par un essai avec le doigt d'essai normalisé conforme à 5.9.2.1.

8.10.4 * Dispositifs de commande TENUS A LA MAIN et pédales de commande
(voir aussi 15.4.7)

8.10.4.1 Limitation des tensions de fonctionnement

Les dispositifs de commande TENUS A LA MAIN et les pédales de commande des APPAREILS EM ainsi que leurs câbles de branchement ne doivent comporter que des conducteurs et des composants fonctionnant à des tensions ne dépassant pas 42,4 V en valeur de crête en courant alternatif ou 60 V en courant continu dans les circuits isolés de la PARTIE RELIEE AU RESEAU par deux MOYENS DE PROTECTION. La limite de 60 V en courant continu s'applique au courant continu avec 10 % d'ondulation crête à crête au maximum. Si l'ondulation dépasse cette grandeur, la limite de 42,4 V de crête s'applique.

La conformité est vérifiée par examen et, si nécessaire par des mesurages de la tension.

8.10.4.2 Câbles de raccordement

~~La connexion et le dispositif d'arrêt~~ Le raccordement et l'arrêt de traction aux deux extrémités d'un câble ~~souple à~~ flexible sur un dispositif de commande TENU A LA MAIN ou ~~à~~ une pédale de commande ~~d'un APPAREIL EM au deux extrémités du câble vers ce dispositif~~ de ~~commande~~ l'APPAREIL EM doivent ~~être conformes~~ satisfaire aux exigences spécifiées pour les CABLES D'ALIMENTATION en 8.11.3, si le détachement ou une longueur raccourcie entre les conducteurs peut donner lieu à une SITUATION DANGEREUSE décrite en 13.1. Cette exigence s'applique également aux autres parties TENUES A LA MAIN si la perturbation ou la rupture d'une ou plusieurs des connexions peut être à l'origine d'une SITUATION DANGEREUSE décrite en 13.1.

La conformité est vérifiée en procédant aux essais de 8.11.3.

8.10.5 * Protection mécanique du câblage

a) Les câbles et conducteurs internes doivent être protégés de façon appropriée contre le contact avec un objet mobile ou les frictions contre des coins tranchants et des arêtes vives au cours desquels les dommages subis par l'isolation peuvent donner lieu à une SITUATION DANGEREUSE décrite en 13.1.

b) Les APPAREILS EM doivent être conçus de telle manière que le câblage, les faisceaux ou les composants ne soient pas susceptibles d'être détériorés au cours de l'assemblage ou de l'ouverture ou de la fermeture des CAPOTS D'ACCES lorsque de telles détériorations peuvent donner lieu à une SITUATION DANGEREUSE décrite en 13.1.

La conformité est vérifiée par inspection et, si ~~cela est approprié~~ nécessaire, par un essai manuel ~~ou par référence au DOSSIER DE GESTION DES RISQUES~~.

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8.10.6 Galets de guidage pour conducteurs isolés

Les galets de guidage des conducteurs isolés des APPAREILS EM doivent être construits de telle manière que les conducteurs mobiles isolés en UTILISATION NORMALE ne soient pas pliés sur un rayon inférieur à cinq fois le diamètre extérieur du conducteur concerné.

La conformité est vérifiée par inspection et par le mesurage des dimensions concernées.

8.10.7 * Isolation du câblage interne

a) Si un gainage isolant est nécessaire pour le câblage interne de l'APPAREIL EM, il doit être convenablement fixé. Un gainage qui ne peut être enlevé que par rupture ou coupure ou qui est fixé aux deux extrémités peut être utilisé pour satisfaire cette exigence.

b) A l'intérieur de l'APPAREIL EM, la gaine d'un câble souple ne doit pas être utilisée comme un MOYEN DE PROTECTION si elle est soumise à des contraintes mécaniques ou thermiques hors des limites de ses caractéristiques ASSIGNEES.

c) Les conducteurs isolés des APPAREILS EM qui, en UTILISATION NORMALE, sont soumis à des températures supérieures à 70 °C doivent posséder une isolation en matériau résistant à la chaleur, si la conformité à la présente norme risque d'être compromise par une détérioration de l'isolation.

La conformité est vérifiée par examen et, si nécessaire, par des essais spéciaux. Les températures sont déterminées comme indiqué en 11.1.

8.11 PARTIES RELIEES AU RESEAU, composants et montage

8.11.1 Séparation du RESEAU D'ALIMENTATION

a) * Les APPAREILS EM doivent comporter un dispositif permettant de séparer électriquement leurs circuits du RESEAU D'ALIMENTATION sur tous les pôles simultanément.

Les APPAREILS EM INSTALLES DE FAÇON PERMANENTE qui sont raccordés à un RESEAU D'ALIMENTATION polyphasé peuvent être dotés d'un dispositif n'interrompant pas le neutre sous réserve que les conditions locales d'installation soient telles qu'en CONDITION NORMALE la tension appliquée au neutre ne soit pas censée dépasser les limites spécifiées en 8.4.2 c).

Pour les APPAREILS EM INSTALLES EN PERMANENCE, le moyen permettant d'isoler électriquement ses circuits du RESEAU D'ALIMENTATION doit pouvoir être verrouillé en position de coupure si:

– une reconnexion donnerait lieu à une SITUATION DANGEREUSE; ou
– un OPERATEUR y compris un PERSONNEL D'ENTRETIEN est incapable de voir le moyen d'isolation depuis sa position prévue.

Le mécanisme de verrouillage peut se trouver dans un interrupteur du RESEAU D'ALIMENTATION fourni par l'ORGANISME RESPONSABLE.

Les exigences applicables au dispositif d'isolation doivent être spécifiées dans les DOCUMENTS D'ACCOMPAGNEMENT.

b) Les dispositifs de séparation doivent soit être incorporés dans l'APPAREIL EM soit, s'ils sont externes, être décrits dans la description technique (voir 7.9.3.1).

c) * Un interrupteur de RESEAU D'ALIMENTATION qui est utilisé pour assurer la conformité avec 8.11.1 a) doit respecter les LIGNES DE FUITE et les DISTANCES DANS L'AIR spécifiées dans l'IEC 61058-1 pour une TENSION TRANSITOIRE RESEAU de 4 kV.

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NOTE Le Tableau 22 de l'IEC 61058-1 spécifie différentes valeurs pour la séparation des contacts en fonction de la TENSION TRANSITOIRE RESEAU à laquelle il est fait référence dans le tableau comme "tension de tenue aux chocs assignée".

d) Un interrupteur de RESEAU D'ALIMENTATION ne doit pas être incorporé à un CABLE D'ALIMENTATION ou à tout autre conducteur souple externe.

e) ~~Le sens des mouvements des organes de manœuvre des interrupteurs de RESEAU D'ALIMENTATION qui est utilisé pour assurer la conformité avec 8.11.1 a) doit être conforme à l'IEC 60447.~~ Les organes de manœuvre d'un interrupteur de RESEAU D'ALIMENTATION qui sont utilisés pour assurer la conformité avec 8.11.1 a) doivent être conformes à l'IEC 60447.

f) ~~Sur les APPAREILS EM non INSTALLES DE FAÇON PERMANENTE un dispositif à fiche adapté servant à les séparer du RESEAU D'ALIMENTATION doit être considéré comme conforme aux exigences de 8.11.1 a). Un CONNECTEUR ou un câble souple avec une FICHE RESEAU peut être utilisé.~~ Dans les APPAREILS EM NON INSTALLES EN PERMANENCE ne disposant pas d'un interrupteur DE RESEAU D'ALIMENTATION, un dispositif à fiche adapté utilisé pour isoler l'APPAREIL EM du RESEAU D'ALIMENTATION doit être considéré comme satisfaisant les exigences de 8.11.1 a). Un CONNECTEUR ou un câble flexible avec une FICHE RESEAU peut être utilisé.

g) Les fusibles ou les dispositifs à semi-conducteurs ne doivent pas servir de dispositifs de séparation au sens du présent paragraphe.

h) * LES APPAREILS EM ne doivent pas être pourvus de dispositifs provoquant leur déconnexion du RESEAU D'ALIMENTATION en produisant un court-circuit qui active un dispositif de protection contre les surintensités.

i) * Toute partie située à l'intérieur de l'ENVELOPPE d'un APPAREIL EM comportant une tension de circuit supérieure à 42,4 V en valeur de crête en courant alternatif ou 60 V en courant continu qui ne peut pas être séparée de son alimentation par un interrupteur externe ou un dispositif à fiche accessible à tout moment doit être protégée contre les contacts même après ouverture de l'ENVELOPPE par des capots supplémentaires ou, dans le cas de montages séparés dans l'espace, être marquée clairement comme dépassant la tension autorisée pour les parties qui peuvent être touchées. L'utilisation du symbole ISO 7000-0434 (voir Tableau D.1, symbole 10) n'est pas suffisante. Un avertissement peut être utilisé à l'extérieur de l'APPAREIL EM.

La conformité est vérifiée par inspection.

Dans le cas d'une partie qui ne peut pas être séparée de l'alimentation par un interrupteur externe ou un dispositif à fiche accessible à tout moment, la conformité est vérifiée par examen du capot exigé ou de l'avertissement (le cas échéant) et, si nécessaire, par l'application du doigt d'essai normalisé de la Figure 6.

8.11.2 * SOCLES DE PRISE DE COURANT MULTIPLE

Les SOCLES DE PRISE DE COURANT MULTIPLE qui font partie intégrante de l'APPAREIL EM doivent être conformes aux exigences de 16.2 d), deuxième tiret, et de 16.2.9.1.

La conformité est vérifiée par examen.

8.11.3 Câbles d'alimentation

8.11.3.1 Application

La FICHE RESEAU des APPAREILS EM ne doit pas être reliée à plus d'un CABLE D'ALIMENTATION.

La conformité est vérifiée par inspection.

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8.11.3.2 Types

Tout CABLE D'ALIMENTATION d'APPAREIL EM doit être au moins aussi robuste qu'un câble souple sous gaine caoutchouc ordinaire (IEC 60245-1:2003, Annexe A, désignation 53) ou qu'un câble souple sous gaine de polychlorure de vinyle ordinaire (IEC 60227-1:1993, Annexe A, désignation 53).

Les CABLES D'ALIMENTATION isolés au polychlorure de vinyle ne doivent pas être utilisés pour les APPAREILS EM ayant des parties métalliques extérieures dont la température dépasse 75 °C et pouvant être touchées par le câble en UTILISATION NORMALE, à moins que ce dernier ne soit ASSIGNE pour cette température. Voir aussi le Tableau 22.

La conformité est vérifiée par inspection et par des mesures.

8.11.3.3 Section des conducteurs des CABLES D'ALIMENTATION

La section NOMINALE des conducteurs des CABLES D'ALIMENTATION des APPAREILS EM ne doit pas être inférieure à celle donnée au Tableau 17.

La conformité est vérifiée par inspection.

Tableau 17 – Section NOMINALE des conducteurs d'un CABLE D'ALIMENTATION

Courant ASSIGNE (*I*) d'un APPAREIL EM A	Section NOMINALE mm² Cu
$I \leq 6$	0,75
$6 < I \leq 10$	1
$10< I \leq 16$	1,5
$16< I \leq 25$	2,5
$25< I \leq 32$	4
$32< I \leq 40$	6
$40< I \leq 63$	10

8.11.3.4 * CONNECTEURS D'APPAREILS

Les CONNECTEURS D'APPAREIL qui sont conformes à l'IEC 60320-1 sont considérés comme conformes à 8.11.3.5 et à 8.11.3.6.

La conformité est vérifiée par inspection de la documentation montrant que le CONNECTEUR D'APPAREIL est conforme aux exigences de l'IEC 60320-1.

8.11.3.5 * Dispositif d'arrêt de traction

a) Les conducteurs des CABLES D'ALIMENTATION doivent être protégés contre les contraintes, y compris de torsion, et leur isolation doit être protégée de l'abrasion au point d'entrée dans l'APPAREIL EM ou dans une PRISE RESEAU par un dispositif d'arrêt de traction.

b) Si un défaut d'isolation total du CABLE D'ALIMENTATION fait dépasser les limites spécifiées en 8.4 aux PARTIES ACCESSIBLES conductrices qui ne sont pas PROTEGEES PAR MISE A LA TERRE, les dispositifs d'arrêt de traction d'un CABLE D'ALIMENTATION doivent être:

- en matériau isolant, ou
- en métal, isolés des PARTIES ACCESSIBLES conductrices non PROTEGEES PAR MISE A LA TERRE par un MOYEN DE PROTECTION, ou
- en métal avec un revêtement isolant qui doit être fixé au dispositif d'arrêt de traction, à moins qu'il ne s'agisse d'une traversée souple qui fasse partie du dispositif de

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protection spécifié en 8.11.3.6 et qui doit être conforme aux exigences relatives à un MOYEN DE PROTECTION.

c) Les dispositifs d'arrêt de traction des CABLES D'ALIMENTATION doivent être conçus de sorte que le câble ne soit pas maintenu par une vis qui porte directement sur son isolation.

d) Les vis qui, le cas échéant, doivent être manœuvrées lors du remplacement du CABLE D'ALIMENTATION ne doivent pas servir à fixer d'autres composants que les éléments du dispositif d'arrêt de traction.

e) Les conducteurs du CABLE D'ALIMENTATION doivent être disposés de telle sorte qu'en cas de défaillance du dispositif d'arrêt de traction, le CONDUCTEUR DE TERRE DE PROTECTION ne soit pas soumis à une traction tant que les conducteurs de phase sont en contact avec leurs bornes.

f) Le dispositif d'arrêt de traction doit empêcher que le CABLE D'ALIMENTATION ne soit poussé à l'intérieur de l'APPAREIL EM ou de la PRISE RESEAU.

La conformité est vérifiée par inspection et par les essais suivants:

UN APPAREIL EM, conçu pour un CABLE D'ALIMENTATION, est soumis à l'essai avec le câble fourni par le FABRICANT.

Les conducteurs des CABLES D'ALIMENTATION sont, si possible, débranchés des bornes de raccordement au réseau ou de la PRISE RESEAU.

Le câble doit être soumis 25 fois à une traction appliquée à la gaine, de la valeur indiquée au Tableau 18. Les tractions sont appliquées dans la direction la plus défavorable sans secousses, chaque fois pendant 1 s.

Immédiatement après, le câble est soumis à un couple de la valeur indiquée au Tableau 18 pendant 1 min.

Tableau 18 – Essais des dispositifs d'arrêt de traction

Masse (*m*) de l'APPAREIL EM kg	**Traction** N	**couple** Nm
$m \leq 1$	30	0,1
$1 < m \leq 4$	60	0,25
$m > 4$	100	0,35

Un dispositif d'arrêt de traction qui laisse la gaine du câble se déplacer longitudinalement de plus de 2 mm ou les extrémités des conducteurs se déplacer de plus de 1 mm par rapport à leur position normale de branchement est considéré comme défaillant.

Les LIGNES DE FUITE et les DISTANCES DANS L'AIR qui subissent une réduction en dessous des valeurs spécifiées en 8.9 constituent une situation de défaillance.

Essayer de pousser le câble dans l'APPAREIL EM ou dans la FICHE RESEAU. Si le câble peut être poussé dans l'APPAREIL EM ou dans la FICHE RESEAU de telle manière que le câble ou des parties internes sont endommagées, le dispositif d'arrêt de traction est considéré comme défaillant.

8.11.3.6 * Dispositifs de protection des câbles

Les CABLES D'ALIMENTATION des appareils autres que les APPAREILS EM FIXES doivent être protégés contre les pliages excessifs à l'entrée de l'appareil ou de la PRISE RESEAU à l'aide d'un dispositif de protection en matière isolante ou au moyen d'une ouverture de forme appropriée dans L'APPAREIL EM.

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La conformité est vérifiée par examen et soit par l'essai décrit en 25.14 de l'IEC 60335-1: 2001 soit par l'essai suivant. Un montage qui passe avec succès l'un de ces essais est considéré comme conforme à la présente exigence.

Un APPAREIL EM pourvu d'un dispositif de protection ou d'une ouverture est placé de manière que l'axe du dispositif de protection, au point de sortie du câble, soit orienté avec un angle de 45° au-dessus de l'horizontale lorsque le câble est exempt de contrainte. Une masse égale à 10 x D^2 g est alors attachée à l'extrémité libre du câble, D étant le diamètre extérieur en millimètres ou, pour les câbles méplats, la plus petite dimension du CABLE D'ALIMENTATION en millimètres.

Si le dispositif de protection est dans un matériau sensible à la température, l'essai est réalisé à 23 °C ± 2 °C.

Les câbles méplats sont pliés dans le plan de leur moindre résistance.

Si le rayon de courbure du câble, immédiatement après l'accrochage de la masse, est inférieur à 1,5 x D à un emplacement quelconque, le dispositif de protection est considéré comme défaillant.

8.11.4 DISPOSITIFS DE RACCORDEMENT AU RESEAU

8.11.4.1 * Exigences générales pour les DISPOSITIFS DE RACCORDEMENT AU RESEAU

Les APPAREILS EM INSTALLES DE FAÇON PERMANENTE et les APPAREILS EM équipés d'un CABLE D'ALIMENTATION non FIXE A DEMEURE qui peut être remplacé par le PERSONNEL D'ENTRETIEN doivent être pourvus de DISPOSITIFS DE RACCORDEMENT AU RESEAU qui assurent un raccordement fiable.

On ne doit pas se fier uniquement aux organes de raccordement pour maintenir en place les conducteurs, sauf si des barrières sont prévues de sorte que les LIGNES DE FUITE et les DISTANCES DANS L'AIR qui servent de MOYEN DE PROTECTION ne puissent pas être réduites à des valeurs inférieures à celles spécifiées en 8.9, en cas de rupture d'un des conducteurs. Voir aussi 8.10.2.

Les bornes des composants autres que les répartiteurs peuvent être utilisées comme organes de raccordement des conducteurs externes, si elles sont conformes aux exigences du présent paragraphe et sont marquées correctement, conformément à 7.3.7.

Les vis et les écrous assurant le serrage des conducteurs externes ne doivent pas servir à fixer d'autres éléments ; ils peuvent toutefois serrer des conducteurs internes si ceux-ci sont disposés de façon à ne pas pouvoir se déplacer lors du raccordement des conducteurs d'alimentation.

La conformité est vérifiée par inspection.

8.11.4.2 Agencement des DISPOSITIFS DE RACCORDEMENT AU RESEAU

a) * Pour les APPAREILS EM comportant des câbles démontables, les bornes prévues pour le raccordement de câbles externes ou des CABLES D'ALIMENTATION, y compris toute BORNE DE PROTECTION DE TERRE, doivent être groupées au plus près pour faciliter les raccordements.

La conformité est vérifiée par inspection.

b) Pour les détails de raccordement du CONDUTEUR DE TERRE DE PROTECTION, voir 8.6.

c) Pour le marquage des DISPOSITIFS DE RACCORDEMENT AU RESEAU, voir 7.3.

d) Les DISPOSITIFS DE RACCORDEMENT AU RESEAU ne doivent pas être accessibles sans l'aide d'un OUTIL.

La conformité est vérifiée par inspection.

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e) Les DISPOSITIFS DE RACCORDEMENT AU RESEAU doivent être disposés ou protégés de manière que si un brin d'un conducteur toronné venait à s'échapper quand les conducteurs sont en place, la mise en court-circuit d'un MOYEN DE PROTECTION soit improbable.

La conformité est vérifiée par inspection et, si nécessaire, par l'essai suivant:

Dénuder l'extrémité d'un conducteur souple ayant la section NOMINALE spécifiée au Tableau 17 sur une longueur de 8 mm.

Un brin du conducteur toronné est laissé libre et les autres brins sont fixés dans la borne.

Plier le brin libre dans toutes les directions possibles, sans repousser la gaine isolante, ni faire d'angles aigus aux points de la ligne de séparation.

Tout contact entre ce brin libre et tout autre partie conduisant au court-circuit d'un MOYEN DE PROTECTION constitue une défaillance.

8.11.4.3 Fixation des bornes de raccordement au réseau

Les bornes doivent être FIXEES de sorte que lors du serrage ou du desserrage des moyens de fixation des conducteurs, le câblage interne ne subisse pas de contrainte et que les LIGNES DE FUITE et les DISTANCES DANS L'AIR ne tombent pas en dessous des valeurs spécifiées en 8.9.

La conformité est vérifiée par inspection et par des mesurages après 10 serrages et desserrages d'un conducteur ayant la plus grande section spécifiée.

8.11.4.4 * Connexions aux bornes de raccordement au réseau

Les bornes munis moyens de serrage pour câbles souples démontables ne doivent pas demander de préparation spéciale du conducteur pour réaliser un raccordement correct, et elles doivent être conçues ou situées de sorte que le conducteur ne soit pas endommagé et ne puisse s'échapper lorsque les moyens de serrage sont bloqués. Voir aussi 8.10.2.

La conformité est vérifiée par inspection des bornes et des conducteurs à l'issue de l'essai de 8.11.3.4.

8.11.4.5 Accessibilité du raccordement

L'espace réservé à l'intérieur de l'APPAREIL EM à un câblage FIXE ou à un CABLE D'ALIMENTATION démontable doit être suffisant pour permettre l'introduction et le raccordement aisés des conducteurs et la mise en place des capots éventuels sans dommage pour les conducteurs ou leur isolation. Il doit être possible de vérifier, avant de mettre en place le CAPOT D'ACCES, que les conducteurs sont correctement raccordés et disposés. Voir aussi 8.10.5.

La conformité est vérifiée par inspection et par un essai d'installation.

8.11.5 * Coupe-circuit et DISJONCTEURS

Un fusible ou un DISJONCTEUR doivent être prévus sur chaque conducteur d'alimentation des APPAREILS EM de CLASSE I et de CLASSE II comportant une connexion de terre fonctionnelle selon 8.6.9 et sur au moins un conducteur d'alimentation pour les autres APPAREILS EM monophasés de CLASSE II, mais avec les restrictions suivantes:

– pour les APPAREILS EM INSTALLES DE FAÇON PERMANENTE, le conducteur neutre ne doit pas comporter de coupe-circuit à fusibles;

– si l'examen montre la présence de deux MOYENS DE PROTECTION entre toutes les parties de polarité opposée à l'intérieur de la PARTIE RELIEE AU RESEAU, et entre toutes les parties de la PARTIE RELIEE AU RESEAU et la terre, alors les fusibles ou les DISJONCTEURS peuvent être omis. Ces exigences d'isolation doivent s'appliquer jusqu'à l'intérieur de tout composant. L'effet des conditions de défaut de court-circuit dans d'autres circuits doit être ~~pris en compte~~ VERIFIE avant l'élimination des fusibles ou des DISJONCTEURS.

Un CONDUCTEUR DE TERRE DE PROTECTION ne doit pas comporter de fusible ou de DISJONCTEUR.

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Les dispositifs de protection doivent posséder une capacité de coupure appropriée pour interrompre le courant de défaut maximal (y compris courant de court-circuit) potentiel.

NOTE Si des fusibles conformes à l'IEC 60127[20)] sont utilisés et que le courant de court-circuit prévu dépasse 35 A ou 10 fois les caractéristiques de courant du fusible, en prenant la plus élevée des deux valeurs, il convient que les fusibles aient une capacité de coupure élevée (1 500 A).

La justification de l'omission des fusibles ou des DISJONCTEURS doit être ~~incluse dans le DOSSIER DE GESTION DES RISQUES~~ documentée.

La conformité est vérifiée par l'inspection de l'APPAREIL EM et ~~du DOSSIER DE GESTION DES RISQUES~~ de la documentation du FABRICANT.

8.11.6 Câblage interne de la PARTIE RELIEE AU RESEAU

a) Le câblage interne de la PARTIE RELIEE AU RESEAU entre le DISPOSITIF DE RACCORDEMENT AU RESEAU ou le SOCLE DE CONNECTEUR et les dispositifs de protection ~~ne doivent pas avoir une section inférieure au minimum exigé~~ doit présenter une section non inférieure au minimum requis pour le CABLE D'ALIMENTATION comme spécifié en 8.11.3.3.

La conformité est vérifiée par inspection.

b) La section des autres conducteurs de la PARTIE RELIEE AU RESEAU et les dimensions des pistes sur les circuits imprimés des APPAREILS EM doivent être suffisantes pour éviter tout incendie en cas de courants de défaut potentiels.

Si nécessaire, la conformité est vérifiée en reliant l'APPAREIL EM à un RESEAU D'ALIMENTATION spécifié à partir duquel on peut s'attendre à obtenir le courant de court-circuit le plus défavorable en cas de défaut survenant dans la PARTIE RELIEE AU RESEAU. On simule ensuite un défaut dans une seule isolation de la PARTIE RELIEE AU RESEAU de telle façon que le courant de défaut soit le plus défavorable. Toute apparition d'une SITUATION DANGEREUSE indiquée en 13.1.2 constitue une défaillance.

9 * Protection contre les DANGERS MECANIQUES des APPAREILS EM et SYSTEMES EM

9.1 DANGERS MECANIQUES des APPAREILS EM

Pour les exigences générales concernant la conception et la construction des APPAREILS EM, se reporter à l'Article 4 et à 15.3.

Le Tableau 19 identifie les paragraphes qui traitent des DANGERS MECANIQUES.

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20) Série IEC 60127, *Coupe-circuit miniatures*

Tableau 19 – DANGERS MECANIQUES couverts par le présent article

DANGER MECANIQUE	Couvert par le paragraphe
DANGER d'écrasement	9.2, 9.4 et 9.8
DANGER de cisaillement	9.2 et 9.8
DANGER de coupure ou de séparation	9.2, 9.3 et 9.8
DANGER d'enchevêtrement	9.2
DANGER de piégeage	9.2
DANGER de piqûre ou de perforation	9.2, 9.3 et 9.8
DANGER de friction ou d'abrasion	9.2 et 9.3
DANGER de projections d'objets	9.5
DANGER d'éjection de fluide à haute pression	9.7
DANGER de chute	9.8
DANGER d'instabilité	9.4
DANGER d'impact	9.2 et 9.8
Déplacement et positionnement du PATIENT	9.2 et 9.4
Vibrations et bruit	9.6

9.2 * DANGERS MECANIQUES associés aux parties en mouvement

9.2.1 * Généralités

Les APPAREILS EM comportant des parties en mouvement doivent être conçus, construits et disposés de telle manière que, lorsqu'ils sont INSTALLES CORRECTEMENT et utilisés comme cela est indiqué dans les DOCUMENTS D'ACCOMPAGNEMENT ou en cas de MAUVAIS USAGE RAISONNABLEMENT PREVISIBLE, les RISQUES associés à ces parties en mouvement soient réduits à un niveau acceptable.

Le RISQUE dû au contact avec les parties en mouvement doit être réduit à un niveau acceptable par l'utilisation de mesures de ~~protection~~ MAITRISE DU RISQUE, en gardant à l'esprit la facilité d'accès, la fonction de L'APPAREIL EM, la forme de ces parties, l'énergie et la vitesse du mouvement ainsi que les bénéfices pour le PATIENT.

Le RISQUE RESIDUEL associé aux parties en mouvement est considéré comme acceptable si l'exposition à ce RISQUE est nécessaire pour que L'APPAREIL EM remplisse sa fonction prévue et si les mesures de MAITRISE DU RISQUE ont été mises en œuvre (par exemple, des avertissements). ~~Si après mise en œuvre de toutes les mesures de protection raisonnables, un DANGER persiste, des marquages d'avertissements doivent être apposés sur L'APPAREIL EM ou être donnés dans les instructions d'utilisation.~~

NOTE 1 Les exigences concernant les parties sujettes à l'usure sont données en 15.2.

NOTE 2 Voir l'ISO 14971:2007, paragraphes 6.2 et 6.5.

9.2.2 ZONE DE PIEGEAGE

9.2.2.1 Généralités

Lorsque cela est réalisable, les APPAREILS EM avec une ZONE DE PIEGEAGE doivent satisfaire à l'une ou plusieurs des exigences ci-après:

– espaces tels que spécifiés en 9.2.2.2; ou

– distance de sécurité telles que spécifiées en 9.2.2.3; ou

– PROTECTIONS et autres mesures ~~de protection~~ de MAITRISE DU RISQUE telles que spécifiées en 9.2.2.4; ou

– activation continue comme spécifié en 9.2.2.5.

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Lorsque la mise en œuvre des mesures ~~de protection~~ de MAITRISE DU RISQUE indiquées ci-dessus est incompatible avec L'UTILISATION PREVUE de l'APPAREIL EM ou du SYSTEME EM, le contrôle du mouvement concerné doit être conforme à 9.2.2.6.

9.2.2.2 Espaces

Une ZONE DE PIEGEAGE est considérée ne pas présenter de DANGER MECANIQUE si les espaces de la ZONE DE PIEGEAGE sont conformes aux dimensions spécifiées au Tableau 20.

NOTE En général, il convient d'utiliser les valeurs pour les adultes. Cependant, dans le cas des dispositifs spécialement conçus pour être utilisés avec des enfants, il convient d'appliquer les dimensions données pour eux.

9.2.2.3 Distances de sécurité

Une ZONE DE PIEGEAGE est considérée ne pas présenter de DANGER MECANIQUE si les distances qui la séparent de L'OPERATEUR, du PATIENT et des autres personnes dépasse les valeurs spécifiées dans l'~~ISO 13852~~ ISO 13857:2008. Ces distances sont mesurées à partir des positions prévues de l'OPERATEUR, du PATIENT et des autres personnes se tenant à proximité de l'APPAREIL EM en UTILISATION NORMALE ou en cas de MAUVAIS USAGE RAISONNABLEMENT PREVISIBLE.

9.2.2.4 * BARRIERES et autres mesures de ~~protection~~ MAITRISE DU RISQUE

9.2.2.4.1 Accès aux ZONES DE PIEGEAGE

Une ZONE DE PIEGEAGE est considérée ne pas présenter de DANGER MECANIQUE si les BARRIERES ~~et les~~ ou autres mesures de ~~protection~~ MAITRISE DU RISQUE (par exemple, électromécaniques):

– sont de construction robuste;

– ne sont pas faciles à contourner ou à rendre inopérantes;

– n'introduisent pas de RISQUE supplémentaire inacceptable.

NOTE Les mesures de MAITRISE DU RISQUE (par exemple, électromécaniques) abordées dans ce paragraphe sont destinées à inclure des systèmes de détection de collision ou d'évitement de collision, tels que ceux utilisant une(des) barrière(s) lumineuses et une(des) rétrorégulation(s) similaire(s).

La conformité est vérifiée par les essais applicables définis en 15.3 pour les ENVELOPPES.

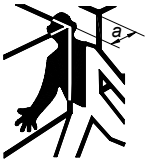
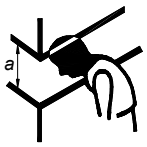
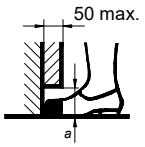
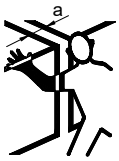
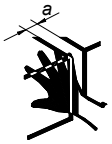
9.2.2.4.2 BARRIERES FIXES

Les BARRIERES FIXES doivent être solidement maintenues en place par des systèmes qui ne peuvent pas être démontés sans l'aide d'un OUTIL.

La conformité est vérifiée par inspection.

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Tableau 20 – Espaces acceptables [a]

Partie du corps	Adulte espace *a* mm	Enfant espace *a* mm	Illustration
Corps	>500	>500	
Tête	>300 ou <120	>300 ou <60	
Jambe	>180	>180	
Pied	>120 ou <35	>120 ou <25	
Orteils	>50	>50	
Bras	>120	>120	
Main, poignet, poing	>100	>100	
Doigt	> 25 ou < 8	> 25 ou < 4	
[a] Les valeurs de ce tableau sont prises dans l'~~ISO 13852:1996~~ ISO 13857:2008.			

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9.2.2.4.3 BARRIERES mobiles

Les BARRIERES mobiles qui peuvent être ouvertes sans l'aide d'un OUTIL:

– doivent rester fixées à L'APPAREIL EM lorsque la BARRIERE est ouverte;

– doivent être associées à un dispositif de verrouillage qui empêche les parties mobiles concernées de commencer à bouger tant que la ZONE DE PIEGEAGE est accessible et qui arrête le mouvement à l'ouverture de la BARRIERE;

– doivent être conçues de telle manière que l'absence ou la défaillance de l'un de leurs composants empêche tout démarrage et arrête les parties en mouvement.

La conformité est vérifiée ~~en réalisant tous les essais applicables et par inspection de l'APPAREIL EM du DOSSIER DE GESTION DES RISQUES~~ par l'inspection de l'APPAREIL EM et en menant les essais applicables.

9.2.2.4.4 Autres mesures de ~~protection~~ MAITRISE DU RISQUE

~~Les mesures de protection doivent être conçues et incorporées au système de contrôle de manière que:~~

~~– les parties mobiles ne puissent se mettre en mouvement tant qu'elles peuvent être atteintes par des personnes;~~

~~– lorsque l'APPAREIL EM a commencé à bouger, la ZONE DE PIEGEAGE ne puisse pas être atteinte ou, si la ZONE DE PIEGEAGE est atteinte, que le mouvement du système soit arrêté. Dans ce dernier cas, il ne doit en résulter ni DANGER ni dommage;~~

~~– un ou plusieurs dispositifs d'arrêt d'urgence équipent L'APPAREIL EM si une CONDITION DE PREMIER DEFAUT de la mesure de protection peut entraîner un RISQUE inacceptable (voir 9.2.4).~~

~~*La conformité est vérifiée par inspection de l'APPAREIL EM et par étude du DOSSIER DE GESTION DES RISQUES.*~~

D'autres mesures de MAITRISE DU RISQUE (par exemple, électromécaniques) doivent être conçues et incorporées au système de contrôle de manière que:

– après que l'APPAREIL EM a commencé à bouger, si la ZONE DE PIEGEAGE est atteinte, le mouvement du système doit s'arrêter; et

– si la mesure de MAITRISE DU RISQUE est vaincue dans une CONDITION DE PREMIER DEFAUT, une seconde mesure de MAITRISE DU RISQUE doit être prévue, comme un ou plusieurs dispositif(s) d'arrêt d'urgence (voir 9.2.4), sinon l'APPAREIL EM doit être SECURISE EN PREMIER DEFAUT (voir 4.7).

La conformité est vérifiée comme suit, si nécessaire:

– *inspection de l'*APPAREIL EM;

– *examen de la construction et des circuits;*

– *conduite des essais applicables, y compris, si nécessaire, les essais en* CONDITION DE PREMIER DEFAUT.

9.2.2.5 * Activation continue

Lorsqu'il est impossible en pratique de rendre la ZONE DE PIEGEAGE inaccessible, ~~celle-ci n'est pas considérée présenter un DANGER MECANIQUE si:~~ il est admis d'utiliser l'activation continue comme une mesure de MAITRISE DU RISQUE.

Une ZONE DE PIEGEAGE n'est pas considérée comme présentant un DANGER MECANIQUE si:

a) Si le mouvement est dans le champ de vision de L'OPERATEUR:

La conformité est vérifiée par inspection.

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b) le mouvement de L'APPAREIL EM ou des ses parties est seulement rendu possible par l'activation continue de la commande par L'OPERATEUR aussi longtemps que la réponse de l'OPERATEUR pour désactiver le dispositif est fiable pour éviter un DOMMAGE;

NOTE Les mouvements opérés manuellement sont également considérés comme satisfaisant au présent article tant que la masse et la vitesse permettent un contrôle adéquat du positionnement sans causer un RISQUE inacceptable.

La conformité est vérifiée par inspection.

c) ~~une ou plusieurs dispositifs d'arrêt d'urgence équipent L'APPAREIL EM dans le cas ou une CONDITION DE PREMIER DEFAUT du système d'activation continue peut entraîner un RISQUE inacceptable (voir 9.2.4).~~

~~*La conformité est vérifiée par inspection de l'APPAREIL EM et par étude du DOSSIER DE GESTION DES RISQUES.*~~

le système d'activation continue est vaincu dans une CONDITION DE PREMIER DEFAUT, une seconde mesure de MAITRISE DU RISQUE doit alors être prévue, comme un ou plusieurs dispositif(s) d'arrêt d'urgence (voir 9.2.4), sinon l'APPAREIL EM doit être SECURISE EN PREMIER DEFAUT (voir 4.7).

La conformité est vérifiée comme suit si nécessaire:

– *inspection de l'*APPAREIL EM;
– *examen de la construction et des circuits;*
– *conduite des essais applicables, y compris, si nécessaire, les essais en* CONDITION DE PREMIER DEFAUT.

9.2.2.6 * Vitesse du ou des mouvements

La vitesse du ou des mouvements qui positionnent des parties de l'APPAREIL EM ou ~~le~~ du PATIENT, lorsqu'un contact avec l'APPAREIL EM peut donner lieu à ~~une SITUATION DANGEREUSE~~ un RISQUE inacceptable, doit être limitée de manière que l'OPERATEUR ait un contrôle adéquat du ~~positionnement sans donner lieu à un RISQUE inacceptable~~ mouvement.

Le dépassement de course (distance d'arrêt) d'un tel mouvement, intervenant après l'actionnement d'une commande pour le stopper, ne doit pas entraîner un RISQUE inacceptable.

~~*La conformité est vérifiée par inspection de l'APPAREIL EM et du DOSSIER DE GESTION DES RISQUES.*~~

La conformité est vérifiée comme suit si nécessaire:

– *inspection des calculs et de l'évaluation du dépassement de course (distance d'arrêt);*
– *tous essais fonctionnels.*

NOTE Les calculs et l'évaluation du dépassement de course (distance d'arrêt) font partie du DOSSIER DE GESTION DES RISQUES.

9.2.3 * Autres DANGERS MECANIQUES associés aux parties en mouvement

9.2.3.1 Mouvement non désiré

Les commandes doivent être positionnées, encastrées ou protégées par d'autres moyens de telle façon qu'elles ne puissent être actionnées accidentellement, ~~en occasionnant un RISQUE INACCEPTABLE, sauf si des considérations ergonomiques propres au PATIENT prévu en décident autrement (par exemple PATIENT présentant des besoins particuliers)~~ sauf si, pour le PATIENT prévu, le PROCESSUS D'INGENIERIE D'APTITUDE A L'UTILISATION conclut autrement (par exemple PATIENT présentant des besoins particuliers) ou si l'activation n'entraîne pas de RISQUE inacceptable.

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La conformité est vérifiée par l'inspection de l'APPAREIL EM et, si le contrôle fait partie des fonctions principales de service, l'inspection du DOSSIER D'INGENIERIE D'APTITUDE A L'UTILISATION.

9.2.3.2 Butées d'extrémité pour dépassement de course

~~Le RISQUE dû au dépassement de la course (au-delà des limites) des parties de L'APPAREIL EM doit être réduit à un niveau acceptable. Des dispositifs de fin de course ou d'autres moyens d'arrêt doivent être fournis pour agir en tant qu'ultime mesure de limitation de course à la fois en CONDITION NORMALE et en CONDITION DE PREMIER DEFAUT.~~

~~De tels moyens doivent avoir la résistance mécanique pour résister aux charges prévues en UTILISATION NORMALE et en cas de MAUVAIS USAGE RAISONNABLEMENT PREVISIBLE.~~

~~*La conformité est vérifiée par inspection de L'APPAREIL EM , du DOSSIER DE GESTION DES RISQUES, des spécifications des matériaux utilisés et des spécifications de mise en œuvre de ces matériaux.*~~

Le dépassement de course au-delà des limites des parties de l'APPAREIL EM doit être empêché. Des butées d'extrémités ou d'autres moyens d'arrêt doivent être fournis pour agir en tant qu'ultime mesure de limitation de course.

De tels moyens doivent avoir la résistance mécanique pour résister aux charges prévues en UTILISATION NORMALE et en cas de mauvais usage raisonnablement prévisible.

La conformité est vérifiée par l'inspection de l'APPAREIL EM et l'essai suivant:

L'APPAREIL EM est:

- *chargé à la CHARGE DE FONCTIONNEMENT EN SECURITE,*
- *déchargé, ou*
- *chargé à tout niveau intermédiaire susceptible de produire le résultat d'essai le plus sévère.*

La partie mobile doit être entraînée contre chaque butée d'extrémité ou autre moyen mécanique pour le nombre de cycles, la vitesse de fonctionnement et les conditions d'essai tels que spécifiés dans le Tableau 33. Les butées d'extrémité ou autres moyens mécaniques requis doivent être capables d'exécuter leur fonction prévue à la fin de l'essai.

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Tableau 33 – Conditions d'essai pour l'essai des butées d'extrémité pour dépassement de course

Construction	Nombre de cycles	Condition d'essai
1. Commande par moteur: Pas de système de limitation de plage prévu [a]	6 000	Entraînement à la vitesse maximale
2. Commande par moteur: Un ou des systèmes de limitation de plage non indépendants[a, b] prévus	50	Mise en défaut de tous les commutateurs simultanément, et entraînement à la vitesse maximale
3. Commande par moteur: Deux ou plusieurs systèmes de limitation de plage indépendants[a, b]	1	Mise en défaut de tous les commutateurs simultanément, et entraînement à la vitesse maximale
4. Commande manuelle ou commande manuelle assistée	50	Entraînement à une vitesse quelconque, y compris un mauvais usage raisonnablement prévisible

[a] Un système de limitation de plage comprend tous les composants requis pour arrêter le mouvement, par exemple, il peut consister en (1) un commutateur de limitation, (2) des circuits capteurs, et (3) un mécanisme d'actionnement mécanique correspondant.

[b] Pour qu'il puisse être qualifié de système de limitation de plage indépendant, chaque système doit, en plus des critères indiqués dans la note[a], être en conformité avec les deux points suivants:

1. le système est capable de mettre hors tension le(les) moteur(s) directement; c'est-à-dire, le commutateur ou le circuit de commande du moteur interrompt le courant du rotor ou du stator du moteur, ou des deux, et
2. le système fournit un moyen par lequel un dysfonctionnement d'un système de limitation de plage devient manifeste pour l'OPERATEUR. Ce peut être un signal sonore, un voyant lumineux ou tout autre indicateur discernable.

9.2.4 * Dispositifs d'arrêt d'urgence

Dans les cas où il est considéré comme nécessaire de disposer d'un ou de plusieurs dispositifs d'arrêt d'urgence, le dispositif d'arrêt d'urgence doit satisfaire à toutes les exigences suivantes.

a) Le dispositif d'arrêt d'urgence doit réduire le RISQUE à un niveau acceptable.

b) La proximité et la réponse de L'OPERATEUR pour actionner le dispositif d'arrêt d'urgence sont fiables pour éviter un DOMMAGE.

c) L'organe de commande du dispositif d'arrêt d'urgence doit être facilement accessible à l'OPERATEUR.

d) Les dispositifs d'arrêt d'urgence ne doivent pas être utilisés dans le fonctionnement normal de L'APPAREIL EM.

e) Le fonctionnement d'un moyen d'arrêt ou d'un arrêt d'urgence ne doit ni introduire de DANGER supplémentaire ni interférer avec l'ensemble de l'opération nécessaire pour éliminer le DANGER MECANIQUE initial.

f) Les dispositifs d'arrêt d'urgence doivent être en mesure de couper le courant correspondant à la pleine charge du circuit concerné, en tenant compte des éventuels courants de moteurs calés et autres conditions similaires.

g) Les organes d'arrêt des mouvements doivent agir à la suite d'une seule action.

h) Le dispositif d'arrêt d'urgence doit posséder un organe de manœuvre de couleur rouge conçu pour être distingué et être facilement identifiable parmi ceux des autres commandes.

i) Un organe de commande qui interrompt/relâche des mouvements mécaniques doit être marqué directement du symbole IEC 60417-5638 (~~DB:~~2002-10) (voir Tableau D.1, symbole 18) ou du mot "STOP " ou alors ces marquages doivent lui être adjacents.

NOTE Si l'organe de commande est un interrupteur qui coupe toute l'énergie, la conformité avec le marquage donné ci-dessus n'est pas exigée.

j) Une fois actionné, le dispositif d'arrêt d'urgence doit maintenir L'APPAREIL EM en condition désactivée jusqu'à ce qu'une action délibérée, différente de celle utilisée pour l'actionner, soit réalisée.

k) Il doit être montré que le dispositif d'arrêt d'urgence est adapté à son application.

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La conformité est vérifiée par l'inspection de l'APPAREIL EM et du DOSSIER DE GESTION DES RISQUES, et par des essais fonctionnels.

9.2.5 * Dégagement du PATIENT

Des moyens doivent être fournis pour permettre le dégagement rapide et en toute sécurité du PATIENT en cas de panne de l'APPAREIL EM ou de coupure de l'alimentation électrique (voir 11.8), d'activation d'une mesure de ~~protection~~ MAITRISE DU RISQUE ou d'un arrêt d'urgence. Les éléments suivants doivent faire l'objet d'une attention particulière:

– Tout mouvement incontrôlé ou non désiré de l'APPAREIL EM qui peut occasionner un RISQUE inacceptable doit être empêché.

– Toute situation où le PATIENT est soumis à des RISQUES inacceptables dus à la proximité de parties en mouvement, à la suppression des voies de sortie normales ou à d'autres DANGERS doit être empêchée.

– Lorsque, après le retrait de parties ayant un contrepoids, d'autres parties de l'APPAREIL EM peuvent bouger de manière dangereuse, des mesures doivent être prévues pour réduire le RISQUE à un niveau acceptable.

La conformité est vérifiée par l'inspection de l'APPAREIL EM et du DOSSIER DE GESTION DES RISQUES, et par des essais fonctionnels.

9.3 * DANGER MECANIQUE associé aux surfaces, angles et arêtes

On doit éviter ou recouvrir les surfaces rugueuses, les angles vifs et les arêtes des APPAREILS EM qui peuvent causer ~~un RISQUE inacceptable~~ des blessures ou des dommages.

Une attention particulière doit être accordée aux arêtes des brides ou des bâtis ainsi qu'à l'ébavurage.

La conformité est vérifiée par l'inspection de l'APPAREIL EM ~~et du DOSSIER DE GESTION DES RISQUES~~.

NOTE 1 Si l'inspection est insuffisante pour déterminer la netteté des arêtes ou des bavures, la justification de 9.3 fournit une référence pour un essai fonctionnel optionnel.

NOTE 2 Un DANGER MECANIQUE lié à un angle vif pourrait couper l'isolation d'un fil, ce qui pourrait entraîner un DANGER électrique. Cette exigence est destinée à couvrir tous ces DANGERS.

9.4 * DANGERS d'instabilité

9.4.1 Généralités

~~Les APPAREILS EM, autres que les APPAREILS EM FIXES et les APPAREILS EM TENUS A LA MAIN, destinés à être placés sur une surface telle qu'un plancher ou une table ne doivent pas basculer ou bouger de manière inattendue au point de pouvoir présenter un RISQUE inacceptable pour le PATIENT, l'OPERATEUR ou toute autre personne.~~

~~NOTE Dans ce paragraphe, on entend par transport le déplacement des APPAREILS EM d'une pièce à une autre au cours de L'UTILISATION NORMALE.~~

Un APPAREIL EM et ses parties, autre qu'un APPAREIL EM FIXE, destiné à être placé sur une surface telle qu'un sol ou une table en UTILISATION NORMALE, ne doit pas basculer (se renverser) ni bouger de façon non désirée.

NOTE Des parties TENUES A LA MAIN d'un APPAREIL EM FIXE sont destinées à être soumises à l'essai.

La conformité est vérifiée en réalisant les essais de 9.4.2 à 9.4.4 (inclus). Chaque essai est réalisé séparément.

9.4.2 * Basculement dû à l'instabilité

9.4.2.1 Instabilité en position de transport

Un APPAREIL EM ou ses parties ne doivent pas basculer lorsqu'ils sont placés dans une position quelconque de transport en UTILISATION NORMALE, sur un plan incliné à 10° par rapport au plan horizontal.

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NOTE Dans ce paragraphe, on entend par transport le déplacement des APPAREILS EM d'une pièce à une autre au cours de L'UTILISATION NORMALE.

La conformité est vérifiée par l'essai suivant:

Avant l'essai, l'APPAREIL EM est préparé comme indiqué dans les DOCUMENTS D'ACCOMPAGNEMENT (ou, en l'absence de spécification, comme indiqué en 9.4.2.2). L'APPAREIL EM ou ses parties sont placé) sur un plan incliné à 10° par rapport au plan horizontal. Si l'APPAREIL EM ou ses parties basculent, cela constitue une défaillance.

9.4.2.2 Instabilité à l'exclusion ~~du~~ de la position de transport

Un APPAREIL EM ou ses parties ne doit/doivent pas basculer lorsqu'ils sont placés dans une quelconque position d'UTILISATION NORMALE, à l'exclusion des positions de transport, sur un plan incliné à 5° par rapport au plan horizontal.

Si un APPAREIL EM ou ses parties basculent lorsqu'ils sont placés dans une quelconque position d'UTILISATION NORMALE, à l'exclusion de toute position de transport, sur un plan incliné selon un angle de 10° par rapport au plan horizontal, ils doivent porter un avertissement indiquant qu'il convient que le transport ne soit réalisé que dans une certaine condition qui doit être clairement décrite dans les instructions d'utilisation ou qui doit faire l'objet d'un marquage sur l'APPAREIL EM avec une indication du RISQUE RESIDUEL si l'APPAREIL EM ou ses parties basculent.

NOTE Pour les exigences concernant les avertissements, voir 7.9.2.2.

La conformité est vérifiée par l'essai suivant:

Avant de conduire l'essai, l'APPAREIL EM est préparé comme suit:

a) L'APPAREIL EM est équipé de tous les connecteurs de raccordement spécifiés: CABLE D'ALIMENTATION et tout cordon d'interconnexion. Il est équipé avec la combinaison la moins favorable de parties amovibles possibles, d'ACCESSOIRES et avec la charge spécifiée en UTILISATION NORMALE.

b) L'APPAREIL EM qui possède un SOCLE DE CONNECTEUR est équipé du CABLE D'ALIMENTATION NON FIXE A DEMEURE spécifié.

c) Les connecteurs de raccordement sont posés sur le plan incliné dans la position la plus défavorable pour la stabilité.

d) Les roulettes/roues éventuelles sont immobilisées temporairement, si nécessaire en les bloquant, dans leur position la plus défavorable.

e) Les portes, les tiroirs, les tablettes et les parties similaires sont placés dans la position la plus défavorable et complètement chargés ou déchargés selon le cas qui est le plus défavorable comme spécifié en UTILISATION NORMALE selon les DOCUMENTS D'ACCOMPAGNEMENT.

f) L'APPAREIL EM comportant des réservoirs pour les liquides est soumis aux essais avec ces réservoirs complètement ou partiellement vides ou remplis, en choisissant l'option la moins favorable.

g) L'APPAREIL EM n'est pas raccordé au RESEAU D'ALIMENTATION.

La surface du plancher d'essai doit être dure et plate (par exemple sol en béton recouvert d'un matériau en vinyle de 2 mm à 4 mm d'épaisseur).

L'APPAREIL EM ou les parties de l'APPAREIL EM sont placés sur un plan incliné à 10° par rapport au plan horizontal, ou, s'il y a un avertissement, la conformité est vérifiée par examen de l'avertissement et l'APPAREIL EM et ses parties sont placées sur un plan incliné à 5° par rapport au plan horizontal. Si l'APPAREIL EM ou ses parties basculent), cela constitue une défaillance.

9.4.2.3 Instabilité due à des forces horizontales et verticales

~~a) Les APPAREILS EM, d'une masse d'au moins 25 kg, autres que les APPAREILS EM FIXES qui sont destinés à être utilisés sur le sol ne doivent pas basculer si on les pousse, si on s'appuie ou si on se repose sur eux, etc.~~

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~~Les surfaces des APPAREILS EM pour lesquelles il existe un RISQUE de basculement de l'appareil si une personne les pousse, s'appuie ou se repose sur elles etc., doivent porter un marquage permanent avec un avertissement CLAIREMENT LISIBLE concernant ce RISQUE, par exemple en utilisant le signe de sécurité ISO 7010-P017 (voir Tableau D.2, signe de sécurité 5).~~

~~*La conformité est vérifiée par inspection et par l'essai suivant:*~~

~~*Avant de conduire l'essai, l'APPAREIL EM est préparé comme décrit en 9.4.2.2. L'APPAREIL EM est placé sur un plan horizontal et une force égale à 25 % de son poids, mais de 220 N au plus, est appliquée dans toute direction, sauf vers le haut. Sauf marquage contraire, la force est appliquée en tout point de l'APPAREIL EM mais pas à plus de 1,5 m du sol. On empêche l'APPAREIL EM de glisser sur le sol à l'aide d'une butée horizontale, ne dépassant pas 20 mm de haut, qui est fixée à plat sur le sol. Si l'application de la force d'essai donne lieu à un mouvement latéral de l'APPAREIL EM, augmenter la hauteur de la butée du minimum nécessaire pour empêcher tout mouvement latéral. Si l'APPAREIL EM bascule, cela constitue une défaillance.~~

~~b) Les APPAREILS EM, autres que les APPAREILS EM FIXES, qui sont destinés à être utilisés au sol ou sur une table, ne doivent pas basculer si une personne s'assoit ou monte sur eux sauf si un avertissement clair concernant ce RISQUE est fourni sur L'APPAREIL EM, par exemple en utilisant les signes de sécurité ISO 7010-P018 ou ISO 7010-P019 selon le cas (voir Tableau D.2, signes de sécurité 6 et 7).~~

~~NOTE Les exigences concernant les surfaces de support PATIENT sont données en 9.8.3.~~

~~*La conformité est vérifiée par inspection et par l'essai suivant:*~~

~~*Avant de conduire l'essai, l'APPAREIL EM est préparé comme décrit en 9.4.2.2. L'APPAREIL EM est placé sur un plan horizontal et une force constante de 800 N dirigée vers le bas est appliquée au point du moment maximal de toute surface de travail d'une aire minimale de 20 cm par 20 cm située à une hauteur ne dépassant pas 1 m du sol, offrant un appui évident pour le repose-pied ou une surface pour s'asseoir, à l'exclusion des surfaces de support PATIENT. Le basculement constitue une défaillance.~~

a) * UN APPAREIL EM ou ses parties ayant une masse égale ou supérieure à 25 kg, autre qu'un APPAREIL EM FIXE, qui est destiné à être utilisé au sol doit être marqué de façon permanente avec un avertissement CLAIREMENT LISIBLE concernant ce RISQUE, par exemple au moyen d'un signe de sécurité ISO 7010-P017 (voir Tableau D.2, signe de sécurité 5), ou bien il ne doit pas basculer lorsqu'on le pousse, l'incline ou le pose, etc.

Si un marquage est prévu parce que l'APPAREIL EM bascule, le marquage doit être visible en UTILISATION NORMALE mais ne doit pas se trouver sur les surfaces sur lesquelles une poussée est associée à une UTILISATION NORMALE (par exemple les surfaces comportant des poignées).

La conformité est vérifiée par l'inspection du marquage fourni ou au moyen de l'essai suivant.

Avant de conduire l'essai, l'APPAREIL EM est préparé comme décrit en 9.4.2.2. L'APPAREIL EM est placé sur un plan horizontal et une force égale à 15 % de son poids, mais de 150 N au plus, est appliquée dans toute direction, sauf vers le haut. Sauf marquage contraire, la force est appliquée en tout point de l'APPAREIL EM mais pas à plus de 1,5 m du sol. On empêche l'APPAREIL EM de glisser sur le sol à l'aide d'une butée horizontale, ne dépassant pas 20 mm de haut, qui est fixée à plat sur le sol. Si l'application de la force d'essai donne lieu à un mouvement latéral de l'APPAREIL EM, augmenter la hauteur de la butée du minimum nécessaire pour empêcher tout mouvement latéral. Un APPAREIL EM sans marquage ne doit pas basculer.

b) Un APPAREIL EM ou ses parties, autre qu'un APPAREIL EM FIXE, qui est destiné à être utilisé sur le sol ou sur une table, doit être marqué de façon permanente avec un avertissement CLAIREMENT LISIBLE concernant ce RISQUE, par exemple au moyen de signes de sécurité

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ISO 7010-P018 ou ISO 7010-P019 le cas échéant (voir Tableau D.2, signes de sécurité 6 et 7), ou bien il ne doit pas basculer si l'on s'assied ou si l'on marche dessus.

NOTE Les exigences concernant les surfaces de support PATIENT sont données en 9.8.3.

Lorsqu'un marquage est prévu du fait que l'APPAREIL EM bascule, le marquage doit être visible en cas de mauvaise utilisation consistant à marcher ou à s'asseoir dessus.

La conformité est vérifiée par l'inspection du marquage fourni ou au moyen de l'essai suivant:

Avant de conduire l'essai, l'APPAREIL EM est préparé comme décrit en 9.4.2.2. L'APPAREIL EM est placé sur un plan horizontal et une force constante de 800 N dirigée vers le bas est appliqué au point du moment maximal de toute surface de travail d'une aire minimale de 20 cm par 20 cm située à une hauteur ne dépassant pas 1 m du sol, offrant un appui évident pour le repose-pied ou une surface pour s'asseoir, à l'exclusion des surfaces de support PATIENT. Un APPAREIL EM sans marquage ne doit pas basculer.

9.4.2.4 * Roulettes et roues

9.4.2.4.1 Généralités

Les moyens utilisés pour déplacer les APPAREILS EM MOBILES, à savoir les roulettes ou les roues, ne doivent pas donner lieu à un RISQUE inacceptable, lorsque L'APPAREIL EM MOBILE est déplacé ou rangé en UTILISATION NORMALE.

9.4.2.4.2 Force de propulsion

La force nécessaire pour déplacer un APPAREIL EM mobile le long d'une surface dure et lisse ne doit pas dépasser 200 N, sauf si les instructions d'utilisation mentionnent que plus d'une personne est nécessaire.

La conformité est vérifiée en plaçant l'APPAREIL EM sur un sol horizontal plat et dur (par exemple un sol en béton recouvert d'un matériau de revêtement de sol en vinyle de 2 mm à 4 mm d'épaisseur) et en mesurant la force nécessaire pour propulser L'APPAREIL EM à une vitesse de 0,4 m/s ± 0,1 m/s. La force est appliquée à une hauteur de 1 m du sol ou au point le plus élevé sur L'EQUIPEMENT EM si sa hauteur est inférieure à 1 m.

9.4.2.4.3 * Franchissement d'un seuil

~~Les APPAREILS EM mobiles d'un poids supérieur à 45 kg doivent pouvoir franchir un seuil de 20 mm. Le fait de franchir un seuil de 20 mm de haut ne doit pas donner lieu à un RISQUE inacceptable.~~

~~*La conformité est vérifiée par l'essai suivant:*~~

~~*L'APPAREIL EM est mis en position de transport avec toutes les CHARGES DE FONCTIONNEMENT EN SECURITE comme indiqué dans les DOCUMENTS D'ACCOMPAGNEMENT. L'APPAREIL EM est déplacé comme en UTILISATION NORMALE 10 fois vers l'avant sur un obstacle plan vertical solide (avec montée et descente) de section rectangulaire, de 20 mm de haut et 80 mm de large qui est fixé à plat sur le sol. Toutes les roues et roulettes doivent heurter l'obstacle à une vitesse de 0,4 m/s ± 0,1 m/s pour les APPAREILS EM MOBILES manuels ou pour les APPAREILS EM MOBILES à moteur, à la vitesse maximale pouvant être maintenue.*~~

~~*Il est inacceptable que l'APPAREIL EM ne puisse passer par-dessus l'obstacle (en raison d'un diamètre de roue trop faible, par exemple). Le basculement ou tout RISQUE inacceptable constitue une défaillance.*~~

~~*Un RISQUE inacceptable est déterminé par examen de l'APPAREIL EM, de ses parties et du DOSSIER DE GESTION DES RISQUES.*~~

~~NOTE Comme exemples de dommages pouvant donner lieu à un RISQUE inacceptable, on peut citer la réduction des LIGNES DE FUITE et des DISTANCES DANS L'AIR en dessous des valeurs indiquées en 8.9, l'accès à des parties qui dépassent les limites de 8.4 ou l'accès à des parties en mouvement qui pourraient causer des DOMMAGES.~~

~~Parmi les critères qui peuvent être utiles pour déterminer si cet essai a donné lieu à un RISQUE inacceptable:~~

~~– ceux des Articles 9 et de 11.6;~~

~~– l'essai de tension de tenue tel qu'il est spécifié en 8.8.3 pour évaluer l'intégrité des ISOLATIONS solides SUPPLEMENTAIRE ET RENFORCEE;~~

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~~– la mesure des LIGNES DE FUITE et des DISTANCES DANS L'AIR pour comparer les valeurs avec les distances minimales spécifiées en 8.9. Les petits éclats qui n'entament pas la protection contre les chocs électriques ou l'humidité peuvent normalement être ignorés.~~

Les APPAREILS EM MOBILES *d'un poids supérieur à 45 kg doivent pouvoir franchir un seuil de 10 mm. Le franchissement d'un seuil de 10 mm ne doit pas entraîner de basculement.*

La conformité est vérifiée par l'essai suivant:

L'APPAREIL EM est mis en position de transport avec toutes les CHARGES DE FONCTIONNEMENT EN SECURITE comme indiqué dans les DOCUMENTS D'ACCOMPAGNEMENT. L'APPAREIL EM est déplacé comme en UTILISATION NORMALE 10 fois vers l'avant sur un obstacle plan vertical solide (avec montée et descente) qui est fixé à plat sur le sol. L'obstacle doit présenter une section rectangulaire de 10 mm ± 0,5 mm de haut et d'au moins 80 mm de large et un rayon de 2 mm ± 0,1 mm aux arêtes supérieures. Le procédé de passage sur l'obstacle doit être appliqué conformément aux instructions des DOCUMENTS D'ACCOMPAGNEMENT ou, si aucune instruction n'est donnée, selon l'essai suivant.

Toutes les roues et roulettes doivent heurter l'obstacle à une vitesse de 0,8 m/s ± 0,1 m/s pour un APPAREIL EM MOBILE manuel ou, pour un APPAREIL EM MOBILE à moteur, à la vitesse maximale qu'il est possible de conserver. Un APPAREIL EM MOBILE manuel est poussé par une force agissant au niveau de sa poignée.

Il est inacceptable que l'APPAREIL EM ne puisse pas passer par-dessus l'obstacle (en raison d'un diamètre de roue trop faible par exemple). Le basculement constitue une défaillance. La SECURITE DE BASE et les PERFORMANCES ESSENTIELLES doivent être conservées.

NOTE Des exemples de dommages pouvant affecter la SECURITE DE BASE comprennent la réduction des LIGNES DE FUITE et des DISTANCES DANS L'AIR en dessous des valeurs spécifiées en 8.9, l'accès à des parties qui dépassent les limites indiquées en 8.4, ou l'accès à des parties mobiles qui pourraient causer un DOMMAGE.

Les critères d'évaluation qui peuvent être utiles pour déterminer si cet essai a conduit à une perte de la SECURITE DE BASE comprennent:

– ceux de l'Article 8 et de 11.6;

– l'essai de tension de tenue de 8.8.3 pour évaluer l'intégrité de l'isolation solide constituant un MOYEN DE PROTECTION; et

– la mesure des LIGNES DE FUITE ou des DISTANCES DANS L'AIR pour comparer les valeurs avec les distances minimales spécifiées en 8.9. Les petits éclats qui n'entament pas la protection contre les chocs électriques ou l'humidité peuvent normalement être ignorés.

9.4.3 * Instabilité provoquée par un mouvement latéral involontaire (y compris un glissement)

9.4.3.1 Instabilité ~~pendant le~~ dans la position de transport

a) Les freins des APPAREILS EM MOBILES motorisés doivent être conçus de telle manière qu'ils soient normalement activés et qu'ils ne puissent être relâchés que par une activation continue de leur commande.

La conformité est vérifiée par inspection.

b) Un APPAREIL EM MOBILE doit être équipé de dispositifs (tels que des dispositifs de blocage) pour empêcher tout déplacement involontaire de l'APPAREIL EM ou de ses parties en position de transport.

La conformité est vérifiée par inspection.

c) ~~Un APPAREIL EM MOBILE qui est destiné à être utilisé sur le sol ne doit pas créer de RISQUE inacceptable dû à un mouvement latéral involontaire.~~

* L'APPAREIL EM MOBILE doit être équipé de dispositifs de blocage des roues ou d'un système de freinage pour empêcher un mouvement non désiré sur une surface inclinée de 10° en position de transport.

La conformité est vérifiée par l'essai suivant:

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Avant de conduire l'essai, l'APPAREIL EM est préparé comme décrit en 9.4.2.2. L'APPAREIL EM MOBILE est placé dans sa position de transport (ou dans la position la plus défavorable en UTILISATION NORMALE) avec la CHARGE DE FONCTIONNEMENT EN SECURITE en place et avec le dispositif de verrouillage activé (par exemple des freins), sur un plan incliné à 10° par rapport au plan horizontal. Si des roulettes sont incorporées, elles sont positionnées de la manière la plus défavorable. A la suite du mouvement élastique initial, du fluage initial et du pivotement initial des roulettes, tout autre déplacement de l'APPAREIL EM MOBILE supérieur à 50 mm (en relation avec le plan incliné) constitue une défaillance. ~~Le RISQUE dû à tout mouvement initial est évalué en tenant compte l'UTILISATION NORMALE de l'APPAREIL EM.~~

9.4.3.2 Instabilité à l'exclusion ~~du déplacement~~ de la position de transport

a) ~~Les APPAREILS EM MOBILES doivent être équipés de dispositifs de blocage des roues ou d'un système de freinage appropriés aux modes d'utilisation prévus et suffisant pour assurer qu'un mouvement non désiré est empêché sur une surface inclinée à 5°.~~
L'APPAREIL EM MOBILE doit être équipé de dispositifs de blocage des roues ou d'un système de freinage pour empêcher un mouvement non désiré sur une surface inclinée de 5° lorsqu'il se trouve dans toute position à l'exclusion de la position de transport.

La conformité est vérifiée par l'essai suivant:

Avant de conduire l'essai, l'APPAREIL EM est préparé comme décrit en 9.4.2.2. L'APPAREIL EM MOBILE avec la CHARGE DE FONCTIONNEMENT EN SECURITE est placé sur une surface plate dure inclinée selon un angle de 5° par rapport au plan horizontal avec les blocages des roues ou le système de freinage activés. A la suite du mouvement élastique initial, le fluage initial et le pivotement initial des roulettes, tout autre déplacement de l'APPAREIL EM MOBILE supérieur à 50 mm (en relation avec le plan incliné) constitue une défaillance. ~~Le RISQUE dû à tout mouvement initial est évalué en tenant compte l'UTILISATION NORMALE de l'APPAREIL EM.~~

b) ~~Un APPAREIL EM TRANSPORTABLE ou un APPAREIL EM FIXE qui est destiné à être utilisé sur le sol ne doit pas donner lieu à un RISQUE inacceptable dû à un mouvement latéral intempestif.~~ L'APPAREIL EM MOBILE doit être équipé de dispositifs de blocage des roues ou d'un système de freinage pour empêcher un mouvement non désiré provenant de forces latérales.

La conformité est vérifiée par l'essai suivant:

Avant de conduire l'essai, l'APPAREIL EM est préparé comme décrit en 9.4.2.2. L'APPAREIL EM est placé sur un plan horizontal avec la CHARGE DE FONCTIONNEMENT EN SECURITE en place et le dispositif de blocage (par exemple les freins) activé. Si des roulettes sont incorporées, elles sont positionnées de la manière la plus défavorable. Une force égale à ~~25~~ 150 % du poids de l'unité mais ne dépassant pas ~~220~~ 150 N, est appliquée dans toute direction sauf vers le haut, au point le plus élevé de l'APPAREIL EM qui n'amène pas de basculement, mais pas à plus de 1,5 m du sol. A la suite du mouvement élastique initial, du fluage initial et du pivotement initial des roulettes, tout autre déplacement de l'APPAREIL EM supérieur à 50 mm (en relation avec le plan horizontal) constitue une défaillance. ~~Le RISQUE dû à tout mouvement initial est évalué en tenant compte de l'UTILISATION NORMALE de l'APPAREIL EM.~~

9.4.4 Poignées et autres dispositifs de manutention

a) Les APPAREILS EM autres que les APPAREILS EM PORTABLES ou leurs parties d'une masse supérieure à 20 kg qui doivent être soulevés en UTILISATION NORMALE ou pendant leur transport/déplacement doivent être équipés de dispositifs de manutention appropriés (par exemple poignées, anneaux de levage, etc.) ou alors les DOCUMENTS D'ACCOMPAGNEMENT doivent indiquer les points par lesquels ils peuvent être soulevés en toute sécurité, sauf si la méthode de manipulation est évidente et qu'aucun ~~DANGER~~ RISQUE inacceptable ne peut apparaître en faisant la manipulation. Si les dispositifs de levage sont des poignées, elles

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doivent être placées de manière appropriée pour permettre à deux personnes ou plus de porter l'APPAREIL EM ou ses parties.

La conformité est vérifiée par pesage (si nécessaire) et par examen de l'APPAREIL EM ou de ses parties ou des DOCUMENTS D'ACCOMPAGNEMENT.

b) Les APPAREILS EM spécifiés par leur FABRICANT comme des appareils PORTABLES d'une masse supérieure à 20 kg doivent comporter une ou plusieurs poignées de transport convenablement placées permettant le transport de l'APPAREIL EM par deux personnes ou plus.

La vérification est effectuée en portant l'appareil.

c) Les poignées et moyens de transport qui équipent les APPAREILS EM PORTABLES doivent résister à la charge décrite dans l'essai suivant:

Les poignées et leurs dispositifs de fixation sont soumis à une force égale à quatre fois le poids de l'APPAREIL EM dans toute direction rencontrée en UTILISATION NORMALE pour le transport/déplacement.

Si un APPAREIL EM PORTABLE dispose de plus d'une poignée, la force est répartie entre les poignées. La répartition des forces est déterminée en mesurant le pourcentage du poids de l'APPAREIL EM qui est soutenu par chaque poignée, L'APPAREIL EM étant en position normale de transport/déplacement. Si l'APPAREIL EM est équipé de plus d'une poignée mais qu'il est conçu pour être facilement porté par une seule poignée, alors chaque poignée est en mesure soutenir la force totale.

La force est appliquée de manière uniforme sur une longueur de 7 cm de la poignée au centre, en commençant à zéro et en augmentant régulièrement de manière que la valeur d'essai soit atteinte entre 5 s et 10 s et qu'elle soit maintenue pendant 1 min.

Les poignées qui se dissocient de l'APPAREIL EM ou qui présentent une déformation permanente quelconque, une fissuration ou un autre signe de claquage constituent une défaillance.

9.5 * DANGER de projections de pièces

9.5.1 Mesures de protection

Lorsqu'une projection de pièces (ou d'objets) peut engendrer un RISQUE inacceptable, l'APPAREIL EM doit être équipé de moyens de protection contre un tel RISQUE.

La conformité est vérifiée en évaluant la bonne adaptation des moyens de protection et par l'inspection du DOSSIER DE GESTION DES RISQUES.

9.5.2 Tubes cathodiques

Tout tube cathodique doit être conforme aux exigences applicables de l'IEC 60065: 2001, Article 18 ou à l'IEC 61965.

La conformité est vérifiée par examen du certificat de conformité correspondant ou par les essais pertinents de l'IEC 60065:2001, Article 18.

9.6 Energie acoustique (y compris infra- et ultrasons) et vibrations

9.6.1 * Généralités

L'APPAREIL EM doit être conçu de manière que l'exposition des personnes à l'énergie acoustique et aux vibrations ne donne pas lieu à un RISQUE inacceptable.

~~*La conformité est vérifiée par l'inspection du DOSSIER DE GESTION DES RISQUES (en tenant compte de l'audibilité des signaux sonores d'alarme et de la sensibilité du PATIENT) et de la conformité avec les essais indiqués en 9.6.2 et 9.6.3.*~~

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La conformité est vérifiée par les essais spécifiés en 9.6.2 et 9.6.3, et, si nécessaire, par l'inspection du DOSSIER DE GESTION DES RISQUES (en tenant compte de l'audibilité des SIGNAUX D'ALARME sonores et de la sensibilité du PATIENT).

9.6.2 * Energie acoustique

9.6.2.1 Energie acoustique audible

En UTILISATION NORMALE, le PATIENT, l'OPERATEUR et les autres personnes ne doivent pas être exposés à une énergie acoustique provenant de l'APPAREIL EM, à l'exception des ~~signaux sonores d'alarme~~ SIGNAUX D'ALARME sonores, qui dépassent les niveaux spécifiés ci-dessous:

– 80 dBA pour une exposition cumulée de 24 h sur une période de 24 h ; une correction de 3 dBA doit être ajoutée à cette valeur lorsqu'on divise par deux la durée d'exposition cumulée sur 24 h (par exemple 83 dBA pour 12 h sur une période de 24 h) ;

– 140 dBC de niveau de pression acoustique ~~non pondéré~~ (crête) pour l'énergie acoustique (bruit) d'impulsions ou d'impacts.

NOTE 1 L'interpolation ou l'extrapolation est autorisée pour les durées d'exposition conformément à la formule suivante, 80 - 10*$\log_{10}$(h/24), en dBA, où h est la durée d'exposition cumulée sur une période de 24 h.

NOTE 2 Dans la mesure où les PATIENTS peuvent présenter une sensibilité plus élevée à l'énergie acoustique (bruit), un niveau plus faible pourrait être plus approprié. Il convient de tenir également compte de la perception des ~~signaux sonores d'alarme~~ SIGNAUX D'ALARME sonores. L'Organisation Mondiale de la Santé a recommandé un niveau d'énergie acoustique (bruit) d'impulsions ou d'impacts maximal de 120 dB pour les enfants.

NOTE 3 Si le niveau de pression acoustique pondéré A dépasse 80 ~~dB (A)~~ dBA, il convient que la mesure de protection contre le bruit soit prise en compte.

La conformité est vérifiée en mesurant le niveau de pression acoustique pondéré A maximal aux distances minimales du PATIENT, de l'OPERATEUR et des autres personnes par rapport à la source d'énergie acoustique (bruit) et, si nécessaire, en calculant le niveau de pression acoustique pondéré A produit par l'APPAREIL EM conformément à l'ISO 3746, l'ISO 9614-1 ou l'IEC 61672-1. Les conditions suivantes s'appliquent.

a) L'APPAREIL EM est mis en fonctionnement dans la CONDITION NORMALE la plus défavorable.

b) Tout moyen de protection mentionné ou stipulé dans les DOCUMENTS D'ACCOMPAGNEMENT est en place au cours de la mesure des sons.

c) Les sonomètres utilisés pour la mesure sont conformes à l'IEC 61672-1 et la IEC 61672-2.

d) La salle d'essai est semi-réverbérante avec un sol très réverbérant. La distance entre des parois ou d'autres objets et la surface de l'APPAREIL EM n'est pas inférieure à 3 m.

e) Lorsque les mesures sonores dans une salle d'essai ne sont pas réalisables (par exemple, pour un APPAREIL EM de grande taille INSTALLE DE FACON PERMANENTE), il est admis que les mesures soient faites in situ.

9.6.2.2 Energie d'infrasons et d'ultrasons

Lorsque cela est applicable, le FABRICANT doit traiter des RISQUES associés aux infrasons ou aux ultrasons dans le cadre du PROCESSUS de GESTION DES RISQUES.

La conformité est vérifiée par inspection du DOSSIER DE GESTION DES RISQUES.

9.6.3 * Vibrations transmises à la main

A l'exception des vibrations directement nécessitées pour l'UTILISATION PREVUE de l'APPAREIL EM, des moyens doivent être mis en place pour protéger le PATIENT, l'OPERATEUR et les autres personnes si en UTILISATION NORMALE l'accélération en valeur efficace pondérée de la fréquence transmise à la main générée par l'APPAREIL EM dépasse la valeur ci-dessous:

– 2,5 m/s^2 pour une période cumulée de 8 h au cours d'une période de 24 h.

– Les accélérations admissibles pour différentes durées sont inversement proportionnelles à la racine carrée de la durée (par exemple l'accélération admissible pour 2 h serait de 5,0 m/s^2).

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NOTE L'interpolation et/ou l'extrapolation est autorisée pour l'accélération admissible conformément à la formule suivante, 2,5 * √(8 / *t*), en m/s², où *t* est la durée cumulée sur une période de 24 h.

La conformité est vérifiée par des mesures aux points de l'appareil en contact manuel avec le PATIENT, l'OPERATEUR ou d'autres personnes. Les mesures sont réalisées conformément à l'ISO 5349-1.

9.7 * Réservoirs et parties sous pression pneumatique et hydraulique

9.7.1 Généralités

Les exigences de ce paragraphe s'appliquent aux réservoirs et aux pièces des APPAREILS EM qui sont soumis à une PRESSION, et dont la rupture pourrait constituer un RISQUE inacceptable.

Les pièces d'un système pneumatique ou hydraulique qui sont utilisées comme un système de support doivent en outre être conformes aux exigences de 9.8.

9.7.2 Parties pneumatiques et hydrauliques

Les parties pneumatiques et hydrauliques des APPAREILS EM ou ACCESSOIRES doivent être conçues de telle manière:

– qu'aucun RISQUE inacceptable ne résulte de pertes de pression ou de pertes de vide;

– qu'aucun RISQUE inacceptable ne résulte d'un jet de fluide dû à des fuites ou des défaillances de composants;

– que les éléments de l'APPAREIL EM ou un ACCESSOIRE, et en particulier les conduites et les tuyaux qui peuvent conduire à un RISQUE inacceptable soient protégés contre les effets externes nocifs;

– que les réservoirs et les cuves similaires (par exemple accumulateurs hydro-pneumatiques) qui peuvent conduire à un RISQUE inacceptable soient automatiquement dépressurisés lorsque l'APPAREIL EM est séparé de son alimentation (par exemple en retirant la fiche pneumatique au niveau du connecteur monté sur la paroi de l'installation). Si cela n'est pas possible, des moyens doivent être fournis pour l'isolation (par exemple coupant le circuit périphérique) ou la dépressurisation locale de ces réservoirs et cuves similaires et pour l'indication de la PRESSION;

– que tous les éléments qui peuvent rester sous PRESSION après la séparation de l'APPAREIL EM ou d'un ACCESSOIRE de son alimentation et qui pourraient engendrer un RISQUE inacceptable soient équipés de dispositifs d'évacuation clairement identifiés et portent une étiquette d'avertissement attirant l'attention sur la nécessité de dépressuriser ces éléments avant tout réglage ou toute opération de maintenance sur l'APPAREIL EM ou sur les ACCESSOIRES.

La conformité est vérifiée par inspection et par l'inspection du DOSSIER DE GESTION DES RISQUES.

9.7.3 Pression maximale

La pression maximale à laquelle une pièce de l'APPAREIL EM peut être soumise en CONDITION NORMALE et en CONDITION DE PREMIER DEFAUT doit être considérée comme étant la plus élevée des pressions suivantes:

a) la pression d'alimentation maximale ASSIGNEE en provenance d'une source extérieure;

b) le réglage de la pression d'une soupape de sécurité comme faisant partie de l'ensemble;

c) la pression maximale qui peut être fournie par une source de pression qui fait partie de l'ensemble, sauf si la pression est limitée par une soupape de sécurité.

9.7.4 Caractéristiques de pression des parties des APPAREILS EM

La pression maximale à laquelle une pièce d'un APPAREIL EM peut être soumise en CONDITION NORMALE et en CONDITION DE PREMIER DEFAUT ne doit pas dépasser la PRESSION MAXIMALE

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ADMISSIBLE DE FONCTIONNEMENT pour cette pièce, à l'exception de ce qui est autorisé pour les soupapes de sécurité en 9.7.7.

~~*La conformité est vérifiée par examen des données du FABRICANT concernant le composant, par l'examen de L'APPAREIL EM, par l'examen du DOSSIER DE GESTION DES RISQUES et, si nécessaire, par un essai fonctionnel.*~~

La conformité est vérifiée par l'inspection des données du FABRICANT pour le composant, l'inspection de l'APPAREIL EM, et, si nécessaire, par un essai fonctionnel.

9.7.5 * Réservoirs sous pression

Un réservoir sous pression doit résister à une PRESSION D'ESSAI HYDRAULIQUE si les deux conditions suivantes sont rencontrées:

– la pression est supérieure à 50 kPa; et

– le produit de la pression et du volume est supérieur à 200 kPa · l.

La conformité est vérifiée par les essais suivants:

LA PRESSION D'ESSAI HYDRAULIQUE doit être la PRESSION MAXIMALE ADMISSIBLE DE FONCTIONNEMENT multipliée par un facteur obtenu à la Figure 32.

La pression est augmentée graduellement jusqu'à la valeur d'essai spécifiée et elle est maintenue à cette valeur pendant 1 min. Un spécimen qui éclate ou se déforme de manière permanente (déformation plastique) ou qui fuit constitue une défaillance. Une fuite au niveau d'un joint d'étanchéité au cours de cet essai n'est pas considérée comme une défaillance sauf si elle se produit à une PRESSION inférieure à 40 % de la valeur d'essai exigée ou inférieure à la PRESSION MAXIMALE ADMISSIBLE DE FONCTIONNEMENT, en retenant la plus élevée des deux valeurs.

Aucune fuite n'est autorisée pour les réservoirs sous pression pour substances toxiques, inflammables ou présentant un autre danger. Pour les autres réservoirs sous pression, aucune fuite n'est autorisée qui engendrerait un RISQUE inacceptable (par exemple jet de fluide à haute pression).

Lorsque des réservoirs sous pression et des tuyaux non marqués (par exemple, ne bénéficiant pas de certification nationale) ne peuvent être soumis à l'essai hydraulique, leur intégrité est vérifiée par d'autres essais appropriés, par exemple pneumatiques en utilisant un dispositif adapté, à la même pression que pour l'essai hydraulique.

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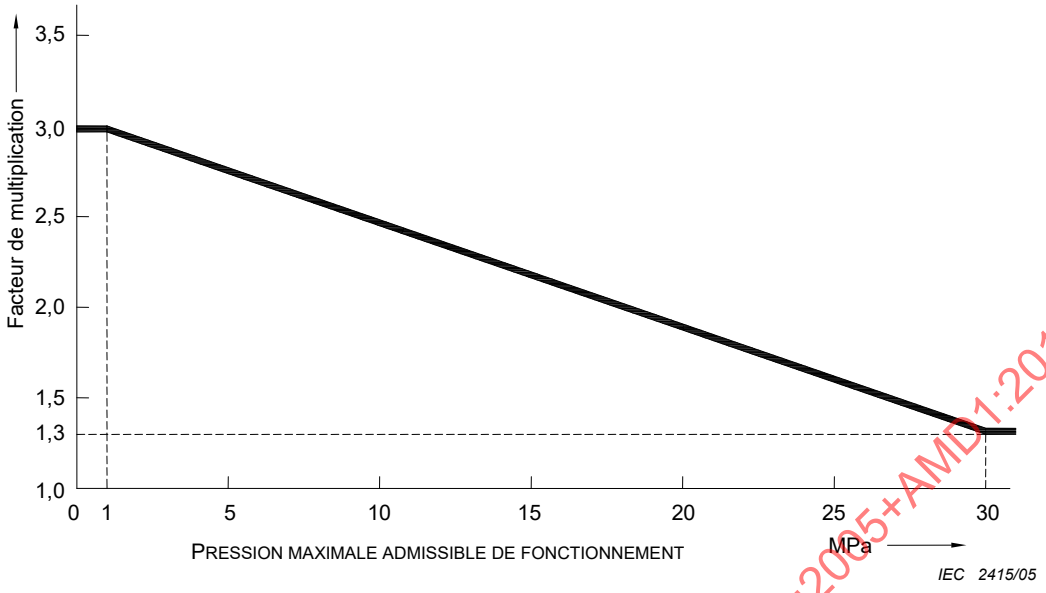


Figure 32 – Rapport entre la PRESSION D'ESSAI HYDRAULIQUE et la PRESSION MAXIMALE ADMISSIBLE DE FONCTIONNEMENT
(voir 9.7.5)

9.7.6 Régulateur de pression

Dans un APPAREIL EM pour lequel 9.7.7 exige une soupape de sécurité, tout régulateur de pression doit pouvoir fonctionner sous la charge ASSIGNEE pendant 100 000 cycles de fonctionnement et doit empêcher la pression de dépasser 90 % de la valeur de réglage de la soupape de sécurité en toute condition d'UTILISATION NORMALE.

~~*La conformité est vérifiée par examen des données du FABRICANT concernant le composant, par l'inspection de l'APPAREIL EM, par l'inspection du DOSSIER DE GESTION DES RISQUES et, si nécessaire, par un essai fonctionnel.*~~

La conformité est vérifiée par l'inspection des données du FABRICANT pour le composant, l'inspection de l'APPAREIL EM, et, si nécessaire, par un essai fonctionnel.

9.7.7 Soupape de sécurité

Les APPAREILS EM doivent être munis d'une ou plusieurs soupapes de sécurité lorsque la PRESSION MAXIMALE ADMISSIBLE DE FONCTIONNEMENT pourrait être dépassée en leur absence.

Une soupape de sécurité doit être conforme à toutes les exigences suivantes:

a) elle doit être placée aussi près que raisonnablement possible du réservoir sous pression ou des pièces du système qu'elle est destinée à protéger;

b) elle doit être mise en place de façon à être facilement accessible pour vérification, entretien et réparation;

c) elle ne doit pouvoir être réglée ou rendue inopérante qu'avec l'aide d'un OUTIL;

d) elle doit avoir son orifice d'échappement placé et dirigé de telle manière que la matière libérée ne soit pas dirigée vers une personne;

e) elle doit avoir son orifice d'échappement placé et dirigé de telle manière que le fonctionnement de la soupape ne dépose pas de matière sur des parties pouvant engendrer un RISQUE inacceptable;

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f) elle doit être d'une capacité de décharge adéquate telle que la pression ne dépasse pas la PRESSION MAXIMALE ADMISSIBLE DE FONCTIONNEMENT du système auquel elle est reliée de plus de 10 % en cas de panne de la commande de la pression fournie;

g) il ne doit pas y avoir de valve d'arrêt entre la soupape de sécurité et les parties qu'elle est destinée à protéger;

h) le nombre minimal de cycles de fonctionnement doit être de 100 000 sauf en présence de dispositifs à utilisation unique tels que des disques d'éclatement.

La conformité est vérifiée par examen des données du FABRICANT concernant le composant, par l'inspection de l'APPAREIL EM, par l'inspection du DOSSIER DE GESTION DES RISQUES et, si nécessaire, par un essai fonctionnel.

9.7.8 Pression d'alimentation maximale ASSIGNEE

Voir 7.2.18.

9.8 * DANGERS MECANIQUES associés aux systèmes de support

9.8.1 Généralités

Lorsque des éléments d'APPAREILS EM sont conçus pour supporter des charges ou pour fournir des forces de manœuvre, les exigences suivantes doivent être appliquées si un défaut mécanique pouvait constituer un RISQUE inacceptable.

– La construction du système de support, de suspension ou de manœuvre doit être conçue en se basant sur les valeurs du Tableau 21 et de la CHARGE TOTALE.

– Les moyens de fixation des ACCESSOIRES doivent être conçus de manière à éviter toute possibilité de fixation incorrecte qui pourrait engendrer un RISQUE inacceptable.

– L'ANALYSE DE RISQUE des systèmes de support doit tenir compte des DANGERS MECANIQUES provenant des charges statiques, dynamiques, de vibrations, d'impacts et de pression, des fondations et d'autres mouvements, de la température, de l'environnement, des conditions de fabrication et d'entretien.

– Tous les effets vraisemblables de défaillance doivent être pris en compte dans l'ANALYSE DE RISQUE. Ceux-ci comprennent la déviation excessive, la déformation plastique, la fracture ductile ou cassante, la fracture de fatigue, l'instabilité (gauchissement), la fissuration par corrosion sous contrainte, l'usure, le fluage du matériau, la détérioration des matériaux et les contraintes résiduelles résultant des PROCESSUS de fabrication, par exemple l'usinage, le montage, le soudage, le traitement à chaud ou le traitement de surface.

– Les DOCUMENTS D'ACCOMPAGNEMENT doivent contenir les instructions concernant la fixation des structures au sol, au mur, au plafond, etc. en tenant compte de la qualité des matériaux utilisés pour réaliser la fixation et ils doivent donner la liste des matériaux adaptés. En outre, des conseils doivent être fournis pour la vérification de la bonne adaptation de la surface de la structure sur laquelle les parties seront fixées.

9.8.2 * FACTEUR DE SECURITE EN TRACTION

Les systèmes de support doivent conserver l'intégrité structurelle pendant la DUREE DE VIE PREVUE de l'APPAREIL EM. Les FACTEURS DE SECURITE EN TRACTION ne doivent pas être inférieurs à ceux donnés au Tableau 21, à moins qu'une méthode alternative ne démontre l'intégrité structurelle tout au long de la DUREE DE VIE PREVUE de l'APPAREIL EM ou que le support soit un repose-pied. Les exigences pour les repose-pieds sont données en 9.8.3.2 a).

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Tableau 21 – Détermination du FACTEUR DE SECURITE EN TRACTION

Situation			FACTEUR DE SECURITE EN TRACTION minimal[a]	
No	**Elément du système**	**Elongation**	**A [b]**	**B [c]**
1	Eléments du système de support non altérés par l'usure	Matériau métallique [d] ayant un allongement spécifique à la rupture supérieur ou égal à 5 %	2,5	4
2	Eléments du système de support non altérés par l'usure	Matériau métallique [d] ayant un allongement spécifique à la rupture inférieur à 5 %	4	6
3	Eléments du système de support altérés par l'usure [e] et absence de DISPOSITIF DE PROTECTION MECANIQUE	Matériau métallique [d] ayant un allongement spécifique à la rupture supérieur ou égal à 5 %	5	8
4	Eléments du système de support altérés par l'usure [e] et absence de DISPOSITIF DE PROTECTION MECANIQUE	Matériau métallique [d] ayant un allongement spécifique à la rupture inférieur à 5 %	8	12
5	Eléments du système de support altérés par l'usure [e] et avec DISPOSITIF DE PROTECTION MECANIQUE (ou système primaire à supports multiples)	Matériau métallique [d] ayant un allongement spécifique à la rupture supérieur ou égal à 5 %	2,5	4
6	Eléments du système de support altérés par l'usure [e] et avec DISPOSITIF DE PROTECTION MECANIQUE (ou système primaire à supports multiples)	Matériau métallique [d] ayant un allongement spécifique à la rupture inférieur à 5 %	4	6
7	DISPOSITIF DE PROTECTION MECANIQUE (ou système de réserve à supports multiples)		2,5	4

[a] Les FACTEURS DE SECURITE EN TRACTION sont destinés à tenir compte de conditions définies en 15.3.7 (c'est-à-dire effets environnementaux, effets d'altération par usure, de corrosion, de fatigue des matériaux ou de vieillissement).

[b] Cas A = La RESISTANCE A LA TRACTION du matériau et toutes les forces externes prévisibles sont quantifiables et connues de manière précise.

[c] Cas B = Différent du cas A. Spécifiquement, la RESISTANCE A LA TRACTION et toutes les forces externes attendues sont connues de manière approximative mais pas avec une précision suffisante pour justifier le FACTEUR DE SECURITE EN TRACTION du cas A.

[d] Pour les matériaux non métalliques, les normes particulières peuvent prescrire des FACTEURS DE SECURITE EN TRACTION (voir justification en Annexe A, Paragraphe 9.8).

[e] Les composants considérés comme altérés par l'usure comprennent: les chaînes, les câbles (cordes), les courroies, les écrous de vis, les ressorts, les flexibles pneumatiques ou hydrauliques, les joints d'étanchéité ou les bagues des pistons pneumatiques ou hydrauliques.

La conformité avec 9.8.1 et 9.8.2 est vérifiée par inspection de l'APPAREIL EM, du DOSSIER DE GESTION DES RISQUES, des spécifications des matériaux utilisés et des spécifications de mise en œuvre de ces matériaux.

~~*Lorsque les résultats d'essai font partie des informations pertinentes, les essais consistent à appliquer graduellement une charge d'essai à l'ensemble support en essai qui est égale à la CHARGE TOTALE fois le FACTEUR DE SECURITE EN TRACTION exigé.*~~ *Si un essai est nécessaire pour démontrer la conformité avec 9.8.1 ou 9.8.2, une charge d'essai égale à la CHARGE TOTALE multipliée par le FACTEUR DE SECURITE EN TRACTION requis est appliquée graduellement sur l'ensemble support soumis à l'essai. L'ensemble support en essai est en équilibre après 1 min, ou sinon il ne doit pas donner lieu à un RISQUE inacceptable.*

NOTE 1 Il peut être nécessaire de soutenir des ensembles qui sont liés à l'ensemble en essai mais qui ne nécessitent pas un facteur de sécurité aussi élevé, par exemple un ensemble en essai exige un FACTEUR DE SECURITE = 8 et l'ensemble qui le supporte est conçu avec un FACTEUR DE SECURITE = 4. Il convient que l'utilisation d'un support supplémentaire soit expliquée dans le rapport d'essai.

NOTE 2 Le temps d'1 min pourrait devoir être plus long pour les matériaux qui pourraient connaître des problèmes de type fluage, comme les plastiques ou d'autres matériaux non métalliques.

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9.8.3 * Résistance des supports PATIENT ou OPERATEUR, ou des systèmes de suspension

9.8.3.1 Généralités

Les parties d'APPAREILS EM destinées à supporter ou à immobiliser des PATIENTS doivent être conçues et fabriquées de ~~façon à réduire au minimum le~~ manière à ce qu'il n'existe aucun RISQUE inacceptable de blessures physiques ~~et~~ ou de relâchement accidentel des moyens de contention.

La CHARGE DE FONCTIONNEMENT EN SECURITE de l'APPAREIL EM ou de ses parties servant de support ou de suspension pour les PATIENTS ou les OPERATEURS doit correspondre à la somme de la masse des PATIENTS ou de la masse des OPERATEURS plus la masse des ACCESSOIRES prévues par le FABRICANT pour être supportées ou suspendues par l'APPAREIL EM ou ses parties.

Sauf indication contraire du FABRICANT, les parties servant de support et de suspension pour des PATIENTS humains adultes ou des OPERATEURS doivent être conçues pour un PATIENT ou un OPERATEUR ayant une masse minimale de 135 kg et des ACCESSOIRES d'une masse minimale de 15 kg.

Lorsqu'un FABRICANT spécifie des applications particulières (par exemple utilisation pédiatrique), la masse maximale du PATIENT incluse dans la CHARGE DE FONCTIONNEMENT EN SECURITE de l'APPAREIL EM ou de ses parties servant de support ou de suspension pour les PATIENTS peut être adaptée. Lorsque la valeur maximale admissible de la masse du PATIENT est inférieure à 135 kg, cette valeur doit être marquée sur l'APPAREIL EM et décrite dans les DOCUMENTS D'ACCOMPAGNEMENT. Lorsque la valeur maximale admissible de la masse du PATIENT est supérieure à 135 kg, cette valeur doit être décrite dans les DOCUMENTS D'ACCOMPAGNEMENT.

La conformité est vérifiée par l'inspection de l'APPAREIL EM (y compris des marquages), des DOCUMENTS D'ACCOMPAGNEMENT, des données du FABRICANT pour le composant, ~~et~~ du DOSSIER DE GESTION DES RISQUES, et, si nécessaire, par un essai fonctionnel.

9.8.3.2 * Forces statiques dues à la charge des personnes

Lorsqu'on analyse les forces et les couples de charge sur les ensembles supports, la partie de la CHARGE DE FONCTIONNEMENT EN SECURITE qui représente la masse des PATIENTS ou des OPERATEURS est répartie sur la surface de support/suspension d'une manière représentant le corps humain (voir l'exemple de la Figure A.19).

NOTE 1 La position du corps humain varie en fonction de la configuration du système de support/suspension et par conséquent la charge qui agit sur différentes sections variera aussi et il convient d'en tenir compte.

Lorsqu'on analyse les forces et les couples de charge sur les ensembles supports, la partie de la CHARGE DE FONCTIONNEMENT EN SECURITE qui représente la masse des ACCESSOIRES doit être répartie comme en UTILISATION NORMALE ou, en leur absence, dans la position la plus défavorable autorisée par la configuration ou les fixations des ACCESSOIRES sur les éléments de support/suspension.

a) Pour un repose pied qui est destiné à supporter de manière temporaire un PATIENT ou un OPERATEUR debout, l'ensemble de la masse du PATIENT ou de l'OPERATEUR est réparti sur une surface de 0,1 m^2.

La conformité est vérifiée par l'inspection de l'APPAREIL EM~~, du DOSSIER DE GESTION DES RISQUES~~, des spécifications des matériaux utilisés et des spécifications de ~~mise en œuvre~~ traitement de ces matériaux, et par l'essai suivant:

Avant de réaliser ces essais, le système de support/~~de~~ suspension du PATIENT est positionné horizontalement dans sa position la plus défavorable en UTILISATION NORMALE.

~~*Une masse égale à deux fois 135 kg ou deux fois la charge de personne prévue, selon la valeur qui est la plus élevée, est appliquée au repose pied sur une zone de 0,1 m^2 pendant 1 min. A l'issue de l'essai, un repose pied et ses fixations qui présente un dommage ou un fléchissement qui engendrerait un RISQUE inacceptable constitue une défaillance.*~~

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Une masse égale à deux fois 135 kg ou à deux fois la charge de la personne prévue, selon la valeur la plus élevée, est appliquée au repose-pied sur une zone de 0,1 m² pendant 1 min. Après l'essai, un repose-pied et ses moyens de fixation qui affichent une détérioration ou un écart permanent par rapport à la normale supérieur à 5° constituent une défaillance. La SECURITE DE BASE et les PERFORMANCES ESSENTIELLES doivent être conservées.

NOTE 2 Des exemples de dommages pouvant affecter la SECURITE DE BASE comprennent la réduction des LIGNES DE FUITE et des DISTANCES DANS L'AIR en dessous des valeurs spécifiées en 8.9, l'accès aux parties qui dépassent les limites indiquées en 8.4 ou l'accès aux parties mobiles qui pourraient conduire à un DOMMAGE.

Les critères d'évaluation pouvant être utiles pour déterminer si cet essai a conduit à une perte de la SECURITE DE BASE comprennent:

– ceux de l'Article 8 et de 11.6;

– l'essai de tension de tenue de 8.8.3 pour évaluer l'intégrité de l'isolation solide constituant un MOYEN DE PROTECTION; et

– la mesure des LIGNES DE FUITE ou des DISTANCES DANS L'AIR pour comparer les valeurs avec les distances minimales spécifiées en 8.9. Les petits éclats qui n'entament pas la protection contre les chocs électriques ou l'humidité peuvent normalement être ignorés.

b) Pour une zone de support/suspension sur laquelle un PATIENT ou un OPERATEUR peut s'asseoir, le fléchissement d'une surface de support de la charge PATIENT ou OPERATEUR ne doit pas engendrer de RISQUE inacceptable.

La conformité est vérifiée par l'inspection de l'APPAREIL EM ~~du DOSSIER DE GESTION DES RISQUES~~, des spécifications des matériaux utilisés et des spécifications de ~~mise en œuvre~~ traitement de ces matériaux, et par l'essai suivant:

Avant de réaliser ces essais, le système de support/~~de~~ suspension du PATIENT est positionné horizontalement dans sa position la plus défavorable en UTILISATION NORMALE.

Une masse de 60 % de la partie de la CHARGE DE FONCTIONNEMENT EN SECURITE représentant le~~s~~ PATIENT~~S~~ ou ~~les~~ l'OPERATEUR~~S~~, comme défini dans les instructions d'utilisation, ou au ~~minimum~~ moins égal à 80 kg, est placée sur ~~un~~ le système de support/suspension ~~avec~~, le centre de la charge étant à 60 mm du bord extérieur du système de support/suspension pendant au moins 1 min. Tout ~~fléchissement~~ écart permanent du système de support/suspension ~~qui pourrait donner lieu à un RISQUE inacceptable~~ ~~inacceptable~~ par rapport à la normale supérieure à 5° constitue une défaillance. La SECURITE DE BASE et les PERFORMANCES ESSENTIELLES doivent être conservées.

NOTE 3 Des exemples de dommages pouvant affecter la SECURITE DE BASE comprennent la réduction des LIGNES DE FUITE et des DISTANCES DANS L'AIR en dessous des valeurs spécifiées en 8.9, l'accès aux parties qui dépassent les limites indiquées en 8.4 ou l'accès aux parties mobiles qui pourraient conduire à un DOMMAGE.

Les critères d'évaluation pouvant être utiles pour déterminer si cet essai a conduit à une perte de la SECURITE DE BASE comprennent:

– ceux de l'Article 8 et de 11.6;

– l'essai de tension de tenue de 8.8.3 pour évaluer l'intégrité de l'isolation solide constituant un MOYEN DE PROTECTION; et

– la mesure des LIGNES DE FUITE ou des DISTANCES DANS L'AIR pour comparer les valeurs avec les distances minimales spécifiées en 8.9. Les petits éclats qui n'entament pas la protection contre les chocs électriques ou l'humidité peuvent normalement être ignorés.

9.8.3.3 * Forces dynamiques dues à la charge des personnes

Lorsque des forces dynamiques (dues à une personne qui s'assoit ou qui se met debout, au PROCESSUS de mobilisation d'un PATIENT ou à des situations similaires) peuvent être exercées sur les parties d'un ~~appareil~~ APPAREIL EM destinées ~~au~~ à supporter ou à ~~la suspension d'~~ suspendre un PATIENT ou ~~d'~~ un OPERATEUR en ~~USAGE NORMAL, elles ne doivent pas engendrer de RISQUE inacceptable~~ UTILISATION NORMALE, l'APPAREIL EM doit conserver la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES.

La conformité est vérifiée par l'essai suivant.

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Avant de réaliser cet essai, le système de support/suspension du PATIENT est positionné horizontalement dans sa position la plus défavorable en UTILISATION NORMALE.

~~*Pour la zone de support/suspension sur laquelle un PATIENT ou un OPERATEUR peut s'asseoir, une masse (telle que définie à la Figure 33) équivalente à la CHARGE DE FONCTIONNEMENT EN SECURITE représentant le PATIENT ou l'OPERATEUR comme ils sont définis dans les instructions d'utilisation est lâchée d'une hauteur de 150 mm au-dessus de la zone d'assise. Il ne doit pas y avoir de perte de fonction ou de dommage structurel qui pourrait donner lieu à un RISQUE inacceptable.*~~

Pour la zone de support/suspension où un PATIENT ou un OPERATEUR peut s'asseoir, le réservoir supérieur du module de chariot supérieur représentant le corps humain décrit sur la Figure 33 est chargé avec la masse appropriée pour obtenir la CHARGE DE FONCTIONNEMENT EN SECURITE représentant le PATIENT ou l'OPERATEUR comme défini dans les DOCUMENTS D'ACCOMPAGNEMENT. Le module de chariot supérieur représentant le corps humain, de masse appropriée, est lâché d'une hauteur de 150 mm au-dessus de la zone d'assise. La SECURITE DE BASE et les PERFORMANCES ESSENTIELLES doivent être conservées.

NOTE Des exemples de dommages pouvant affecter la SECURITE DE BASE comprennent la réduction des LIGNES DE FUITE et des DISTANCES DANS L'AIR en dessous des valeurs spécifiées en 8.9, l'accès aux parties qui dépassent les limites indiquées en 8.4 ou l'accès aux parties mobiles qui pourraient conduire à un DOMMAGE.

Les critères d'évaluation pouvant être utiles pour déterminer si cet essai a conduit à une perte de la SECURITE DE BASE comprennent:

– ceux de l'Article 8 et de 11.6;
– l'essai de tension de tenue de 8.8.3 pour évaluer l'intégrité de l'isolation solide constituant un MOYEN DE PROTECTION; et
– la mesure des LIGNES DE FUITE ou des DISTANCES DANS L'AIR pour comparer les valeurs avec les distances minimales spécifiées en 8.9. Les petits éclats qui n'entament pas la protection contre les chocs électriques ou l'humidité peuvent normalement être ignorés.

9.8.4 * Systèmes avec DISPOSITIFS DE PROTECTION MECANIQUE

9.8.4.1 Généralités

a) Un DISPOSITIF DE PROTECTION MECANIQUE doit être prévu lorsqu'un système de support ou l'un de ses élément altéré par l'usure présente un FACTEUR DE SECURITE EN TRACTION supérieur ou égal aux valeurs spécifiées aux lignes 5 et 6 mais inférieur à celles des lignes 3 et 4 du Tableau 21.

b) Le DISPOSITIF DE PROTECTION MECANIQUE doit:

– être conçu sur la base d'une CHARGE TOTALE, qui doit inclure les effets de la CHARGE DE FONCTIONNEMENT EN SECURITE lorsque cela est applicable;
– avoir des FACTEURS DE SECURITE EN TRACTION pour toutes les pièces qui ne soient pas inférieurs à ceux de la ligne 7 du Tableau 21;
– s'activer avant que le déplacement ne crée un RISQUE inacceptable;
– tenir compte de 9.2.5 et de 9.8.4.3.

~~*La conformité est vérifiée par inspection de l'APPAREIL EM, du DOSSIER DE GESTION DES RISQUES, des spécifications des matériaux utilisés et des spécifications de mise en œuvre de ces matériaux.*~~

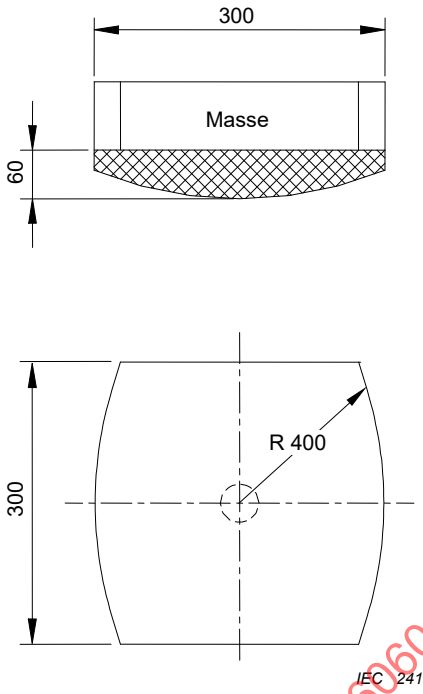
La conformité est vérifiée comme suit si nécessaire:

– *inspection des calculs et de l'évaluation du dépassement de course (distance d'arrêt à partir de l'instant d'engagement du DISPOSITIF DE PROTECTION MECANIQUE jusqu'à l'instant d'immobilisation);*
– *tout essai fonctionnel.*

NOTE Les calculs et l'évaluation du dépassement de course (distance d'arrêt à partir de l'instant d'engagement du DISPOSITIF DE PROTECTION MECANIQUE jusqu'à l'instant d'immobilisation) font partie du DOSSIER DE GESTION DES RISQUES.

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Dimensions en millimètres



NOTE ~~Le chariot supérieur de l'appareillage de masse d'essai représentant le corps humain est en bois ou en matériau similaire. La partie inférieure est de la mousse. La résilience ou le coefficient d'expansion élastique de la mousse (caractéristiques ILD ou IFD) n'est pas spécifié dans la mesure où lorsqu'une masse importante chute, les propriétés de la mousse sont probablement sans conséquence. La mousse est cylindrique plutôt que sphérique.~~

Le réservoir supérieur du module de chariot supérieur représentant le corps humain est en bois, en métal ou en matériau similaire. Le réservoir est destiné à contenir la masse appropriée représentant le corps humain, généralement un matériau à densité élevée (par exemple, du plomb). La partie inférieure est de la mousse. La résilience ou le coefficient d'expansion élastique de la mousse (caractéristiques ILD ou IFD) n'est pas spécifié dans la mesure où lorsqu'une masse importante chute, les propriétés de la mousse sont probablement sans conséquence. La mousse est cylindrique plutôt que sphérique.

Figure 33 – ~~Masse d'essai~~ Module de chariot supérieur représentant le corps ~~humain~~ ~~(voir 9.8.3.3)~~

9.8.4.2 Utilisation après activation d'un DISPOSITIF DE PROTECTION MECANIQUE

Si un APPAREIL EM peut encore être utilisé après défaillance des moyens de suspension ou de manœuvre et l'activation d'un DISPOSITIF DE PROTECTION MECANIQUE comme un câble secondaire (corde secondaire), il doit devenir évident pour l'OPERATEUR que le DISPOSITIF DE PROTECTION MECANIQUE a été activé.

Le DISPOSITIF DE PROTECTION MECANIQUE doit nécessiter l'utilisation d'un OUTIL pour être réarmé ou remplacé.

La conformité est vérifiée par inspection de l'APPAREIL EM.

9.8.4.3 DISPOSITIF DE PROTECTION MECANIQUE prévu pour une activation unique

Si un DISPOSITIF DE PROTECTION MECANIQUE est destiné à fonctionner une seule fois, les exigences suivantes doivent être satisfaites:

– Toute utilisation de l'APPAREIL EM doit être impossible avant que le DISPOSITIF DE PROTECTION MECANIQUE ne soit remplacé.

– Les DOCUMENTS D'ACCOMPAGNEMENT doivent prescrire que lorsque le DISPOSITIF DE PROTECTION MECANIQUE a été activé, le PERSONNEL D'ENTRETIEN doit être appelé et le DISPOSITIF DE PROTECTION MECANIQUE doit être remplacé avant que l'APPAREIL EM puisse de nouveau être utilisé.

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– L'APPAREIL EM doit porter en permanence le marquage avec le signe de sécurité ISO 7010-W001 (voir Tableau D.2, signe de sécurité 2).

– Le marquage doit être adjacent au DISPOSITIF DE PROTECTION MECANIQUE ou situé de telle manière que sa relation avec le DISPOSITIF DE PROTECTION MECANIQUE soit évidente pour la personne qui réalise les opérations de service ou de réparation.

NOTE Voir aussi 15.3.7.

La conformité est vérifiée comme suit:

– *par ~~examen~~ l'inspection de l'APPAREIL EM, des DOCUMENTS D'ACCOMPAGNEMENT~~, du DOSSIER DE GESTION DES RISQUES,~~ et des spécifications des matériaux utilisés ainsi que les spécifications de ~~mise en œuvre~~ traitement de ces matériaux;*

– *une chaîne, un câble (corde), une bande, un ressort, une courroie, un écrou de vis, un flexible pneumatique ou hydraulique, une partie de structure ou élément similaire, utilisé pour supporter une charge, est défait (mis en défaut) (pour essayer le DISPOSITIF MECANIQUE DE PROTECTION) par tout moyen pratique, provoquant ainsi la chute de la charge normale maximale de la position la plus défavorable autorisée par la construction de l'APPAREIL EM. Si le système supporte un PATIENT ou un OPERATEUR, la charge doit inclure la CHARGE DE FONCTIONNEMENT EN SECURITE comme défini en 9.8.3.1.*

Tout signe manifeste de dommage sur le DISPOSITIF DE PROTECTION MECANIQUE qui affecterait sa capacité à remplir sa fonction prévue constituerait une défaillance.

9.8.5 Systèmes sans DISPOSITIFS DE PROTECTION MECANIQUE

Un DISPOSITIF DE PROTECTION MECANIQUE n'est pas exigé si:

– les parties du système de support ne sont pas affectées par l'usure mais présentent des FACTEURS DE TRACTION DE SECURITE supérieurs ou égaux aux valeurs spécifiées aux lignes 1 et 2 du Tableau 21; ou

– les parties du système de support sont affectées par l'usure mais présentent des FACTEURS DE TRACTION DE SECURITE supérieurs ou égaux aux valeurs spécifiées aux lignes 3 et 4 du Tableau 21.

La conformité est vérifiée par l'inspection de l'APPAREIL EM, la documentation de conception et ~~du~~ le DOSSIER DE GESTION DES RISQUES.

10 * Protection contre les DANGERS dus aux rayonnements involontaires ou excessifs

10.1 Rayonnements X

10.1.1 * APPAREILS EM non destinés à produire des rayonnements X à des fins de diagnostic ou de thérapie

~~Pour les APPAREILS EM qui ne sont pas destinés à produire des rayons X à des fins de diagnostic ou de thérapie mais qui pourraient produire des rayonnements ionisants, le débit de dose ne doit pas dépasser 36 pA/kg (5μSv/h) (0,5 mR/h) à une distance de 5 cm d'une surface de l'APPAREIL EM tenant compte des rayonnements d'arrière-plan.~~

Pour les APPAREILS EM non destinés à produire des rayonnements X à des fins de diagnostic ou de thérapie mais qui pourraient produire des rayonnements ionisants, le débit de KERMA DANS L'AIR ne doit pas dépasser 5 μGy/h à une distance de 5 cm d'une surface de l'APPAREIL EM en tenant compte du rayonnement d'arrière-plan.

Si l'UTILISATION PREVUE de l'APPAREIL EM requiert une proximité permanente avec un PATIENT, il convient que l'exposition annuelle résultante soit acceptable, en tenant compte de la partie du corps irradiée, des réglementations nationales et/ou des recommandations internationales.

NOTE 1 La valeur du débit de dose est donnée dans le ICRP 60 [39].

NOTE 2 Dans les pays membres du CENELEC, la quantité de rayonnements ionisants est réglementée par la directive 96/29/EURATOM du 13 mai 1996 du Conseil Européen. Cette directive exige qu'en tout point à 10 cm de

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la surface de l'appareil, le débit de dose ne dépasse pas 1 µSv/h (0,1 mR/h) en tenant compte du niveau d'arrière plan.

La conformité est vérifiée par l'essai suivant:

La quantité de rayonnements est déterminée au moyen d'un moniteur de rayonnements du type chambre ionisante d'une surface efficace de 10 cm² ou par des appareils de mesure d'autres types donnant des résultats équivalents.

L'APPAREIL EM est mis en fonctionnement sous la TENSION RESEAU ASSIGNEE la plus défavorable et avec tout dispositif de commande réglé de manière à donner le rayonnement maximal tout en maintenant l'APPAREIL EM en UTILISATION NORMALE.

Les dispositifs de commande préréglés internes qui ne sont pas destinés à être réglés au cours de la DUREE DE VIE PREVUE de l'APPAREIL EM ne sont pas pris en compte.

Les mesures sont réalisées à une distance de 5 cm de toute surface à laquelle les OPERATEURS autres que ceux du PERSONNEL D'ENTRETIEN:

- *peuvent avoir accès sans l'aide d'un OUTIL;*
- *qui est volontairement équipée d'un dispositif d'accès; ou*
- *dans laquelle il est possible de pénétrer que ce soit avec ou sans l'aide d'un OUTIL;*

~~*Toute mesure supérieure à 36 pA/kg (5 µSv/h) (0,5 mR/h) réglée au niveau de rayonnement d'arrière plan constitue une défaillance.*~~

Toute mesure excédant 5 µGy/h ajustés pour le niveau de rayonnement d'arrière-plan constitue une défaillance.

NOTE 3 Cette PROCEDURE d'essai est équivalente à celle de l'Annexe H de l'IEC 60950-1:~~2001~~ 2005.

10.1.2 APPAREILS EM destinés à produire des rayonnements X à des fins de diagnostic ou de thérapie

~~Le FABRICANT doit traiter dans le PROCESSUS de GESTION DES RISQUES du RISQUE de rayonnements X non désirés, provenant D'APPAREILS EM conçus pour produire des rayonnements X à des fins de diagnostic et de thérapie. Voir l'IEC 60601-1-3 et voir aussi 1.3.~~

Les rayonnements X non désirés, provenant d'APPAREILS EM conçus pour produire des rayonnements X à des fins de diagnostic ou de thérapie, doivent être réduits autant que possible par application des normes particulières et collatérales applicables ou, en l'absence de ces normes, par application du PROCESSUS de GESTION DES RISQUES.

Pour les rayonnements X désirés, voir aussi 12.4.5.2 et 12.4.5.3.

La conformité est vérifiée par l'application des normes particulières et collatérales applicables ou l'inspection du DOSSIER DE GESTION DES RISQUES.

10.2 Rayonnements alpha, bêta, gamma, neutroniques et d'autres particules

Lorsque c'est applicable, le FABRICANT doit traiter dans le cadre du PROCESSUS de GESTION DES RISQUES les RISQUES associés aux rayonnements alpha, bêta, gamma, neutroniques et d'autres particules.

La conformité est vérifiée par inspection du DOSSIER DE GESTION DES RISQUES.

10.3 Rayonnements à micro-ondes

~~Lorsque c'est applicable, le FABRICANT doit traiter dans le cadre du PROCESSUS de GESTION DES RISQUES les RISQUES associés aux rayonnements à micro-ondes~~

~~*La conformité est vérifiée par inspection du DOSSIER DE GESTION DES RISQUES.*~~

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La densité de puissance des rayonnements à micro-ondes non désirés aux fréquences comprises entre 1 GHz et 100 GHz ne doit pas dépasser 10 W/m^2 en tout point à 50 mm d'une surface de l'APPAREIL EM dans les conditions d'essai de référence. Cette exigence ne s'applique pas aux parties de l'appareil dans lesquelles des rayonnements à micro-ondes sont propagés intentionnellement, par exemple les ports de sortie de guide d'onde.

NOTE Cette exigence est équivalente à celle du Paragraphe 12.4 de l'IEC 60601-1:2001.

La conformité est vérifiée par la revue des calculs du FABRICANT et, si nécessaire, l'essai suivant:

L'APPAREIL EM est mis en fonctionnement sous la TENSION RESEAU ASSIGNEE la plus défavorable et avec tout dispositif de commande réglé de manière à donner le rayonnement à micro-ondes maximal tout en maintenant l'APPAREIL EM en UTILISATION NORMALE.

Les dispositifs de commande préréglés internes qui ne sont pas destinés à être réglés au cours de la DUREE DE VIE prévue de l'APPAREIL EM ne sont pas pris en compte.

Les mesures sont réalisées à une distance de 50 mm de toute surface à laquelle les OPERATEURS autres que ceux du PERSONNEL D'ENTRETIEN:

- *peuvent avoir accès sans l'aide d'un OUTIL;*
- *sont volontairement équipés d'un dispositif d'accès; ou*
- *savent comment pénétrer, que ce soit à l'aide d'un OUTIL ou non.*

Toute mesure excédant 10 W/m^2 dans les conditions d'essai de référence constitue une défaillance.

10.4 * Lasers ~~et diodes émettrices lasers (LED)~~

~~Les exigences correspondantes de l'IEC 60825-1:1993 s'appliquent.~~ Pour les lasers produisant ou amplifiant les rayonnements électromagnétiques dans la plage de longueurs d'onde comprise entre 180 nm et 1 mm, les exigences pertinentes de l'IEC 60825-1:2007 doivent s'appliquer. Si des barrières contre la lumière laser ou des produits similaires sont utilisés dans un appareil, ils doivent ~~être conformes~~ satisfaire aux exigences de l'IEC 60825-1:~~1993~~2007.

NOTE Pour les appareils à laser destinés à être utilisés sur des hommes ou des animaux à des fins de chirurgie, de thérapie, de diagnostic médical, cosmétiques ou vétérinaires et classés comme produits laser de Classe 3b ou de Classe 4 comme défini dans l'IEC 60825-1, voir également l'IEC 60601-2-22 [59].

La conformité est vérifiée en suivant les PROCEDURES applicables de l'IEC 60825-1:~~1993~~2007.

10.5 Autres rayonnements électromagnétiques visibles

Lorsque c'est applicable, le FABRICANT doit traiter dans le cadre du PROCESSUS de GESTION DES RISQUES les RISQUES associés aux rayonnements électromagnétiques visibles, autres que ceux produits par des lasers et des diodes émettrices à laser (voir 10.4)

La conformité est vérifiée par inspection du DOSSIER DE GESTION DES RISQUES.

10.6 Rayonnements infrarouges

Lorsque c'est applicable, le FABRICANT doit traiter dans le cadre du PROCESSUS de GESTION DES RISQUES les RISQUES associés aux rayonnements infrarouges autres que ceux produits par les lasers et les diodes émettrices à laser (voir 10.4).

La conformité est vérifiée par inspection du DOSSIER DE GESTION DES RISQUES.

10.7 Rayonnements ultraviolets

Lorsque c'est applicable, le FABRICANT doit traiter dans le cadre du PROCESSUS de GESTION DES RISQUES les RISQUES associés aux rayonnements ultraviolets autres que ceux produits par les lasers et les diodes émettrices à laser (voir 10.4).

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La conformité est vérifiée par inspection du DOSSIER DE GESTION DES RISQUES.

11 * Protection contres les températures excessives et les autres DANGERS

11.1 * Températures excessives à l'intérieur des APPAREILS EM

11.1.1 * Température maximale en UTILISATION NORMALE

Lorsqu'un APPAREIL EM est mis en fonctionnement dans le cas le plus défavorable de l'UTILISATION NORMALE avec la température ambiante de fonctionnement maximale spécifiée dans la description technique (voir 7.9.3.1):

– les parties des APPAREILS EM ne doivent pas atteindre des températures supérieures aux valeurs données aux Tableaux 22 et 23;

– les APPAREILS EM ne doivent pas entraîner un échauffement des surfaces du coin d'essai supérieur à 90 ° C; et

– les COUPE-CIRCUIT THERMIQUES ne doivent pas fonctionner en CONDITION NORMALE.

Tableau 22 – Températures maximales admissibles des parties

Parties	Température maximale °C
Isolation, y compris l'isolation de l'enroulement [a]	
– Matériau de la classe A	105
– Matériau de la classe E	120
– Matériau de la classe B	130
– Matériau de la classe F	155
– Matériau de la classe H	180
Parties portant un marquage T	T [b]
Autres composants et autres matériaux	[c]
Parties en contact avec un liquide inflammable ayant un point d'éclair de T °C	T-25
Bois	90

[a] La classification des matériaux isolants est conforme à l'IEC 60085. Toute incompatibilité des matériaux d'un système isolant qui pourraient réduire la limite maximale de température du système à des valeurs inférieures aux limites des matériaux individuels doit être prise en compte.

[b] Le marquage T fait référence à la température maximale de fonctionnement marquée.

[c] Pour chaque matériau et chaque composant, on doit tenir compte des caractéristiques de température pour chaque matériau ou composant pour déterminer la température maximale appropriée. Chaque composant doit être utilisé conformément à ses caractéristiques de température. En cas de doute, il est recommandé d'effectuer l'essai à la bille de 8.8.4.1.

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Tableau 23 – Températures maximales admissibles pour les parties des APPAREILS EM qui sont susceptibles d'être touchées

APPAREILS EM et ses parties		Température maximale [a] °C		
		Métaux et liquides	Verre, porcelaine, matière vitreuse	Matière moulée plastique, caoutchouc, bois
Surfaces externes des APPAREILS EM susceptibles d'être touchées pendant un temps "*t*".	$t < 1$ s	74	80	86
	1 s ≤ t < 10 s	56	66	71
	10 s ≤ t < 1 min	51	56	60
	1 min ≤ t	48	48	48

[a] Ces valeurs limites de température sont applicables pour le contact avec la peau saine d'adultes. Elles ne sont pas applicables lorsque des surfaces importantes de la peau (10 % de la surface totale du corps ou plus) peuvent être en contact avec une surface chaude. Cela s'applique également dans le cas de contact de la peau avec plus de 10 % de la surface de la tête. Le cas échéant, des limites appropriées doivent être déterminées et documentées dans le DOSSIER DE GESTION DES RISQUES.

Tableau 24 – Températures maximales admissibles pour le contact de la peau avec des PARTIES APPLIQUEES des APPAREILS EM

PARTIES APPLIQUEES des APPAREILS EM		Température maximale [a] [b] °C		
		Métaux et liquides	Verre, porcelaine, matière vitreuse	Matière moulée plastique, caoutchouc, bois
PARTIE APPLIQUEE en contact avec le PATIENT pendant un temps "*t*"	$t < 1$ min	51	56	60
	1 min ≤ t < 10 min	48	48	48
	10 min ≤ t	43	43	43

[a] Ces valeurs limites de température sont applicables pour la peau saine d'adultes. Elles ne sont pas applicables lorsque des surfaces importantes de la peau (10 % de la surface totale du corps ou plus) peuvent être en contact avec une surface chaude. Elles ne s'appliquent pas dans le cas de contact de la peau avec plus de 10 % de la surface de la tête. Le cas échéant, des limites appropriées doivent être déterminées et documentées dans le DOSSIER DE GESTION DES RISQUES.

[b] Lorsqu'il est nécessaire que les PARTIES APPLIQUEES dépassent les limites de température du Tableau 24 pour apporter un bénéfice clinique, le DOSSIER DE GESTION DES RISQUES doit contenir la documentation montrant que le bénéfice apporté prévaut toute augmentation du RISQUE associé.

11.1.2 * Température des PARTIES APPLIQUEES

11.1.2.1 PARTIES APPLIQUEES destinées à fournir de la chaleur à un PATIENT

La température (surfaces chaudes ou froides) ou (le cas échéant) les effets cliniques doivent être déterminés et documentés dans le DOSSIER DE GESTION DES RISQUES. Les températures et les effets cliniques doivent être stipulés dans les instructions d'utilisation.

11.1.2.2 * PARTIES APPLIQUEES non destinées à fournir de la chaleur à un PATIENT

Les limites du Tableau 24 doivent s'appliquer à la fois en CONDITION NORMALE et en CONDITION DE PREMIER DEFAUT. Si la température ~~à la~~ de surface d'une PARTIE APPLIQUEE dépasse 41 °C:

– la température maximale doit être ~~stipulée~~ indiquée dans les instructions d'utilisation;

– les conditions de contact sécurisé telles la durée ou l'état du PATIENT, doivent être indiquées; et

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– les effets cliniques relatifs aux caractéristiques telles que la surface du corps, la maturité des PATIENTS, les médicaments pris ou la pression ~~de~~ en surface doivent être déterminés et documentés dans le DOSSIER DE GESTION DES RISQUES.

Aucune justification n'est exigée tant que la température ne dépasse pas 41 °C.

Si les analyses documentées dans le DOSSIER DE GESTION DES RISQUES démontrent que les températures de la PARTIE APPLIQUEE ne peuvent pas être affectées par le fonctionnement de l'APPAREIL EM y compris en CONDITION DE PREMIER DEFAUT, la mesure de la température de la PARTIE APPLIQUEE selon 11.1.3 n'est pas requise.

Les surfaces des PARTIES APPLIQUEES qui sont refroidies ~~à des valeurs inférieures aux températures ambiantes~~ sous la température ambiante peuvent également ~~entraîner des DANGERS~~ être sources de RISQUE inacceptable et doivent être évaluées ~~dans le cadre~~ lors du PROCESSUS de GESTION DES RISQUES.

11.1.3 * Mesures

Lorsque l'estimation de l'ingénierie par les FABRICANTS indique que les limites de température ne peuvent être dépassées, aucune mesure n'est exigée. Lorsque de telles estimations indiquent que le local d'essai n'influencera pas les mesures, la mesure peut être omise. Toutefois, la justification d'une telle estimation doit être documentée dans le DOSSIER DE GESTION DES RISQUES. Si le coin d'essai est utilisé, ses surfaces ne doivent pas dépasser 90 °C.

Pour les parties D'APPAREILS EM qui sont susceptibles d'être touchées et pour les PARTIES APPLIQUEES, la probabilité d'un contact et la durée du contact est déterminée et documentée dans le DOSSIER DE GESTION DES RISQUES.

La conformité avec les exigences de 11.1.1 et de 11.1.2 est vérifiée par inspection du DOSSIER DE GESTION DES RISQUES et des instructions d'utilisation, du fonctionnement de l'APPAREIL EM et par des mesures de température comme indiqué ci-après:

a) Positionnement

1) LES APPAREILS EM sont soumis aux essais dans leur(s) position(s) d'UTILISATION NORMALE.

2) L'APPAREIL EM est placé dans un local d'essai. Le local d'essai est constitué de deux parois perpendiculaires, d'un plancher et, si nécessaire, d'un plafond, le tout en contre-plaqué peint en noir mat de 20 mm d'épaisseur. Les dimensions linéaires du local d'essai sont d'au moins 115 % de celles de l'APPAREIL EM en essai.

L'APPAREIL EM est positionné dans le local d'essai de la manière suivante:

- *Un APPAREIL EM normalement utilisé sur un plancher ou sur une table est placé aussi près des parois que cela est susceptible de se produire en UTILISATION NORMALE.*
- *Un APPAREIL EM normalement fixé sur un mur est monté sur l'une des paroi aussi près de l'autre paroi et du plancher ou du plafond que cela est susceptible de se produire en UTILISATION NORMALE.*
- *Un APPAREIL EM normalement fixé au plafond est monté sur le plafond et placé aussi près des parois que cela est susceptible de se produire en UTILISATION NORMALE.*

3) Un APPAREIL EM PORTATIF est suspendu dans l'air dans sa position normale.

4) Un APPAREIL EM destiné à être installé dans une armoire ou contre un mur est monté selon la description technique (voir 7.9.3.1), en utilisant des parois en contreplaqué peint en noir mat, de 10 mm d'épaisseur pour simuler les parois de l'armoire si la description technique le spécifie ainsi et de 20 mm d'épaisseur pour simuler les murs d'un bâtiment.

b) Alimentation électrique

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– *Un APPAREIL EM ayant des éléments chauffants est mis en fonctionnement comme en UTILISATION NORMALE, avec tous les éléments chauffants sous tension à moins d'en être empêché par des verrous de commutation, à une tension d'alimentation égale à 110 % de la tension maximale ASSIGNEE.*

– *Un APPAREIL EM entraîné par un moteur est mis en fonctionnement sous charge normale, au TAUX D'UTILISATION normal et à la tension la plus défavorable comprise entre 90 % de la tension ASSIGNEE minimale et 110 % de la tension ASSIGNEE maximale.*

– *Les appareils combinés chauffants et entraînés par moteur et les autres APPAREILS EM sont soumis aux essais à la fois à 110 % de la tension ASSIGNEE maximale et à 90 % de la tension ASSIGNEE minimale.*

– *Lorsque des modules sont soumis aux essais séparément, la configuration d'essai simule les conditions du cas le plus défavorable d'UTILISATION NORMALE qui pourraient affecter le résultat d'essai.*

c) Stabilisation thermique

– *Pour les APPAREILS EM à SERVICE non CONTINU:*

Après fonctionnement en mode d'attente/repos jusqu'à l'obtention de la STABILITE THERMIQUE, on fait fonctionner l'APPAREIL EM en UTILISATION NORMALE suivant des cycles consécutifs jusqu'à nouvelle obtention de la STABILITE THERMIQUE ou pendant 7 h, en prenant la durée la plus courte. Les périodes "marche" et "arrêt" de chaque cycle sont les périodes ASSIGNEES de "marche" et "arrêt";

– *Pour les APPAREILS EM à SERVICE CONTINU:*

On fait fonctionner l'APPAREIL EM jusqu'à obtention de la STABILITE THERMIQUE.

d) Mesures de la température

– *Méthode par la mesure de la résistance (pour les enroulements):*

La valeur de l'échauffement d'un enroulement en cuivre est calculée à partir de la formule suivante:

$$\Delta T = \frac{R_2 - R_1}{R_1}(234{,}5 + T_1) - (T_2 - T_1)$$

où

ΔT *est l'échauffement en °C ;*

R_1 *est la résistance au début de l'essai en* Ω *;*

R_2 *est la résistance à la fin de l'essai en* Ω *;*

T_1 *est la température ambiante au début de l'essai en °C ;*

T_2 *est la température ambiante à la fin de l'essai en °C.*

Au début de l'essai, les enroulements doivent être à température ambiante.

NOTE Lorsque la méthode de la résistance est utilisée, il est recommandé de déterminer la résistance des enroulements à la fin de l'essai, en effectuant des mesures aussitôt que possible après ouverture du circuit, puis à des intervalles rapprochés, de façon à pouvoir tracer une courbe de variations de la résistance en fonction du temps, pour déterminer la valeur au moment de l'ouverture du circuit.

– *Méthode du thermocouple et autres méthodes (pour toutes les mesures):*

La mesure est réalisée par des dispositifs ou des capteurs choisis et positionnés de manière à avoir un effet négligeable sur la température de la partie en essai.

Lorsque des thermocouples sont utilisés pour déterminer la température des enroulements, les limites de température du Tableau 22 doivent être réduites de 10 °C.

La température de l'isolation électrique, autre que celle des enroulements, est déterminée à la surface de l'isolation, aux endroits où un défaut pourrait provoquer un court-circuit, un

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contournement d'un MOYEN DE PROTECTION, un contournement d'une isolation ou une réduction des LIGNES DE FUITE ou des DISTANCES DANS L'AIR en dessous des valeurs spécifiées pour le type d'isolation en 8.9.

Le point de séparation des conducteurs d'un câble multibrins et les points de pénétration des fils isolés dans les douilles sont des exemples d'endroits où les températures pourraient être mesurées.

e) Critères d'essai

Au cours de l'essai les COUPE-CIRCUIT THERMIQUES ne sont pas désactivés.

La température maximale d'une partie est déterminée en mesurant l'échauffement de la partie en essai et en l'ajoutant à la température ambiante maximale autorisée spécifiée dans la description technique (voir 7.9.3.1). Lorsque des dispositifs de régulation thermique rendent cette méthode inappropriée, d'autres méthodes de mesure sont justifiées dans le DOSSIER DE GESTION DES RISQUES.

11.1.4 PROTECTIONS

Les PROTECTIONS utilisées pour éviter le contact avec des surfaces accessibles chaudes ou froides des APPAREILS EM ne doivent pouvoir être démontées qu'à l'aide d'un OUTIL.

La vérification est effectuée par inspection.

11.2 * Prévention du feu

11.2.1 * Solidité et rigidité exigées pour la prévention des DANGERS liés au feu dans les APPAREILS EM

Les ENVELOPPES doivent avoir la solidité et la rigidité nécessaires pour éviter un feu pouvant apparaître à la suite de leur affaissement total ou partiel dû à un MAUVAIS USAGE RAISONNABLEMENT PREVISIBLE.

La conformité est vérifiée par les essais de résistance mécanique pour les ENVELOPPES (voir 15.3).

11.2.2 * APPAREILS ET SYSTEMES EM utilisés avec des ENVIRONNEMENTS RICHES EN OXYGENE

11.2.2.1 RISQUE de feu dans un ENVIRONNEMENT RICHE EN OXYGENE

Dans les APPAREILS EM ET SYSTEMES EM, le RISQUE d'incendie dans un ENVIRONNEMENT RICHE EN OXYGENE doit être réduit autant que possible en CONDITION NORMALE ou dans les CONDITIONS DE PREMIER DEFAUT (telles qu'identifiées en 11.2.3). On considère qu'il existe un RISQUE inacceptable d'incendie dans un ENVIRONNEMENT RICHE EN OXYGENE lorsqu'une source d'inflammation est en contact avec une matière inflammable et qu'il n'y a aucun moyen qui limiterait la propagation d'un incendie.

NOTE 1 Pour les concentrations en oxygène jusqu'à 25 % à une atmosphère ou des pressions partielles jusqu'à 27,5 kPa pour des pressions atmosphériques supérieures, les exigences de 13.1.1 sont considérées comme suffisantes.

a) * On considère qu'une source d'inflammation est présente dans un ENVIRONNEMENT RICHE EN OXYGENE lorsqu'une des conditions suivantes existe en CONDITION NORMALE et dans les CONDITIONS DE PERMIER DEFAUT (y compris tension et courant):

1) la température du matériau est portée à sa température d'inflammation;

2) les températures pourraient affecter les soudures ou les joints de soudures en causant des desserrements, des contournements ou d'autres défaillances qui pourraient donner lieu à la création d'arcs ou à l'augmentation de la température de la matière jusqu'à sa température d'inflammation;

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3) des parties liées à la sécurité se fissurent ou changent de forme extérieure en exposant à des températures supérieures à 300 °C ou à des étincelles (voir 4) et 5) ci-dessous) en raison de la surchauffe;

4) les températures des parties ou des composants pourraient dépasser 300 °C ;

5) les étincelles fournissent une énergie d'inflammation en dépassant les limites indiquées par les Figures 35 à 37 (incluse).

Les points 4) et 5) traitent du cas le plus défavorable lorsque l'atmosphère est composée de 100 % d'oxygène, que la matière de contact (pour le point 5) est de la soudure et que le combustible est du coton. Il convient de tenir compte des combustibles et des concentrations d'oxygène disponibles lorsqu'on applique ces exigences spécifiques. Les écarts éventuels avec ces limites du cas le plus défavorable (sur la base de concentrations en oxygène plus faibles ou de combustibles moins inflammables) doivent être justifiés et documentés dans le DOSSIER DE GESTION DES RISQUES.

Comme alternative à 11.2.2.1 a) 5), l'essai suivant peut être utilisé pour déterminer s'il existe une source d'inflammation.

Tout d'abord, il faut identifier le ou les endroits à l'intérieur de L'APPAREIL EM où des arcs pourraient causer une inflammation. Ensuite, identifier la ou les matières des parties entre lesquelles les étincelles peuvent se produire. Des spécimens de la même matière sont ensuite utilisés pour réaliser les broches de contact de l'appareillage d'essai (voir Figure 34).

D'autres paramètres pour l'essai sont les suivants: concentration en oxygène, combustible, paramètres électriques (courant, tension, capacité, inductance ou résistance). Ces paramètres doivent être choisis de telle manière qu'ils représentent le cas le plus défavorable pour l'APPAREIL EM.

NOTE 2 Pour les APPAREILS EM qui comportent un circuit non couvert par les Figures 35 à 37 (incluse), la tension ou le courant d'essai peuvent être réglés à trois fois les valeurs du cas le plus défavorable avec l'autre paramètre réglé à la valeur du cas le plus défavorable pour déterminer s'il peut y avoir inflammation ou non.

Deux broches de contact faites dans la matière à étudier sont placées en opposition (voir Figure 34). Une des broches a un diamètre de 1 mm, l'autre de 3 mm. La source électrique est connectée à ces broches comme indiqué aux Figures 35 à 37. Un morceau de coton est placé près des surfaces de contact des deux broches. Les contacts sont baignés en permanence dans un flux d'oxygène à une vitesse inférieure à 0,5 m/s via un tube. La cathode est déplacée vers l'anode pour fermer les contacts puis tirée en arrière pour les ouvrir de nouveau. Un minimum de 300 essais doit être effectué avant de décider que les étincelles ne provoquent pas d'inflammation. Si les étincelles deviennent plus petites en raison du mauvais état des surfaces des électrodes, celles-ci sont nettoyées avec une lime. Si le coton noircit parce qu'il s'est oxydé, il est alors remplacé. Aux Figures 36 et 37, la résistance utilisée pour contrôler le courant qui s'écoule dans l'inductance et la constante de temps pour charger le condensateur sont choisies de telle manière qu'elles aient un impact minimal sur l'énergie de l'étincelle. On procède aux essais par examen visuel sans que le condensateur soit en place ou avec la bobine d'inductance contournée.

La situation avec respectivement la tension ou le courant à la valeur la plus élevée et l'absence d'inflammation définit la limite supérieure. Une limite supérieure de sécurité est donnée en divisant respectivement la limite supérieure de tension ou de courant par le facteur de marge de SECURITE de trois.

NOTE 3 Le facteur de marge de SECURITE est considéré couvrir l'incertitude des expériences d'arcs et la variabilité des paramètres sous-jacents comme la pression, la qualité du coton ou des matériaux des contacts.

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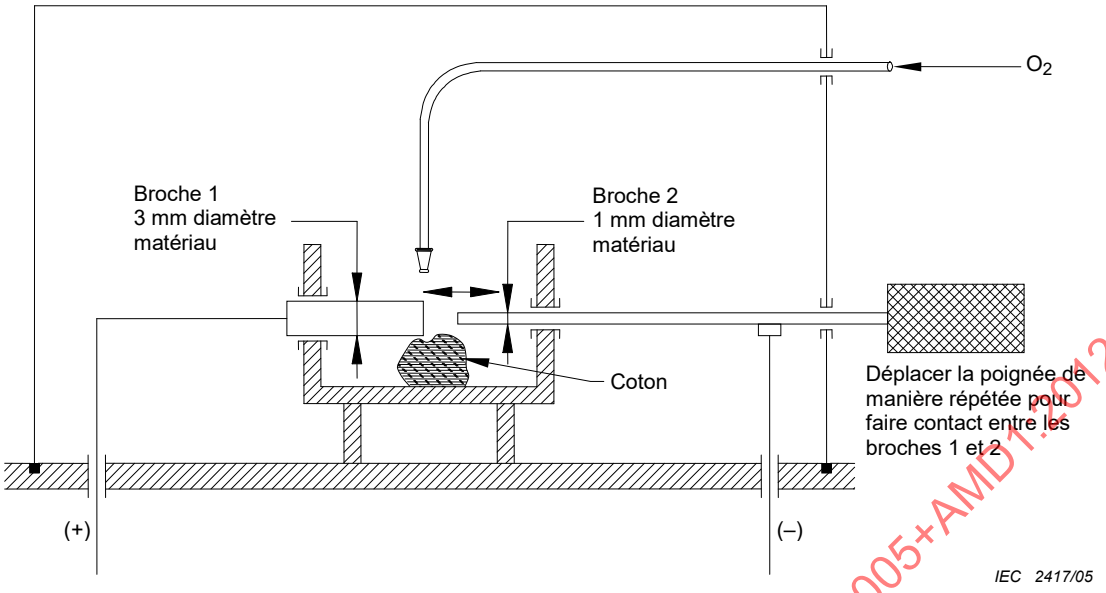


Figure 34 – Appareillage d'essai d'inflammation par étincelles
(voir 11.2.2.1)

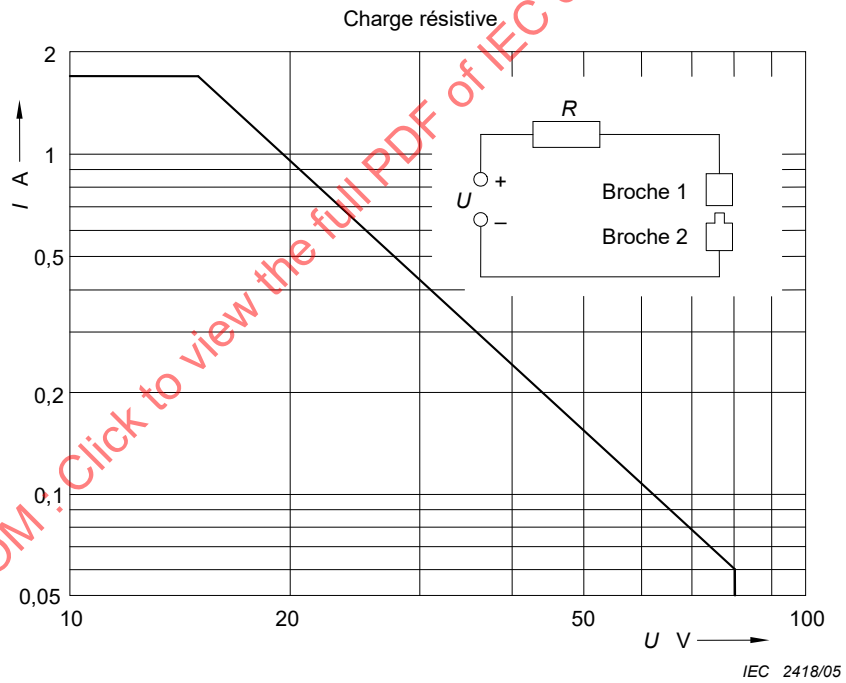


Figure 35 – Courant maximal admissible *I* en fonction de la tension maximale admissible *U* mesuré dans un circuit purement résistif dans un ENVIRONNEMENT RICHE EN OXYGENE
(voir 11.2.2.1)

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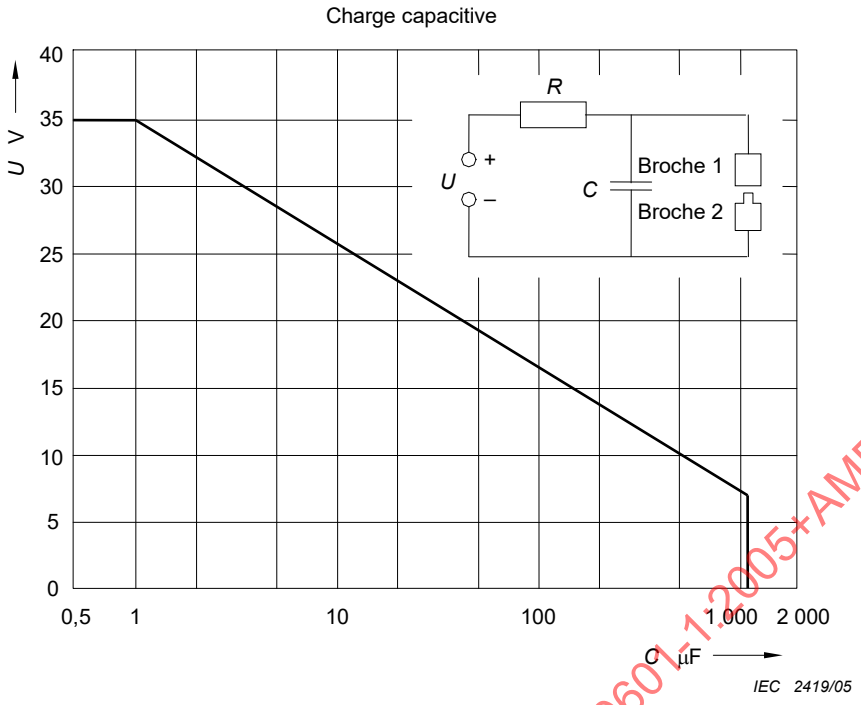


Figure 36 – Tension maximale admissible *U* en fonction de la capacité *C* mesurée dans un circuit capacitif utilisé dans un ENVIRONNEMENT RICHE EN OXYGENE
(voir 11.2.2.1)

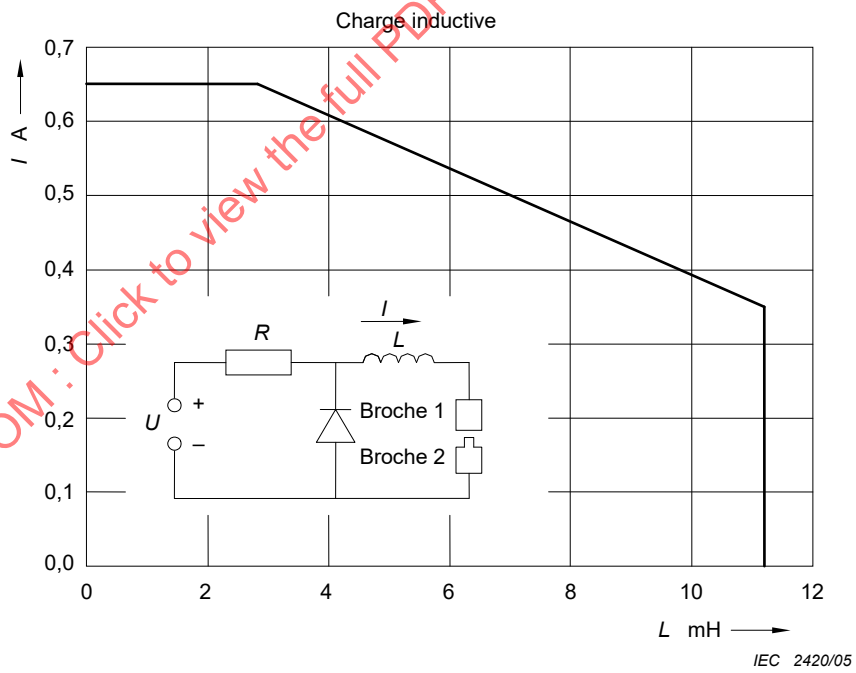


Figure 37 – Courant maximal admissible *I* en fonction de l'inductance *L* mesurée dans un circuit inductif dans un ENVIRONNEMENT RICHE EN OXYGENE
(voir 11.2.2.1)

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b) On estime que les configurations suivantes, seules ou en combinaison, selon ce qui est approprié (tel que déterminé par l'application du PROCESSUS de GESTION DES RISQUES), fournissent un RISQUE résiduel acceptable d'incendie dans un ENVIRONNEMENT RICHE EN OXYGENE:

1) Les composants électriques qui se trouvent dans un compartiment avec un ENVIRONNEMENT RICHE EN OXYGENE doivent être alimentés par des alimentations électriques dont le niveau d'énergie est limité. Ces niveaux d'énergie doivent être inférieurs à ceux qui sont considérés comme suffisants pour l'inflammation (voir 11.2.2 1 a)).

La conformité est vérifiée par examen de la conception et par mesure ou calcul des valeurs de puissance, d'énergie et de température en CONDITION NORMALE et en CONDITION DE PREMIER DEFAUT (comme identifié en 11.2.3).

ou

2) * Les compartiments qui contiennent des parties ou des composants qui peuvent constituer une source d'inflammation (comme défini en 11.2.2.1 a)) uniquement en CONDITION DE PREMIER DEFAUT (comme identifié en 11.2.3) et dans lesquels l'oxygène peut pénétrer (par exemple à cause d'une fuite non détectée) doivent être ventilés afin que la concentration en oxygène ne dépasse pas 25 %.

La conformité est vérifiée par l'essai suivant:

La concentration en oxygène est mesurée sur une période qui permette d'avoir la concentration en oxygène la plus élevée. On choisit les réglages de commande les moins favorables. Les conditions de fuite d'oxygène sont choisies de telle manière qu'elles entraînent la fuite minimale qui pourrait être détectée par l'OPERATEUR (par exemple en raison d'une défaillance de la fonction du dispositif). Si la concentration en oxygène dépasse 25 % en présence de parties ou de composants qui pourraient être une source d'inflammation y compris au moment d'application de l'énergie, cela constitue une défaillance.

ou

3) * Un compartiment qui contient des parties ou des composants qui peuvent constituer une source d'inflammation (comme défini en 11.2.2.1 a)) uniquement en CONDITION DE PREMIER DEFAUT (comme identifié en 11.2.3) est séparé d'un autre compartiment qui contient un ENVIRONNEMENT RICHE EN OXYGENE en scellant tous les joints et tout orifice destiné à des câbles, à des arbres ou à d'autres usages. L'effet des éventuelles fuites et défaillances en CONDITION DE PREMIER DEFAUT (comme identifié en 11.2.3) qui pourraient causer une inflammation doit être évalué par une EVALUATION DU RISQUE pour déterminer les intervalles de maintenance appropriés.

La conformité est vérifiée par examen visuel et par l'inspection de la documentation fournie par le FABRICANT y compris le DOSSIER DE GESTION DES RISQUES.

ou

4) Les composants électriques à l'intérieur d'un compartiment contenant un ENVIRONNEMENT RICHE EN OXYGENE qui peuvent devenir une source d'inflammation (comme défini en 11.2.2.1 a)) uniquement en CONDITIONS DE PREMIER DEFAUT (comme identifié en 11.2.3) doivent être enfermés de telle manière qu'en cas d'inflammation à l'intérieur de l'ENVELOPPPE, le feu s'éteigne rapidement de lui même et qu'aucune quantité dangereuse de gaz toxiques n'atteigne le PATIENT.

La conformité est vérifiée en faisant démarrer un incendie à l'intérieur de l'ENVELOPPE. S'il n'est pas évident que des gaz toxiques ne puissent pas atteindre le PATIENT, alors le gaz qui pourrait atteindre le PATIENT est analysé.

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11.2.2.2 * Sorties d'évacuation extérieures pour un ENVIRONNEMENT RICHE EN OXYGENE

Des sorties d'évacuation extérieure d'un ENVIRONNEMENT RICHE EN OXYGENE ne doivent pas être situées de telle manière qu'un RISQUE d'inflammation apparaisse en raison d'un composant électrique quelconque (qui pourrait causer une étincelle en UTILISATION NORMALE ou en CONDITION DE PREMIER DEFAUT) (comme identifié en 11.2.3) monté à l'extérieur de l'APPAREIL EM ou du SYSTEME EM. Le RISQUE d'inflammation est considéré comme suffisamment faible si la concentration en oxygène dans l'environnement immédiat du composant électrique ne dépasse pas 25 % dans les conditions de fonctionnement les moins favorables.

La conformité est vérifiée par inspection.

11.2.2.3 Connexions électriques dans des ENVIRONNEMENTS RICHES EN OXYGENE

Les connexions électriques à l'intérieur d'un compartiment contenant un ENVIRONNEMENT RICHE EN OXYGENE en UTILISATION NORMALE ne doivent pas produire d'étincelles en raison d'un desserrement ou d'une rupture à moins qu'elles ne soient limitées en puissance et en énergie aux valeurs identifiées en 11.2.2.1 a) 5).

On prévient le desserrement ou la rupture par les méthodes suivantes ou par des méthodes équivalentes:

– Les fixations à vis doivent être protégées contre le desserrement en cours d'utilisation par des méthodes comme le vernissage, l'utilisation de rondelles à ressort ou l'application de couples appropriés.
– Les connexions de câbles soudées, serties et à broches qui sortent de l'ENVELOPPE doivent comprendre une fixation mécanique supplémentaire.

La conformité est vérifiée par examen visuel.

11.2.3 CONDITIONS DE PREMIER DEFAUT liées aux ENVIRONNEMENTS RICHES EN OXYGENE avec des APPAREILS EM ET DES SYSTEMES EM

– Défaillance d'un système de ventilation construit selon 11.2.2.1 b) 2).
– Défaillance d'une barrière construite conformément à 11.2.2.1 b) 3).
– Défaillance d'un composant qui crée une source d'inflammation (comme défini en 11.2.2.1 a)).
– Défaillance de l'isolation (qu'elle soit en matière solide ou constituée par un espacement) qui assure l'équivalent d'au moins un MOYEN DE PROTECTION PATIENT mais de moins de deux MOYENS DE PROTECTION PATIENT (comme décrit en 8.8 et en 8.9) qui pourrait constituer une source d'inflammation (comme défini en 11.2.2.1 a)).
– Défaillance d'un composant pneumatique qui donne lieu à une fuite d'un gaz enrichi en oxygène.

11.3 * Exigences de construction pour les ENVELOPPES contre le feu des APPAREILS EM

Ce paragraphe donne des moyens alternatifs pour assurer la conformité avec certaines SITUATIONS DANGEREUSES et certaines conditions de défaut comme identifié en 13.1.2. En pratiquant ainsi, les exigences de construction suivantes doivent être satisfaites ou analysées de manière spécifique dans le DOSSIER DE GESTION DES RISQUES et si elles ne sont pas satisfaites, une justification particulière doit être donnée.

a) Un fil électrique isolé à l'intérieur d'une ENVELOPPE contre le feu doit présenter une classification d'inflammabilité équivalente à FV-1 ou d'un degré meilleur, selon les parties appropriées de la série IEC 60695. Les connecteurs, les cartes de circuits imprimés et les matériaux isolants sur lesquels des composants sont montés doivent présenter une classification d'inflammabilité FV-2 ou d'un degré meilleur selon la IEC 60695-11-10.

   La conformité est vérifiée par inspection des données concernant les matériaux ou en réalisant les essais FV spécifiés dans l'IEC 60695-11-10 sur trois spécimens des parties

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correspondantes qui sont soumises à l'essai. Les spécimens peuvent correspondre à l'un des cas suivants:

1) *parties complètes; ou*
2) *sections d'une partie, y compris la zone avec l'épaisseur de paroi la moins importante et tout orifice de ventilation.*

Les composants certifiés selon l'IEC 60695-11-10 n'ont pas à être soumis aux essais.

b) L'ENVELOPPE contre le feu doit satisfaire aux exigences suivantes:

1) Le fond ne doit pas présenter d'ouvertures ou alors, dans les proportions spécifiées à la Figure 39, il doit être construit avec des déflecteurs comme spécifié à la Figure 38, ou il doit être en métal, perforé comme spécifié dans le Tableau 25, ou être un écran métallique avec une maille ne dépassant pas 2 mm × 2 mm centre à centre et un diamètre de fil d'au moins 0,45 mm.

2) Les côtés ne doivent pas avoir d'ouvertures dans la surface qui est incluse à l'intérieur de la ligne C de la Figure 39.

3) L'ENVELOPPE et tout déflecteur ou toute barrière contre les flammes doivent être en métal (à l'exception du magnésium) ou dans des matériaux non métalliques à l'exception des constructions selon le Tableau 25 et des constructions avec maille présentant une classification d'inflammabilité FV-2 (ou plus performante) pour les APPAREILS EM TRANSPORTABLES et de FV-1 (ou plus performante) selon l'IEC 60695-11-10, pour les APPAREILS EM FIXES ou STATIONNAIRES.

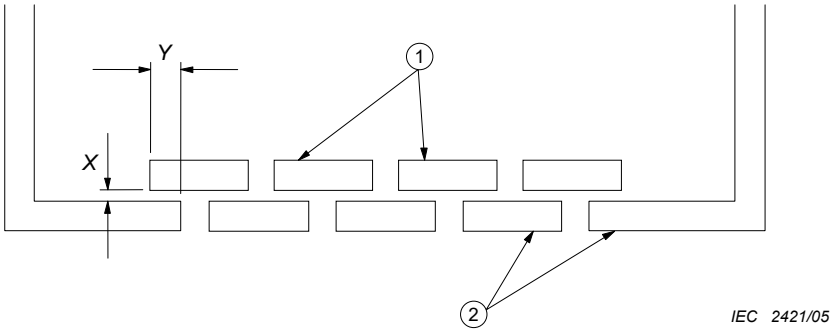
   L'ENVELOPPE et tout déflecteur ou toute barrière contre les flammes doit présenter une rigidité adéquate.

La conformité est vérifiée par inspection. En cas de doute, la classification d'inflammabilité b) 3) est vérifiée comme en a).

Tableau 25 – Perforation acceptable du fond d'une ENVELOPPE

Epaisseur minimale mm	Diamètre maximal des trous mm	Espacement minimal des trous centre à centre mm
0,66	1,14	1,70 (233 trous/645 mm^2)
0,66	1,19	2,36
0,76	1,15	1,70
0,76	1,19	2,36
0,81	1,91	3,18 (72 trous/645 mm^2)
0,89	1,90	3,18
0,91	1,60	2,77
0,91	1,98	3,18
1,00	1,60	2,77
1,00	2,00	3,00

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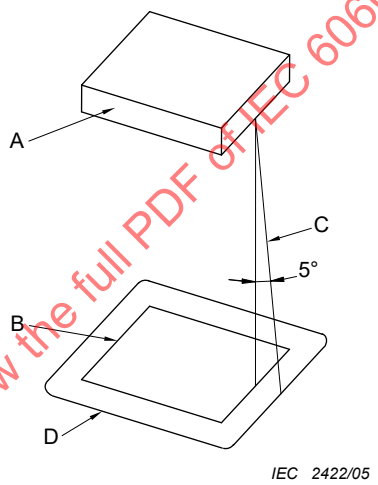


Y = deux fois X mais jamais moins de 25 mm

① Plaques de déflecteurs (peuvent être sous le fond de l'ENVELOPPE)

② Fond de l'ENVELOPPE

Figure 38 – Déflecteur
(voir 11.3)



Légende

A Partie ou composant de L'APPAREIL EM qui est considéré comme une source d'incendie. Il est constitué d'un composant entier ou d'une partie de l'APPAREIL EM s'il n'est pas protégé / blindé d'une autre manière ou de la portion non protégée / blindée d'un composant qui est partiellement protégé / blindé par son boîtier.

B Projection du contour de A sur le plan horizontal.

C Ligne oblique qui trace la zone minimale du fond et des côtés à construire comme spécifié en 11.3 b) 1) et en 11.3 b) 2). Cette ligne fait une projection selon un angle de 5° par rapport à la verticale à chaque point autour du périmètre de A et elle est orientée de manière à tracer la zone maximale.

D Zone minimale du fond à construire comme spécifié en 11.3 b) 1).

Figure 39 – Zone du fond d'une ENVELOPPE comme spécifié en 11.3 b) 1)
(voir 11.3)

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11.4 * APPAREILS EM et SYSTEMES EM destinés à être utilisés avec des produits anesthésiques inflammables

Les APPAREILS EM, les SYSTEMES EM ou leurs parties décrits dans les DOCUMENTS D'ACCOMPAGNEMENT destinés à être utilisés avec des produits anesthésiques inflammables (CATEGORIE AP) ou des produits anesthésiques inflammables avec oxydants (CATEGORIE APG) doivent être conformes aux exigences de l'Annexe G.

11.5 * APPAREILS EM et SYSTEMES EM destinés à être utilisés avec des produits inflammables

Le PROCESSUS de GESTION DES RISQUES du FABRICANT doit traiter la possibilité d'incendie et les actions de réduction associées.

La conformité est déterminée par inspection du DOSSIER DE GESTION DES RISQUES.

11.6 Débordement, renversement, fuites, pénétration d'eau ou de particules, nettoyage, désinfection, stérilisation et compatibilité avec des substances utilisées avec des APPAREILS EM

11.6.1 Généralités

La construction d'un APPAREIL EM et d'un SYSTEME EM doit garantir un degré suffisant de protection contre les débordements, renversements, fuites, pénétration d'eau ou de particules, nettoyage, désinfection et stérilisation ainsi que la compatibilité avec les substances utilisées avec l'APPAREIL EM.

11.6.2 * Débordements dans les APPAREILS EM

~~Si l'APPAREIL EM incorpore un réservoir ou un récipient pour le stockage de liquides susceptible d'être trop rempli ou de déborder en UTILISATION NORMALE, alors le liquide qui déborde du réservoir ou du récipient ne doit pas mouiller de MOYEN DE PROTECTION susceptible d'être défavorablement affecté par un tel liquide, ni créer de RISQUE inacceptable. Sauf indication contraire figurant sur le marquage ou dans les instructions d'utilisation, aucune SITUATION DANGEREUSE (comme spécifié ici) ou aucun RISQUE inacceptable dû à un débordement ne doit être encouru si un APPAREIL EM TRANSPORTABLE est incliné selon un angle de 15°.~~

~~*La conformité est vérifiée en remplissant complètement le réservoir et en y ajoutant ensuite une quantité supplémentaire égale à 15 % de sa contenance versée régulièrement pendant 1 min.*~~

~~*Puis l'APPAREIL EM TRANSPORTABLE est incliné d'un angle de 15° en partant de la position d'UTILISATION NORMALE, dans le ou les sens les moins favorables (au besoin après un nouveau remplissage).*~~

~~*Après ces PROCEDURES, l'APPAREIL EM doit passer avec succès les essais appropriés de tension de tenue et de COURANT DE FUITE et ne doit présenter aucune trace d'humidité sur des parties électriques non isolées ou sur l'isolation de parties électriques susceptibles d'engendrer une SITUATION DANGEREUSE.*~~

Si le niveau de remplissage maximal est indiqué par un marquage sur l'APPAREIL EM et qu'un avertissement ou une notice de sécurité est donné, aucune SITUATION DANGEREUSE (telle que spécifiée en 13.1) ni RISQUE inacceptable dû(e) à un débordement ne doit se développer lorsque le réservoir ou le récipient de stockage de liquide est rempli à sa capacité maximale et que l'APPAREIL EM TRANSPORTABLE est incliné à un angle de 10°, ou pour un APPAREIL EM MOBILE dépassant 45 kg, lorsqu'il est déplacé sur un seuil comme décrit en 9.4.2.4.3.

Si aucun avertissement ni aucune notice de sécurité concernant le niveau de remplissage maximal n'est donné(e), aucune SITUATION DANGEREUSE (telle que spécifiée en 13.1) ni aucun RISQUE inacceptable dû(e) à un débordement ne doit se développer lorsque le réservoir ou le récipient de stockage de liquide est rempli à 15 % de plus que la capacité maximale et que

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l'APPAREIL EM TRANSPORTABLE est incliné à un angle de 10°, ou pour un APPAREIL EM MOBILE dépassant 45 kg, lorsqu'il est déplacé sur un seuil comme décrit en 9.4.2.4.3.

La conformité est vérifiée comme suit:

Si des avertissements ou des notices de sécurité concernant le débordement sont marqué(e)s sur l'APPAREIL EM TRANSPORTABLE, le réservoir de liquide est rempli au niveau maximal indiqué.

Si aucun(e) avertissement ou notice de sécurité concernant le débordement n'est marqué(e) sur l'APPAREIL EM TRANSPORTABLE, le réservoir de liquide est rempli complètement, puis une quantité supplémentaire égale à 15 % de la capacité du réservoir est versée progressivement pendant 1 min.

L'APPAREIL EM TRANSPORTABLE est ensuite incliné à un angle de 10° dans le ou les sens les moins favorables (au besoin après un nouveau remplissage) en partant de la position d'UTILISATION NORMALE.

UN APPAREIL EM MOBILE dépassant 45 kg est déplacé sur un seuil comme décrit en 9.4.2.4.3.

Après ces PROCEDURES, l'APPAREIL EM doit passer avec succès les essais appropriés de tension de tenue et de COURANT DE FUITE et ne doit présenter aucune trace d'humidité sur des parties électriques non isolées ou sur l'isolation électrique de parties susceptibles d'engendrer la perte de la SECURITE DE BASE ou des PERFORMANCES ESSENTIELLES en CONDITION NORMALE *ou en combinaison avec une CONDITION DE PREMIER DEFAUT (sur la base d'un examen visuel).*

11.6.3 * Renversement sur ~~un~~ des APPAREILS EM et ~~sur un~~ des SYSTEMES EM

Les APPAREILS EM et les SYSTEMES EM nécessitant la manipulation de liquides en UTILISATION NORMALE, comprenant les APPAREILS EM ou les SYSTEMES EM utilisés dans un environnement où le PROCESSUS DE GESTION DES RISQUES a déterminé qu'un renversement sur l'APPAREIL EM est susceptible de se produire, doivent être construits de ~~telle manière qu'un~~ sorte que le renversement ne mouille pas des parties qui sont susceptibles d'engendrer ~~une SITUATION DANGEREUSE~~ la perte de la SECURITE DE BASE ou des PERFORMANCES ESSENTIELLES.

La conformité est vérifiée par l'inspection du DOSSIER DE GESTION DES RISQUES et au moyen l'essai suivant:

L'APPAREIL EM est positionné selon 5.4 a). Une certaine quantité de liquide est versée de manière continue en un point de la surface supérieure de l'APPAREIL EM. Le type de liquide, le volume, la durée de versement et l'emplacement sont déterminés lors de ~~l'application du PROCESSUS de GESTION DES RISQUES~~ de l'ANALYSE DE RISQUES. ~~Toutes les conditions d'essai sont identifiées par inspection du DOSSIER de GESTION DES RISQUES.~~ Les conditions d'essai qui simulent le cas de renversement le plus défavorable doivent être documentées dans le DOSSIER DE GESTION DES RISQUES.

Après ces PROCEDURES, l'APPAREIL EM doit passer avec succès les essais appropriés de tension de tenue et de COURANT DE FUITE et ne doit présenter aucune trace d'humidité sur des parties électriques non isolées ou sur l'isolation de parties électriques susceptibles d'engendrer ~~une SITUATION DANGEREUSE~~ la perte de la SECURITE DE BASE ou des PERFORMANCES ESSENTIELLES en CONDITION NORMALE ou en combinaison avec une CONDITION DE PREMIER DEFAUT (sur la base d'un examen visuel).

11.6.4 * Fuite

Voir 13.2.6.

11.6.5 * Pénétration d'eau ou de corps solides dans les APPAREILS EM et les SYSTEMES EM

Les ENVELOPPES des APPAREILS EM et des SYSTEMES EM conçues pour procurer un degré spécifié de protection contre les effets nuisibles de la pénétration d'eau ou de corps solides doivent procurer cette protection conformément à la classification de l'IEC 60529. Voir aussi 7.2.9.

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La conformité est vérifiée par les essais de l'IEC 60529, l'APPAREIL EM étant placé dans la position la moins favorable en UTILISATION NORMALE et par inspection.

Après ces PROCEDURES, l'APPAREIL EM ne doit ~~montrer~~ présenter aucun signe de contournement de l'isolation (ou des composants électriques) ~~qui pourrait~~ susceptible d'engendrer ~~une SITUATION DANGEREUSE~~ la perte de la SECURITE DE BASE ou des PERFORMANCES ESSENTIELLES en CONDITION NORMALE ou en combinaison avec une CONDITION DE PREMIER DEFAUT (sur la base d'un examen visuel), puis les essais appropriés de tension de tenue et de COURANT DE FUITE sont réalisés.

11.6.6 Nettoyage et désinfection des APPAREILS EM et des SYSTEMES EM

Les APPAREILS EM et les SYSTEMES EM et leurs parties, y compris les PARTIES APPLIQUEES et les ACCESSOIRES, doivent être capables de résister sans dommage ou détérioration des dispositions de SECURITE aux PROCESSUS de nettoyage ou de désinfection spécifiés dans les instructions d'utilisation. Voir aussi 7.9.2.12.

~~Le FABRICANT doit évaluer les effets des nettoyages/désinfections multiples au cours de la DUREE DE VIE PREVUE de l'APPAREIL EM ou du SYSTEME EM, de leurs parties et des ACCESSOIRES et s'assurer qu'aucun RISQUE inacceptable n'apparaîtra. Les résultats de l'évaluation doivent être documentés dans le DOSSIER DE GESTION DES RISQUES.~~

Le FABRICANT doit évaluer les effets de multiples nettoyages/désinfections comme indiqué dans les instructions d'utilisation pendant la DUREE DE VIE PREVUE de l'APPAREIL EM, du SYSTEME EM, de leurs parties et de leurs ACCESSOIRES et garantir que ces PROCESSUS n'entraînent pas la perte de la SECURITE DE BASE ou des PERFORMANCES ESSENTIELLES.

Lorsque la conformité à la présente norme pourrait être ~~affectée~~ effectuée par le nettoyage ou la désinfection des APPAREILS EM et des SYSTEMES EM, de leurs parties et des ACCESSOIRES, ils sont nettoyés ou désinfectés une fois conformément aux méthodes spécifiées en respectant toute période de refroidissement ou de séchage éventuelle. Après ces PROCEDURES, les APPAREILS EM, leurs parties ou ACCESSOIRES ne doivent présenter aucun signe de détérioration pouvant engendrer un RISQUE inacceptable (examen visuel) puis les essais appropriés de tension de tenue et de COURANT DE FUITE sont effectués. Le DOSSIER DE GESTION DES RISQUES est inspecté pour vérifier que le FABRICANT a évalué les effets des nettoyages multiples.

11.6.7 Stérilisation des APPAREILS EM et des SYSTEMES EM

Les APPAREILS EM, les SYSTEMES EM et leurs parties ou ACCESSOIRES destinés à être stérilisés, doivent être évalués et documentés conformément à ~~l'ISO 11134,~~ l'ISO 11135-1, l'ISO 11137-1 ou l'ISO 17665-1, selon le cas. Voir aussi 7.9.2.12.

Après ces PROCEDURES, les APPAREILS EM, les SYSTEMES EM et leurs parties ou ACCESSOIRES ne doivent présenter aucun signe de détérioration pouvant engendrer un RISQUE inacceptable (examen visuel) puis les essais appropriés de tension de tenue et de COURANT DE FUITE sont effectués et le DOSSIER DE GESTION DES RISQUES est inspecté.

11.6.8 * Compatibilité avec les substances utilisées avec l'APPAREIL EM

Lorsque c'est applicable, le FABRICANT doit traiter dans le cadre du PROCESSUS de GESTION DES RISQUES des RISQUES associés à la compatibilité avec les substances utilisées avec l'APPAREIL EM. Ces RISQUES peuvent être traités par l'application des normes ISO ou IEC appropriées (étant donnée la présomption de RISQUE acceptable selon 4.2) telles que l'ISO 15001 [70] pour les composants contenant de l'oxygène à des pressions supérieures à 50 kPa ou par les propres essais du FABRICANT et ses mesures de MAITRISE DU RISQUE.

La conformité est vérifiée par inspection du DOSSIER DE GESTION DES RISQUES.

11.7 Biocompatibilité des APPAREILS EM et des SYSTEMES EM

Les APPAREILS EM, les SYSTEMES EM et leurs parties ou ACCESSOIRES destinés à entrer en contact direct ou indirect avec les tissus, cellules ou fluides corporels biologiques doivent être évalués et documentés conformément au guide et aux principes de la série de normes ISO 10993.

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La conformité est vérifiée par inspection des informations fournies par le FABRICANT.

11.8 * Coupure de l'alimentation / du RESEAU D'ALIMENTATION vers L'APPAREIL EM

~~L'APPAREIL EM doit être conçu de telle manière qu'une coupure et un rétablissement de l'alimentation ne crée pas de SITUATION DANGEREUSE autre que l'interruption de la fonction prévue.~~

Les APPAREILS EM doivent être conçus de telle sorte qu'une coupure et une restauration de l'alimentation n'entraînent pas la perte de la SECURITE DE BASE ou des PERFORMANCES ESSENTIELLES.

NOTE Cela peut nécessiter des essais avec différentes durées et différents états des APPAREILS EM.

La conformité est vérifiée par la coupure et le rétablissement des alimentations correspondantes.

12 * Précision des commandes, des instruments et protection contre les caractéristiques de sortie présentant des risques

12.1 Précision des commandes et des instruments

Lorsque cela est applicable, le FABRICANT doit traiter dans le cadre du PROCESSUS de GESTION DES RISQUES les RISQUES associés à la précision des commandes et des instruments.

La conformité est vérifiée par inspection du DOSSIER DE GESTION DES RISQUES.

12.2 APTITUDE A L'UTILISATION de l'APPAREIL EM

~~Le FABRICANT doit traiter dans le cadre du PROCESSUS de GESTION DES RISQUES les RISQUES de mauvaise APTITUDE A L'UTILISATION, y compris ceux liés à l'identification, au marquage et aux documents (voir 7.1.1 et 16.2). Voir l'IEC 60601-1-6 et également 1.3.~~

~~*La conformité est vérifiée par l'inspection des résultats du PROCESSUS DE GESTION DES RISQUES.*~~

Le FABRICANT doit traiter le(s) RISQUE(S) de faible APTITUDE A L'UTILISATION, comprenant les risques associés à l'identification, au marquage et aux documents, au moyen d'un PROCESSUS D'INGENIERIE DE L'APTITUDE A L'UTILISATION satisfaisant à l'IEC 60601-1-6.

La conformité est vérifiée comme indiqué dans l'IEC 60601-1-6.

12.3 ~~Systèmes d'alarme~~ SYSTEMES D'ALARME

~~Lorsque cela est applicable, le FABRICANT doit traiter dans le cadre du PROCESSUS de GESTION DES RISQUES le besoin de systèmes d'alarme comme moyen de MAITRISE DU RISQUE et traiter tous les RISQUES associés au fonctionnement ou à la défaillance du système d'alarme. Voir la IEC 60601-1-8 et également 1.3.~~

~~*La conformité est vérifiée par l'examen du DOSSIER DE GESTION DES RISQUES.*~~

Si le FABRICANT a mis en œuvre un SYSTEME D'ALARME, ce SYSTEME D'ALARME doit satisfaire à l'IEC 60601-1-8.

La conformité est vérifiée comme indiqué dans l'IEC 60601-1-8.

12.4 Protection contre les caractéristiques de sortie présentant des risques

12.4.1 * Dépassement intentionnel des limites de sécurité

Lorsque cela est applicable, le FABRICANT doit traiter dans le cadre du PROCESSUS de GESTION DES RISQUES les RISQUES associés aux valeurs de sortie dangereuses provenant du dépassement intentionnel des limites de sécurité.

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La conformité est vérifiée par l'examen du DOSSIER DE GESTION DES RISQUES.

12.4.2 Indication ~~des paramètres~~ concernant la sécurité

~~Lorsque cela est applicable, le FABRICANT doit traiter dans le cadre du PROCESSUS de GESTION DES RISQUES le besoin d'indication des paramètres qui sont associés aux valeurs de sortie dangereuses.~~

Le cas échéant, le FABRICANT doit traiter dans le PROCESSUS de GESTION DES RISQUES la nécessité d'indiquer toute caractéristique de sortie dangereuse.

EXEMPLE 1 Avant de délivrer de l'énergie ou des substances à un PATIENT, l'énergie, le débit ou le volume est indiqué de manière quantitative.

EXEMPLE 2 Pendant l'activation d'une caractéristique de sortie de rayonnement X, une lumière jaune clignotante est affichée.

La conformité est vérifiée par inspection du DOSSIER DE GESTION DES RISQUES.

12.4.3 * Sélection accidentelle de valeurs excessives des caractéristiques de sortie

Lorsque l'APPAREIL EM est un appareil à usages multiples conçu pour fournir à la fois des intensités de sorties faibles et fortes pour des traitements différents, le FABRICANT doit traiter dans le PROCESSUS de GESTION DES RISQUES les RISQUES associés à la sélection accidentelle d'une valeur de sortie excessive.

La conformité est vérifiée par l'inspection du DOSSIER DE GESTION DES RISQUES.

12.4.4 Sortie incorrecte

Lorsque cela est applicable, le FABRICANT doit traiter dans le cadre du PROCESSUS de GESTION DES RISQUES les RISQUES associés aux sorties incorrectes.

EXEMPLE Les RISQUES associés à une délivrance incorrecte d'énergie ou de substances à un PATIENT peuvent être traités en prévoyant une alarme pour alerter l'OPERATEUR de toute déviation importante par rapport au niveau réglé de délivrance.

La conformité est vérifiée par l'inspection du DOSSIER DE GESTION DES RISQUES.

12.4.5 Rayonnements à des fins de diagnostic ou de thérapie

12.4.5.1 Limites

Pour les APPAREILS EM conçus pour produire des rayonnements à des fins de diagnostic ou de thérapie, des dispositions adaptées doivent être prises pour protéger les PATIENTS, les OPERATEURS, les autres personnes et les dispositifs sensibles situés à proximité contre les rayonnements involontaires ou excessifs qui sont émis par les APPAREILS EM.

NOTE Les rayonnements provenant des APPAREILS EM destinés à une application aux PATIENTS à des fins de diagnostic ou de thérapie sous surveillance médicale peuvent dépasser les limites normalement acceptables pour la population dans son ensemble.

Selon ce qui est approprié, des normes particulières doivent spécifier des exigences, des limites et des essais de conformité pour assurer la sécurité en matière de rayonnements.

12.4.5.2 Appareils à rayonnement X de diagnostic

~~Lorsque cela est applicable, le FABRICANT doit traiter dans le cadre du PROCESSUS de GESTION DES RISQUES les RISQUES associés aux rayonnements aux rayons X de diagnostic. Voir la IEC 60601-1-3 et également 1.3.~~

~~*La conformité est vérifiée par l'inspection du DOSSIER DE GESTION DES RISQUES.*~~

Les APPAREILS EM et les SYSTEMES EM conçus pour produire des rayonnements X à des fins d'imagerie de diagnostic doivent satisfaire à l'IEC 60601-1-3.

La conformité est vérifiée comme indiqué dans l'IEC 60601-1-3.

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12.4.5.3 Appareils de radiothérapie

Lorsque cela est applicable, le FABRICANT doit traiter dans le cadre du PROCESSUS de GESTION DES RISQUES les RISQUES associés à la radiothérapie.

La conformité est vérifiée par l'inspection du DOSSIER DE GESTION DES RISQUES.

12.4.5.4 Autres APPAREILS EM produisant des rayonnements à des fins de diagnostic ou de thérapie

Lorsque cela est applicable, le FABRICANT doit traiter dans le cadre du PROCESSUS de GESTION DES RISQUES les RISQUES associés aux APPAREILS EM qui produisent des rayonnements utilisés à des fins de diagnostic ou de thérapie autres que les RISQUES associés aux rayons X utilisés à des fins de diagnostic et à la radiothérapie (voir 12.4.5.2 et 12.4.5.3).

La conformité est vérifiée par l'inspection du DOSSIER DE GESTION DES RISQUES.

12.4.6 Pression acoustique utilisée à des fins de diagnostic ou de thérapie

Lorsque cela est applicable, le FABRICANT doit traiter dans le cadre du PROCESSUS de GESTION DES RISQUES les RISQUES associés à la pression acoustique utilisée à des fins de diagnostic ou de thérapie.

La conformité est vérifiée par l'inspection du DOSSIER DE GESTION DES RISQUES.

13 * SITUATIONS DANGEREUSES et conditions de défaut pour les APPAREILS EM

13.1 SITUATIONS DANGEREUSES particulières

13.1.1 Généralités

Lorsqu'on applique les CONDITIONS DE PREMIER DEFAUT telles qu'elles sont décrites en 4.7 et listées en 13.2, l'une à la fois, aucune des SITUATIONS DANGEREUSES des Paragraphes 13.1.2 à 13.1.4 (inclus) ne doit apparaître dans l'APPAREIL EM.

La défaillance de tout composant pris individuellement qui pourrait entraîner une SITUATION DANGEREUSE est décrite en 4.7.

13.1.2 * Emissions, déformation d'ENVELOPPE ou dépassement de température maximale

Les SITUATIONS DANGEREUSES suivantes ne doivent pas apparaître:

– émission de flammes, de métal fondu, de substance toxique ou inflammable, en quantités dangereuses;

– déformation des ENVELOPPES telle que la conformité à 15.3.1 est compromise;

– températures des PARTIES APPLIQUEES dépassant les valeurs admises identifiées au Tableau 24 lorsque les mesures sont réalisées selon 11.1.3;

– températures de parties d'APPAREILS EM qui ne sont pas des PARTIES APPLIQUEES mais qui sont susceptibles d'être touchées et qui dépassent les valeurs autorisées du Tableau 23 lorsqu'elles sont mesurées et réglées comme indiqué en 11.1.3;

– dépassement de 1,5 fois les valeurs autorisées pour "autres composants et matières" identifiés au Tableau 22, moins 12,5 °C. Les limites pour les enroulements sont données aux Tableaux 26, 27 et 31. Dans tous les autres cas, les valeurs autorisées du Tableau 22 s'appliquent.

Les températures doivent être mesurées en utilisant la méthode décrite en 11.1.3.

Les CONDITIONS DE PREMIER DEFAUT indiquées en 4.7, 8.1 b), 8.7.2 et 13.2.2, concernant l'émission de flammes, de métal fondu ou de substances inflammables, ne doivent pas être appliquées aux parties et aux composants lorsque:

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– La construction ~~ou le~~ du circuit d'alimentation limite la puissance dissipée en CONDITION DE PREMIER DEFAUT à moins de 15 W ou l'énergie dissipée à moins de 900 J.

La conformité est vérifiée en absorbant 15 W du circuit d'alimentation pendant 1 min. Si après 1 min. le circuit d'alimentation ne peut fournir 15 W, ce circuit doit être considéré comme limitant la puissance dissipée à moins de 15 W. La documentation de conception correspondante est également revue.

ou

– Les circuits secondaires satisfont à toutes les conditions suivantes:

- montés sur un matériau d'une classification d'inflammabilité FV1 conformément à l'IEC 60695-11-10 ou supérieure;
- ils sont mis sous tension à une tension de 60 V continue ou 42,2 V crête ou moins en CONDITION NORMALE et en CONDITION DE PREMIER DEFAUT;
- ils sont limités à 100 VA ou limités à 6 000 J en CONDITION DE PREMIER DEFAUT;
- ils utilisent une isolation des fils de types PVC, TFE, PTFE, FEP, polychloroprène ou polybromure.

La conformité est vérifiée par l'évaluation de la documentation de conception.

ou

– Le composant est un COMPOSANT AUX CARACTERISTIQUES A HAUTE FIABILITE tel que décrit en 4.9.

La conformité est vérifiée par l'évaluation de la documentation de conception.

ou

– Ils sont complètement enfermés dans une ENVELOPPE contre le feu.

La conformité est vérifiée par examen et évaluation de la documentation de conception pour assurer que l'ENVELOPPE est construite conformément à 11.3.

NOTE Il convient que les essais du présent paragraphe soient réalisés dans l'ordre indiqué à l'Annexe B.

A l'issue des essais du présent article, les COUPE-CIRCUIT THERMIQUES et les DISJONCTEURS sont examinés pour déterminer que leur réglage n'a pas été modifié (par un échauffement, des vibrations ou d'autres causes) de manière suffisante pour affecter leur fonction de sécurité.

13.1.3 Dépassement du COURANT DE FUITE ou des limites de tension

Les SITUATIONS DANGEREUSES suivantes ne doivent pas apparaître:

– dépassement des limites du COURANT DE FUITE en CONDITION DE PREMIER DEFAUT comme indiqué en 8.7.3 ;

– dépassement des limites de tension pour les PARTIES ACCESSIBLES y compris les PARTIES APPLIQUEES indiquées en 8.4.2.

13.1.4 DANGERS MECANIQUES particuliers

Pour les DANGERS MECANIQUES particuliers, voir 9.1 à 9.8 (inclus).

13.2 CONDITIONS DE PREMIER DEFAUT

13.2.1 Généralités

Pendant l'introduction des CONDITIONS DE PREMIER DEFAUT indiquées en 13.2.2 à 13.2.13 (inclus), les CONDITIONS NORMALES identifiées en 8.1 a) doivent également être appliquées dans la combinaison la moins favorable.

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13.2.2 CONDITION DE PREMIER DEFAUT électrique

Les exigences et les essais concernant cette CONDITION DE PREMIER DEFAUT se trouvent en 8.1.

13.2.3 Surchauffe des transformateurs dans les APPAREILS EM

Les exigences et les essais concernant cette CONDITION DE PREMIER DEFAUT se trouvent en 15.5.

13.2.4 Défaillance des THERMOSTATS

Les exigences et les essais concernant cette CONDITION DE PREMIER DEFAUT se trouvent en 13.2.13 et 15.4.2 pour les situations de surcharge.

Les THERMOSTATS sont court-circuités ou interrompus, la condition la moins favorable étant retenue.

13.2.5 Défaillance des dispositifs pour la limitation de la température

Les exigences et les essais concernant cette CONDITION DE PREMIER DEFAUT se trouvent en 13.2.13 et 15.4.2 pour les situations de surcharge.

Les THERMOSTATS sont court-circuités ou interrompus, la condition la moins favorable étant retenue.

13.2.6 Fuite de liquide

Les APPAREILS EM doivent être construits de telle manière que du liquide qui pourrait s'échapper en CONDITION DE PREMIER DEFAUT n'entraîne pas un RISQUE inacceptable.

Du fait que seules de petites quantités de liquide s'en échappent lorsqu'elles fuient, les batteries scellées rechargeables sont exemptes de la présente exigence.

Un PROCESSUS de GESTION DES RISQUES doit être utilisé pour déterminer les conditions d'essai appropriées pour les APPAREILS EM.

La conformité est vérifiée par inspection du DOSSIER DE GESTION DES RISQUES.

13.2.7 Altération du refroidissement pouvant entraîner une ~~DANGER~~ SITUATION DANGEREUSE

Les APPAREILS EM doivent être conçus de telle manière qu'ils restent SECURISES EN PREMIER DEFAUT lorsque les systèmes de refroidissement cessent de fonctionner de la manière prévue.

Les altérations du refroidissement qui peuvent apparaître sont simulées, par exemple:

– *les ventilateurs individuels sont bloqués consécutivement;*
– *la ventilation par les ouvertures, sur le haut et les côtés est altérée en couvrant les aérations sur le haut de l'ENVELOPPE ou en positionnant l'APPAREIL EM contre un mur;*
– *le blocage des filtres est simulé;*
– *la circulation d'un liquide de refroidissement est interrompue.*

Les températures qui dépassent les limites données en 13.1.2 constituent une défaillance.

La conformité est vérifiée en utilisant les méthodes d'essai indiquées en 11.1, qui sont appliquées dans la mesure du possible.

13.2.8 Blocage des parties mobiles

Les APPAREILS EM doivent être conçus d'une manière telle qu'ils restent SECURISES EN PREMIER DEFAUT lorsque les parties mobiles se coincent.

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Les parties mobiles sont bloquées si l'APPAREIL EM:

– *comporte des PARTIES mobiles ACCESSIBLES y compris des PARTIES APPLIQUEES susceptibles d'être coincées, ou*

– *est susceptible de fonctionner sans surveillance / présence (y compris les APPAREILS EM qui sont commandés automatiquement ou à distance), ou*

– *comporte un ou plusieurs moteurs avec un couple du rotor calé plus petit que le couple à pleine charge.*

Si l'APPAREIL EM a plus d'une partie mobile, telles qu'elles sont décrites ci-dessus, une seule partie à la fois est bloquée. Si une CONDITION DE PREMIER DEFAUT peut bloquer plusieurs moteurs, alors tous les moteurs sont bloqués simultanément. Pour des critères d'essai complémentaires, voir 13.2.10.

13.2.9 * Interruption et court-circuit des condensateurs de moteur

Les APPAREILS EM doivent être conçus de telle manière qu'ils restent SECURISES EN PREMIER DEFAUT lorsque les condensateurs du moteur sont court-circuités ou déconnectés.

La vérification est effectuée en réalisant l'essai suivant:

Les moteurs avec un condensateur dans le circuit d'un enroulement auxiliaire, sont mis en fonctionnement avec un rotor calé conformément à 13.2.10, avec le condensateur court-circuité ou déconnecté tour à tour. Les tensions du condensateur sont mesurées avec un côté déconnecté (circuit ouvert) et ne doivent pas dépasser leurs valeurs ASSIGNEES. Une tension mesurée qui dépasse la valeur ASSIGNEE constitue une défaillance.

L'essai avec le condensateur court-circuité n'est pas effectué si le moteur est pourvu d'un condensateur conforme à l'IEC 60252-1 et si l'APPAREIL EM n'est pas prévu pour une utilisation sans surveillance/présence (y compris ceux à commande automatique ou à commande à distance).

Pour des critères d'essai complémentaires, voir 13.2.10.

13.2.10 * Critères d'essai complémentaires pour les APPAREILS EM fonctionnant avec un moteur

Pour chacun des essais en CONDITION DE PREMIER DEFAUT de 13.2.8 et 13.2.9, prenant en compte les exceptions spécifiées en 13.1.2, les APPAREILS EM fonctionnant avec un moteur doivent être mis en fonctionnement en commençant en CONDITION A FROID, à la tension ASSIGNEE ou à la limite supérieure de la gamme de tensions ASSIGNEE pendant les périodes de temps suivantes:

a) *30 s pour:*
   – *les APPAREILS EM PORTATIFS,*
   – *les APPAREILS EM dont l'interrupteur doit être maintenu fermé manuellement,*
   – *les APPAREILS EM sur lesquels une pression manuelle continue doit s'exercer;*

b) *5 min pour les autres APPAREILS EM qui ne sont prévus que pour une utilisation sous surveillance / présence (l'utilisation sous surveillance / avec présence exclut les APPAREILS EM automatiques ou commandés à distance qui pourraient fonctionner en l'absence de l'OPERATEUR);*

c) *pendant la durée maximale d'une minuterie, si un tel dispositif met fin au fonctionnement, pour les APPAREILS EM non cités en a) ou b);*

d) *aussi longtemps que nécessaire pour établir la STABILITE THERMIQUE pour tous les APPAREILS EM restants.*

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Les températures des enroulements sont déterminées à la fin des périodes d'essai spécifiées ou au moment du fonctionnement des fusibles, des COUPE-CIRCUIT THERMIQUES, des dispositifs de protection du moteur et dispositifs analogues.

Les températures sont mesurées comme spécifié en 11.1.3 d).

Les températures qui dépassent les limites du Tableau 26 constituent une défaillance.

13.2.11 Défaillances des composants dans les APPAREILS EM utilisés en présence d'ENVIRONNEMENTS RICHES EN OXYGENE

Les exigences et les essais concernant ces CONDITIONS DE PREMIER DEFAUT se trouvent dans en 11.2.2.

13.2.12 Défaillance de parties qui pourraient entraîner un DANGER MECANIQUE

Les exigences et les essais concernant ces CONDITIONS DE PREMIER DEFAUT se trouvent à l'Article 9 et en 15.3.

Tableau 26 – * Limites de température des enroulements de moteurs

Température en °C

Type d'APPAREIL EM	Classe d'isolation				
	Classe A	Classe B	Classe E	Classe F	Classe H
APPAREILS EM avec minuterie et non prévus pour une utilisation sans surveillance / présence et APPAREILS EM devant fonctionner pendant 30 s ou 5 min	200	225	215	240	260
Autres APPAREILS EM					
– si protégés par impédance, valeur maximale	150	175	165	190	210
– si protégés par des dispositifs de protection qui fonctionnent pendant la première heure, valeur maximale	200	225	215	240	260
– après la première heure, valeur maximale	175	200	190	215	235
– après la première heure, moyenne arithmétique	150	175	165	190	210
NOTE Les limites de températures de ce tableau sont tirées de l'IEC 61010-1:2001 [22].					

13.2.13 * Surcharge

13.2.13.1 * Conditions générales d'essai de surcharge

~~A l'issue des essais de 13.2.13.2 à 13.2.13.4 (inclus), les APPAREILS EM, lorsque qu'ils sont refroidis approximativement à la température ambiante, doivent rester sûrs.~~

Après les essais de 13.2.13.2 à 13.2.13.4 (inclus), l'APPAREIL EM, lorsqu'il est refroidi à 3 °C de la température de l'environnement d'essai, doit rester sûr.

La conformité est déterminée par l'inspection des APPAREILS EM ou par les essais appropriés (tel que l'essai de tension de tenue de l'isolation du moteur conformément à 8.8.3).

Pour l'isolation des matériaux thermoplastiques servant de MOYEN DE PROTECTION (voir 8.8), l'essai de pression à la bille spécifié en 8.8.4.1 a) est réalisé à une température de 25 °C supérieure à la température de l'isolation mesurée au cours des essais de 13.2.13.2 à 13.2.13.4 (inclus).

13.2.13.2 APPAREIL EM avec éléments chauffants

a) La conformité des APPAREILS EM comportant des éléments chauffants est vérifiée comme suit:

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1) *Pour les APPAREILS EM à commande thermostatique comportant des éléments chauffants, prévus pour être encastrés ou pour un fonctionnement sans surveillance / présence, ou ayant un condensateur non protégé par fusible ou un dispositif analogue connecté en parallèle avec les contacts du THERMOSTAT: par les essais de 13.2.13.2 b) et 13.2.13.2 c);*

2) *Pour les APPAREILS EM comportant des éléments chauffants ASSIGNES pour un fonctionnement autre qu'en SERVICE CONTINU: par les essais de 13.2.13.2 b) et 13.2.13.2 c);*

3) *pour les autres APPAREILS EM comportant des éléments chauffants: par l'essai de 13.2.13.2 b).*

Si plus d'un de ces essais est applicable au même APPAREIL EM, ces essais sont effectués successivement.

Si, au cours de l'un de ces essais, un COUPE CIRCUIT THERMIQUE SANS REENCLENCHEMENT AUTOMATIQUE fonctionne, si un élément chauffant ou une partie intentionnellement faible se rompt ou si le courant est interrompu d'une autre façon avant établissement de la STABILITE THERMIQUE sans la possibilité de rétablissement automatique, la période de chauffage est terminée. Cependant, si l'interruption est due à la rupture d'un élément chauffant ou d'une partie intentionnellement faible, l'essai est répété sur un deuxième spécimen. La mise en court-circuit d'un élément chauffant ou d'une partie intentionnellement faible dans le deuxième spécimen ne constitue pas par elle-même une non-conformité. Toutefois si un des deux spécimens n'est pas conforme aux conditions spécifiées en 13.1.2, cela constitue une défaillance.

b) *L'APPAREIL EM comportant des éléments chauffants est soumis à l'essai dans les conditions spécifiées en 11.1, mais sans dégagement de chaleur approprié, la tension d'alimentation étant de 90 % ou 110 % de la tension d'alimentation ASSIGNEE, la condition la plus défavorable étant retenue.*

Si un COUPE-CIRCUIT THERMIQUE SANS REENCLENCHEMENT AUTOMATIQUE fonctionne ou si le courant est interrompu de façon différente sans la possibilité de rétablissement automatique avant établissement de la STABILITE THERMIQUE, la période de fonctionnement est terminée. Si l'interruption du courant ne se produit pas, on coupe l'alimentation de l'APPAREIL EM dès établissement de la STABILITE THERMIQUE et on le laisse refroidir jusqu'à environ la température ambiante.

Pour les APPAREILS EM ASSIGNES pour un fonctionnement autre que le SERVICE CONTINU, la durée de l'essai est égale à la durée de fonctionnement ASSIGNEE.

c) *Les parties chauffantes des APPAREILS EM sont soumises aux essais avec l'APPAREIL EM fonctionnant en CONDITION NORMALE, avec une tension d'alimentation de 110 % de la tension d'alimentation ASSIGNEE et comme spécifié en 11.1. Les conditions d'essai suivantes sont satisfaites:*

1) *Toute commande servant à limiter la température en CONDITION NORMALE, à l'exception d'un COUPE CIRCUIT THERMIQUE, est mise hors service.*

2) *Si l'APPAREIL EM est muni de plus d'une commande, elles sont mises hors service à tour de rôle.*

3) *L'APPAREIL EM est mis en fonctionnement selon le CYCLE D'UTILISATION ASSIGNE jusqu'à ce que la STABILITE THERMIQUE soit atteinte quelle que soit la durée de fonctionnement ASSIGNEE.*

13.2.13.3 APPAREILS EM comportant des moteurs

a) La conformité des APPAREILS EM comportant des moteurs est vérifiée comme suit:

1) *Pour la partie moteur de l'APPAREIL EM, la conformité est vérifiée par les essais de 13.2.8 à 13.2.10 (inclus), 13.2.13.3 b),13.2.13.3 c) et 13.2.13.4 , pour autant qu'ils soient*

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applicables. Pour les moteurs situés dans des circuits ayant une tension ne dépassant pas 42,4 V de valeur crête en courant alternatif ou 60 V en courant continu et pour lesquels il est difficile d'obtenir des mesures précises de température en raison des faibles dimensions ou de la conception du moteur, il est permis d'utiliser l'essai suivant à la place de la mesure de température pour déterminer la conformité à 13.2.9 et à 13.2.10.

Le moteur est recouvert d'une seule épaisseur de toile ayant les caractéristiques suivantes:

- *en coton blanc;*
- *masse de 26-28 m2 par kg; et*
- *13 fils au cm dans une direction et 11 fils par cm dans l'autre.*

L'inflammation de la toile de coton au cours de l'essai ou à l'issue de celui-ci constitue une défaillance.

2) Pour les APPAREILS EM qui comportent également des éléments chauffants, les essais sont réalisés à la tension prescrite, avec la partie moteur et les éléments chauffants fonctionnant simultanément de façon à créer la condition la moins favorable.

3) Si plus d'un essai est applicable au même APPAREIL EM, ces essais doivent être effectués successivement.

b) La protection des moteurs contre le fonctionnement en surcharge est vérifiée si ces moteurs sont:

1) prévus pour être commandés à distance ou automatiquement (par un seul dispositif de commande sans protection redondante), ou

2) susceptibles d'être mis en FONCTIONNEMENT CONTINU sans surveillance / présence.

La conformité est déterminée en faisant fonctionner l'APPAREIL EM dans les conditions de charge normales et à la tension ASSIGNEE ou à la tension maximale de la gamme de tensions ASSIGNEES, jusqu'à l'obtention de la STABILITE THERMIQUE (voir 11.1.3).

La charge est ensuite augmentée de façon à ce que l'intensité du courant augmente par échelons appropriés, la tension d'alimentation étant maintenue à sa valeur initiale.

Lorsque la STABILITE THERMIQUE est établie, la charge est de nouveau augmentée. Cette charge est augmentée progressivement, et ce par échelons progressifs appropriés, jusqu'à ce que le dispositif de protection contre la surcharge fonctionne, ou jusqu'à ce qu'on ne note plus d'augmentation de température.

La température de l'enroulement du moteur est déterminée lors de chaque période stable. Si la valeur maximale enregistrée dépasse la valeur indiquée dans le Tableau 27, cela constitue une défaillance.

Tableau 27 – Température maximale stabilisée d'un enroulement moteur

Classe d'isolation	Température maximale °C
A	140
B	165
E	155
F	180
H	200

Si la charge ne peut être modifiée sur l'APPAREIL EM par échelons appropriés, le moteur est retiré de l'APPAREIL EM pour subir l'essai.

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L'essai de fonctionnement en surcharge pour les moteurs placés dans des circuits avec une tension n'excédant pas 42,4 V de valeur crête en courant alternatif ou 60 V en courant continu est réalisé uniquement si une possibilité de surcharge est déterminée par inspection ou par revue de la conception. Il n'est pas nécessaire de réaliser cet essai lorsque, par exemple, des circuits électroniques de pilotage maintiennent un courant de fonctionnement pratiquement constant.

c) Les APPAREILS EM comportant des moteurs triphasés sont mis en fonctionnement avec une charge normale, connectés à du triphasé (RESEAU D'ALIMENTATION) avec une phase déconnectée. Les périodes de fonctionnement sont conformes à celles de 13.2.10.

13.2.13.4 * APPAREILS EM ASSIGNES pour un fonctionnement autre que le SERVICE CONTINU

Les APPAREILS EM ASSIGNES pour un fonctionnement autre que le SERVICE CONTINU à l'exception:

– *des APPAREILS EM PORTATIFS;*

– *des APPAREILS EM dont l'interrupteur doit être maintenu fermé manuellement;*

– *des APPAREILS EM sur lesquels une pression manuelle continue doit s'exercer;*

– *des APPAREILS EM avec une minuterie et un système de sauvegarde de minuterie;*

sont mis en fonctionnement avec une charge normale et une tension ASSIGNEE ou à la limite supérieure de la gamme de tensions ASSIGNEES jusqu'à ce que la température de pointe n'augmente pas de plus de 5 °C par heure ou jusqu'à ce que le dispositif de protection fonctionne.

Les températures de l'enroulement du moteur sont déterminées lorsque la STABILITE THERMIQUE est établie ou immédiatement avant le fonctionnement du dispositif de protection. Les températures de l'enroulement du moteur qui dépassent les valeurs spécifiées en 13.2.10 constituent une défaillance.

Si, en utilisation normale, un dispositif de réduction de charge fonctionne au sein de l'appareil em, on continue l'essai avec l'appareil em tournant au ralenti.

14 * SYSTEMES ELECTROMEDICAUX PROGRAMMABLES (SEMP)

14.1 * Généralités

~~Les exigences du présent article doivent s'appliquer aux SEMP sauf:~~

~~– lorsque le SSEP n'assure pas la sécurité de base ni les performances essentielles; ou~~

~~– lorsque l'application de l'ISO 14971 démontre que la défaillance du SSEP ne conduit pas à un RISQUE inacceptable.~~

~~NOTE 1 Le présent article exige qu'un PROCESSUS soit suivi tout au long du CYCLE DE DEVELOPPEMENT du SEMP et qu'un ENREGISTREMENT de ce PROCESSUS soit réalisé. Les concepts de GESTION DU RISQUE et un CYCLE DE DEVELOPPEMENT de SSEP sont les fondements d'un tel PROCESSUS. Cependant, comme un PROCESSUS de GESTION DES RISQUES est déjà exigé par la présente norme, le présent article définit les éléments minimaux du CYCLE DE DEVELOPPEMENT DU SEMP et uniquement les éléments supplémentaires pour les SEMP qui doivent être considérés comme faisant partie du PROCESSUS de GESTION DES RISQUES (voir 4.2).~~

~~NOTE 2 Il est reconnu que le CONSTRUCTEUR pourrait ne pas être en mesure de suivre tous les PROCESSUS identifiés à l'Article 14 pour chaque élément constitutif du SEMP, tel que les logiciels sur étagère, les sous-systèmes d'origine non médicale et les dispositifs d'ancienne génération. Dans ce cas, il convient que le FABRICANT tienne particulièrement compte des besoins en matière de mesures supplémentaires de MAITRISE DU RISQUE.~~

~~*La conformité est déterminée par l'application des exigences de 14.2 à 14.13 (inclus), par inspection du DOSSIER DE GESTION DES RISQUES et l'évaluation des PROCESSUS cités dans le présent article.*~~

~~NOTE 3 Cette évaluation pourrait être réalisée par audit interne.~~

Les exigences de 14.2 à 14.12 (inclus) doivent s'appliquer aux SEMP, sauf si:

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– aucun des SOUS-SYSTEME ELECTRONIQUE PROGRAMMABLE (SSEP) n'assure la fonctionnalité nécessaire pour la SECURITE DE BASE ou les PERFORMANCES ESSENTIELLES; ou

– l'application de la GESTION DES RISQUES telle que décrite en 4.2 démontre que la défaillance d'un quelconque SSEP n'engendre aucun RISQUE inacceptable.

Les exigences de 14.13 sont applicables à tout SEMP destiné à être incorporé dans un RESEAU INFORMATIQUE, que les exigences de 14.2 à 14.12 s'appliquent ou non.

NOTE 1 Le présent article exige qu'un PROCESSUS soit suivi tout au long du CYCLE DE DEVELOPPEMENT DU SEMP et qu'un ENREGISTREMENT de ce PROCESSUS soit réalisé. Les concepts de GESTION DES RISQUES et un CYCLE DE DEVELOPPEMENT DE SEMP sont les fondements d'un tel PROCESSUS. Cependant, étant donné qu'un PROCESSUS de GESTION DES RISQUES est déjà exigé par la présente norme, le présent article définit les éléments minimaux du CYCLE DE DEVELOPPEMENT DU SEMP et uniquement les éléments supplémentaires pour les SEMP qui doivent être considérés comme faisant partie du PROCESSUS de GESTION DES RISQUES (voir 4.2).

NOTE 2 Si une mesure de MAITRISE DU RISQUE est mise en œuvre dans le SSEP, il est nécessaire d'appliquer l'Article 14 pour démontrer que la défaillance du SSEP n'engendre aucun RISQUE inacceptable.

NOTE 3 Il est reconnu que le FABRICANT pourrait ne pas être en mesure de suivre tous les PROCESSUS identifiés à l'Article 14 pour chaque élément constitutif du SEMP, tel que les logiciels de provenance inconnue (LDPI), les sous-systèmes d'origine non médicale et les dispositifs d'ancienne génération. Dans ce cas, il convient que le FABRICANT tienne particulièrement compte des besoins en matière de mesures supplémentaires de MAITRISE DU RISQUE. Un LDPI est défini dans l'IEC 62304:2006 comme un "élément logiciel qui est déjà développé et généralement disponible et qui n'a pas été développé pour être incorporé dans le dispositif médical (également appelé 'logiciel de série') ou logiciel précédemment développé pour lequel les ENREGISTREMENTS suffisants des PROCESSUS de développement ne sont pas disponibles".

La conformité est vérifiée par l'inspection de toute la documentation requise, et, le cas échéant, par l'évaluation des exigences de 14.2 à 14.13 (inclus).

NOTE 4 Cette évaluation pourrait être réalisée par audit interne.

Lorsque les exigences de 14.2 à 14.13 s'appliquent, les exigences du paragraphe 4.3, de l'Article 5, de l'Article 7, de l'Article 8 et de l'Article 9 de l'IEC 62304:2006 doivent également s'appliquer au développement ou à la modification de logiciels pour chaque SSEP.

La conformité est déterminée par l'inspection et l'évaluation requises par le paragraphe 1.4 de l'IEC 62304:2006.

NOTE 5 Le PROCESSUS de développement de logiciels requis pour la conformité avec la présente norme n'inclut pas la surveillance de la post-production ni la maintenance requises par l'Article 6 de l'IEC 62304:2006).

14.2 * Documentation

~~En plus des ENREGISTREMENTS et des documents exigés par l'ISO 14971, les documents produits par l'application de l'Article 14 doivent être suivis et doivent faire partie du DOSSIER DE GESTION DES RISQUES.~~

~~NOTE Voir la Figure H.3 à titre de guide.~~

Les documents exigés à l'Article 14 doivent être revus, approuvés, diffusés et modifiés conformément à une PROCEDURE formelle de contrôle de la documentation.

14.3 * Plan de GESTION DES RISQUES

Le plan de GESTION DES RISQUES exigé par le Paragraphe ~~3.5 de l'ISO 14971~~ 4.2.2 doit également inclure une référence au plan de VALIDATION SEMP (voir 14.11).

14.4 * CYCLE DE DEVELOPPEMENT DE SEMP

Un CYCLE DE DEVELOPPEMENT DE SEMP doit être documenté.

NOTE ~~1~~ L'Article H.2 explique plus en détail le CYCLE DE DEVELOPPEMENT DE SEMP.

~~NOTE 2 L'IEC 62304 [26] définit des exigences générales pour les PROCESSUS complémentaires et les activités spécifiques au développement de logiciel.~~

Le CYCLE DE DEVELOPPEMENT SEMP doit inclure un ensemble d'étapes définies.

A chaque étape, les activités à réaliser et les méthodes de VERIFICATION à appliquer à ces activités doivent être définies.

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Chaque activité doit être définie y compris ses entrées et sorties.

Chaque étape doit identifier les activités de GESTION DES RISQUES qu'il faut réaliser avant l'étape concernée.

Le CYCLE DE DEVELOPPEMENT SEMP doit être adapté à un développement spécifique par la réalisation de plans qui détaillent les activités, les étapes et les programmes.

Le CYCLE DE DEVELOPPEMENT SEMP doit inclure des exigences de documentation.

14.5 * Résolution des problèmes

Le cas échéant, un système documenté pour la résolution des problèmes pendant et entre toutes les phases et activités du CYCLE DE VIE DE DEVELOPPEMENT DE SEMP doit être développé et suivi.

En fonction du type de produit, le système de résolution des problèmes peut:

– être défini comme une partie du CYCLE DE DEVELOPPEMENT DE SEMP;

– permettre de rendre compte de problèmes potentiels ou existants touchant la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES;

– inclure une évaluation de chaque problème pour les RISQUES associés;

– identifier les critères à satisfaire pour prononcer une conclusion;

– identifier les actions à entreprendre pour résoudre chaque problème.

14.6 PROCESSUS de GESTION DES RISQUES

14.6.1 * Identification des DANGERS connus et prévisibles

Lors de l'établissement de la liste des DANGERS connus ou prévisibles, le FABRICANT doit prendre en compte les DANGERS associés aux aspects logiciels et matériels ~~des~~ du SEMP, y compris ceux associés à l'incorporation du SEMP à un RESEAU INFORMATIQUE, aux composants ~~de COUPLAGE DE RESEAUX/DONNEES, composants~~ d'origine tierce ~~partie~~ et aux sous-systèmes d'ancienne génération.

NOTE En plus des éléments donnés à l'Annexe ~~D~~ E de l'ISO 14971:2007, ~~il convient que~~ la liste des causes possibles de DANGERS associé~~e~~s aux SEMP ~~comprenne~~ peut comprendre:

~~– la défaillance d'un COUPLAGE DE RESEAUX/ DONNEES dans la fourniture des caractéristiques nécessaires aux SEMP pour atteindre sa SECURITE DE BASE et ses PERFORMANCES ESSENTIELLES;~~

– le retour non désiré [physique et données] (les possibilités englobent: entrée non demandée, entrée hors plage ou incohérente, et entrée produite par une interférence électromagnétique);

– les données indisponibles;

– le manque d'intégrité des données;

– les données incorrectes;

– la synchronisation incorrecte des données;

– les interactions non désirées à l'intérieur et parmi les SSEP;

– les aspects ou qualités inconnus des logiciels de tierces parties;

– les aspects ou qualités inconnus des SSEP de tierces parties;

– le manque de sécurité des données et ses effets sur la confidentialité des données, en particulier vulnérabilité aux falsifications, interaction non désirée avec d'autres programmes et virus;

– la défaillance du RESEAU INFORMATIQUE à fournir les caractéristiques nécessaires au SEMP pour atteindre sa SECURITE DE BASE ou ses PERFORMANCES ESSENTIELLES. Voir les exemples en Annexe H.7.2.

14.6.2 * MAITRISE DU RISQUE

Les exigences suivantes pour les SEMP complètent le ~~Paragraphe 6.1 de l'ISO 14971~~ 4.2.2.

Des outils et des PROCEDURES convenablement validés doivent être choisis et identifiés pour mettre en œuvre chaque mesure de MAITRISE DU RISQUE. Ces outils et PROCEDURES doivent

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être appropriés pour assurer que chaque mesure de MAITRISE DU RISQUE réduit de manière satisfaisante le ou les RISQUES identifiés.

14.7 * Spécification des exigences

Pour le SEMP et chacun de ses sous-systèmes (par exemple un SSEP), il doit exister une spécification documentée des exigences.

NOTE Des exemples de structures d'un SEMP sont donnés à l'Article H.1.

La spécification d'exigence pour un système ou un sous-système doit inclure et distinguer toute mesure de PERFORMANCE ESSENTIELLE et de MAITRISE DU RISQUE mise en œuvre par le système ou le sous-système concerné.

14.8 * Architecture

Pour le SEMP et chacun de ses sous-systèmes, une architecture doit être spécifiée pour satisfaire à la spécification de l'exigence.

Le cas échéant, pour réduire le RISQUE à un niveau acceptable, la spécification d'architecture doit utiliser:

a) des COMPOSANTS AUX CARACTERISTIQUES A HAUTE FIABILITE;

b) des fonctions à sécurité positive;

c) la redondance;

d) la diversité;

e) * le partitionnement de la fonctionnalité;

f) une conception défensive, par exemple par limitation des effets dangereux potentiels en réduisant la puissance de sortie disponible ou en introduisant des moyens pour limiter le déplacement des organes de manœuvre.

La spécification d'architecture doit prendre en compte:

g) * l'allocation des mesures de MAITRISE DES RISQUES aux sous-systèmes et aux composants des SEMP;

NOTE Les sous-systèmes et les composants comprennent les capteurs, les organes de manœuvre, les SSEP et les interfaces.

h) les types de défaillance des composants et leurs effets;

i) les défaillances ayant des causes communes;

j) les défaillances systématiques;

k) l'intervalle de temps entre les essais et la couverture du diagnostic;

l) maintenabilité;

m) la protection contre LE MAUVAIS USAGE RAISONNABLEMENT PREVISIBLE;

n) la spécification ~~de COUPLAGE DES RESEAUX/DONNEES~~ du RESEAU INFORMATIQUE, le cas échéant.

14.9 * Conception et réalisation

Le cas échéant, la conception doit être scindée en sous-systèmes, chacun ayant à la fois une spécification pour la conception et une pour les essais.

Les données descriptives ~~pour~~ relatives à l'environnement de conception doivent être ~~incluses dans le DOSSIER DE GESTION DES RISQUES~~ documentées.

NOTE Voir l'Article ~~H.3~~ H.4a) pour les exemples d'éléments d'environnement de la conception.

14.10 * VERIFICATION

La VERIFICATION est exigée pour toutes les fonctions qui mettent en œuvre les mesures de la SECURITE DE BASE et des PERFORMANCES ESSENTIELLES ou de MAITRISE DU RISQUE.

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Un plan de VERIFICATION doit être élaboré pour montrer comment ces fonctions doivent être vérifiées. Ce plan doit indiquer:

– à quelle(s) étape(s) la VERIFICATION doit être réalisée pour chaque fonction;
– le choix et la documentation des stratégies, activités et techniques de VERIFICATION ainsi que le niveau approprié d'indépendance du personnel réalisant la VERIFICATION;
– la sélection et l'utilisation des outils de VERIFICATION;
– les critères de couverture pour la VERIFICATION.

NOTE Voici des exemples de méthodes et de techniques:

– lectures croisées;
– inspections;
– analyse statistique;
– analyse dynamique;
– essai de type boîte blanche;
– essai de type boîte noire;
– essais statistiques.

La VERIFICATION doit être conduite conformément au plan de VERIFICATION. Les résultats des activités de VERIFICATION doivent être documentés.

14.11 * VALIDATION SEMP

Un plan de VALIDATION SEMP doit inclure la validation de la SECURITE DE BASE et des PERFORMANCES ~~ESSENTIELLES et doit exiger des vérifications du fonctionnement non désiré des SEMP~~.

Les méthodes utilisées pour la VALIDATION DU SEMP doivent être documentées.

La VALIDATION SEMP doit être conduite conformément au plan de VALIDATION SEMP. Les résultats des activités de VALIDATION SEMP doivent être documentés.

La personne qui a la responsabilité globale de la VALIDATION SEMP doit être indépendante de l'équipe de conception. Le FABRICANT doit documenter la justification pour le niveau d'indépendance.

Aucun membre d'une équipe de conception ne doit être responsable de la VALIDATION SEMP d'un produit conçu par son équipe.

Toutes les relations professionnelles des membres de l'équipe de VALIDATION SEMP avec des membres de l'équipe de conception doivent être documentées dans le DOSSIER DE GESTION DES RISQUES.

~~Une référence aux méthodes et aux résultats de la VALIDATION SEMP doit être incluse dans le DOSSIER DE GESTION DES RISQUES.~~

14.12 * Modification

Si tout ou partie des résultats de conception résulte d'une modification d'une conception antérieure, soit le présent article s'applique intégralement comme s'il s'agissait d'une nouvelle conception, soit le maintien de la validité de toute documentation de conception antérieure doit être évalué dans le cadre d'une PROCEDURE de modification/changement documentée.

Lorsqu'un logiciel est modifié, les exigences du paragraphe 4.3, de l'Article 5, de l'Article 7, de l'Article 8 et de l'Article 9 de l'IEC 62304:2006 doivent également s'appliquer à la modification.

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14.13 * ~~Connexion de SEMP par un COUPLAGE DE RESEAUX / DONNEES à d'autres appareils~~
SEMP destiné à être incorporé dans un RESEAU INFORMATIQUE

~~Si le SEMP est destiné à être relié par un COUPLAGE DE RESEAUX / DONNEES à d'autres appareils qui sont hors du contrôle du FABRICANT du SEMP, la description technique doit:~~

~~a) spécifier les caractéristiques du COUPLAGE DE RESEAUX / DONNEES nécessaires pour que le SEMP satisfasse à son UTILISATION PREVUE;~~

~~b) faire la liste des SITUATIONS DANGEREUSES qui résultent d'une défaillance du COUPLAGE DE RESEAUX / DONNEES pour fournir les caractéristiques spécifiées;~~

~~c) indiquer à l'ORGANISME RESPONSABLE:~~

- ~~que la connexion du SEMP à un COUPLAGE DE RESEAUX / DONNEES qui inclut d'autres appareils pourrait donner lieu à des RISQUES non identifiés précédemment pour les PATIENTS, les OPERATEURS ou des tiers;~~
- ~~qu'il convient que l'ORGANISME RESPONSABLE identifie, analyse, évalue et contrôle ces RISQUES;~~
- ~~que des modifications ultérieures apportées au COUPLAGE DE RESEAUX / DONNEES pourraient introduire de nouveaux RISQUES et exiger une analyse complémentaire; et~~
- ~~que des modifications du COUPLAGE DE RESEAUX / DONNEES incluent:~~
  - ~~des modifications dans la configuration du COUPLAGE DE RESEAUX / DONNEES;~~
  - ~~la connexion d'unités supplémentaires au COUPLAGE DE RESEAUX / DONNEES;~~
  - ~~la déconnexion des unités du COUPLAGE DE RESEAUX / DONNEES;~~
  - ~~la mise à jour d'appareils connectés au COUPLAGE DE RESEAUX / DONNEES;~~
  - ~~la mise à niveau d'appareils connectés au COUPLAGE DE RESEAUX / DONNEES.~~

Si le SEMP est destiné à être incorporé dans un RESEAU INFORMATIQUE qui n'est pas validé par le FABRICANT DU SEMP, le FABRICANT doit rendre disponibles les instructions de mise en œuvre de cette connexion, y compris les éléments suivants:

a) l'objet de la connexion du SEMP à un RESEAU INFORMATIQUE;

b) les caractéristiques requises du RESEAU INFORMATIQUE incorporant le SEMP;

c) la configuration requise du RESEAU INFORMATIQUE incorporant le SEMP;

d) les spécifications techniques de la connexion au réseau du SEMP, y compris les spécifications de sécurité;

e) le flux d'informations prévu entre le SEMP, le RESEAU INFORMATIQUE et les autres appareils sur le RESEAU INFORMATIQUE et l'acheminement prévu dans le RESEAU INFORMATIQUE; et

NOTE 1 Ceci peut inclure des aspects d'efficacité et de sécurité des données et du système dans la mesure où ils sont liés à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES (voir aussi l'Article H.6 et l'IEC 80001-1:2010).

f) une liste des SITUATIONS DANGEREUSES résultant d'une défaillance du RESEAU INFORMATIQUE pour fournir les caractéristiques requises pour satisfaire l'objectif de la connexion du SEMP au RESEAU INFORMATIQUE.

NOTE 2 Connecter un SEMP à un autre appareil dans le but de transférer des données crée un RESEAU INFORMATIQUE à deux nœuds. Par exemple, connecter un SEMP à une imprimante crée un RESEAU INFORMATIQUE. Si le FABRICANT a validé le SEMP avec l'imprimante, le réseau résultant est considéré comme étant sous le contrôle du FABRICANT.

La conformité est vérifiée par l'inspection des instructions.

Dans les DOCUMENTS D'ACCOMPAGNEMENT, le FABRICANT doit indiquer à l'ORGANISME RESPONSABLE que:

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– la connexion du SEMP à un RESEAU INFORMATIQUE qui inclut d'autres appareils pourrait donner lieu à des RISQUES non identifiés précédemment pour les PATIENTS, les OPERATEURS ou des tiers;

– il convient que l'ORGANISME RESPONSABLE identifie, analyse, évalue et contrôle ces RISQUES;

NOTE 3 L'IEC 80001-1:2010 donne des directives pour aider l'ORGANISME RESPONSABLE à traiter ces RISQUES.

– des modifications ultérieures du RESEAU INFORMATIQUE pourraient introduire de nouveaux RISQUES et nécessiter une analyse supplémentaire; et

– les modifications au RESEAU INFORMATIQUE incluent:

- des changements de configuration du réseau informatique;
- la connexion d'unités supplémentaires au RESEAU INFORMATIQUE;
- la déconnexion d'unités du RESEAU INFORMATIQUE;
- la mise à jour d'un appareil connecté au RESEAU INFORMATIQUE; et
- la mise à niveau d'un appareil connecté au RESEAU INFORMATIQUE.

La conformité est vérifiée par l'inspection des DOCUMENTS D'ACCOMPAGNEMENT.

15 Construction de L'APPAREIL EM

15.1 * Groupements des commandes et indicateurs des APPAREILS EM

~~Lorsque c'est applicable, le FABRICANT doit traiter dans le cadre du PROCESSUS de GESTION DES RISQUES les RISQUES associés à l'ordonnancement des commandes et des indicateurs des APPAREILS EM.~~

~~*La conformité est vérifiée par l'inspection du DOSSIER DE GESTION DES RISQUES.*~~

Le cas échéant, le FABRICANT doit traiter les RISQUES associés aux groupements des commandes et des indicateurs de l'APPAREIL EM lors du PROCESSUS D'INGENIERIE DE L'APTITUDE A L'UTILISATION. Voir 12.2.

La conformité est vérifiée comme indiqué dans l'IEC 60601-1-6.

15.2 * Aptitude à l'entretien

Les pièces des APPAREILS EM sujettes à usure mécanique, dégradation électrique et environnementale ou vieillissement susceptibles d'engendrer un RISQUE inacceptable doivent être accessibles pour inspection, remplacement et maintenance s'il est admis qu'elles restent sans vérification pendant une longue période.

Les pièces des APPAREILS EM qui sont susceptibles d'être remplacées ou réglées doivent être situées et sécurisées de manière à permettre l'inspection, les opérations d'entretien, le remplacement et le réglage sans dommage ou interférence sur les parties adjacentes ou le câblage.

La conformité est vérifiée par l'inspection des pièces mentionnées ci-dessus dans le présent paragraphe et par l'inspection de leur emplacement.

15.3 Résistance mécanique

15.3.1 Généralités

~~LES APPAREILS EM ou leurs pièces doivent présenter une résistance mécanique appropriée et ne doivent pas engendrer un RISQUE inacceptable dû à la contrainte de moulage ou lorsqu'ils sont soumis aux contraintes mécaniques causées par les poussées, les impacts, les chutes et les manipulations brutales.~~

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Les APPAREILS EM ou leurs parties doivent présenter une résistance mécanique appropriée et ne doivent pas engendrer une perte de la SECURITE DE BASE ou des PERFORMANCES ESSENTIELLES due à la contrainte de moulage ou lorsqu'ils sont soumis aux contraintes mécaniques causées par les poussées, les impacts, les chutes et les manipulations brutales.

La conformité est vérifiée en procédant aux essais du Tableau 28. Les essais ne sont pas appliqués aux poignées, aux leviers, aux boutons, à la face des tubes cathodiques (voir 9.5.2), ou aux couvercles transparents ou translucides des dispositifs d'indication et de mesure sauf si en retirant la poignée, le levier, le bouton ou le couvercle, il apparaît un RISQUE inacceptable de choc électrique.

NOTE Des exemples de dommages ~~qui peuvent donner lieu à un RISQUE inacceptable~~ pouvant affecter la SECURITE DE BASE comprennent la réduction des lignes de fuite et des distances dans ~~L'AIR~~ l'air en dessous ~~de celles~~ des valeurs spécifiées en 8.9, l'accès aux parties qui dépassent les limites indiquées en 8.4 ou l'accès aux parties ~~en mouvement~~ mobiles qui pourraient ~~causer~~ conduire à un dommage.

Les critères d'évaluation pouvant être utiles pour déterminer ~~si les essais du Tableau 28 ont donné lieu à un RISQUE inacceptable~~ cet essai a conduit à une perte de la SECURITE DE BASE comprennent:

– ceux de l'Article 8 et de 11.6;

– l'essai de tension de tenue de 8.8.3 pour évaluer l'intégrité de ~~l'ISOLATION~~ l'isolation solide ~~SUPPLEMENTAIRE ou RENFORCEE~~ constituant un MOYEN DE PROTECTION; et

– la mesure des LIGNES DE FUITE ou des DISTANCES DANS L'AIR pour comparer les valeurs avec les distances minimales spécifiées en 8.9. Les petits éclats qui n'entament pas la protection contre les chocs électriques ou l'humidité peuvent normalement être ignorés.

Tableau 28 – Matrice d'essai de résistance mécanique

Type D'APPAREIL EM	Essai
PORTATIF	Poussée (15.3.2)
	Chute (15.3.4.1)
	Suppression de la contrainte de moulage (15.3.6)
PORTE SUR LE CORPS	Poussée (15.3.2)
	Impacts (15.3.3)
	Chute (15.3.4.1)
	Suppression de la contrainte de moulage (15.3.6)
PORTABLE	Poussée (15.3.2)
	Impacts (15.3.3)
	Chute (15.3.4.2)
	Suppression de la contrainte de moulage (15.3.6)
MOBILE	Poussée (15.3.2)
	Impacts (15.3.3)
	Manipulations brutales (15.3.5)
	Suppression de la contrainte de moulage (15.3.6)
FIXE ou FIXE	Poussée (15.3.2)
	Impacts (15.3.3)
	Suppression de la contrainte de moulage (15.3.6)

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15.3.2 * Essai de poussée

Les ENVELOPPES des APPAREILS EM doivent avoir une rigidité suffisante pour protéger contre un RISQUE inacceptable.

La conformité est vérifiée par l'essai suivant.

Les parties externes d'une ENVELOPPE sont soumises à une force continue de 250 N ± 10 N pendant 5 s, appliquée au moyen d'un OUTIL d'essai adapté permettant le contact sur une surface plane circulaire de 30 mm de diamètre. Toutefois, cet essai n'est pas appliqué à l'ENVELOPPE d'un APPAREIL EM qui a une masse supérieure à 18 kg.

Après l'essai, tout dommage prolongé qui donne lieu à un RISQUE inacceptable ~~déterminé à partir de l'inspection du DOSSIER DE GESTION DES RISQUES~~ constitue une défaillance.

NOTE Voir les critères de conformité en 15.3.1.

15.3.3 * Essai d'impacts

Les ENVELOPPES des APPAREILS EM doivent avoir une résistance aux impacts suffisante pour protéger contre un RISQUE inacceptable.

La conformité est vérifiée par l'essai suivant.

A l'exception des APPAREILS EM PORTATIFS et de leurs pièces qui sont tenues à la main en UTILISATION NORMALE, les ENVELOPPES et les autres parties isolantes externes, dont la détérioration pourrait donner lieu à un RISQUE inacceptable, sont soumises aux essais comme indiqué ci-dessous.

Un spécimen composé d'une ENVELOPPE complète ou d'une partie de celle-ci représentant la zone non renforcée la plus importante est placé sur un support en position normale. On laisse tomber librement une bille d'acier lisse solide de 50 mm de diamètre environ ayant une masse de 500 g ± 25 g d'une hauteur de position de 1,3 m sur chaque partie concernée du spécimen.

Pour l'essai des surfaces verticales, la bille d'acier est suspendue par une corde et on peut la laisser osciller comme un pendule pour appliquer un impact horizontal, en la lâchant d'une distance verticale de 1,3 m une fois sur chaque partie du spécimen.

L'essai n'est pas appliqué aux écrans plats, au verre des APPAREILS EM (par exemple analyseurs de films) ou aux tubes cathodiques (voir 9.5.2).

Après l'essai, tout dommage prolongé qui donne lieu à un RISQUE inacceptable ~~déterminé à partir de l'inspection du DOSSIER DE GESTION DES RISQUES~~ constitue une défaillance.

NOTE Voir les critères de conformité en 15.3.1.

15.3.4 * Essai de chute

15.3.4.1 APPAREILS EM PORTATIFS

Les APPAREILS EM PORTATIFS, les ACCESSOIRES et ~~leurs pièces qui sont TENUS A LA MAIN en UTILISATION NORMALE~~ les parties d'APPAREILS EM ne doivent ~~pas engendrer un~~ entraîner aucun RISQUE inacceptable à la suite d'une chute libre.

La conformité est vérifiée ~~par~~ en effectuant l'essai suivant.

On laisse tomber librement le spécimen soumis à l'essai, avec toute CHARGE DE FONCTIONNEMENT EN SECURITE en place, une fois à partir de chacune des trois orientations de départ différentes rencontrées en UTILISATION NORMALE de la hauteur à laquelle l'APPAREIL EM, l'ACCESSOIRE ou la partie d'APPAREIL EM est utilisé (comme spécifié dans les DOCUMENTS D'ACCOMPAGNEMENT) ou d'une hauteur de 1 m, selon celle qui est la plus élevée, sur une plaque de bois dur de 50 mm ± 5 mm d'épaisseur (par exemple, bois dur > 600 kg/m³) à plat sur du béton ou sur une base rigide similaire.

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~~*Après l'essai, les APPAREILS EM PORTATIFS et les pièces D'APPAREILS EM TENUES A LA MAIN en UTILISATION NORMALE ne doivent pas engendrer de RISQUE inacceptable.*~~

*Après l'essai, l'APPAREIL EM PORTATIF, l'*ACCESSOIRE *ou la partie d'APPAREIL EM ne doit entraîner aucun RISQUE inacceptable.*

15.3.4.2 * APPAREILS EM PORTABLES

Les APPAREILS EM PORTABLES ~~et leurs pièces doivent résister à la contrainte engendrée par une chute libre sur une surface dure~~, les ACCESSOIRES et les parties d'APPAREILS EM doivent supporter la contrainte causée par une chute libre d'une hauteur telle qu'indiquée au Tableau 29 sur une surface dure.

La conformité est vérifiée par l'essai suivant.

Le spécimen à soumettre à l'essai avec la CHARGE DE FONCTIONNEMENT EN SECURITE en place est élevé jusqu'à une hauteur telle qu'indiquée au Tableau 29 au-dessus d'une plaque de bois dur d'une épaisseur de 50 mm ± 5 mm d'épaisseur (par exemple > 600 kg/m^3) qui est posée à plat sur un sol en béton ou une base rigide similaire. Les dimensions de la plaque sont au moins égales à celles du spécimen à soumettre aux essais. On laisse tomber le spécimen trois fois depuis chaque orientation dans laquelle il peut être placé en UTILISATION NORMALE.

Tableau 29 – Hauteur de chute

Masse (*m*) de l'APPAREIL EM PORTABLE ou de ses parties kg	**Hauteur de chute** cm
$m \leq 10$	5
$10 < m \leq 50$	3
$m > 50$	2

Après l'essai, tout dommage prolongé qui donne lieu à un RISQUE inacceptable ~~déterminé à partir de l'inspection du DOSSIER DE GESTION DES RISQUES de l'APPAREIL EM ou des parties de l'APPAREIL EM qui sont PORTABLES~~ constitue une défaillance.

NOTE Voir les critères de conformité en 15.3.1.

15.3.5 * Essai de manipulations brutales

Les APPAREILS EM MOBILES ou leurs pièces qui sont MOBILES doivent résister à la contrainte causée par les manipulations et les mouvements brutaux et ne doivent pas engendrer de RISQUE inacceptable.

La conformité est vérifiée par les essais suivants.

Le spécimen est soumis aux essais en position de transport avec toute CHARGE DE FONCTIONNEMENT EN SECURITE en place et dans la condition la plus défavorable admise en UTILISATION NORMALE. Pendant l'essai, des précautions appropriées doivent être prises pour empêcher un déséquilibre causé par la contrainte/le choc lié(e) aux manipulations brutales.

a) *Choc de montée de marche*

Le spécimen est poussé trois fois dans ~~sa direction normale~~ son sens de déplacement normal à une vitesse de ~~0,4~~ 0,48 m/s ± 0,1 m/s, ou, pour les APPAREILS EM MOBILES à moteur, à la vitesse maximale qu'il est possible de conserver, contre une ~~marche ascendante~~ butée plane en bois dur solide ayant une face avant ~~verticale~~ de 40 mm qui est fixée solidement à un sol par ailleurs totalement plat. La direction du mouvement est perpendiculaire à la face de l'obstacle. Il n'est pas nécessaire que le spécimen passe par dessus ~~l'obstacle~~ la butée de 40 mm.

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b) *Choc de descente de marche*

Le spécimen est poussé trois fois dans ~~sa direction normale~~ son sens de déplacement normal à une vitesse de ~~0,4~~ 0,48 m/s ± 0,1 m/s, ou, pour les APPAREILS EM MOBILES à moteur, à la vitesse maximale qu'il est possible de conserver, pour tomber d'une marche verticale d'une hauteur de 40 mm fixée à plat sur une base rigide (par exemple du béton). La direction du mouvement est perpendiculaire à la face de la marche descendante.

Au cours de l'essai de choc de descente, si une partie autre que la roulette entre en contact avec ~~l'obstacle~~ la butée avant que celle-ci touche le sol, l'APPAREIL EM continue d'être poussé jusqu'à ce qu'il ait terminé la descente.

c) *Choc de chambranle (passage de porte)*

Le spécimen est déplacé à trois reprises dans sa direction normale de déplacement à une vitesse de ~~0,4~~ 0,8 m/s ± 0,1 m/s, ou, pour les APPAREILS EM MOBILES motorisés, à la vitesse maximale pouvant être maintenue, contre un obstacle vertical en bois dur d'une largeur et d'une épaisseur de 40 mm fixé sur un support rigide vertical (par exemple du béton). La hauteur de l'obstacle vertical doit être supérieure au(x) point(s) de contact de l'APPAREIL EM. La direction du mouvement est perpendiculaire à la face de l'obstacle.

Après chaque essai, tout dommage prolongé qui donne lieu à un RISQUE inacceptable ~~déterminé à partir de l'inspection du DOSSIER DE GESTION DES RISQUES de l'APPAREIL EM ou des parties de l'APPAREIL EM qui sont MOBILES~~ constitue une défaillance.

NOTE 1 Voir les critères de conformité en 15.3.1.

NOTE 2 L'instabilité de l'APPAREIL EM, lorsque celui-ci reste exempt de dommage causé par une contrainte/un choc lié(e) aux manipulations brutales, est évaluée conformément à 9.4.

15.3.6 * Essai de suppression de la contrainte de moulage

Les ENVELOPPES en matériaux moulés ou thermoplastiques thermoformés doivent être construites de telle manière que tout retrait ou toute déformation du matériau dû à la libération de contraintes internes causées par l'opération de moulage ou de thermoformage ne donne pas lieu à un RISQUE inacceptable.

La conformité est vérifiée par inspection de la construction et des données disponibles lorsque approprié ou par l'essai suivant.

Un spécimen constitué de l'APPAREIL EM complet ou de l'ENVELOPPE avec toute structure de support est placé dans un four à circulation d'air à une température de 10 °C supérieure à la température maximale observée sur l'ENVELOPPE au cours de l'essai de 11.1.3 mais pas à une température inférieure à 70 °C, pendant 7 h, puis est laissé refroidir et revenir à la température ambiante.

NOTE Il n'est pas nécessaire de maintenir l'humidité relative à une valeur spécifique au cours de ce conditionnement.

Pour les APPAREILS EM de grande taille pour lesquels il n'est pas possible en pratique de conditionner une ENVELOPPE complète, il est autorisé d'utiliser une partie de l'ENVELOPPE représentative de l'ensemble complet en termes d'épaisseur, de forme y compris les éléments de support mécanique.

Il ne doit pas être constaté de dommage donnant lieu à un RISQUE inacceptable.

15.3.7 * Influences environnementales

La sélection et le traitement des matériaux utilisés dans la construction des APPAREILS EM doivent tenir compte de l'UTILISATION PREVUE de la DUREE DE VIE PREVUE et des conditions de transport et de stockage.

Les APPAREILS EM doivent être conçus et construits de telle manière qu'au cours de leur DUREE DE VIE PREVUE, toute corrosion, tout vieillissement, toute usure mécanique ou toute dégradation des matières biologiques due à l'influence de bactéries, de plantes, d'animaux et

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similaires ne réduise pas leurs propriétés mécaniques d'une manière qui engendre un RISQUE inacceptable. Voir aussi 15.2.

La conformité est vérifiée par inspection:

– *de l'APPAREIL EM, des DOCUMENTS D'ACCOMPAGNEMENT et des spécifications du FABRICANT des matériaux utilisés et des spécifications de mise en œuvre de ces matériaux;*

– *des essais et ou des calculs pertinents du FABRICANT.*

15.4 Composants et assemblage général des APPAREILS EM

15.4.1 Construction des connecteurs

La conception et la construction des connexions/raccords électriques, hydrauliques, pneumatiques et pour les gaz, des APPAREILS EM, doivent être telles qu'un branchement incorrect de ces connexions/raccords accessibles, pouvant être enlevés sans l'aide d'un OUTIL, soit impossible, lorsqu'une telle manœuvre pourraient entraîner un RISQUE inacceptable. En particulier:

a) Les fiches destinées au branchement des conducteurs PATIENT ou des câbles PATIENT doivent être conçues de sorte qu'elles ne puissent être ~~reliées~~ connectées à ~~d'autres~~ des socles ~~destinés à d'autres fonctions~~ sur le même APPAREIL EM prévus pour d'autres fonctions, sauf s'il ~~est~~ peut être démontré ~~que cette possibilité n'entraîne~~ qu'aucun RISQUE inacceptable ne peut en résulter.

La conformité est vérifiée par l'inspection des conducteurs PATIENT, des câbles PATIENT, des connecteurs et des socles et, si l'échange des conducteurs, câbles, conducteurs ou socles est possible, par l'inspection du DOSSIER DE GESTION DES RISQUES.

b) Les raccords de gaz médicaux sur les APPAREILS EM devant recevoir des gaz différents en UTILISATION NORMALE ne doivent pas être interchangeables. Voir aussi l'ISO 407 [27].

La conformité est vérifiée par l'inspection ~~du DOSSIER DE GESTION DES RISQUES~~ de tous les connecteurs de gaz médicaux.

15.4.2 Dispositifs de commande de la température et de la surcharge

15.4.2.1 Application

a) Les COUPE-CIRCUIT THERMIQUES et les DISJONCTEURS ~~à~~ avec réenclenchement automatique ne doivent pas être utilisés dans les APPAREILS EM ~~lorsque ce réenclenchement~~ si leur utilisation peut ~~engendrer~~ conduire à une SITUATION DANGEREUSE telle que décrite en 13.1 du fait de ce réenclenchement.

La conformité est vérifiée par inspection de la documentation de conception et du DOSSIER DE GESTION DES RISQUES.

b) Les APPAREILS EM ne doivent pas comporter de COUPE-CIRCUIT THERMIQUES ayant une fonction de sécurité si leur remise en service ne peut intervenir que par une opération de soudure susceptible d'influer sur la valeur de fonctionnement.

La conformité est vérifiée par l'inspection de la documentation de conception ~~et du DOSSIER DE GESTION DES RISQUES.~~.

c) ~~Lorsqu'~~ Dans les APPAREILS EM où une défaillance d'un THERMOSTAT ~~d'un APPAREIL EM peut créer un DANGER, on doit prévoir~~ pourrait conduire à une SITUATION DANGEREUSE telle que décrite en 13.1, un COUPE-CIRCUIT THERMIQUE indépendant sans REENCLENCHEMENT AUTOMATIQUE ~~supplémentaire et indépendant~~ doit être prévu en sus. La température de fonctionnement du dispositif supplémentaire doit dépasser la température normalement atteinte au réglage maximal du dispositif normal de commande (THERMOSTAT) tout en restant dans les limites de sécurité de températures ~~prévues~~ pour ~~sa~~ la fonction prévue de l'APPAREIL EM.

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La conformité est vérifiée par inspection de la documentation de conception et du DOSSIER DE GESTION DES RISQUES.

d) ~~La~~ Une perte de fonction ~~d'un~~ de l'APPAREIL EM ~~causée~~ entraînée par ~~l'intervention~~ le fonctionnement d'un COUPE-CIRCUIT THERMIQUE ou d'un DISJONCTEUR ne doit pas ~~engendrer de SITUATION DANGEREUSE~~ conduire à la perte des PERFORMANCES ESSENTIELLES ou à l'une quelconque des SITUATIONS DANGEREUSES décrites en 13.1.

La conformité est vérifiée par inspection de la documentation de conception et du DOSSIER DE GESTION DES RISQUES.

e) Les condensateurs ou autres dispositifs anti-étincelles des APPAREILS EM ne doivent pas être raccordés entre les contacts des COUPE-CIRCUIT THERMIQUES.

La conformité est vérifiée par inspection.

f) L'utilisation de COUPE-CIRCUIT THERMIQUES ou de DISJONCTEURS dans la conception ne doit pas affecter la sécurité des APPAREILS EM.

La conformité est vérifiée par inspection et, si applicable, par les essais suivants.

Vérifier la conformité des dispositifs de coefficients de température positifs (CTP) avec l'IEC 60730-1:~~1999~~ 2010 Articles 15, 17, J.15 et J.17 selon ce qui est applicable.

Les COUPE-CIRCUIT THERMIQUES et les DISJONCTEURS sont soumis aux essais en faisant fonctionner les APPAREILS EM dans les conditions décrites à l'Article 13.

Les COUPE-CIRCUIT THERMIQUES A REENCLENCHEMENT AUTOMATIQUE et les DISJONCTEURS à réenclenchement automatique y compris les circuits qui assurent des fonctions équivalentes (autres que les CTP) sont soumis 200 fois à l'essai de fonctionnement sauf agrément selon la norme IEC de composants appropriée.

Les COUPE-CIRCUIT THERMIQUES et les DISJONCTEURS sans réenclenchement automatique sont soumis 10 fois à l'essai de fonctionnement, s'ils ne sont pas agréés selon la norme IEC de composants appropriée (voir 4.5) ou le FABRICANT n'a pas fourni de données adaptées pour démontrer la fiabilité du composant pour assurer sa fonction liée à la SECURITE.

Les dispositifs de protection thermiques peuvent être soumis à des essais indépendamment des APPAREILS EM lorsqu'un avis d'ingénierie indique que procéder ainsi ne peut pas affecter les résultats d'essai.

g) LES APPAREILS EM comportant un réservoir de liquide pourvu d'un système de chauffage doivent être munis d'un dispositif de protection contre la surchauffe au cas où le chauffage serait enclenché alors que le réservoir est vide. Un RISQUE inacceptable ne doit pas apparaître à la suite d'une surchauffe.

La conformité est vérifiée en faisant fonctionner l'APPAREIL EM visé avec son réservoir vide jusqu'au déclenchement du dispositif de protection.

h) Les APPAREILS EM qui incorporent des éléments chauffants tubulaires doivent être protégés contre la surchauffe dans les deux conducteurs lorsqu'une liaison conductrice à la terre peut donner lieu à une surchauffe.

La conformité est vérifiée par inspection de la documentation de conception et du DOSSIER DE GESTION DES RISQUES.

15.4.2.2 Réglages de la température

Lorsque les THERMOSTATS des APPAREILS EM comportent des dispositifs permettant de régler leur température de fonctionnement, le réglage doit être clairement indiqué.

La conformité est vérifiée par inspection.

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15.4.3 * Batteries d'accumulateurs

15.4.3.1 Enceinte contenant des batteries

~~Dans les APPAREILS EM, les enceintescontenant des batteries qui peuvent laisser échapper des gaz pouvant engendrer un DANGER en cours de charge ou de décharge doivent être ventilées afin de réduire le RISQUE d'accumulation et d'inflammation.~~

Dans les APPAREILS EM, les boîtiers contenant des batteries d'où peuvent s'échapper des gaz pendant la charge ou la décharge doivent être aérés de manière à éviter tout RISQUE inacceptable dû à l'accumulation de gaz et à empêcher une possible inflammation.

Les compartiments de batteries des APPAREILS EM doivent être conçus pour éviter toute mise en court-circuit accidentelle des batteries, si de tels courts-circuits entraînent une SITUATION DANGEREUSE décrite en 13.1.

La conformité est vérifiée par inspection de la documentation de conception et le cas échéant, du DOSSIER DE GESTION DES RISQUES.

15.4.3.2 Raccordement

Si une SITUATION DANGEREUSE peut résulter d'un branchement ou d'un remplacement incorrect d'une batterie, l'APPAREIL EM doit comporter un moyen pour empêcher une inversion de polarité lors du branchement. Voir aussi 7.3.3 et 8.2.2.

La conformité est vérifiée par inspection.

15.4.3.3 Protection contre les surcharges

Lorsque la surcharge d'une batterie d'un APPAREIL EM peut donner lieu à un RISQUE inacceptable, la conception doit empêcher les surcharges.

La conformité est vérifiée par inspection de la documentation de conception.

15.4.3.4 Batteries au lithium

~~Les batteries au lithium utilisées dans les APPAREILS EM qui peuvent être source de DANGER doivent être conformes aux exigences de l'IEC 60086-4. Voir aussi 7.3.3.~~

Les batteries au lithium primaires doivent satisfaire aux exigences de l'IEC 60086-4. Les batteries au lithium secondaires doivent satisfaire aux exigences de l'IEC 62133. Voir aussi 7.3.3.

NOTE Les batteries comprennent à la fois les piles isolées et les ensembles de piles, c'est-à-dire des blocs de batteries.

La conformité est vérifiée par l'inspection de la documentation de conception de la batterie ou par la réalisation des essais ~~donnés~~ identifiés dans l'IEC 60086-4 pour les batteries au lithium primaires et dans l'IEC 62133 pour les batteries au lithium secondaires.

15.4.3.5 * Protection contre les surintensités et les surtensions

Une SOURCE ELECTRIQUE INTERNE d'un APPAREIL EM doit être munie d'un dispositif aux caractéristiques ASSIGNEES appropriées pour assurer la protection contre l'incendie dû à des courants excessifs, si la section et la disposition du câblage interne ou les caractéristiques nominales des composants peuvent donner lieu à un incendie en cas de court-circuit. Les dispositifs de protection doivent posséder une capacité de coupure appropriée pour couper le courant de défaut maximal (y compris courant de court-circuit) qui peut s'écouler. La justification de l'omission des ~~FUSIBLES~~ fusibles ou des DISJONCTEURS doit être ~~incluse dans le DOSSIER DE GESTION DES RISQUES~~ documentée.

L'essai de court-circuit entre le pôle positif et le pôle négatif d'une SOURCE ELECTRIQUE INTERNE dans la zone comprise entre les contacts de sortie de la SOURCE ELECTRIQUE INTERNE et le dispositif de protection suivant peut être omis si deux MOYENS DE PROTECTION DE

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L'OPERATEUR sont prévus. En alternative, un essai de court-circuit ne doit pas donner lieu à l'une quelconque des SITUATIONS DANGEREUSES de 13.1.2.

La conformité est vérifiée par l'inspection de la présence des moyens de protection et si nécessaire par examen de la documentation de conception ~~et du DOSSIER DE GESTION DES RISQUES~~. En alternative, mener l'essai de court-circuit: aucune des SITUATIONS DANGEREUSES de 13.1.2 ne doit survenir.

15.4.4 * Voyants lumineux

A moins que l'indication correspondante ne soit apparente d'une autre façon pour l'OPERATEUR placé en position normale de commande, des voyants lumineux doivent être prévus pour indiquer que l'APPAREIL EM est prêt pour une UTILISATION NORMALE. Le marquage prévu en 7.4.1 n'est pas suffisant à cet effet.

Si l'APPAREIL EM possède un état d'attente ou d'échauffement d'une durée supérieure à 15 s, il doit être équipé d'un voyant lumineux supplémentaire, sauf s'il est apparent d'une autre manière pour l'OPERATEUR par rapport à la position de fonctionnement normal.

Des voyants lumineux doivent être prévus sur les APPAREILS EM qui comportent des éléments chauffants non incandescents pour indiquer que ces éléments sont actifs, si une SITUATION DANGEREUSE existe sauf si elle est apparente d'une autre manière pour l'OPERATEUR par rapport à la position de fonctionnement normal.

NOTE Cela ne s'applique pas aux plumes chauffantes des appareils enregistreurs.

Des voyants lumineux doivent être prévus sur les APPAREILS EM pour indiquer la présence d'une sortie, lorsque le fonctionnement accidentel ou prolongé du circuit de sortie peut présenter une SITUATION DANGEREUSE.

Les couleurs des voyants lumineux sont données en 7.8.1.

Dans les APPAREILS EM comportant un système de charge de la SOURCE ELECTRIQUE INTERNE, le mode de charge doit être distinctement indiqué à l'OPERATEUR.

La conformité est vérifiée en examinant la présence et le fonctionnement de dispositifs indicateurs visibles depuis la position d'UTILISATION NORMALE.

15.4.5 Commandes de présélection

Lorsque cela est applicable, le FABRICANT doit traiter dans le cadre du PROCESSUS de GESTION DES RISQUES les RISQUES associés aux commandes de présélection.

La conformité est vérifiée par l'inspection du DOSSIER DE GESTION DES RISQUES.

15.4.6 Organes de manœuvre des commandes des APPAREILS EM

15.4.6.1 Fixation, prévention des défauts de réglage

a) Tous les organes de manœuvre des APPAREILS EM doivent être fixés de manière à ne pouvoir être arrachés ou se desserrer en UTILISATION NORMALE.

b) ~~Les commandes dont le réglage peut donner lieu à une SITUATION DANGEREUSE pour le PATIENT ou l'OPERATEUR en cours d'utilisation de l'APPAREIL EM doivent être fixées de manière que toute indication d'échelle corresponde toujours à la position de la commande.~~

~~Dans ce cas, l'indication se rapporte à des positions "Marche" ou "Arrêt", à des graduations d'échelle ou à d'autres indications de position.~~

Les commandes doivent être fixées de manière que toute indication d'échelle corresponde toujours à la position de la commande.

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c) Le raccordement incorrect du dispositif indicateur avec le composant correspondant doit être évité grâce à une construction convenable, s'ils peuvent être séparés sans l'aide d'un OUTIL.

La vérification est effectuée par inspection et par des essais manuels. Pour les commandes par rotation, on doit appliquer les couples indiqués dans le Tableau 30 entre le bouton de commande et son axe pendant au moins 2 s dans chaque sens alternativement. L'essai est répété 10 fois.

Un bouton qui tourne par rapport à l'axe constitue une défaillance.

Si une traction axiale est nécessaire en UTILISATION NORMALE, la conformité est vérifiée en appliquant pendant 1 min une force axiale de 60 N pour les composants électriques et de 100 N pour les autres composants.

Tableau 30 – Couples d'essai pour les commandes par rotation

Diamètre de saisie (*d*) du bouton de commande mm [a]	**Couple** Nm
$10 \leq d < 23$	1,0
$23 \leq d < 31$	2,0
$31 \leq d < 41$	3,0
$41 \leq d < 56$	4,0
$56 \leq d \leq 70$	5,0
$d > 70$	6,0
[a] Le diamètre de saisie (*d*) est la largeur maximale du bouton de commande quelle que soit sa forme (par exemple bouton de commande avec pointeur).	

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15.4.6.2 Limitation du mouvement

Des butées d'une résistance mécanique appropriée doivent être prévues pour les parties tournantes ou mobiles des commandes des APPAREILS EM, si cela est nécessaire pour éviter de passer involontairement du maximum au minimum du paramètre commandé, ou vice versa~~, lorsque cela peut entraîner une SITUATION DANGEREUSE~~.

La vérification est effectuée par inspection et par des essais manuels. Pour les commandes par rotation, les couples indiqués dans le Tableau 30 sont appliqués pendant au moins 2 s dans chaque sens alternativement. L'essai est répété 10 fois.

~~Il ne doit se produire aucun RISQUE inacceptable~~ Lorsqu'une traction axiale est susceptible d'être exercée sur les parties tournantes ou mobiles des commandes d'APPAREILS EM en UTILISATION NORMALE, il ne doit se produire aucun changement involontaire du paramètre commandé.

La conformité est vérifiée en appliquant pendant 1 min une force axiale de 60 N pour les composants électriques et de 100 N pour les autres composants.

15.4.7 Dispositifs de commande PORTATIFS et pédales de commande, raccordés par câble (voir aussi 8.10.4)

15.4.7.1 Résistance mécanique

a) Les dispositifs de commande PORTATIFS des APPAREILS EM doivent être conformes à 15.3.4.1.

b) Les pédales de commande des APPAREILS EM doivent pouvoir supporter le poids d'un adulte.

La conformité est vérifiée en appliquant à la pédale de commande, dans sa position d'UTILISATION NORMALE, une force de 1 350 N pendant 1 min. La force est appliquée sur une surface de 30 mm de diamètre. Il ne doit se produire aucune détérioration du dispositif créant un RISQUE inacceptable.

15.4.7.2 Fonctionnement accidentel de l'APPAREIL EM

Le réglage des dispositifs de commande PORTATIFS et des pédales de commande ne doit pas subir de changement qui entraîne un RISQUE inacceptable, s'ils sont accidentellement placés dans une position anormale.

La conformité est vérifiée en plaçant le dispositif de commande dans toutes les positions anormales possibles sur une surface plate. Tout changement de réglage inopiné créant un RISQUE inacceptable constitue une défaillance.

15.4.7.3 * Pénétration de liquides

a) Les pédales de commande des APPAREILS EM doivent être protégées au moins selon le degré IPX1 conformément à l'IEC 60529.

La conformité est vérifiée par les essais de l'IEC 60529.

b) ~~Dans les APPAREILS EM, les ENVELOPPES des pédales de commande qui contiennent des circuits électriques doivent présenter un degré de protection classé au moins IPX6 selon l'IEC 60529 si elles sont destinées à une UTILISATION NORMALE dans des zones où la présence de liquides est probable (comme les salles des urgences et les salles d'opération). La probabilité d'un tel cas doit être estimée en tant que partie du PROCESSUS de GESTION DES RISQUES~~.

Dans les APPAREILS EM, les ENVELOPPES des pédales de commande, utilisées dans des zones telles que les salles des urgences ou les salles d'opération où il y a une grande probabilité de présence de liquides sur le sol et contenant des circuits électriques, doivent être au moins de classe IPX6 selon l'IEC 60529.

La conformité est ~~déterminée~~ vérifiée par l'inspection des DOCUMENTS D'ACCOMPAGNEMENT, de la documentation de conception, ~~du DOSSIER DE GESTION DES RISQUES et en réalisant les~~ et par la réalisation des essais appropriés de l'IEC 60529.

15.4.8 Câblage interne des APPAREILS EM

Des fils en aluminium de section inférieure à 16 mm^2 ne doivent pas être utilisés dans des APPAREILS EM.

La conformité est vérifiée par inspection.

15.4.9 Réservoirs d'huile

a) Les réservoirs d'huile des APPAREILS EM PORTABLES doivent être d'une étanchéité interdisant les pertes d'huile dans toute position. La conception du réservoir doit permettre l'expansion de l'huile.

b) Les réservoirs d'huile des APPAREILS EM MOBILES doivent être d'une étanchéité interdisant les pertes d'huile durant le transport, mais ils peuvent être équipés d'un dispositif de décompression qui peut fonctionner en UTILISATION NORMALE.

c) Les APPAREILS EM ou leurs parties qui contiennent de l'huile et sont partiellement étanches doivent comporter un dispositif de vérification du niveau d'huile pour détecter les fuites (voir 7.9.3.1).

La conformité est vérifiée par inspection de l'APPAREIL EM , de la description technique et par un essai manuel.

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15.5 * TRANSFORMATEURS D'ALIMENTATION des APPAREILS EM et transformateurs assurant la séparation conformément à 8.5

15.5.1 Surchauffe

15.5.1.1 * Transformateurs

Les transformateurs des APPAREILS EM doivent être protégés contre la surchauffe en cas de court-circuit ou de surcharge se produisant au niveau de tout enroulement de sortie.

La conformité est vérifiée par les essais de 15.5.1.2 et 15.5.1.3 selon le cas dans les conditions suivantes.

Chaque enroulement est soumis aux essais, à tour de rôle, avec les paramètres suivants présentant la valeur la plus défavorable:

– *tension primaire maintenue entre 90 % et 110 % de la tension ASSIGNEE*

– *fréquence d'entrée ASSIGNEE*

– *les charges sur les autres enroulements variant de non chargés à chargés comme en UTILISATION NORMALE*

Un court-circuit ou une charge résistive, selon le cas, est appliqué aux extrémités des enroulements ou au premier point qui peut être court-circuité en CONDITION DE PREMIER DEFAUT.

~~*Les composants destinés à empêcher la surchauffe du transformateur en conditions de court-circuit et de surcharge sont inclus comme une partie des essais de 15.5.1.2 et de 15.5.1.3 tant qu'il est improbable qu'une condition de court-circuit ou de surcharge apparaisse pour laquelle ils n'assureraient pas la protection. Une défaillance de tels circuits à assurer la protection est considérée comme improbable lorsque l'isolation (y compris l'espacement) est égale à au moins un MOYEN DE PROTECTION DE L'OPERATEUR comme cela est défini à l'Article 8 et lorsque des composants ayant des caractéristiques à haute fiabilité sont utilisés.*~~

Les composants destinés à empêcher la surchauffe du transformateur durant un court-circuit et les conditions de surcharge sont inclus dans les essais de 15.5.1.2 et 15.5.1.3 dès lors que:

– *le composant est un composant à caractéristiques à haute fiabilité, et*

– *deux MOYENS DE PROTECTION DE L'OPERATEUR sont prévus entre les contacts de sortie du transformateur et le COMPOSANT AUX CARACTERISTIQUES A HAUTE FIABILITE.*

Au cours des essais, aucun enroulement ne doit s'ouvrir, aucune SITUATION DANGEREUSE ne doit apparaître et les températures maximales des enroulements ne doivent pas dépasser les valeurs du Tableau 31. Après les essais de court-circuit et de surcharge, le transformateur doit également subir avec succès l'essai de tension de tenue (tel qu'il est décrit en 8.8.3) entre les enroulements primaires et secondaires, entre les enroulements primaires et le châssis et entre les enroulements secondaires et le châssis. Les essais sont réalisés dans les conditions spécifiées en 11.1, soit dans l'APPAREIL EM soit dans des conditions simulées sur le banc d'essai.

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Tableau 31 – Températures maximales admissibles des enroulements des transformateurs dans des conditions de surcharge et de court-circuit à une température ambiante de 25 °C (± 5 °C)

Parties	Température maximale °C
Enroulements et noyaux en contact avec eux, si l'isolation de l'enroulement est :	
– en matériaux de la classe A	150
– en matériaux de la classe B	175
– en matériaux de la classe E	165
– en matériaux de la classe F	190
– en matériaux de la classe H	210

15.5.1.2 Essai de court-circuit

L'enroulement de sortie en essai est court-circuité. L'essai est continué jusqu'à ce que le dispositif de protection fonctionne ou que la STABILITE THERMIQUE soit atteinte. Pour les transformateurs qui ne sont pas soumis aux essais à 5 fois la fréquence et à 5 fois la tension de 15.5.2a) ou aux essais à 2 fois la fréquence et à 2 fois la tension de 15.5.2 b), le court-circuit est directement appliqué à travers les enroulements de sortie.

15.5.1.3 Essai de surcharge

Les enroulements équipés de plus d'un dispositif de protection peuvent nécessiter plusieurs essais de surcharge pour évaluer complètement les cas de charge et de fonctionnement des fusibles du cas le plus défavorable en UTILISATION NORMALE.

L'essai de surcharge peut être appliqué après rectification.

Si l'essai de court-circuit est réalisé sans le fonctionnement d'un dispositif de protection, (comme un circuit de limitation de courant), l'essai de surcharge n'est pas nécessaire.

a) *Cet essai (a) est réalisé si le courant auquel le dispositif de protection fonctionne ne peut pas être déterminé sur la base d'une revue des dispositifs de protection fournis et de leurs données de performance, sinon c'est l'essai b) qui est réalisé.*

   L'enroulement en essai est chargé à sa charge en UTILISATION NORMALE jusqu'à atteindre la STABILITE THERMIQUE. La charge est ensuite progressivement réglée suivant des paliers appropriés pour s'approcher du courant minimal auquel le dispositif de protection fonctionne. Chaque réglage de la charge est suivi d'un laps de temps suffisant pour atteindre la STABILITE THERMIQUE et le courant de charge et la température doivent être notés.

   A la suite du fonctionnement d'un dispositif de protection, b) est réalisé.

b) *Si le dispositif de protection qui a fonctionné en a) est extérieur au transformateur, il est contourné. L'enroulement en essai est chargé sur la base du type de dispositif de protection comme suit.*

   – *Coupe-circuit à fusibles conformes à l'IEC 60127-1:*

     30 min au courant d'essai déterminé dans le Tableau 32.

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Tableau 32 – Courant d'essai pour les transformateurs

Valeur marquée du courant ASSIGNE (*I*) du coupe circuit de protection A	Quotient du courant d'essai par le courant ASSIGNE du coupe circuit
$I \leq 4$	2,1
$4 < I \leq 10$	1,9
$10 < I \leq 25$	1,75
$I > 25$	1,6

– *Coupe-circuit à fusibles non conformes à l'IEC 60127-1:*

pendant 30 min au courant selon les caractéristiques fournies par le fabricant du coupe circuit à fusible, spécifiquement le courant d'élimination de 30 min. En l'absence de données sur un tel courant, le courant d'essai du Tableau 32 est utilisé jusqu'à l'obtention de la STABILITE THERMIQUE.

– *Autre dispositif de protection:*

jusqu'à la STABILITE THERMIQUE à un courant juste inférieur à celui qui a déclenché le dispositif en a).

Cette partie de l'essai de surcharge est terminée à l'issue de la durée spécifiée ou à l'ouverture d'un deuxième dispositif de protection.

15.5.2 * Tension de tenue

Le présent paragraphe n'est pas applicable aux transformateurs fonctionnant à une fréquence supérieure à 1 kHz, qui sont soumis à l'essai conformément à 8.8.3.

Les enroulements des transformateurs des APPAREILS EM doivent posséder une isolation adéquate pour empêcher les courts-circuits internes qui pourraient engendrer une surchauffe lorsque celle-ci pourrait donner lieu à une SITUATION DANGEREUSE.

La tension de tenue de l'isolation électrique entre spires et couches de chaque enroulement d'un TRANSFORMATEUR d'APPAREIL EM lorsque la défaillance du transformateur pourrait donner lieu à une SITUATION DANGEREUSE doit être suffisante pour satisfaire aux essais suivants, après le pré-conditionnement humide (voir 5.7).

a) *Les enroulements de transformateurs dont la tension ASSIGNEE ≤ 500 V ou la fréquence ASSIGNEE ≤ 60 Hz sont soumis à l'essai avec une tension à travers cet enroulement égale à cinq fois la tension ASSIGNEE ou cinq fois la limite supérieure de la plage des tensions ASSIGNEES de cet enroulement à une fréquence au moins égale à cinq fois la fréquence ASSIGNEE (la fréquence assignée étant la fréquence normale de fonctionnement de la tension d'entrée du transformateur).*

b) *Les enroulements de transformateurs dont la tension ASSIGNEE dépasse 500 V ou la fréquence ASSIGNEE dépasse 60 Hz sont soumis à l'essai avec une tension à travers cet enroulement égale à deux fois la tension ASSIGNEE ou deux fois la limite supérieure de la plage des tensions ASSIGNEES de cet enroulement à une fréquence au moins égale à deux fois la fréquence ASSIGNEE (la fréquence assignée étant la fréquence normale de fonctionnement de la tension d'entrée du transformateur).*

Toutefois, dans les deux cas précités, la contrainte exercée sur l'isolation des spires et des couches de n'importe quel enroulement du transformateur est telle que la tension d'essai qui apparaît sur l'enroulement en appliquant la plus haute tension ASSIGNEE ne soit pas supérieure à la tension d'essai spécifiée au Tableau 6, pour un MOYEN DE PROTECTION, si la tension ASSIGNEE d'un tel enroulement est considérée comme la tension de service. Si cela se produisait, la tension d'essai sur l'enroulement primaire devrait être réduite en conséquence. La fréquence d'essai peut être adaptée pour produire dans le noyau approximativement l'induction magnétique qui y règne en UTILISATION NORMALE. Lorsque le noyau du transformateur est isolé de toutes les connexions conductrices externes (comme cela est le

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cas dans la plupart des transformateurs toriques), les connexions au noyau décrites ci-dessous peuvent être omises.

– *Les transformateurs triphasés peuvent être soumis à l'essai à l'aide d'un dispositif d'essai triphasé ou en effectuant trois essais successifs à l'aide d'un dispositif d'essai monophasé.*

– *La valeur de la tension d'essai par rapport au noyau et à un éventuel écran placé entre les enroulements primaire et secondaire est conforme à la spécification du transformateur correspondant. Si l'enroulement primaire comporte un point de raccordement identifié pour le neutre du RESEAU D'ALIMENTATION, ce point est relié au noyau (et à l'écran s'il existe), sauf si le noyau (et le cas échéant l'écran) est spécifié pour être relié à une partie du circuit non mise à la terre. Pour cette simulation, relier le noyau (et l'écran) à une source d'une tension et d'une fréquence appropriées compte tenu du point de raccordement identifié.*

  Si un tel point de raccordement n'a pas été identifié, chaque sortie de l'enroulement primaire est successivement reliée au noyau (et le cas échéant à l'écran), sauf si le noyau (et l'écran) sont spécifiés pour être reliés à une partie du circuit non mise à la terre.

  Pour cette simulation, relier le noyau (et l'écran) à une source d'une tension et d'une fréquence appropriées compte tenu de l'extrémité de l'enroulement primaire visée.

– *Au cours de l'essai, tous les enroulements non destinés à être reliés au RESEAU D'ALIMENTATION sont sans charge (circuit ouvert). Les enroulements devant être mis à la terre en un point ou être mis en service avec un point presque au potentiel de terre ont ce point relié au noyau, sauf si ce dernier est spécifié pour être relié à une partie du circuit non mise à la terre.*

  Pour cette simulation, relier le noyau à une source d'une tension et d'une fréquence appropriées compte tenu des enroulements visés.

– *Au début, il ne faut pas appliquer plus de la moitié de la tension prescrite, la tension est ensuite portée en 10 s à sa valeur totale qui est maintenue pendant 1 min, après quoi la tension est rapidement réduite et coupée.*

– *Les essais ne sont pas réalisés à des fréquences de résonance.*

La conformité est vérifiée comme suit:

Pendant l'essai, tout contournement, toute perforation en un point quelconque de l'isolation constitue une défaillance. On ne doit pas constater de détérioration visible du transformateur après l'essai.

On ne tient pas compte des effets de couronne légers, dès lors qu'ils cessent lorsque la tension d'essai tombe temporairement à une valeur inférieure, qui cependant doit être supérieure à la TENSION DE SERVICE et que les décharges ne provoquent pas une chute de la tension d'essai.

15.5.3 * Construction des transformateurs utilisés pour assurer la séparation comme cela est décrit en 8.5

~~Les transformateurs des APPAREILS EM qui constituent un MOYEN DE PROTECTION selon 8.5 doivent être conformes à 5.12 de l'IEC 61558-1:1997.~~

~~*La conformité est vérifiée comme indiqué dans l'IEC 61558-1.*~~

Les transformateurs des APPAREILS EM qui forment des MOYENS DE PROTECTION comme requis par 8.5 doivent satisfaire à ce qui suit:

– Les moyens doivent être prévus de manière à empêcher le déplacement des spires d'extrémité au-delà de l'isolation entre les enroulements.

– Lorsqu'un écran de protection relié à la terre ne possède qu'une seule spire, il doit présenter un chevauchement isolé non inférieur à 3 mm. La largeur de l'écran doit être au moins égale à la longueur d'enroulement axial de l'enroulement primaire.

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– La sortie des fils depuis les enroulements internes des transformateurs toriques doit être munie d'un double gainage satisfaisant aux exigences applicables à deux MOYENS DE PROTECTION et présentant une épaisseur de paroi totale d'au moins 0,3 mm, s'étendant d'au moins 20 mm à l'extérieur de l'enroulement.

– L'isolation entre les enroulements primaires et secondaires doit satisfaire à 8.8.2.

– Les LIGNES DE FUITE et les DISTANCES DANS L'AIR doivent satisfaire à 8.9.4, avec les exceptions qui suivent:

  • Les fils de bobinage émaillés ou laqués sont considérés comme contribuant chacun de 1 mm aux LIGNES DE FUITE spécifiées en 8.9.4 pour les MOYENS DE PROTECTION DU PATIENT.

  • LES LIGNES DE FUITE sont mesurées jusqu'au joint entre deux parties d'une barrière d'isolation, excepté lorsque:

    – les deux parties formant le joint sont liées par thermoscellage ou autre moyen à l'endroit concerné;

    ou

    – le joint est entièrement rempli d'adhésif aux endroits nécessaires et l'adhésif relie les surfaces de la barrière d'isolation de sorte que l'humidité ne peut pas s'infiltrer dans le joint.

  • Les LIGNES DE FUITE dans les transformateurs moulés sont considérées comme inexistantes s'il peut être démontré qu'aucune bulle de gaz n'est présente et que l'épaisseur de l'isolation entre les enroulements primaires et secondaires émaillés ou laqués est égale à au moins 1 mm pour les tensions de référence *U* non supérieures à 250 V et augmente en proportion pour les tensions de référence plus élevées.

La conformité est vérifiée par l'inspection de la construction du transformateur et la mesure des distances requises.

16 * SYSTEMES EM

16.1 * Exigences générales pour les SYSTEMES EM

Après installation ou modification ultérieure, un SYSTEME EM ne doit pas engendrer de RISQUE inacceptable.

Seuls les DANGERS dus à la combinaison de différents appareils pour constituer un SYSTEME EM doivent être pris en compte.

NOTE Il est rappelé aux ORGANISMES RESPONSABLES que l'assemblage des SYSTEMES EM et les modifications au cours de leur durée de service réelle exigent une évaluation de leur conformité aux exigences de la présente norme.

Un SYSTEME EM doit fournir:

– dans l'ENVIRONNEMENT DU PATIENT, le niveau de sécurité équivalent à l'APPAREIL EM conforme à la présente norme; et

– en dehors de l'ENVIRONNEMENT DU PATIENT, le niveau de sécurité correspondant équivalent aux appareils électriques conformes aux normes de sécurité IEC ou ISO respectives.

Des essais doivent être réalisés:

– en CONDITION NORMALE sauf spécification contraire, et

– dans les conditions de fonctionnement spécifiées par le FABRICANT du SYSTEME EM.

Les essais de sécurité qui ont déjà été effectués sur les appareils du SYSTEME EM pris individuellement conformément aux normes pertinentes ne doivent pas être répétés.

Le FABRICANT d'un SYSTEME EM qui peut être (re)configuré par L'ORGANISME RESPONSABLE ou par L'OPERATEUR peut utiliser des méthodes de GESTION DES RISQUES pour déterminer quelles configurations présentent les RISQUES les plus élevés et quelles mesures sont nécessaires

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pour assurer que le SYSTEME EM de toute configuration possible ne présente pas de RISQUE inacceptable.

Les APPAREILS non EM, lorsqu'ils sont utilisés dans un SYSTEME EM, doivent être conformes aux normes de sécurité IEC ou ISO qui sont applicables à ces appareils.

Un appareil dans lequel la protection contre les chocs électriques repose seulement sur L'ISOLATION PRINCIPALE ne doit pas être utilisé dans un SYSTEME EM.

La conformité est vérifiée par l'inspection des documents ou certificats appropriés.

16.2 * DOCUMENTS D'ACCOMPAGNEMENT d'un SYSTEME EM

Un SYSTEME EM (y compris un SYSTEME EM modifié) doit être accompagné de documents contenant toutes les données nécessaires pour que le SYSTEME EM soit utilisé comme prévu par le FABRICANT et une adresse à laquelle l'ORGANISME RESPONSABLE peut s'adresser. Les DOCUMENTS D'ACCOMPAGNEMENT doivent être considérés comme faisant partie du SYSTEME EM.

NOTE Les DOCUMENTS D'ACCOMPAGNEMENT peuvent être fournis sous format électronique, par exemple fichier électronique ou CD-ROM, pour les SYSTEMES EM capables d'afficher ou d'imprimer ces documents.

Ces documents doivent comprendre:

a) les DOCUMENTS D'ACCOMPAGNEMENT fournis par le FABRICANT pour chaque APPAREIL EM (voir 7.8.2);

b) les DOCUMENTS D'ACCOMPAGNEMENT fournis par le FABRICANT pour chaque APPAREIL non EM;

c) les informations suivantes:

- la spécification du SYSTEME EM, y compris l'utilisation prévue par le FABRICANT et une liste de tous les articles composant le SYSTEME EM;
- des instructions pour l'installation, l'assemblage et la modification du SYSTEME EM pour assurer une conformité permanente à la présente norme;
- des instructions de nettoyage et, si applicable, de stérilisation et de désinfection de chaque appareil ou partie d'appareil faisant partie du SYSTEME EM (voir 11.6.6 et 11.6.7);
- les mesures supplémentaires de sécurité qu'il convient d'appliquer, au cours de l'installation du SYSTEME EM;
- quelles parties du SYSTEME EM sont appropriées pour une utilisation dans l'ENVIRONNEMENT DU PATIENT;
- les mesures supplémentaires qu'il convient de prendre lors de la maintenance préventive;
- si un SOCLE DE PRISES MULTIPLES existe et qu'il est une entité séparée, un avertissement précisant qu'il ne doit pas être placé sur le sol;
- un avertissement précisant qu'un SOCLES DE PRISES MULTIPLES additionnel ou un fil prolongateur ne doit pas être connecté au SYSTEME EM;
- un avertissement indiquant de ne connecter que des unités ayant été spécifiées comme des parties du SYSTEME EM ou comme compatibles avec le SYSTEME EM;
- la charge maximale autorisée pour le ou les SOCLES DE PRISES MULTIPLES utilisés avec le SYSTEME EM;
- une instruction précisant que les SOCLES DE PRISES MULTIPLES fournis avec le SYSTEME EM ne doivent être utilisés que pour alimenter un appareil prévu pour constituer une partie du SYSTEME EM;
- une explication sur les RISQUES encourus en connectant un appareil non médical, qui est fourni en tant qu'entité d'un SYSTEME EM, directement à une prise de courant murale lorsque cet appareil non médical est destiné à être alimenté via un SOCLES DE PRISES MULTIPLES avec un transformateur de séparation;

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– une explication sur les RISQUES encourus en reliant un appareil qui n'a pas été fourni en tant qu'entité du SYSTEME ME au SOCLE DE PRISES MULTIPLES;

– les conditions environnementales admissibles pour l'utilisation du SYSTEME EM y compris les conditions de transport et de stockage; et

– les instructions pour l'OPERATEUR de ne pas toucher simultanément les parties auxquelles il est fait référence en 16.4 et le PATIENT.

d) conseils pour l'ORGANISME RESPONSABLE:

– pour réaliser toutes les PROCEDURES de réglage, de nettoyage, de stérilisation et de désinfection spécifiées ici; et

– que l'assemblage des SYSTEMES EM et les modifications au cours de leur durée de service réelle exigent une évaluation de leur conformité aux exigences de la présente norme.

La conformité est vérifiée par inspection.

16.3 * Alimentation

Si l'APPAREIL EM est prévu pour être alimenté par un autre appareil inclus dans un SYSTEME EM, les instructions d'utilisation doivent spécifier cet autre appareil de manière suffisante afin d'assurer la conformité avec les exigences de la présente norme (voir 4.10.1, 5.5 f) et 7.9.2.3). Voir aussi la Figure F.5.

Si un SYSTEME EM:

– est destiné à recevoir de l'énergie depuis une alimentation isolée (IPS) ou une alimentation sans interruption (UPS), et

– le SYSTEME EM peut appeler de forts courants transitoires lors du démarrage ou de l'arrêt, ou en fonctionnement,

le FABRICANT doit restreindre ces courants transitoires au niveau autorisé selon la spécification de l'IPS ou de l'UPS sur laquelle le SYSTEME EM est destiné à s'alimenter.

Si aucune IPS ni UPS n'est spécifiée, le niveau réel de courant transitoire doit être indiqué dans la description technique et dans les instructions d'installation.

La conformité est vérifiée par inspection.

16.4 ENVELOPPES

Les parties d'un APPAREIL non EM situées dans l'ENVIRONNEMENT DU PATIENT qui, après enlèvement, sans utilisation d'un OUTIL, des capots, des connecteurs etc., peuvent être touchées par l'OPERATEUR au cours d'une opération d'entretien, d'étalonnage, ou autre, doivent fonctionner avec une tension ne dépassant pas la tension spécifiée en 8.4.2 c) fournie par une source qui est séparée du RESEAU D'ALIMENTATION au moyen de deux MOYENS DE PROTECTION OPERATEUR (voir 8.5.1).

La conformité est vérifiée par inspection.

16.5 * DISPOSITIFS DE SEPARATION

Si les valeurs admissibles des COURANTS DE FUITE peuvent être dépassées à cause de la CONNEXION FONCTIONNELLE entre des APPAREILS EM et d'autres appareils d'un SYSTEME EM ou d'autres systèmes, alors des mesures de sécurité incorporant un DISPOSITIF DE SEPARATION doivent être appliquées.

Le DISPOSITIF DE SEPARATION doit avoir la tension de tenue, les LIGNES DE FUITE et les DISTANCES DANS L'AIR exigées pour un MOYEN DE PROTECTION OPERATEUR correspondant à la tension la plus élevée qui survient à travers le DISPOSITIF DE SEPARATION en condition de défaut.

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La TENSION DE SERVICE doit être la tension la plus élevée survenant à travers le DISPOSITIF DE SEPARATION en condition de défaut, mais elle ne doit pas être inférieure à la TENSION RESEAU maximale.

NOTE 1 Pour les appareils de la CLASSE I, les différences de potentiel peuvent apparaître entre la terre de protection de l'APPAREIL EM et la terre de protection des autres parties du SYSTEME EM en l'absence de terre de protection commune.

NOTE 2 Parmi les situations qui exigent un DISPOSITIF DE SEPARATION, il y a les CONNEXIONS FONCTIONNELLES avec un système d'appel d'urgence ou un système de traitement des données.

La conformité est vérifiée par les essais de 8.8 et 8.9.

16.6 * COURANTS DE FUITE

16.6.1 COURANT DE CONTACT

En CONDITION NORMALE, le COURANT DE CONTACT circulant entre des parties du SYSTEME EM dans l'ENVIRONNEMENT DU PATIENT ou provenant de celles-ci ne doit pas dépasser 100 µA.

Dans le cas d'une interruption de tout CONDUCTEUR DE TERRE DE PROTECTION non INSTALLE DE FAÇON PERMANENTE, le COURANT DE CONTACT circulant entre des parties d'un SYSTEME EM dans l'ENVIRONNEMENT DU PATIENT ou provenant de celles-ci ne doit pas dépasser 500 µA.

NOTE Pour les besoins du présent article, le COURANT DE FUITE provenant des surfaces extérieures accessibles des appareils est également considéré comme étant un COURANT DE CONTACT.

16.6.2 COURANT DE FUITE A LA TERRE depuis un SOCLE DE PRISES MULTIPLES

Si le SYSTEME EM ou une partie du SYSTEME EM est alimenté par un SOCLE DE PRISES MULTIPLES, le courant dans le CONDUCTEUR DE TERRE DE PROTECTION du SOCLE DE PRISES MULTIPLES ne doit pas dépasser 5 mA.

16.6.3 * COURANT DE FUITE PATIENT

Le COURANT DE FUITE PATIENT et le COURANT DE FUITE PATIENT total d'un SYSTEME EM en CONDITION NORMALE ne doit pas dépasser les valeurs spécifiées pour les APPAREILS EM telles qu'elles sont données au Tableau 3 et au Tableau 4 (voir aussi 8.7.3 et 16.1).

Le COURANT DE FUITE PATIENT total peut être mesuré à l'installation.

La conformité avec les exigences de 16.6.1, 16.6.2 et 16.6.3 est vérifiée par inspection et par mesurage en utilisant un appareil de mesure comme spécifié en 8.7.4.4.

16.6.4 Mesurages

16.6.4.1 Conditions générales pour les SYSTEMES EM

a) *Le COURANT DE CONTACT, le COURANT DE FUITE PATIENT, le COURANT DE FUITE PATIENT total et le COURANT DE FUITE A LA TERRE total ~~de tout SOCLE DE PRISES MULTIPLES~~ sont mesurés après que le SYSTEME EM a été amené à ~~la~~ sa température de fonctionnement comme suit:*

Le SYSTEME EM est mis en fonctionnement:

– *Pour les SYSTEMES EM qui ne sont pas prévus pour un SERVICE CONTINU;*

Après fonctionnement en mode attente/ repos jusqu'à l'obtention de la STABILITE THERMIQUE, on fait fonctionner le SYSTEME EM en UTILISATION NORMALE suivant des cycles consécutifs jusqu'à nouvelle obtention de la STABILITE THERMIQUE ou pendant 7 h, en prenant la durée la plus courte. Les périodes "marche" et "arrêt" de chaque cycle sont les périodes ASSIGNEES "marche" et "arrêt";

– *Pour les SYSTEMES EM prévus pour un SERVICE CONTINU;*

On fait fonctionner le SYSTEME EM jusqu'à obtention de la STABILITE THERMIQUE.

b) *Le SYSTEME EM est relié à une source d'alimentation dont la tension est égale à la plus haute TENSION RESEAU ASSIGNEE. Lorsque les caractéristiques d'un SYSTEME EM ne peuvent être mesurées correctement qu'après son installation sur le site de L'ORGANISME*

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RESPONSABLE, avant son utilisation clinique, le SYSTEME EM est raccordé au RESEAU D'ALIMENTATION local.

NOTE Lorsque l'examen de la disposition des circuits et de la disposition des composants et matériaux du SYSTEME EM montre qu'il n'y a aucune possibilité de DANGER, quel qu'il soit, le nombre d'essais peut être réduit.

16.6.4.2 Raccordement du SYSTEME EM au circuit d'alimentation de mesurage

a) *Le SYSTEME EM est soumis aux essais après son assemblage conformément à ces DOCUMENTS D'ACCOMPAGNEMENT.*

b) *Dispositions de mesurage*

S'il n'est pas utilisé de transformateur de séparation pour les mesures de COURANT DE FUITE (par exemple pour la mesure du COURANT DE FUITE DE SYSTEMES EM à très forte puissance), la terre de référence des circuits de mesure est alors raccordée à la terre de protection du RESEAU D'ALIMENTATION.

NOTE 1 Il est recommandé de positionner le circuit de mesure aussi loin que possible des fils d'alimentation non protégés par un écran et (sauf spécification contraire dans les paragraphes suivants) d'éviter de placer le SYSTEME EM sur ou à proximité d'une grande surface métallique reliée à la terre.

NOTE 2 Cependant, il convient que les PARTIES APPLIQUEES, y compris les câbles PATIENT (si présents), soient placées sur une surface isolante ayant une constante diélectrique d'environ 1 (par exemple polystyrène expansé) et environ 200 mm au-dessus de la surface métallique reliée à la terre.

16.7 * Protection contre les DANGERS MECANIQUES

Si un DANGER MECANIQUE existe, le SYSTEME EM doit satisfaire les exigences applicables de l'Article 9.

La conformité est vérifiée par inspection ou par les essais applicables.

16.8 Interruption de l'alimentation électrique de parties d'un SYSTEME EM

~~Un SYSTEME EM doit être conçu de telle manière qu'une interruption et un rétablissement de l'alimentation pour le SYSTEME EM dans son ensemble ou pour une partie quelconque du SYSTEME EM n'entraîne pas une SITUATION DANGEREUSE autre que l'interruption de la fonction prévue.~~

Un SYSTEME EM doit être conçu de telle sorte qu'une interruption et une restauration de l'alimentation du SYSTEME EM dans son entier ou de toute partie du SYSTEME EM ne conduise pas à la perte de la SECURITE DE BASE ou des PERFORMANCES ESSENTIELLES.

La conformité est vérifiée par l'interruption et le rétablissement des alimentations électriques correspondantes, une par une puis de toutes les connexions simultanément.

16.9 Connexions et câblage de SYSTEME EM

16.9.1 Bornes de branchement et connecteurs

La conception et la construction des connexions/raccords électriques, hydrauliques, pneumatiques et pour les gaz~~, des APPAREILS EM,~~ doivent être telles qu'un branchement incorrect de ces ~~connexions/raccords~~ connecteurs accessibles, pouvant être enlevés sans l'aide d'un OUTIL, soit impossible, ~~lorsqu'une telle manœuvre pourrait entraîner une SITUATION DANGEREUSE~~ sauf s'il peut être prouvé qu'aucun RISQUE inacceptable ne peut en découler. En particulier:

~~– Les connecteurs doivent être conformes à 15.4.1.~~

– Les fiches destinées au branchement des conducteurs PATIENT ou des câbles PATIENT doivent être conçues de sorte qu'elles ne puissent pas être connectées à d'autres socles ~~sur le~~ du même SYSTEME EM qui sont susceptibles d'être situés dans l'ENVIRONNEMENT DU PATIENT sauf s'il peut être démontré ~~que cette possibilité ne peut résulter en aucune SITUATION DANGEREUSE~~ qu'aucun RISQUE inacceptable ne peut en découler.

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La conformité est vérifiée par l'inspection des conducteurs PATIENT, des câbles PATIENT, des connecteurs et des socles et, si l'échange des conducteurs, câbles, conducteurs ou socles est possible, par l'inspection du DOSSIER DE GESTION DES RISQUES.

– Les raccords de gaz médicaux sur les SYSTEMES EM devant recevoir des gaz différents en UTILISATION NORMALE ne doivent pas être interchangeables. Voir aussi l'ISO 407 [27].

La conformité est vérifiée par l'inspection ~~et, si possible, en inversant les connecteurs~~ de tous les raccords de gaz médicaux.

16.9.2 PARTIES RELIEES AU RESEAU, composants et montage

16.9.2.1 * SOCLES DE PRISES MULTIPLES

a) Un SOCLE DE PRISES MULTIPLES doit:

– seulement permettre le branchement avec l'utilisation d'un OUTIL (voir Figure I.1), ou

– être d'un type qui ne peut pas accepter des FICHES RESEAU quel que soit le type spécifié dans l'IEC/TR 60083), ou

– être alimenté par un transformateur de séparation (voir 16.9.2.1 d) et l'Annexe I).

La conformité est vérifiée par inspection.

b) Un SOCLE DE PRISES MULTIPLES:

– doit être marqué avec le signe de sécurité ISO 7010-W001 (voir Tableau D.2, signe de sécurité 2) de manière à être visible en UTILISATION NORMALE et:

  – doit être marqué soit individuellement soit en combinaisons, avec la valeur maximale admissible de sortie continue en ampères ou en voltampères, ou

  – doit être marqué pour indiquer quel appareil ou parties d'appareil peuvent être fixés en toute sécurité.

– peut être une entité séparée ou faire partie intégrante de l'APPAREIL EM ou de l'APPAREIL non EM.

NOTE Il n'y a pas d'exigence de marquage de chaque socle.

La conformité est vérifiée par inspection.

c) Le SOCLE DE PRISES MULTIPLES doit être conforme à l'IEC 60884-1 et aux exigences suivantes:

– Les LIGNES DE FUITE et les DISTANCES DANS L'AIR doivent être conformes à 8.9.

– Il doit être conforme à la construction de la CLASSE I et le CONDUCTEUR DE TERRE DE PROTECTION doit être raccordé aux contacts de mise à la terre dans les socles de prises de courant.

– Les BORNES DE TERRE DE PROTECTION et les CONNEXIONS DE TERRE DE PROTECTION doivent ~~être conformes~~ satisfaire à 8.6 ~~avec comme seule différence que l'impédance totale du circuit de terre de protection pour un SYSTEME EM peut aller jusqu'à 400 mΩ ou plus, si les conditions de 8.6.4 b) sont satisfaites~~.

– Les ENVELOPPES doivent être conformes à 8.4.2 d).

– Les DISPOSITIFS DE RACCORDEMENT AU RESEAU et le câblage doivent être conformes à 8.11.4, si cela est applicable.

– Les CARACTERISTIQUES ASSIGNEES des composants ne doivent pas être en contradiction avec les conditions d'utilisation (voir 4.8).

– La conception et la construction des bornes de branchement et des connecteurs des SOCLES DE PRISES MULTIPLES doivent empêcher le branchement incorrect des connecteurs accessibles, pouvant être enlevés sans l'aide d'un OUTIL

– Les exigences concernant les CABLES D'ALIMENTATION telles qu'elles sont décrites au 8.11.3 doivent être satisfaites.

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d) * Si le SOCLE DE PRISES MULTIPLES est combiné à un transformateur de séparation, les exigences complémentaires suivantes s'appliquent:

– ~~Le transformateur de séparation doit être conforme aux exigences de l'IEC 61558-2-1, à l'exception des exigences concernant la puissance maximale de sortie ASSIGNEE de 1 kVA et le degré de protection IPX4, qui ne s'appliquent pas.~~

Le transformateur de séparation doit être conforme à la présente norme. En alternative, le transformateur de séparation peut être conforme aux exigences de l'IEC 61558-2-1, avec l'exception que les exigences concernant la puissance maximale de sortie ASSIGNEE de 1 kVA et le degré de protection IPX4 ne s'appliquent pas.

NOTE 1 Etant donné qu'un transformateur de séparation n'est pas un TRANSFORMATEUR D'ALIMENTATION RESEAU, il ne nécessite pas plus qu'une ISOLATION PRINCIPALE.

NOTE 2 La limitation de la puissance de sortie n'est pas expliquée dans l'IEC 61558-2-1 et la puissance de sortie ASSIGNEE est définie par le fusible de l'installation et par le câble d'alimentation admissible utilisé. Cependant, les caractéristiques du transformateur de séparation n'ont pas à être soigneusement choisies, en tenant compte des variations du courant de charge du SYSTEME EM pour assurer que la tension fournie aux différentes entités du SYSTEME EM reste dans les limites spécifiées pour l'appareil.

~~NOTE 3 Il convient que l'IEC 61558-2-1 soit utilisée avec la norme générale IEC 61558-1.~~

– Le transformateur de séparation doit être construit selon la CLASSE I.

– Le degré de protection contre la pénétration d'eau tel qu'il est donné dans la IEC 60529 doit être spécifié.

– Le transformateur de séparation doit être marqué selon les exigences de 7.2 et 7.3.

– Le SOCLE DE PRISES MULTIPES doit être raccordé en permanence au transformateur de séparation ou le socle de prises du transformateur de séparation doit être d'un type qui ne peut pas accepter de FICHES RESEAU quel que soit le type identifié dans la IEC/TR 60083 (voir Figure I.1 et I.2).

La conformité est vérifiée par inspection et comme cela est décrit dans les paragraphes correspondants de la présente norme.

16.9.2.2 * CONNEXIONS DE TERRE DE PROTECTION dans les SYSTEMES EM

Pour chaque partie d'un SYSTEME EM qui partage un câblage réseau, l'impédance et le courant admissible du circuit total de mise à la terre de protection d'un SYSTEME EM, lorsqu'ils sont soumis à un essai commun, doivent satisfaire à 8.6.4. L'impédance entre la broche de terre de protection de la FICHE RESEAU et toute partie qui est PROTEGEE PAR MISE A LA TERRE ne doit pas dépasser 200 mΩ.

Les CONNEXIONS DE TERRE DE PROTECTION doivent être réalisées de manière telle qu'en enlevant un seul appareil du SYSTEME EM on n'interrompe pas la mise à la terre de protection de toute autre partie du SYSTEME EM, sans déconnecter en même temps l'alimentation électrique de cette partie.

Les CONDUCTEURS DE TERRE DE PROTECTION supplémentaires ne doivent pouvoir être retirés qu'à l'aide d'un OUTIL.

La conformité est vérifiée par inspection.

16.9.2.3 Protection des conducteurs

Les conducteurs qui relient différents appareils d'un SYSTEME EM doivent être protégés contre les dommages mécaniques.

La conformité est vérifiée par inspection.

17 * Compatibilité électromagnétique des APPAREILS ET DES SYSTEMES EM

Au cours du PROCESSUS de GESTION DES RISQUES, le FABRICANT doit traiter les RISQUES associés:

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– aux phénomènes électromagnétiques qui existent aux emplacements où les APPAREILS ou les SYSTEMES EM sont destinés à être utilisés comme indiqué dans les DOCUMENTS D'ACCOMPAGNEMENT; et

– à l'introduction par les APPAREILS ou SYSTEMES EM de phénomènes électromagnétiques dans l'environnement de nature à dégrader les performances des autres dispositifs, appareils et systèmes électriques.

Voir l'IEC 60601-1-2 et également 1.3.

La conformité est vérifiée par l'examen du DOSSIER DE GESTION DES RISQUES.

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Annexe A
(informative)

Lignes directrices générales et justifications

A.1 Lignes directrices générales

Les exigences relatives aux APPAREILS EM et aux SYSTEMES EM diffèrent des exigences applicables aux autres types d'appareils électriques du fait de la relation particulière qui existe entre ces APPAREILS EM ou SYSTEMES EM et le PATIENT, l'OPERATEUR et l'entourage. Les aspects suivants jouent un rôle important dans cette relation:

a) impossibilité pour le PATIENT ou l'OPERATEUR de déceler la présence de certains DANGERS, tels que les rayonnements ionisants ou non ionisants;

b) absence de réactions normales chez le PATIENT qui peut être malade, inconscient, anesthésié, immobilisé, etc.;

c) absence de protection normale offerte par la peau du PATIENT contre les courants, quand elle est traversée ou traitée pour obtenir une faible résistance électrique;

d) assistance ou suppléance de fonctions vitales pouvant dépendre de la fiabilité d'un APPAREIL EM ou d'un SYSTEME EM;

e) liaison simultanée de plusieurs APPAREILS EM avec le PATIENT;

f) combinaisons, souvent ad hoc, d'un APPAREIL EM à grande puissance avec un APPAREIL EM sensible, à faibles signaux;

g) application directe de circuits électriques au corps humain, par contacts avec la peau ou par insertion de sondes dans des organes internes;

h) conditions, particulièrement dans les salles d'opérations, pouvant créer une combinaison d'humidité, de buée ou de DANGERS d'incendie ou d'explosion dus à la présence d'air, d'oxygène ou de protoxyde d'azote.

Si l'APPAREIL EM est associé à un autre appareil électrique pour former un SYSTEME EM, des exigences supplémentaires s'appliquent. Elles sont indiquées à l'Article 16. Dans certains cas, il est fait référence à d'autres parties de la présente norme. Si un article ou un paragraphe est spécifiquement destiné à être applicable uniquement aux APPAREILS EM, le titre et le contenu de cet article ou paragraphe l'indiquera. Dans le cas contraire, l'article ou le paragraphe pourrait être applicable à des SYSTEMES EM comme à des APPAREILS EM.

A.2 Sécurité des APPAREILS EM et des SYSTEMES EM

La SECURITE DE BASE et les PERFORMANCES ESSENTIELLES des APPAREILS EM et des SYSTEMES EM, telles qu'elles sont décrites dans l'IEC/TR 60513 [12] sont des éléments de la situation de sécurité totale, comprenant la sécurité des APPAREILS EM, la sécurité de l'installation à laquelle l'APPAREIL EM ou le SYSTEME EM est connecté et la sécurité de l'application.

La SECURITE DE BASE et les PERFORMANCES ESSENTIELLES des APPAREILS EM ET DES SYSTEMES EM sont exigées pour l'UTILISATION NORMALE et pour le mauvais usage raisonnablement prévisible à la fois en CONDITION NORMALE et dans les CONDITIONS DE PREMIER DEFAUT. La fiabilité de fonctionnement est considérée comme un aspect de la sécurité pour les APPAREILS EM d'assistance vitale et lorsque l'interruption d'un examen ou d'un traitement constitue ~~un DANGER~~ une SITUATION DANGEREUSE pour le PATIENT.

Une construction adéquate, une disposition du matériel et des DOCUMENTS D'ACCOMPAGNEMENT de nature à empêcher les erreurs d'utilisation sont considérés comme des aspects de la sécurité.

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Les précautions de sécurité sont considérées comme acceptables si elles procurent une protection adéquate sans restriction inopportune de la fonction normale.

Généralement, il est présumé que les APPAREILS EM et les SYSTEMES EM sont mis en œuvre sous la responsabilité de personnes qualifiées ou autorisées, que l'OPERATEUR a l'aptitude exigée pour une application médicale particulière et qu'il agit conformément aux instructions d'utilisation.

La sécurité totale des APPAREILS EM peut être le résultat de:

– la sécurité intrinsèque de part la conception;
– des mesures de protection incorporées dans les APPAREILS EM ou des mesures de protection supplémentaires, telles que l'emploi d'écrans ou de vêtements de protection; et
– des informations sur la sécurité, telles que les restrictions dans les instructions d'utilisation concernant le transport, le montage ou le positionnement, le branchement, la mise en service, le fonctionnement et la position de l'OPERATEUR et de ses assistants par rapport à l'APPAREIL EM pendant l'utilisation.

A.3 Guide pour la troisième édition

Dans la troisième édition, certains articles et paragraphes de la deuxième édition ont été supprimés, par exemple lorsque l'article ou le paragraphe était indiqué comme ” Non utilisé''. Toutefois, les articles ou paragraphes de la seconde édition qui contenaient l'indication "Aucune exigence générale" ont été conservés de façon à ce que les normes particulières ou collatérales puissent s'y référer. L'indication "Aucune exigence générale" a été remplacée par une référence au PROCESSUS de GESTION DES RISQUES dans la mesure où l’'"exigence générale" est telle que, en l'absence de norme particulière ou collatérale, ces questions sont traitées dans le cadre de la GESTION DES RISQUES.

Lors de l'élaboration de la troisième édition, les normes de sécurité fondamentales ainsi que les guides ISO/IEC ont été pris en considération dans toute la mesure du possible, compatible avec la relation particulière entre l'APPAREIL EM ou le SYSTEME EM et le PATIENT, l'OPERATEUR et l'environnement.

Le format de la troisième édition a été aligné avec les exigences essentielles de la Partie 2 des Directives ISO/IEC. Toutes les sections de la deuxième édition, à l'exception de la Section 1, ont été converties en articles principaux. Cette modification a été introduite car les sections ne sont plus autorisées selon les règles de rédaction et le nouveau système de numérotation permettra de modifier un article sans affecter le numéro d'autres parties de la norme.

Les références normatives de l'Annexe L de la deuxième édition ont été déplacées à l'Article 2. Les références informatives sont énumérées dans la Bibliographie.

Les définitions de l'Article 3 ont été réorganisées en une seule liste alphabétique dans la mesure où l'organisation des définitions par catégorie devenait de plus en plus difficile et les résultats de moins en moins intuitifs. L'index est élargi afin d'identifier chaque page où un terme est utilisé dans le corps de texte de la norme. Un certain nombre de termes nouvellement définis a été introduit à l'appui d'exigences nouvelles ou élargies.

Une exigence générale relative au PROCESSUS de GESTION DES RISQUES a été introduite en 4.2.

L'Article 8 a été restructuré en profondeur afin de regrouper en un seul article l'ensemble des exigences relatives à la sécurité électrique. Les exigences de l'Article 8 ont été revues par rapport aux exigences de sécurité relatives aux appareils de la technologie de l'information dans l'IEC 60950-1 et harmonisées lorsque approprié, compte tenu de la relation particulière de l'APPAREIL EM et du PATIENT, de l'OPERATEUR et de l'environnement.

L'Article 9 sur la protection contre les DANGERS mécaniques a été révisé en profondeur pour traiter un large éventail de DANGERS que l'APPAREIL EM pourrait poser à l'OPERATEUR ou au PATIENT. Les exigences concernant la résistance mécanique des APPAREILS EM lorsqu'ils sont

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soumis aux contraintes de poussée, d'impacts, de chute et de manipulation brutale sont données en 15.3.

La norme traite désormais de l'APTITUDE A L'UTILISATION en 12.2 par opposition aux "erreurs de l'utilisateur ou erreurs humaines".

La Section six de la seconde édition concernant la protection contre les DANGERS de combustion des mélanges anesthésiques inflammables a été déplacée dans une annexe normative. A l'origine, cette annexe devait être informative en raison de l'utilisation rare de ces anesthésiques ; cela n'a pas été le cas à la suite de commentaires de Comités nationaux qui ont indiqué la possibilité que certains FABRICANTS puissent encore vouloir proposer des APPAREILS EM pour ces applications.

La limite de température de surface donnée en 11.1.2.2 pour les PARTIES APPLIQUEES en contact avec le PATIENT pendant 10 min ou plus a été portée de 41 °C à 43 °C. Le FABRICANT doit toutefois indiquer dans les DOCUMENTS D'ACCOMPAGNEMENT si la température de surface d'une PARTIE APPLIQUEE dépasse 41 °C.

Les exigences de l'IEC 60601-1-4 [14] pour les SYSTEMES ELECTROMEDICAUX PROGRAMMABLES, tels qu'ils apparaissent en 52.1 de la deuxième édition, ont été incorporées dans le corps de la présente norme dans un nouvel Article 14.

Les exigences de l'IEC 60601-1-1 [13] relatives aux SYSTEMES EM ont été incorporées dans le corps de la présente norme dans un nouvel Article 16.

A.4 Justifications d'articles et de paragraphes spécifiques

Le texte ci-dessus donne les justifications d'articles et de paragraphes spécifiques de la présente norme, avec les références des articles et paragraphes suivant celles du corps du document.

Paragraphe 1.1 – Domaine d'application

Le domaine d'application de la présente norme est établi par référence aux définitions des APPAREILS EM et des SYSTEMES EM. Il s'agit de définir clairement le domaine d'application de la présente norme par rapport aux exigences pour les autres types d'appareils électriques.

Les appareils de laboratoire compris dans le domaine d'application de l'IEC 61010-1 [22] ne sont pas couverts par la présente norme, excepté lorsqu'un FABRICANT incorpore ces appareils dans un SYSTEME EM.

La présente norme ne s'applique pas aux dispositifs médicaux actifs implantables couverts par l'ISO 14708-1 [31], sauf lorsque celle-ci exige la conformité avec l'IEC 60601-1.

La présente norme ne s'applique pas à d'autres appareils électriques à moins qu'ils ne relèvent de la définition des APPAREILS EM ou des SYSTEMES EM.

Paragraphe 1.3 – Normes collatérales

Les normes collatérales ont été développées par le comité d'études 62 de manière à étendre la norme générale. Les normes collatérales se divisent en deux catégories:

– les normes qui traitent les exigences de SECURITE DE BASE et de PERFORMANCES ESSENTIELLES qui sont communes à un sous-groupe d'APPAREILS EM. Par exemple, le sous-comité 62B a élaboré l'IEC 60601-1-3 pour donner les exigences générales de protection contre les rayonnements ionisants des équipements à rayonnements X de diagnostic médical de manière à maintenir l'équivalent de dose pour le PATIENT, l'OPERATEUR et les autres personnes concernées aussi faible que raisonnablement possible; ou

– les normes qui donnent les exigences supplémentaires de SECURITE DE BASE ou de PERFORMANCES ESSENTIELLES qui traitent des caractéristiques des APPAREILS EM ou des SYSTEMES EM qui ne sont pas complètement traitées dans la norme générale. A la date de publication de la présente publication, trois normes collatérales de cette catégorie ont été

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publiées par le sous-comité 62A: CEM (IEC 60601-1-2), Aptitude à l'utilisation (IEC 60601-1-6) et systèmes d'alarme (IEC 60601-1-8).

Les éditions des IEC 60601-1-2, IEC 60601-1-3, IEC 60601-1-6 et IEC 60601-1-8 qui existent au moment de la publication de la présente troisième édition de la norme générale ont toutes été développées en liaison avec la deuxième édition de la norme générale (IEC 60601-1: 1988). Il est prévu que des éditions révisées de ces normes collatérales, faisant spécifiquement référence à la présente troisième édition, seront développées et publiées dès que possible. Comme indiqué en 1.3, elles deviendront normatives à la date de leur publication et elles doivent s'appliquer avec la présente norme.

Jusqu'à ce que les nouvelles éditions de ces normes collatérales soient publiées, il convient que les utilisateurs de la présente norme appliquent les éditions existantes dans la mesure du possible lorsqu'elles sont appropriées aux APPAREILS EM ou SYSTEME EM concernés. Toutefois, certaines exigences de ces normes collatérales pourraient ne pas être compatibles avec la présente norme.

Les exigences de deux des normes collatérales élaborées pour la deuxième édition de la IEC 60601-1 ont été incorporées dans le corps de la présente norme. Il s'agit de:

– l'IEC 60601-1-1:2000, *Appareils électromédicaux – Règles générales de sécurité – Norme collatérale : Règles de sécurité pour systèmes électromédicaux*

– l'IEC 60601-1-4:1996, *Appareils électromédicaux – Règles générales de sécurité – Norme collatérale: Systèmes électromédicaux programmables et son amendement 1 (1999)*[21)]

Bien que ces deux normes demeurent jusqu'à ce que toutes les normes particulières fondées sur la deuxième édition de l'IEC 60601-1 aient été alignées avec la présente norme, elles ne sont pas applicables lorsque la présente norme est appliquée.

Des normes collatérales supplémentaires peuvent être publiées de temps à autre si des besoins sont identifiés. Bien que ces normes ne soient pas mentionnées dans la présente norme, elles établissent tout de même des exigences générales qui doivent être prises en compte si elles sont applicables. Les lecteurs sont invités à consulter les registres des normes internationales en vigueur qui sont suivis par leurs organismes de normalisation pour voir quelles normes collatérales applicables ont été publiées.

Paragraphe 1.4 – Normes particulières

Une norme particulière peut spécifier:

– les articles ou paragraphes de la présente norme qui s'appliquent sans modification;

– les articles, paragraphes (ou parties de ceux-ci) de la présente norme qui ne sont pas applicables;

– les articles, paragraphes (ou parties de ceux-ci) de la présente norme qui sont remplacés par un article ou un paragraphe de la norme particulière; ou

– les articles et paragraphes complémentaires.

Une norme particulière peut comporter:

a) des exigences qui entraînent une augmentation de la SECURITE DE BASE ou des PERFORMANCES ESSENTIELLES;

b) des exigences moins rigoureuses que celles de la présente norme lorsque celles-ci ne peuvent être maintenues, par exemple du fait de la puissance fournie par l'APPAREIL EM;

c) des exigences relatives aux qualités de fonctionnement, à la fiabilité, aux interfaces, etc.;

d) la précision des caractéristiques; ou

e) l'aménagement et la limitation des conditions d'environnement.

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21) Il existe une edition consolidée 1.1 (2000) comprenant l'IEC 60601-1-4 (1996) et son Amendement 1 (1999).

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Article 2 – Références normatives

Cet article donne une liste des documents cités dans d'autres parties normatives de la présente norme de manière à les rendre indispensables pour l'application du document. Toutefois, la conformité avec les documents de la présente liste est seulement exigée lorsqu'ils sont cités en référence dans une exigence de la présente norme. Par exemple, s'il est fait référence à un article, un paragraphe, un tableau ou une figure spécifique, alors l'utilisateur de la présente norme n'a à se conformer qu'aux exigences de l'article, du paragraphe, du tableau ou de la figure en question pour satisfaire à l'exigence de la présente norme.

Les références non datées ne sont faites qu'à un document complet ou à une partie principale d'un document et uniquement s'il est accepté qu'il sera possible d'utiliser toutes les modifications futures du document référencé pour les besoins de la présente norme. Par exemple, une référence non datée est faite à l'IEC 60529 car il est prévu que le FABRICANT utilisera toujours la dernière édition de cette norme pour l'attribution des codes IP aux ENVELOPPES.

Il faut comprendre que les références non datées incluent tous les amendements et toutes les révisions du document référencé.

Les références datées sont faites lorsque les exigences d'une édition particulière sont à utiliser pour satisfaire à une exigence de la présente norme. Les amendements ou révisions ultérieurs de références datées devront être incorporés par amendement à la présente norme. ~~Par exemple, une référence datée est faite à l'IEC 60825-1 parce que les parties applicables de cette norme sont appliquées à des diodes électroluminescentes (DEL) et que le CE 76 de l'IEC était en train de commencer les travaux de la troisième édition de l'IEC 60825-1 et envisageait de retirer les exigences concernant les DEL.~~

Les références à des articles, des paragraphes, des tableaux et des figures spécifiques d'un autre document sont toujours datées.

Article 3 – Terminologie et définitions

Cet article contient les définitions des termes qui sont nécessaires à la compréhension des exigences de la présente norme. Nombreux sont les termes qui proviennent de la deuxième édition. Toutefois, des termes ont été ajoutés au cours de l'élaboration de nouvelles exigences ou d'exigences modifiées. Lorsque cela a été possible, les définitions qui existaient dans d'autres normes ont été recopiées ou adaptées.

Sauf dans le cas où elle documenterait d'autres termes définis, une définition n'est donnée que si le terme est utilisé plus d'une fois dans le texte de la norme.

Les termes définis sont imprimés en PETITES MAJUSCULES pour aider le lecteur à les identifier dans le corps de la norme. Si la casse normale est utilisée, les mots ont leur sens normal en français. Le comité s'est efforcé d'éviter d'utiliser le même mot à la fois comme terme défini et avec son sens normal en français. Parfois, cela n'a pas été possible. Par exemple, le mot "procédure" est utilisé comme terme défini dans PROCEDURE de démarrage et signifie spécifiquement "manière particulière de réaliser une activité" pour démarrer l'APPAREIL EM ou le SYSTEME EM. Il est également utilisé dans la définition de PATIENT dans son sens général en français, c'est-à-dire "être vivant (personne ou animal) subissant une procédure médicale, chirurgicale ou dentaire."

Paragraphe 3.8 – PARTIES APPLIQUEES

Les parties qui sont destinées à entrer en contact avec les PATIENTS peuvent présenter de plus grands DANGERS que les autres parties de l'ENVELOPPE et, en conséquence, ces PARTIES APPLIQUEES font l'objet d'exigences plus sévères, par exemple pour les limites de température et (compte tenu de la classification B/BF/CF) pour le COURANT DE FUITE.

NOTE Certaines autres PARTIES ACCESSIBLES des ENVELOPPES des APPAREILS EM sont soumises à des essais qui sont plus exigeants que ceux effectués sur les ENVELOPPES d'autres sortes d'appareils, car le PATIENT peut les toucher, ou l'OPERATEUR peut toucher ces parties et le PATIENT simultanément.

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Afin de déterminer les exigences applicables, il est nécessaire d'établir une distinction entre les PARTIES APPLIQUEES et les parties qui sont simplement considérées comme l'ENVELOPPE.

Ainsi, généralement:

– une lampe infrarouge de thérapie n'a pas de PARTIE APPLIQUEE car il n'est pas nécessaire de l'amener en contact direct avec le PATIENT;

– la seule partie d'une table de radiologie qui soit une PARTIE APPLIQUEE est la partie supérieure sur laquelle est allongé le PATIENT;

– de même, dans un scanner IRM, la seule PARTIE APPLIQUEE est la table qui supporte le PATIENT.

Toutefois, une partie qui entre involontairement en contact avec un PATIENT inconscient, anesthésié ou immobilisé peut présenter les mêmes RISQUES qu'une PARTIE APPLIQUEE qui vient nécessairement en contact avec le PATIENT. D'autre part, une partie pouvant être atteinte et touchée par un PATIENT actif peut ne pas présenter plus de RISQUE pour ce PATIENT que pour un OPERATEUR.

La définition des première et seconde éditions n'avait pas abordé ce problème. Le second amendement de la deuxième édition a élargi la définition pour inclure les parties qui peuvent venir en contact avec le PATIENT, mais la nouvelle définition posait toujours problème.

Dans la présente édition, le Paragraphe 4.6 exige que le PROCESSUS de GESTION DES RISQUES identifie les parties autres que les PARTIES APPLIQUEES qui doivent être soumises aux mêmes exigences que les PARTIES APPLIQUEES. Elles peuvent comprendre les parties d'APPAREILS non EM dans un SYSTEME EM.

Il convient que des normes particulières identifient spécifiquement la ou les PARTIES APPLIQUEES dans des types particuliers d'APPAREILS EM.

Afin d'établir quelles parties sont des PARTIES APPLIQUEES et ce que sont les CONNEXIONS PATIENT, on emploie le PROCESSUS suivant dans l'ordre indiqué.

a) Déterminer si l'APPAREIL EM a une PARTIE APPLIQUEE et si oui, identifier l'étendue de cette PARTIE APPLIQUEE (ces décisions étant basées sur des considérations non électriques).

b) S'il n'y a pas de PARTIE APPLIQUEE, il n'y a pas de CONNEXION(S) PATIENT.

c) S'il y a une PARTIE APPLIQUEE, il peut y avoir une ou plusieurs CONNEXIONS PATIENT. Même si la PARTIE APPLIQUEE ne présente pas de partie conductrice accessible, une feuille appliquée conformément à 8.7.4.7 est considérée comme une CONNEXION PATIENT.

d) Lorsqu'une partie conductrice de la PARTIE APPLIQUEE n'est pas en contact direct avec le PATIENT, mais n'en n'est pas séparée et qu'un courant peut s'écouler à travers une telle partie de ou vers le PATIENT, on doit la traiter comme une CONNEXION PATIENT individuelle.

NOTE Les exigences de séparation pertinentes sont celles qui se rapportent aux MOYENS DE PROTECTION DU PATIENT.

Une PARTIE APPLIQUEE peut comporter une ou plusieurs fonctions. Chaque fonction peut inclure une ou une plusieurs CONNEXIONS PATIENT. Une CONNEXION PATIENT peut être une électrode destinée à transporter du courant, ou la connexion électrique peut être étrangère à l'objectif, par exemple avec une ligne de fluide intravasculaire ou un support de PATIENT.

Voir également la justification de 3.78.

Les Figures A.1 à A.7 (incluse) fournissent des exemples de la façon dont les PARTIES APPLIQUEES et les CONNEXIONS PATIENT sont identifiées afin d'appliquer les exigences relatives au COURANT DE FUITE PATIENT et au COURANT AUXILIAIRE PATIENT dans divers APPAREILS EM et SYSTEMES EM.

Les Figures A.1 et A.2 représentent un moniteur ECG qui inclut le moniteur ECG, le câble PATIENT, les conducteurs PATIENT et les électrodes ECG. Dans les Figures A.1 et A.2:

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– La PARTIE APPLIQUEE inclut les électrodes et les parties des conducteurs PATIENT ou du câble PATIENT qui doivent ~~être physiquement~~ entrer en contact physique avec le PATIENT en UTILISATION NORMALE.

– L'application de la GESTION DES RISQUES pourrait ~~permettre d'~~ identifier d'autres parties du conducteur PATIENT ou du câble PATIENT qui doivent être traitées comme des PARTIES APPLIQUEES ~~en raison~~ du fait de la probabilité ~~de~~ qu'elles entrent en contact avec le PATIENT.

– Les CONNEXIONS PATIENT comprennent les électrodes ~~d'électrocardiogramme~~ ECG, qui font toutes partie de la même fonction de la PARTIE APPLIQUEE.

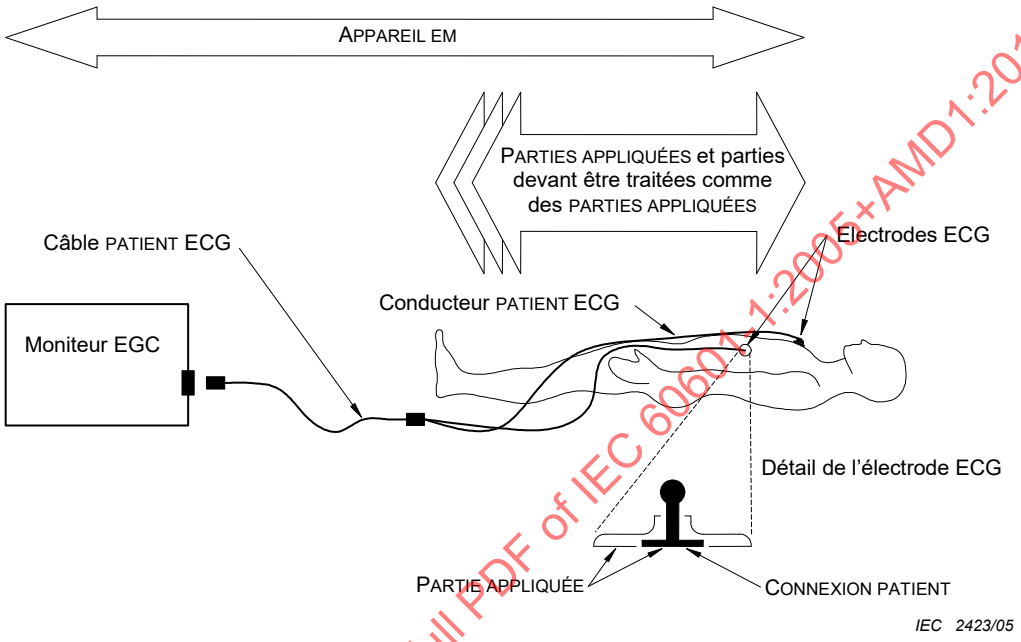


Figure A.1 – Identification de l'APPAREIL EM, des PARTIES APPLIQUEES et des CONNEXIONS PATIENT dans un moniteur d'électrocardiogramme

La Figure A.2 montre l'isolation nécessaire pour une PARTIE APPLIQUEE de TYPE F. Les parties situées dans les limites de la ligne pointillée constituent le circuit PATIENT.

Dans la Figure A.2, l'isolation exigée de la PARTIE APPLIQUEE est:

– un MOYEN DE PROTECTION PATIENT entre la terre et les parties à l'intérieur de la ligne pointillée basé sur la TENSION RESEAU;

– deux MOYENS DE PROTECTION PATIENT entre la terre et les parties à l'intérieur de la ligne pointillée basés sur la tension transportée par ces parties; et

– deux MOYENS DE PROTECTION PATIENT entre les parties sous tension (y compris le réseau) et les parties à l'intérieur de la ligne pointillée.

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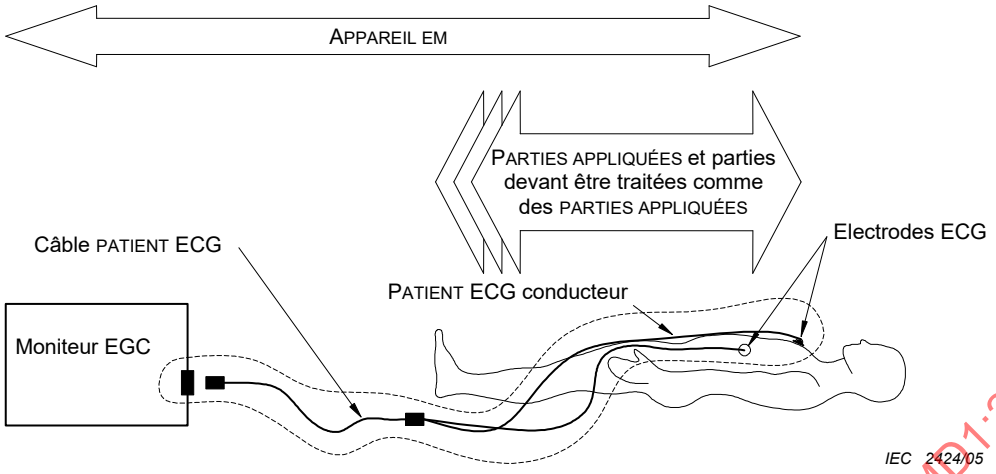


Figure A.2 – Exemple d'isolation d'une PARTIE APPLIQUEE DE TYPE F avec isolation incorporée dans l'APPAREIL EM

La Figure A.3 montre une PARTIE APPLIQUEE DE TYPE F avec isolation incorporée dans un transducteur. Les parties situées à l'intérieur de la ligne pointillée constituent le circuit PATIENT. Il existe des parties à l'extérieur de la ligne pointillée qui sont soumises aux exigences pour les PARTIES APPLIQUEES comme cela est déterminé par le PROCESSUS de GESTION DES RISQUES.

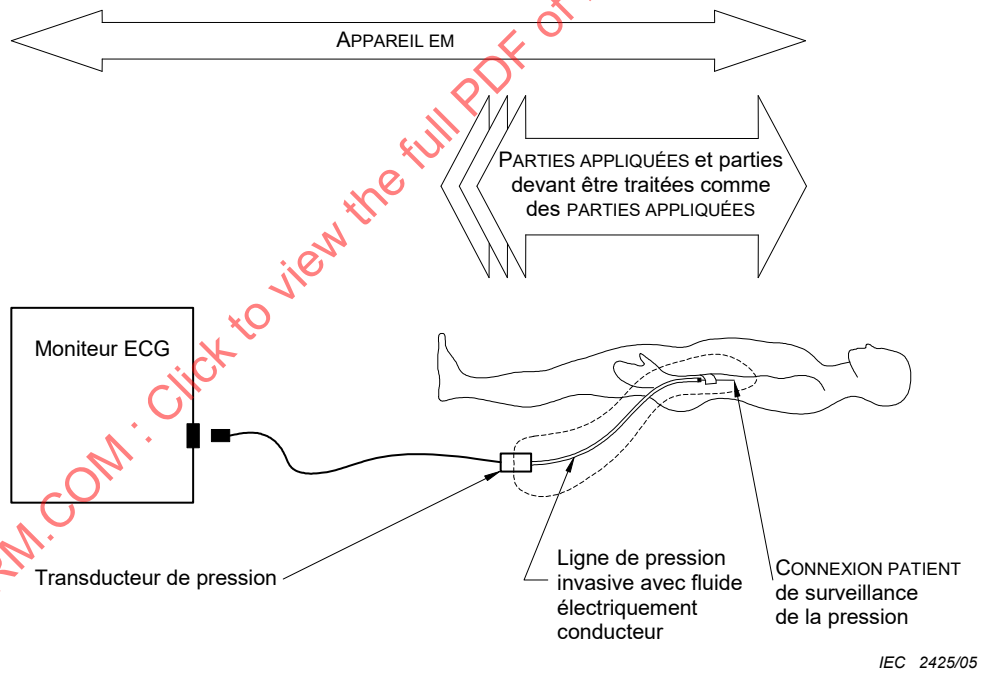


Figure A.3 – Identification de l'APPAREIL EM, DES PARTIES APPLIQUEES et des CONNEXIONS PATIENT dans un moniteur PATIENT avec dispositifs de surveillance endovasculaire de la pression

La Figure A.4 illustre un moniteur PATIENT avec électrocardiogramme et dispositifs de surveillance endovasculaire de la pression. Dans cet exemple:

– L'APPAREIL EM inclut le moniteur d'électrocardiogramme (ECG), le câble PATIENT ECG, les conducteurs PATIENT et ~~ses~~ leurs électrodes, et le transducteur de pression et sa ligne de fluide.

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– La ou les PARTIE APPLIQUEE(s) inclu(en)t les électrodes ~~d'électrocardiogramme~~ ECG et les parties du câble PATIENT et des conducteurs PATIENT qui doivent ~~physiquement être~~ entrer en contact physique avec le PATIENT en UTILISATION NORMALE; et la ligne de surveillance de la pression par fluide.

– L'application de la GESTION DES RISQUES pourrait ~~permettre d'~~ identifier d'autres parties du câble PATIENT ECG, des conducteurs PATIENT ou du transducteur de pression ~~devant~~ qui doivent être traitées comme des PARTIES APPLIQUEES ~~en raison~~ du fait de la probabilité ~~de~~ qu'elles entrent en contact avec le PATIENT.

– Les CONNEXIONS PATIENT ECG se composent des électrodes d'électrocardiogramme.

– La CONNEXION PATIENT de surveillance de la pression se compose du fluide conducteur d'électricité de la ligne de pression. Pour la mesure du COURANT DE FUITE PATIENT et du COURANT AUXILIAIRE PATIENT, une électrode est placée dans le fluide conducteur et traitée comme une CONNEXION PATIENT individuelle.

– Si les CONNEXIONS PATIENT associées à la fonction ECG ne sont pas séparées au niveau électrique de la CONNEXION PATIENT associée à la fonction de surveillance de la pression, elles sont traitées comme deux fonctions de la même PARTIE APPLIQUEE.

– Si les CONNEXIONS PATIENT associées à la fonction ECG sont séparées d'un point de vue électrique de la CONNEXION PATIENT associée à la fonction de surveillance de la pression, elles sont traitées comme des PARTIES APPLIQUEES séparées.

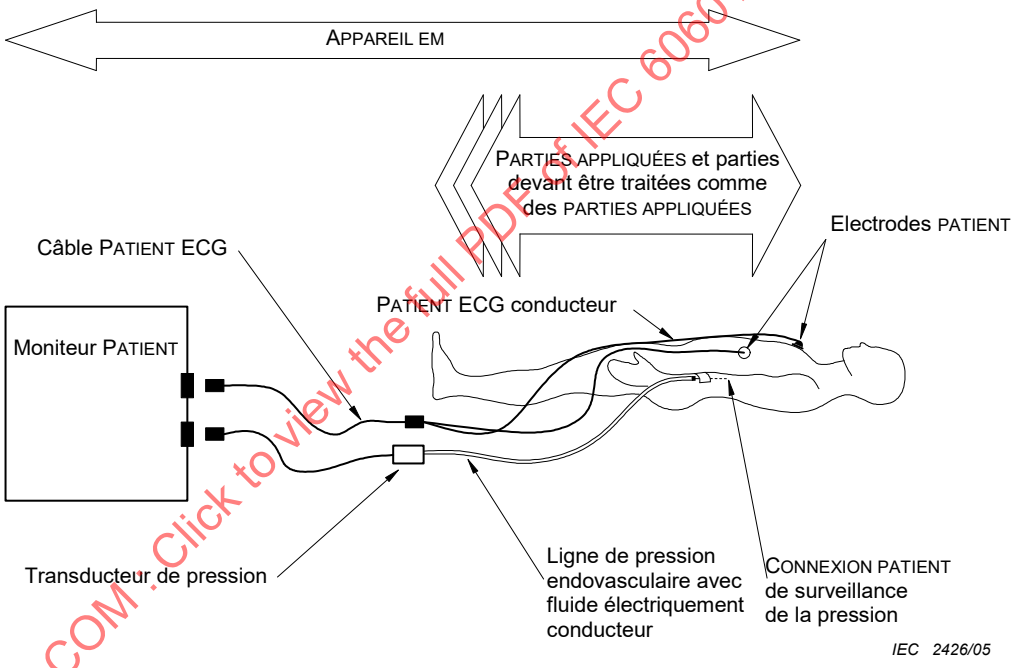


Figure A.4 – Identification de l'APPAREIL EM, DES PARTIES APPLIQUEES et des CONNEXIONS PATIENT dans un moniteur PATIENT multifonctions avec dispositifs de surveillance endovasculaire de la pression

La Figure A.5 illustre un SYSTEME EM à rayons X dans lequel:

– ~~Le SYSTEME~~ L'APPAREIL EM inclut ~~un~~ l'ensemble gaine équipée, la table de radiologie et le support mural, qui font tous partie de l'APPAREIL EM. D'autres parties du SYSTEME EM telles que le générateur de rayons X et la console de l'OPERATEUR ne sont pas montrées.

– La ou les PARTIES APPLIQUEES incluent la surface de la table et la partie avant du support mural, dans la mesure où ces parties doivent être physiquement en contact avec le PATIENT en UTILISATION NORMALE.

– L'application de la GESTION DES RISQUES pourrait permettre d'identifier certaines parties de l'ensemble gaine équipée et d'autres parties de la table et du support mural ~~devant~~ qui ont à être traitées comme des PARTIES APPLIQUEES ~~en raison~~ du fait de la probabilité ~~de~~ qu'elles entrent en contact avec le PATIENT.

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– Les CONNEXIONS PATIENT se composent des parties conductrices de ces PARTIES APPLIQUEES qui sont en contact électriquement avec le PATIENT.

– Le FABRICANT peut préciser que la table et le support mural sont des fonctions différentes de la même PARTIE APPLIQUEE.

– Comme alternative, le FABRICANT peut préciser que la table et le support mural sont des PARTIES APPLIQUEES différentes.

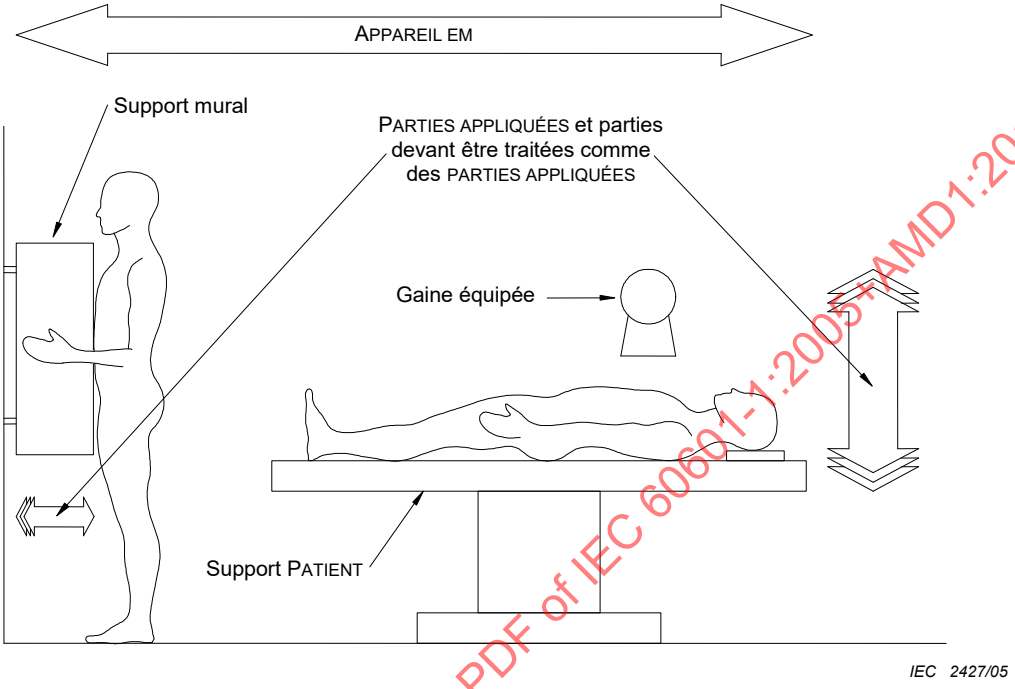


Figure A.5 – Identification des PARTIES APPLIQUEES et des CONNEXIONS PATIENT dans un SYSTEME EM A RAYONS X

La Figure A.6 illustre un neurostimulateur électrique transcutané (TENS) destiné à être porté sur la ceinture du PATIENT et connecté à des électrodes appliquées sur le haut du bras du PATIENT. Dans ce cas:

– L'APPAREIL EM inclut le stimulateur TENS, le câble des électrodes et les électrodes.

– La PARTIE APPLIQUEE inclut les électrodes et les parties du câble des électrodes qui doivent être physiquement en contact avec le PATIENT en UTILISATION NORMALE.

– L'application de la GESTION DES RISQUES pourrait permettre de déterminer que le boîtier du stimulateur et sa boucle de ceinture doivent également être traités comme des PARTIES APPLIQUEES en raison de la probabilité de contact avec le PATIENT.

– Les CONNEXIONS PATIENT comprennent les électrodes, qui font toutes partie de la même fonction de cette PARTIE APPLIQUEE.

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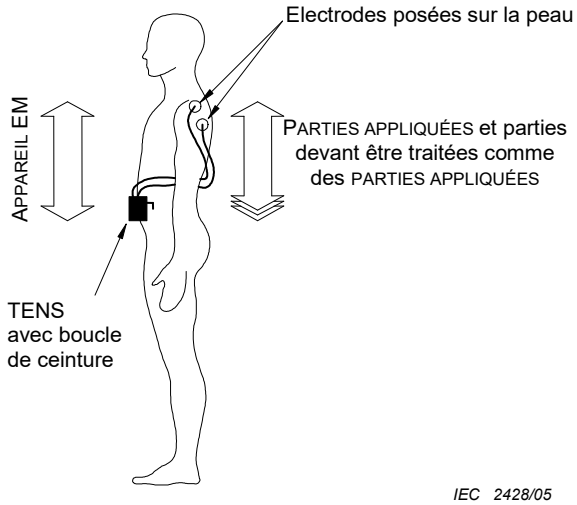


Figure A.6 – Identification de l'APPAREIL EM, des PARTIES APPLIQUEES et des CONNEXIONS PATIENT dans un neurostimulateur électrique transcutané (TENS) destiné à être porté sur la ceinture du PATIENT et connecté à des électrodes sur le haut du bras du PATIENT

La Figure A.7 illustre un APPAREIL EM / SYSTEME EM de traitement d'électrocardiogramme (ECG) dans lequel:

– Le SYSTEME EM inclut le module ECG, le câble PATIENT, les conducteurs PATIENT et ~~des~~ les électrodes, ainsi que le micro-ordinateur et tous ses ACCESSOIRES (non illustrés).

– Le FABRICANT peut décider de spécifier l'une des situations suivantes:

  - Le module ECG, son câble PATIENT, les conducteurs PATIENT et les électrodes font partie de l'APPAREIL EM, et l'ordinateur ne fait pas partie de l'APPAREIL EM. Cela correspondrait à un SYSTEME EM.
  - Le module ECG, son câble PATIENT, les conducteurs PATIENT et les électrodes font partie de l'APPAREIL EM, et l'ordinateur est ~~une partie séparée~~ un élément séparé de l'APPAREIL EM. Cela correspondrait aussi à un SYSTEME EM.
  - Le module ECG, son câble PATIENT, les conducteurs PATIENT et les électrodes, avec l'ordinateur, constituent un élément unique d'APPAREIL EM et non un SYSTEME EM.

– La PARTIE APPLIQUEE inclut les électrodes et les parties des conducteurs PATIENT ou du câble PATIENT qui doivent ~~être physiquement~~ entrer en contact physique avec le PATIENT en UTILISATION NORMALE.

– L'application de la GESTION DES RISQUES pourrait ~~permettre d'~~ identifier d'autres parties du conducteur PATIENT ou du câble PATIENT ~~devant~~ qui doivent être traitées comme des PARTIES APPLIQUEES ~~en raison~~ du fait de la probabilité ~~de~~ qu'elles entrent en contact avec le PATIENT.

– Les CONNEXIONS PATIENT comprennent les électrodes ECG, qui font toutes partie de la même fonction de la PARTIE APPLIQUEE.

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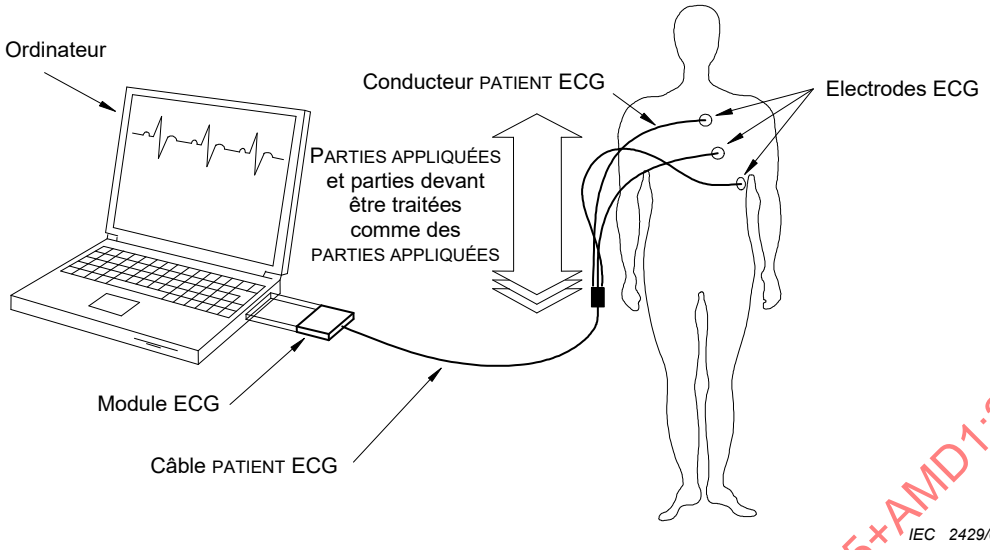


Figure A.7 – Identification de l'APPAREIL EM ou du SYSTEME EM, des PARTIES APPLIQUEES et des CONNEXIONS PATIENT dans un micro-ordinateur avec un module d'électrocardiogramme

Le paragraphe 4.6 ne s'appliquerait probablement pas à des PARTIES ACCESSIBLES de l'APPAREIL EM qui sont positionnées selon leur USAGE PREVU de telle manière que le PATIENT ne puisse les toucher que par un mouvement délibéré. Ceci repose sur l'hypothèse selon laquelle un PATIENT pourrait réagir à un stimulus négatif. De plus, de tels PATIENTS ont probablement à entrer en contact avec des appareils autres que des APPAREILS EM, tels que des lampes de chevet, des ordinateurs personnels, des radios, etc.

Paragraphe 3.9 – ISOLATION PRINCIPALE

Cette définition n'inclut pas l'isolation utilisée exclusivement à des fins fonctionnelles.

Paragraphe 3.10 – SECURITE DE BASE

LA SECURITE DE BASE ~~fait référence à un dispositif qui n'engendre pas de dommages pour le PATIENT dans le cadre de son fonctionnement~~ concerne un dispositif n'entraînant pas de DOMMAGE consécutif à son fonctionnement.

LA SECURITE DE BASE est souvent une forme passive de protection (telle que blindage contre des rayonnements ou mise à la terre électrique).

LES PERFORMANCES ESSENTIELLES font généralement référence à des APPAREILS EM ou des SYSTEMES EM qui fonctionnent comme prévu sans engendrer de DANGER. Une défaillance des PERFORMANCES ESSENTIELLES peut être soit l'absence de performances (par exemple performance de maintien de la vie) soit une performance incorrecte (par exemple dose incorrecte délivrée au PATIENT).

En général, la SECURITE DE BASE fait référence aux propriétés d'un produit qui ne sont pas spécifiques à un dispositif et les PERFORMANCES ESSENTIELLES font référence à une classe de produits (comme les défibrillateurs capables de délivrer le choc électrique correct).

Alors que les termes SECURITE DE BASE et PERFORMANCES ESSENTIELLES sont généralement considérés comme s'excluant mutuellement, il existe des DANGERS qui peuvent être liés à la fois à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES simultanément.

Paragraphe 3.15 – CLAIREMENT LISIBLE

La vision ou l'acuité visuelle peut être soumise à l'essai par la lecture d'une échelle de Snellen à une distance de 6 m. La vision de près peut être soumise à l'essai au moyen d'une carte de Jaeger. En examinant un grand nombre de personnes, les médecins ont décidé ce

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qu'il convient qu'un être humain "normal" soit capable de voir à diverses distances. Ceci est la description de la vision normale.

Paragraphe 3.17 – COMPOSANT AUX CARACTERISTIQUES A HAUTE FIABILITE

Le concept de haute fiabilité fait référence uniquement aux caractéristiques particulières du composant. Ces caractéristiques sont celles sur lesquelles on se fonde pour assurer la sécurité du produit. Il convient qu'un tel COMPOSANT AUX CARACTERISTIQUES A HAUTE FIABILITE soit identifié dans les DOCUMENTS D'ACCOMPAGNEMENT par le FABRICANT (par exemple pour la maintenance) Voir également la justification de 4.9.

Paragraphe 3.18 – SERVICE CONTINU

Bien que les termes SERVICE CONTINU ou "autre que le SERVICE CONTINU" soient utilisés en ce qui concerne les APPAREILS EM, certaines parties des APPAREILS EM peuvent être ASSIGNEES différemment. Par exemple, un générateur électrochirurgical peut être ASSIGNE pour le SERVICE CONTINU alors que la PARTIE APPLIQUEE est ASSIGNEE pour un fonctionnement autre que le SERVICE CONTINU.

Paragraphe 3.20 – PARTIE APPLIQUEE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION

Une PARTIE APPLIQUEE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION est protégée uniquement contre les décharges des défibrillateurs conformes à l'IEC 60601-2-4 [15]. Des défibrillateurs de niveau de tension supérieur pourraient endommager les PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION.

Paragraphe 3.21 – CABLE D'ALIMENTATION NON FIXE A DEMEURE

Les ensembles de câbles font l'objet de l'IEC 60320-1.

Paragraphe 3.22 – APPLICATION CARDIAQUE DIRECTE

Une distinction est faite entre l'utilisation des PARTIES APPLIQUEES qui pourraient venir en contact direct avec le cœur du PATIENT et toutes les autres circonstances de contact avec le PATIENT. La fibrillation ventriculaire peut être causée par un courant bien plus faible traversant une zone de contact de petite taille là où un fil ou un cathéter est en contact direct avec le cœur qu'un courant traversant tout autre point de contact sur ou dans le corps du PATIENT.

Paragraphe 3.23 – DOUBLE ISOLATION

L'ISOLATION PRINCIPALE et l'ISOLATION SUPPLEMENTAIRE peuvent, si nécessaire, être soumises aux essais séparément. Lorsque plusieurs couches d'isolation ne peuvent être soumises aux essais séparément, le système d'isolation est considéré comme une ISOLATION RENFORCEE.

Paragraphe 3.24 – CYCLE D'UTILISATION

Les termes "durée de marche" et "durée d'arrêt" sont considérés comprendre des "salves" de fonctionnement et de désactivation ainsi que le FONCTIONNEMENT CONTINU.

Paragraphe 3.26 – ENVELOPPE

L'ENVELOPPE d'un APPAREIL EM ou des parties d'un APPAREIL EM inclut toutes les PARTIES ACCESSIBLES, boutons, câbles, connecteurs et autres éléments accessibles similaires. Cela comprend toutes les PARTIES ACCESSIBLES de connexions externes entre d'autres parties séparées.

Paragraphe 3.27 – PERFORMANCE ESSENTIELLE

~~Il est reconnu depuis longtemps qu'un APPAREIL EM qui ne fonctionne pas correctement peut donner lieu à un RISQUE inacceptable pour les PATIENTS, LES OPERATEURS, ou les autres personnes. Toutes les caractéristiques ou toutes les fonctions qui doivent être assurées correctement pour éviter tout DOMMAGE pour le PATIENT, l'OPERATEUR ou d'autres personnes sont importantes, mais toutes les caractéristiques ou fonctions des APPAREILS EM ne sont pas des PERFORMANCES ESSENTIELLES. Lorsqu'une défaillance de fonctionnement peut donner lieu à un RISQUE inacceptable pour le PATIENT, l'OPERATEUR ou d'autres personnes, alors ces caractéristiques ou fonctions sont considérées comme des PERFORMANCES ESSENTIELLES pour les besoins de la présente norme.~~

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~~L'évaluation de ce RISQUE est réalisée à partir de l'hypothèse selon laquelle l'aspect de la performance en question a été perdu ou dégradé et elle tient compte de la probabilité qu'il y aurait un DOMMAGE (qui dans certains exemples pourrait être de 100 %) et de la GRAVITE de ce DOMMAGE. L'application du PROCESSUS de GESTION DES RISQUES assure que la probabilité de perte de l'aspect performance est suffisamment faible pour rendre le RISQUE RESIDUEL acceptable.~~

~~Il y a un problème de PERFORMANCE ESSENTIELLE lorsque la caractéristique ou la fonction en question est absente ou que ses caractéristiques sont dégradées à un point tel que L'APPAREIL EM ou le SYSTEME EM n'est plus adapté à son UTILISATION PREVUE.~~

~~Exemples de PERFORMANCES ESSENTIELLES:~~

- ~~précision d'une fonction assurant la vie ou l'administration correcte d'un médicament par un pousse-seringue lorsqu'une administration imprécise/incorrecte causerait un RISQUE inacceptable pour le PATIENT;~~
- ~~capacité d'un électrocardiographe/moniteur à la reprise après les effets de la décharge d'un défibrillateur lorsqu'une défaillance de reprise pourrait conduire à une réponse incorrecte du personnel médical qui présenterait un RISQUE inacceptable pour le PATIENT;~~
- ~~fonctionnement correct d'une alarme dans un système de surveillance d'unité de soins intensifs ou de salle d'opération lorsqu'une alarme incorrecte/l'absence d'alarme pourrait conduire à une réponse incorrecte du personnel médical qui présenterait un RISQUE inacceptable pour le PATIENT; ou~~
- ~~valeur de sortie correcte d'une information de diagnostic provenant d'un APPAREIL EM qui est susceptible d'être considérée comme fiable pour déterminer le traitement, lorsqu'une information incorrecte pourrait conduire à un traitement inapproprié qui présenterait un RISQUE inacceptable pour le PATIENT.~~

~~La PERFORMANCE ESSENTIELLE est identifiée sans tenir compte de la probabilité d'occurrence des facteurs qui pourraient donner lieu à une perte de fonctionnalité. Ces facteurs sont pris en compte dans le PROCESSUS de GESTION DES RISQUES.~~

~~Il est prévu que les normes particulières et collatérales de la famille de l'IEC 60601 identifient les PERFORMANCES ESSENTIELLES spécifiques.~~

Il est reconnu depuis longtemps qu'un APPAREIL EM ou un SYSTEME EM qui ne fonctionne pas correctement pourrait donner lieu à un RISQUE inacceptable pour les PATIENTS, les OPERATEURS, ou d'autres personnes. Le concept de "sécurité" a donc été élargi par rapport aux considérations sur la SECURITE DE BASE des première et deuxième éditions de la présente norme, afin d'intégrer le concept de PERFORMANCES ESSENTIELLES.

Afin d'exécuter son UTILISATION PREVUE, l'APPAREIL EM ou le SYSTEME EM doit fonctionner dans certaines limites. Ces limites sont généralement spécifiées par le FABRICANT mais elles peuvent être spécifiées par la présente norme, une norme collatérale ou une norme particulière de la famille de l'IEC 60601.

Des exemples de PERFORMANCES ESSENTIELLES sont:

- l'administration correcte d'un médicament au moyen d'un pousse-seringue lorsqu'une administration imprécise/incorrecte entraînerait un RISQUE inacceptable pour le PATIENT;
- la capacité d'un électrocardiographe/moniteur à la reprise après les effets de la décharge d'un défibrillateur lorsqu'une défaillance de reprise pourrait conduire à une réponse incorrecte du personnel médical qui présenterait un RISQUE inacceptable pour le PATIENT;
- le fonctionnement correct d'un SYSTEME D'ALARME dans un système de surveillance d'unité de soins intensifs ou de salle d'opération lorsqu'un SIGNAL D'ALARME incorrect/absent pourrait conduire à une réponse incorrecte du personnel médical qui présenterait un RISQUE inacceptable pour le PATIENT; ou
- la valeur de sortie correcte d'une information de diagnostic provenant d'un APPAREIL EM qui est susceptible d'être considéré comme fiable pour déterminer le traitement,

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lorsqu'une information incorrecte pourrait conduire à un traitement inapproprié qui présenterait un RISQUE inacceptable pour le PATIENT.

Pour les besoins de la présente norme, les performances relatives aux aspects de la SECURITE DE BASE de l'APPAREIL EM, telles que les performances de l'ISOLATION PRINCIPALE, ne sont pas considérées comme des PERFORMANCES ESSENTIELLES.

Il est prévu que les normes particulières et collatérales de la famille de l'IEC 60601 identifient les PERFORMANCES ESSENTIELLES spécifiques.

Paragraphe 3.33 – CONNEXION FONCTIONNELLE

Le terme défini de CONNEXION FONCTIONNELLE est utilisé pour faciliter la définition d'un SYSTEME EM. La CONNEXION FONCTIONNELLE est un couplage entre des éléments d'un SYSTEME EM, y compris la possibilité de fourniture d'énergie.

L'indication "ou autre" pourrait comprendre par exemple, des connexions mécaniques, optiques ou sans fil.

Paragraphe 3.35 – BORNE DE TERRE FONCTIONNELLE

Dans les APPAREILS EM, les connexions de terre fonctionnelles peuvent être réalisées au moyen d'une BORNE DE TERRE FONCTIONNELLE accessible à l'OPERATEUR. En variante, la présente norme permet aussi de réaliser une connexion de terre fonctionnelle pour un APPAREIL EM DE CLASSE II par l'intermédiaire du conducteur vert et jaune d'un CABLE D'ALIMENTATION. Dans ce cas, les parties auxquelles ce conducteur est connecté ne peuvent pas être des PARTIES ACCESSIBLES (voir 8.6.9) et doivent être isolées des PARTIES ACCESSIBLES.

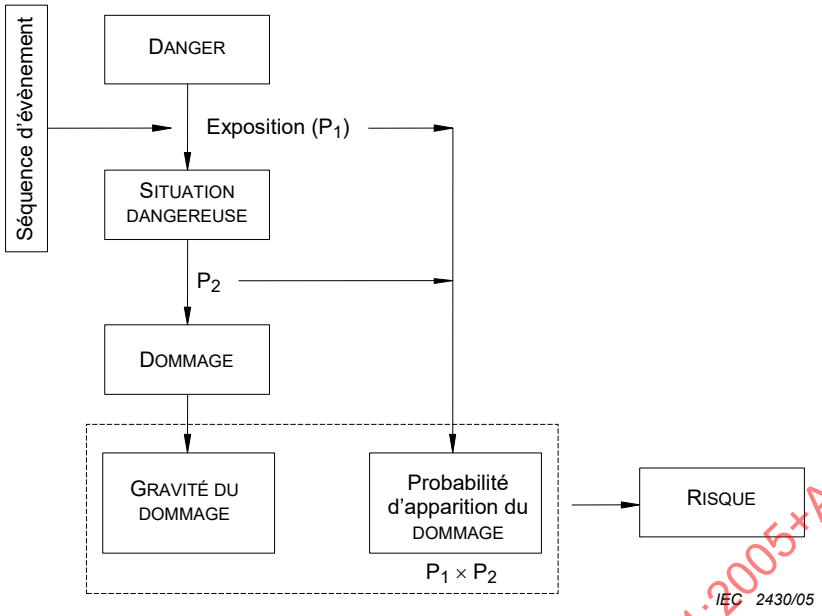
Paragraphe 3.38 – DOMMAGE

La définition de DOMMAGE se fonde sur la définition de l'ISO 14971 modifiée pour inclure les animaux. Cette modification a été introduite depuis que le domaine d'application de la IEC 60601-1 inclut la sécurité des animaux.

Paragraphe 3.40 – SITUATION DANGEREUSE

Dans le cadre de la présente norme, un DANGER ne peut pas donner lieu à un DOMMAGE avant qu'une suite d'évènements ou d'autres circonstances (y compris l'UTILISATION NORMALE) ne conduisent à une SITUATION DANGEREUSE. A la suite du PROCESSUS de GESTION DES RISQUES, l'acceptabilité du RISQUE lié peut être évaluée en estimant à la fois la GRAVITE et la probabilité d'apparition du DOMMAGE qui pourrait résulter de cette SITUATION DANGEREUSE (voir Figure A.8 adaptée du projet de 2ème édition de l'ISO 14971).

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NOTE P_1 est la probabilité d'apparition d'une SITUATION DANGEREUSE.
P_2 est la probabilité qu'une SITUATION DANGEREUSE conduise à un DOMMAGE.

Figure A.8 – Représentation graphique de la relation du DANGER, de la séquence d'évènements, de SITUATION DANGEREUSE et de DOMMAGE

Paragraphe 3.44 – ~~UTILISATION PREVUE~~

~~L'ISO 14971:2000 a défini le terme composé UTILISATION PREVUE/DESTINATION PREVUE car, au moment de l'élaboration de cette version, il n'y avait pas de consensus sur le terme à utiliser. La directive européenne sur les appareils médicaux utilise "destination prévue," tandis que les règlements des USA utilisent "utilisation prévue." Les deux termes ont essentiellement la même définition. Après quelques années d'expérience dans l'application de l'ISO 14971, il a été généralement accepté que le terme combiné est lourd et un consensus s'est dégagé pour l'utilisation du terme abrégé "utilisation prévue." La deuxième édition de l'ISO 14971 (en préparation) devrait utiliser "utilisation prévue" comme terme préférentiel, "destination prévue" étant un "terme admis." Pour éviter un manque d'homogénéité avec la future édition de l'ISO 14971, la présente norme a adopté le terme défini abrégé UTILISATION PREVUE. La définition elle-même est identique à celle de l'ISO 14971:2000 et à la définition attendue dans la deuxième édition de l'ISO 14971.~~

Paragraphe 3.49 – PARTIES RELIEES AU RESEAU

Il est nécessaire d'avoir une définition du terme "PARTIE RELIEE AU RESEAU" afin d'identifier les parties auxquelles certaines exigences s'appliquent. La définition donnée dans les première et seconde éditions de la présente norme dépendait d'un autre terme défini, "liaison conductrice". Au cours de l'élaboration de la présente édition, la définition de "liaison conductrice" s'est révélée problématique et les exigences ont été révisées de manière que le terme défini ne soit plus nécessaire. Cela exigeait une nouvelle définition du terme PARTIE RELIEE AU RESEAU, en s'attachant aux MOYENS DE PROTECTION qui séparent la PARTIE RELIEE AU RESEAU des autres parties.

Paragraphe 3.50 – FICHE RESEAU

Il est nécessaire d'avoir une définition de FICHE RESEAU afin d'identifier la fiche à laquelle certaines exigences s'appliquent. Le terme "fiche réseau" sans définition couvrirait également d'autres connecteurs compris dans les APPAREILS EM qui transportent la TENSION RESEAU.

Paragraphe 3.56 – TENSION RESEAU MAXIMALE

Plusieurs exigences et essais de la présente norme renvoient à la possibilité qu'une tension non prévue provenant d'une source externe soit connectée au PATIENT ou à certaines parties

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de l'APPAREIL EM. L'amplitude réelle d'une telle tension est inconnue mais on estime qu'elle est liée à la tension du RESEAU D'ALIMENTATION à l'emplacement où l'APPAREIL EM est utilisé. Voir également la justification de 8.5.3.

Pendant les premières étapes de préparation de la présente édition, un terme défini “tension d'alimentation de référence” a été introduit pour éviter la répétition de formulations trop longues. Au cours de la revue des commentaires des Comités nationaux sur un projet initial, une certaine confusion est apparue entre le terme défini “tension d'alimentation de référence” et le terme non défini “tension de référence”, qui était utilisé dans le cadre des exigences sur la tension de tenue, les LIGNES DE FUITE et les DISTANCES DANS L'AIR.

Afin de clarifier les exigences, le terme "tension d'alimentation de référence” a été remplacé par TENSION RESEAU MAXIMALE et “tension de référence” a été remplacé par les termes définis TENSION DE SERVICE et TENSION DE SERVICE DE CRETE.

Paragraphe 3.57 – PRESSION MAXIMALE ADMISSIBLE DE FONCTIONNEMENT

La PRESSION MAXIMALE ADMISSIBLE DE FONCTIONNEMENT est déterminée par une personne compétente, prenant en considération la spécification de la conception d'origine, la valeur assignée par le FABRICANT, l'état présent du réservoir et les conditions d'utilisation.

Dans certains pays, cette valeur pourrait être révisée en baisse périodiquement.

Paragraphe 3.58 – MOYEN DE PROTECTION

Un des principes qui a prévalu dans le développement de la troisième édition de la présente norme a été de la rendre moins prescriptive que la deuxième édition, en particulier concernant les Articles 17 et 20. Le concept de MOYEN DE PROTECTION a été conçu comme un concept générique qui pourrait couvrir un certain nombre d'éléments comme les CONNEXIONS DE TERRE DE PROTECTION, l'ISOLATION PRINCIAPLE, l'ISOLATION SUPPLEMENTAIRE, les impédances, etc.; et qui pourrait être étendu pour inclure d'autres éléments servant dans la même installation mais qui n'ont pas encore été envisagés ou qui ne sont pas encore praticables. Ce concept, associé à l'exigence générale selon laquelle les APPAREILS EM doivent avoir deux MOYENS DE PROTECTION, s'accordait avec l'approche de premier défaut qui a été unanimement retenue dans la troisième édition. Il permet d'adopter une approche cohérente pendant toute la conception en évitant de s'enliser dans des paragraphes trop descriptifs.

Ce concept s'accordait également avec la décision de distinguer la protection des PATIENTS de celle des OPERATEURS.

Les commentaires des Comités nationaux pendant l'élaboration de la présente édition laissaient à entendre que le concept pourrait être étendu pour s'appliquer à la protection contre des DANGERS autres que les chocs électriques. Il a toutefois été décidé qu'une telle modification ne se justifiait pas au vu des avantages apportés.

Paragraphe 3.59 – MOYEN DE PROTECTION DU PATIENT

Voir la justification de 8.5.1.

Paragraphe 3.60 – MOYEN DE PROTECTION DE L'OPERATEUR

Voir la justification de 8.5.1.

Paragraphe 3.63 – APPAREIL ELECTRO-MEDICAL

La présente définition d'APPAREIL EM exclut les connexions multiples au même RESEAU D'ALIMENTATION particulier, mais n'exclut pas différents connecteurs vers différents RESEAUX D'ALIMENTATION particuliers. Toutefois, il convient d'éviter la connexion à plus d'un RESEAU D'ALIMENTATION différent au même moment. Alors qu'il pourrait être possible de concevoir des appareils équipés pour être connectés simultanément à deux RESEAUX D'ALIMENTATION différents d'une manière électriquement sûre, les ~~DANGERS~~ SITUATIONS DANGEREUSES particuliers qui pourraient apparaître n'ont pas été identifiés dans la présente norme.

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La présente norme applique plusieurs termes à la description de l'APPAREIL EM, des ACCESSOIRES et des parties d'APPAREIL EM. Ils sont FIXES (3.30), STATIONNAIRES (3.118), TRANSPORTABLES (3.130), MOBILES (3.65), PORTABLES (3.85), PORTATIFS (3.37) et PORTES (3.144). Pour une meilleure compréhension de la relation entre ces termes, le graphique de la Figure A.20 a été développé.

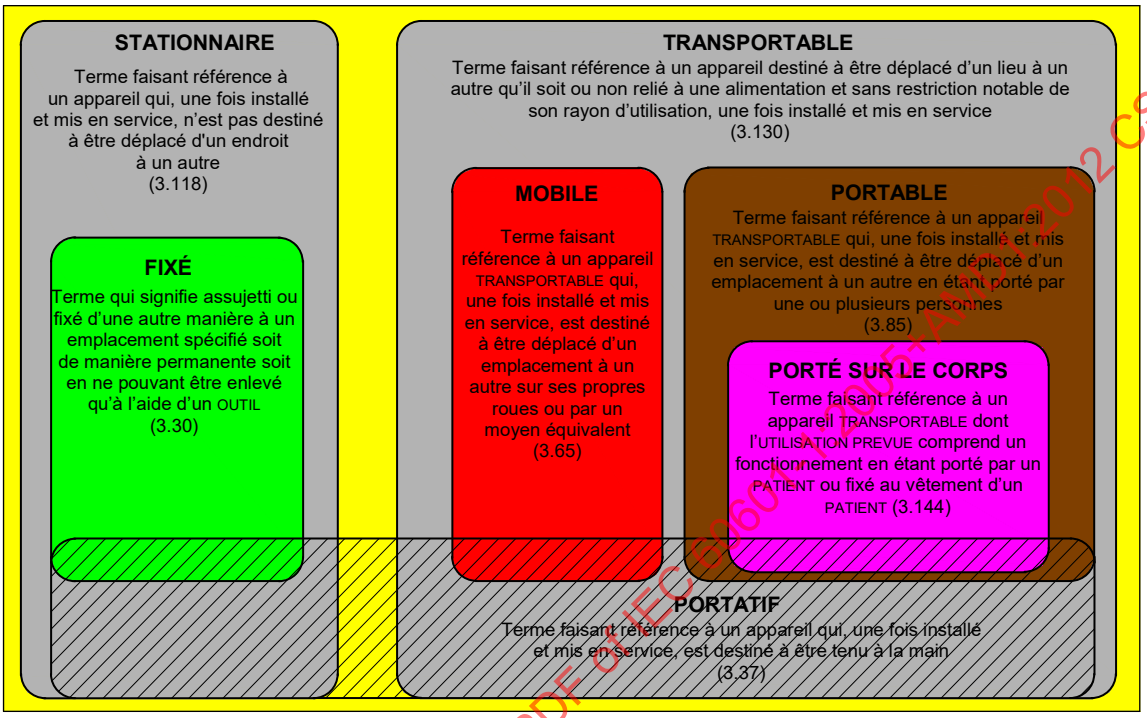


Figure A.20 – Relations entre les termes utilisés pour décrire les appareils, les ACCESSOIRES ou les parties d'appareils

Paragraphe 3.64 – SYSTEME ELECTRO-MEDICAL

Il est de pratique courante chez les FABRICANTS, les ORGANISMES RESPONSABLES et les OPERATEURS de connecter les APPAREILS EM et d'autres appareils médicaux ou non médicaux à des SOCLES DE PRISES MULTIPLES. L'ajout de tels montages dans la définition d'un SYSTEME EM les fait entrer dans le domaine d'application de la présente norme et permet ainsi de spécifier des exigences appropriées pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES.

Pour minimiser autant que possible la diminution du niveau de sécurité de la présente norme, le raccordement d'un SOCLE DE PRISE DE COURANT MULTIPLE au RESEAU D'ALIMENTATION est soumis à certaines conditions. Le Paragraphe 16.9.2.1 exige que les SOCLES DE PRISES DE COURANT MULTIPLES soient construits de manière à satisfaire aux exigences s'appliquant aux APPAREILS EM traités dans la présente norme.

Paragraphe 3.66 – REFERENCE DU MODELE OU DU TYPE

La REFERENCE DU MODELE OU DU TYPE est destinée à établir la relation de l'APPAREIL EM avec les publications commerciales et techniques, les DOCUMENTS D'ACCOMPAGNEMENT et entre les parties séparables des APPAREILS EM. Il est également important d'identifier les APPAREILS EM ou ACCESSOIRES en cas d'alerte de sécurité ou d'autre action de terrain exigée.

Paragraphe 3.67 – SOCLE DE PRISES MULTIPLES

La définition est issue de l'IEC 60884-1.

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Dans la deuxième édition de l'IEC 60601-1-1 [13], il existait des définitions pour les socles portatifs multiples et les socles réseau auxiliaires. Dans la présente édition, ces définitions ont été regroupées.

Un socle de prise de courant individuel faisant partie d'un appareil est également considéré comme un SOCLE DE PRISES MULTIPLES.

Les SOCLES DE PRISES MULTIPLES sont parfois nécessaires et comportent des avantages et des inconvénients qui doivent être étudiés afin de parvenir à un compromis. Les SOCLES DE PRISES MULTIPLES peuvent être nécessaires pour les raisons suivantes:

– réduire au minimum le nombre de CABLES D'ALIMENTATION sur le sol,

– permettre d'utiliser tous les appareils nécessaires au traitement ou au diagnostic correct malgré un nombre insuffisant de socles FIXES de prises de courant réseau,

– améliorer la mobilité en ayant tous les appareils sur un même chariot,

– réduire les différences de potentiel au sein du câblage de terre de protection par rapport à celles apparaissant sur certaines installations FIXES.

Il convient d'éviter autant que possible d'utiliser des SOCLES DE PRISES MULTIPLES pour les raisons suivantes:

– des COURANTS DE FUITE A LA TERRE combinés peuvent entraîner:

  • un COURANT DE FUITE A LA TERRE excessif en CONDITION NORMALE,

  • un COURANT DE CONTACT excessif en cas de rupture du CONDUCTEUR DE TERRE DE PROTECTION en CONDITION DE PREMIER DEFAUT du câble d'alimentation du SOCLE DE PRISES MULTIPLES;

– la disponibilité du RESEAU D'ALIMENTATION dépend de la fiabilité d'un seul socle FIXE de prise de courant réseau;

– une interruption complète de l'alimentation électrique est possible et peut demander un long délai de réglage pour réactiver le SYSTEME EM complet;

– une seule LIAISON DE TERRE DE PROTECTION à l'installation électrique est fournie, ce qui est moins fiable que lorsque chaque partie du SYSTEME EM est directement mise à la terre;

– la résistance de terre de protection augmente.

La solution optimale consiste à installer un nombre adéquat de socles FIXES de prise de courant réseau selon les règles d'installation appropriées.

Paragraphe 3.68 – COUPLAGE DE RESEAU / DONNEES

La définition de COUPLAGE DE RESEAUX / DONNEES a été élaborée de manière à ne pas se limiter à une technologie particulière, telle que la transmission électronique par fils. Cette définition permet d'intégrer la transmission électronique sans fil, infrarouge, optique, etc., ainsi que toute autre technologie future.

Paragraphe 3.73 – OPERATEUR

L'OPERATEUR est défini comme la personne qui manipule l'appareil qui pourrait être un APPAREIL EM ou tout élément d'appareil dans le contexte d'un SYSTEME EM. Cette personne pourrait être:

– un professionnel de la santé utilisant l'appareil avec un PATIENT,

– soit un PATIENT soit une personne sans compétence médicale particulière aidant un PATIENT dans un environnement de soins à domicile,

– une personne qui utilise l'appareil pour compenser ou réduire les effets d'une maladie, d'une blessure ou d'une incapacité, ou

– la personne qui installe, assemble, entretient ou répare l'appareil.

Dans la présente norme, les personnes qui installent, assemblent, entretiennent ou réparent les appareils sont également désignées sous le terme "PERSONNEL D'ENTRETIEN".

De nombreuses exigences de la présente norme sont construites de telle manière que le PERSONNEL D'ENTRETIEN soit exposé au même RISQUE RESIDUEL que la personne qui utilise

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l'appareil pour son UTILISATION PREVUE. Toutefois, le PERSONNEL D'ENTRETIEN qui est souvent constitué d'ingénieurs ou de techniciens est présumé avoir certaines compétences techniques et prendre en compte la description technique. D'autres OPERATEURS sont présumés avoir des compétences différentes et suivre les instructions d'utilisation. C'est pourquoi la présente norme suppose dans certaines circonstances que la sécurité du PERSONNEL D'ENTRETIEN dépend partiellement de sa connaissance et de sa formation pour prendre les précautions appropriées lors de l'accès aux parties dangereuses. Les autres OPERATEURS sont présumés compétents pour utiliser les APPAREILS EM et les SYSTEMES EM mais pas nécessairement pour éviter les RISQUES qui peuvent apparaître au cours d'un entretien.

Paragraphe 3.75 – ENVIRONNEMENT RICHE EN OXYGENE

Pour une concentration en oxygène de 25 %, l'augmentation de la vitesse de combustion d'une bande de papier est modérée (30 %) (selon NFPA 99 [42]). Dans NFPA 99, 23,5 % est défini comme une atmosphère enrichie en oxygène qui exige des mesures de protection, mais cette valeur est également permise pour les chambres à oxygène présentant des pressions supérieures à 200 kPa. La NASA admet des concentrations de 25,9 % dans ses navettes spatiales (NFPA 53 [41]). UL 2601-1 [44] utilise 25 % comme valeur seuil. Un spécimen de carte de circuit imprimé en résine époxyde se consume incomplètement à 20,9 % et à 25,9 % (longueur de combustion de 3 cm et 8,3 cm) et complètement à 30 %, selon Rimanosky, E.M. et al., ASTM STP 1267 [36].

Lorsqu'on considère en première analyse la relation entre la propagation de flammes et la quantité d'oxygène, il apparaîtrait raisonnable que la propagation de flammes soit proportionnelle à la quantité d'oxygène totale disponible localement qui est donnée par la pression partielle. Toutefois, l'expérience montre que cela n'est vrai que dans une certaine mesure. Les Figures C-1.2.2(a) et (b) de la NFPA 53: 1999 et la Figure A.3.3.14.4 de la NFPA 99: 2002 montrent que pour les bandes de papier, l'augmentation de la propagation de flammes, avec la concentration en oxygène à une pression absolue donnée, est plus forte que l'augmentation de la propagation de flammes à la pression absolue à une concentration donnée. Pour la limite entre "combustion complète" et "combustion incomplète", la concentration en oxygène paraît atteindre la même valeur (14 %) à des pressions élevées indépendamment de la pression absolue (et partielle). C'est pourquoi, pour être en sécurité, deux nombres sont donnés dans la définition. La limite de concentration assure que pour des pressions ambiantes inférieures à une atmosphère, le danger n'augmente pas. La limite de pression partielle assure que pour des pressions plus élevées (par exemple en chambres à oxygène), la situation est sûre.

Paragraphe 3.77 – COURANT AUXILIAIRE PATIENT

Le COURANT AUXILIAIRE PATIENT est un courant nécessaire pour:

– que l'APPAREIL EM remplisse sa fonction, par exemple formation d'images par impédance électrique, contrôle de la respiration par des changements d'impédance;

– contrôler le bon fonctionnement de l'APPAREIL EM, par exemple impédance par contact des électrodes avec le PATIENT;

– le fonctionnement de l'APPAREIL EM;

ou cela est consécutif du fonctionnement de l'APPAREIL EM. Le courant de polarisation d'un amplificateur pour signaux physiologiques est un exemple.

Le COURANT AUXILIAIRE PATIENT pourrait avoir une fonction, mais pas physiologique, ou il pourrait ne pas avoir de fonction.

Paragraphe 3.78 – CONNEXION PATIENT

L'un des DANGERS associés à l'application de CONNEXIONS PATIENT réside dans le fait que le COURANT DE FUITE peut s'écouler à travers le PATIENT par l'intermédiaire des CONNEXIONS PATIENT. On fixe des limites particulières à l'intensité de ces courants, à la fois en CONDITION NORMALE et en diverses conditions de défaut.

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NOTE Le courant qui s'écoule à travers le PATIENT, entre diverses CONNEXIONS PATIENT, est connu sous le nom de COURANT AUXILIAIRE PATIENT. Le COURANT DE FUITE qui s'écoule à travers le PATIENT vers la terre est connu sous le nom de COURANT DE FUITE PATIENT.

La définition du terme CONNEXION PATIENT est destinée à assurer l'identification de chacune des parties individuelles de la PARTIE APPLIQUEE entre lesquelles un courant pourrait s'écouler en tant que COURANT AUXILIAIRE PATIENT, et à partir desquelles un COURANT DE FUITE PATIENT pourrait s'écouler à travers un PATIENT relié à la terre.

Dans certains cas, il sera nécessaire d'effectuer des mesurages du COURANT DE FUITE PATIENT et du COURANT AUXILIAIRE PATIENT pour déterminer quelles parties des PARTIES APPLIQUEES sont des CONNEXIONS PATIENT individuelles.

Les CONNEXIONS PATIENT ne sont pas toujours accessibles au toucher. Toutes les parties conductrices de la PARTIE APPLIQUEE qui entrent en contact électrique avec le PATIENT, ou qui ne sont empêchées de le faire que par une isolation ou des espacements dans l'air ne satisfaisant pas aux essais de tension de tenue correspondants ou aux exigences de DISTANCES DANS L'AIR et de LIGNES DE FUITE spécifiées dans la présente norme, sont des CONNEXIONS PATIENT. Voir également la justification de 3.8.

On peut citer comme exemples ce qui suit.

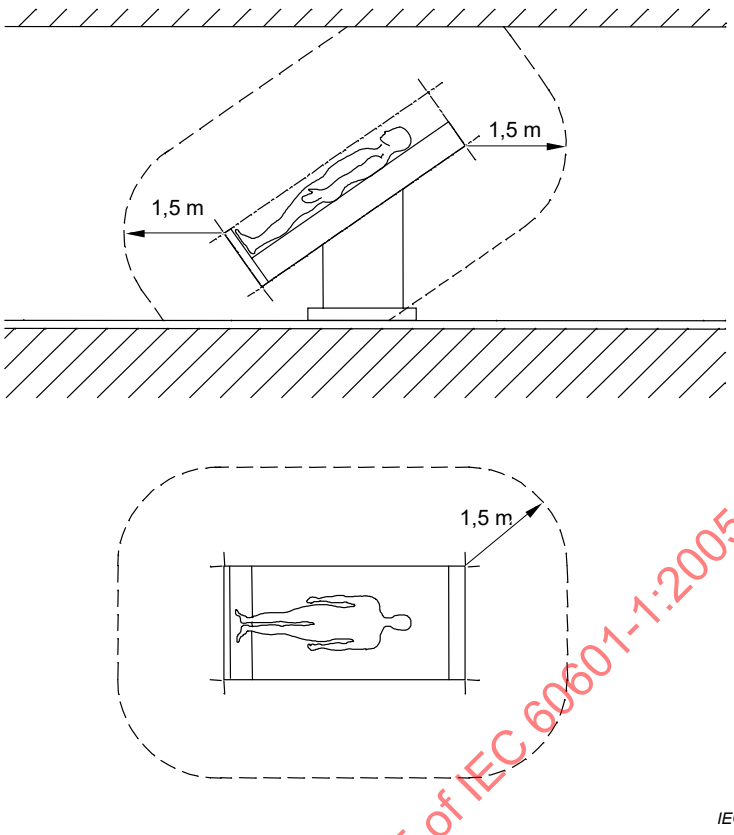
– Le dessus d'une table supportant un PATIENT est une PARTIE APPLIQUEE. Les draps ne procurent pas une isolation adéquate et les parties conductrices du dessus de la table seraient donc classées comme CONNEXIONS PATIENT.
– L'ensemble de distribution ou l'aiguille d'un régulateur de perfusion est une PARTIE APPLIQUEE. Les parties conductrices du régulateur séparées de la colonne de fluide (potentiellement conductrice) par une isolation inadéquate seraient des CONNEXIONS PATIENT.

Lorsqu'une PARTIE APPLIQUEE a une surface réalisée en matériau isolant, le paragraphe 8.7.4.7 d) spécifie qu'elle subit l'essai en utilisant une feuille métallique ou une solution saline. Elle est alors considérée comme une CONNEXION PATIENT.

Paragraphe 3.79 – ENVIRONNEMENT PATIENT

Il est difficile pour cette norme de définir des dimensions pour le volume dans lequel le diagnostic, la surveillance ou le traitement est effectué. Les dimensions requises pour l'ENVIRONNEMENT DU PATIENT données dans la Figure A.9 ont été confirmées dans la pratique.

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NOTE Les dimensions de la figure montrent l'étendue minimale de l'ENVIRONNEMENT DU PATIENT dans un espace libre.

Figure A.9 – Exemple d'ENVIRONNEMENT DU PATIENT

Paragraphe 3.81 – TENSION DE SERVICE CRETE

Cette définition a été tirée de 1.2.9.~~7~~8 de l'IEC 60950-1:~~2001~~2005. Il convient que l'utilisation de ce terme avec le terme défini de TENSION DE SERVICE rende plus facile la compréhension des exigences de COORDINATION DE L'ISOLEMENT tirées de l'IEC 60950-1 pour ceux qui connaissent déjà bien cette norme. Voir également la justification de 3.56.

Paragraphe 3.99 – ISOLATION RENFORCEE

Le terme “système d'isolation” n'implique pas que l'isolation doive être d'une seule pièce homogène. Elle pourrait comprendre plusieurs couches ne pouvant être soumises à l'essai séparément en tant qu'ISOLATION SUPPLEMENTAIRE ou ISOLATION PRINCIPALE.

Paragraphe 3.110 – CIRCUIT SECONDAIRE

Cette définition est fondée sur la définition du même terme en 1.2.8.~~4~~5 de l'IEC 60950-1: ~~2001~~2005, et identifie les circuits soumis à des surtensions provisoires inférieures à la PARTIE RELIEE AU RESEAU et qui présentent par conséquent des valeurs inférieures pour les tensions de tenue d'essai et les DISTANCES DANS L'AIR.

Paragraphe 3.112 – DISPOSITIF DE SEPARATION

L'assemblage d'appareils dans un SYSTEME EM pourrait impliquer des connexions transportant du courant ou des signaux. Dans les deux cas, les mêmes exigences de séparation sont nécessaires.

Paragraphe 3.115 – ENTREE/SORTIE DE SIGNAL

Si une ENTREE/SORTIE DE SIGNAL transporte des signaux électriques, ou si elle transporte des signaux non électriques mais qu'elle implique néanmoins un raccordement conducteur avec

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d'autres appareils (par exemple par l'intermédiaire d'une fibre optique avec gaine métallique), il peut être nécessaire d'installer une séparation appropriée par rapport à d'autres circuits afin de satisfaire aux exigences de la présente norme. Comme alternative, une ENTREE/SORTIE DE SIGNAL pourrait ne pas avoir de raccordements conducteurs, auquel cas elle satisfait automatiquement aux exigences de SECURITE DE BASE électrique.

Paragraphe 3.120 – RESEAU D'ALIMENTATION

Une source d'alimentation externe en courant continu (par exemple dans une ambulance) est considérée comme un RESEAU D'ALIMENTATION. UN APPAREIL EM spécifié pour être raccordé à une alimentation de ce type doit satisfaire à toutes les exigences relatives aux APPAREILS EM alimentés par réseaux. Par le passé, certains APPAREILS EM spécifiés comme ayant une alimentation de ce type avaient une liaison directe entre l'ENVELOPPE et un côté de l'alimentation, supposé être au niveau du potentiel de terre. En cas de coupure du raccordement de ce côté de l'alimentation, l'ENVELOPPE d'un APPAREIL EM de ce type prend en charge le potentiel d'alimentation et dépasse par conséquent la limite spécifiée pour un COURANT DE CONTACT. Les première et deuxième éditions de la présente norme avaient pour objectif d'exclure une telle disposition, mais cela n'a pas toujours été compris par les utilisateurs de la norme. Cette justification a été ajoutée pour clarifier l'exigence.

Paragraphe 3.132 – PARTIE APPLIQUEE DE TYPE B

Les PARTIES APPLIQUEES DU TYPE B procurent le degré le plus bas de protection PATIENT de tous les types de PARTIES APPLIQUEES et ne conviennent pas à une APPLICATION CARDIAQUE DIRECTE.

La ou les CONNEXIONS PATIENT d'une PARTIE APPLIQUEE DE TYPE B pourraient être:

– PROTEGEES PAR MISE A LA TERRE;

– reliées à la terre mais non PROTEGEES PAR MISE A LA TERRE; ou

– flottantes, mais non isolées de la terre au degré exigé pour une PARTIE APPLIQUEE DE TYPE BF.

Paragraphe 3.133 – PARTIE APPLIQUEE DE TYPE BF

Les PARTIES APPLIQUEES DE TYPE BF assurent un degré de protection PATIENT supérieur à celui procuré par les PARTIES APPLIQUEES DE TYPE B. Ce degré de protection est obtenu en isolant les CONNEXIONS PATIENT des parties reliées à la terre et des autres PARTIES ACCESSIBLES de L'APPAREIL EM, en limitant ainsi l'amplitude du courant qui s'écoulerait à travers le PATIENT, dans l'éventualité où une tension non prévue provenant d'une source externe est reliée au PATIENT, et de ce fait appliquée entre les CONNEXIONS PATIENT et la terre. Toutefois, les PARTIES APPLIQUEES DU TYPE BF ne conviennent pas à une APPLICATION CARDIAQUE DIRECTE.

Paragraphe 3.134 – PARTIE APPLIQUEE DE TYPE CF

Les PARTIES APPLIQUEES DU TYPE CF procurent le degré le plus élevé de protection PATIENT. Ce degré de protection est obtenu en augmentant l'isolation de la CONNEXION PATIENT par rapport aux parties reliées à la terre et aux autres PARTIES ACCESSIBLES de l'APPAREIL EM, en limitant davantage l'intensité de courant qui pourrait s'écouler à travers le PATIENT. Les PARTIES APPLIQUEES DU TYPE CF conviennent à une APPLICATION CARDIAQUE DIRECTE dans la mesure où le COURANT DE FUITE PATIENT est concerné, bien qu'elles puissent ne pas convenir à d'autres égards, tels que la stérilité ou la biocompatibilité.

Paragraphe 3.139 – TENSION DE SERVICE

Cette définition a été tirée de 1.2.9.6 de l'IEC 60950-1:~~2001~~2005. L'utilisation de ce terme avec le terme défini de TENSION DE SERVICE DE CRETE devrait rendre plus facile la compréhension des exigences de COORDINATION DE L'ISOLEMENT tirées de l'IEC 60950-1 pour ceux qui connaissent déjà bien cette norme. Voir également la justification de 3.56.

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Paragraphe 4.1 – Conditions d'application aux appareils em et systèmes em

~~La condition d'application de la gestion des risques aux appareils em et systèmes em inclut le mauvais usage raisonnablement previsible. Le fabricant identifie le mauvais usage raisonnablement previsible dans le cadre de l'analyse des risques (voir 4.2 de l'ISO 14971:2000). Cette identification pourrait inclure les résultats du processus d'ingénierie d'aptitude à l'utilisation.~~

La condition d'application de la GESTION DES RISQUES aux APPAREILS EM et aux SYSTEMES EM inclut le mauvais usage raisonnablement prévisible. Le FABRICANT identifie le mauvais usage raisonnablement prévisible au cours de l'ANALYSE DU RISQUE (voir 4.2). Cette identification pourrait inclure les résultats d'un PROCESSUS d'INGENIERIE D'APTITUDE A L'UTILISATION.

Paragraphe 4.2 – PROCESSUS de GESTION DES RISQUES pour APPAREILS EM et SYSTEMES EM

L'une des modifications introduites dans la troisième édition de la présente norme réside dans le fait que, dans le cadre de la spécification des exigences de SECURITE DE BASE minimales et de PERFORMANCES ESSENTIELLES, des dispositions ont été prises pour l'évaluation de la pertinence du PROCESSUS de conception lorsque celui-ci fournit une alternative appropriée aux essais en laboratoire avec des critères de réussite/échec spécifiques (par exemple lors de l'évaluation de la sécurité de nouvelles technologies). L'application de ce principe conduit à l'introduction d'une exigence générale prévoyant un PROCESSUS de GESTION DES RISQUES dans le cadre de la démonstration de la conformité à la présente norme.

Il est de la responsabilité du FABRICANT de s'assurer que la conception et la construction de l'APPAREIL EM lui permettent d'être adapté à son UTILISATION PREVUE et que tout RISQUE associé à son utilisation soit acceptable lorsqu'il est comparé aux avantages. L'ISO 14971 spécifie une PROCEDURE ~~permettant~~ pour permettre au FABRICANT d'identifier les DANGERS associés à L'APPAREIL EM ou au SYSTEME EM et à ses ~~accessoires~~ ACCESSOIRES, afin d'estimer et d'évaluer les RISQUES associés à ces DANGERS, et de maîtriser ces ~~RISQUES et de surveiller l'efficacité de cette maîtrise~~.

Le domaine d'application de la présente norme est limité à l'examen de type de l'APPAREIL EM et des SYSTEMES EM; il ne s'étend pas à la surveillance du cycle de vie. Pour cette raison, la surveillance des informations de production et de post-production et leur planification, comme requises par l'ISO 14971:2007, sont exclues du PROCESSUS de GESTION DES RISQUES décrit dans la présente norme. L'exigence de l'ISO 14971:2007 de revue périodique de l'adaptabilité du PROCESSUS de GESTION DES RISQUES est exclue également.

La conformité avec les articles de la présente norme qui contiennent des exigences spécifiques, vérifiables est présumée réduire le ou les RISQUES associés à un niveau acceptable.

Il convient que le FABRICANT réalise cette détermination à un niveau système. Il convient que le FABRICANT évalue les RISQUES résultant de l'intégration de composants système séparés dans un seul système. Il est recommandé que cette évaluation inclue tous les aspects des informations échangées entre les composants du système. Même lorsque ces composants sont des composants électriques non EM, le RISQUE potentiel lié à l'intégration de ces composants dans un SYSTEME EM doit être pris en compte. Des exigences supplémentaires concernant l'intégration d'appareils non médicaux dans un SYSTEME EM sont décrites à l'Article 16. Il donne les exigences pour un SYSTEME EM et indique comment les RISQUES associés à l'APPAREIL non EM sont traités.

Il convient de noter que la conformité avec l'ISO 14971 n'exige pas que le FABRICANT ait un système formel de qualité en place.

Ce PROCESSUS de GESTION DES RISQUES donne lieu à un ensemble d'ENREGISTREMENTS et à d'autres documents: le DOSSIER DE GESTION DES RISQUES. La conformité du PROCESSUS de GESTION DES RISQUES est vérifiée par inspection du DOSSIER DE GESTION DES RISQUES.

Dans tous les cas, le FABRICANT doit être considéré comme l'expert concernant le dispositif en développement et les DANGERS associés à son utilisation.

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Lorsque les essais de conformité se font par inspection ou revue du DOSSIER DE GESTION DES RISQUES, seules les parties concernées du DOSSIER DE GESTION DES RISQUES ont besoin d'être revues, par exemple les calculs ou les résultats d'essai des FABRICANTS ou la détermination de l'acceptabilité des RISQUES.

Certaines exigences de la présente norme utilisent le terme RISQUE inacceptable, d'autres le terme SITUATION DANGEREUSE. Tous les RISQUES inacceptables résultent d'une SITUATION DANGEREUSE, toutes les SITUATIONS DANGEREUSES ne donnent pas lieu à un RISQUE inacceptable.

C'est la règle suivante qui a été utilisée pour décider ~~du terme~~ de l'expression à utiliser dans une exigence.

~~– RISQUE inacceptable est utilisé lorsque le FABRICANT doit, ou est autorisé à, juger de l'acceptabilité du RISQUE. Ce jugement doit être étayé par une justification appropriée comme l'expérience, des données historiques, etc.~~

~~– SITUATION DANGEREUSE est utilisé lorsque la possibilité de DOMMAGE détermine si certaines exigences s'appliquent. Dans ces cas, la seule détermination à faire par un FABRICANT est celle de l'existence ou non d'une SITUATION DANGEREUSE; cette détermination est faite sans tenir compte du RISQUE résultant de cette SITUATION DANGEREUSE.~~

~~– Le terme DANGER est utilisé lorsque le DANGER n'est pas nécessairement exposé.~~

– L'expression "aucun RISQUE inacceptable" est utilisée lorsque le FABRICANT doit ou est autorisé à porter un jugement sur l'acceptabilité du RISQUE. Ce jugement doit être étayé par une justification appropriée comme l'expérience, des données historiques, etc.

– L'expression "aucune SITUATION DANGEREUSE" est utilisée lorsque le FABRICANT doit démontrer (au moyen d'un dessin technique ou d'une description technique, par exemple) qu'il n'existe aucune exposition à un DANGER ou qu'aucune possibilité de DOMMAGE ne peut se développer. Dans ces cas, la seule détermination que doit réaliser un FABRICANT est de savoir s'il existe ou non une SITUATION DANGEREUSE; cette détermination est réalisée indépendamment de l'acceptabilité du RISQUE qui pourrait se développer à partir de cette SITUATION DANGEREUSE.

– L'expression "aucun DANGER" n'est jamais utilisée.

On trouvera ci-dessous des lignes directrices relatives à la manière d'utiliser divers éléments du PROCESSUS de GESTION DES RISQUES tel que défini dans l'ISO 14971 dans le contexte de l'IEC 60601-1.

– **UTILISATION PREVUE:** L'UTILISATION PREVUE est déterminée au plus haut niveau de l'APPAREIL EM ou du SYSTEME EM et il convient qu'elle soit utilisée dans l'identification des DANGERS ou SITUATIONS DANGEREUSES relatifs à l'utilisation de l'APPAREIL EM ou du SYSTEME EM. L'UTILISATION PREVUE n'est pas (ou très rarement) utilisée dans l'évaluation de composants spécifiques. De plus, l'UTILISATION PREVUE est la donnée principale lorsqu'on détermine quels aspects des fonctions cliniques de l'APPAREIL EM ou du SYSTEME EM constituent la PERFORMANCE ESSENTIELLE telle que requise par 4.3.

– **Identification des DANGERS:** La présente norme et l'ISO 14971 exigent une identification de tous les DANGERS et SITUATIONS DANGEREUSES associés aux APPAREILS EM ou aux SYSTEMES EM, que cette identification soit effectuée ou non dans une norme de sécurité internationale (voir 4.2.2, Note 1, et 4.2.3.2). Cela est valable pour l'UTILISATION NORMALE, pour un mauvais usage raisonnablement prévisible et pour des CONDITIONS DE PREMIER DEFAUT. Toutefois, lorsque des DANGERS ou SITUATIONS DANGEREUSES identifiés dans la présente norme ne peuvent pas apparaître pour l'APPAREIL EM ou SYSTEME EM spécifique, l'identification des DANGERS sera effectuée seulement pour documenter le fait que les exigences correspondantes de la présente norme ne s'appliquent pas. Dans ce cas, une EVALUATION DES RISQUES ou une VERIFICATION supplémentaire de conformité n'est pas exigée. Lorsqu'une exigence s'applique, aucune identification des DANGERS n'est nécessaire (puisque la norme l'a déjà effectuée). Par exemple, aucun DANGER de choc électrique n'apparaît dans les APPAREILS EM ne comportant pas de tensions capables de produire des COURANTS DE FUITE dépassant les limites applicables telles que spécifiées en 8.4.2 c).

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– **EVALUATION DES RISQUES:** Le RISQUE est évalué à deux moments dans le PROCESSUS de GESTION DES RISQUES - avant et après la mise en application de mesures de MAITRISE DU RISQUE. L'évaluation avant la mise en application de mesures de MAITRISE DU RISQUE est applicable aux exigences de la présente norme seulement afin de montrer que le RISQUE associé est acceptable sans l'application d'une exigence. Toutefois, lorsque la présente norme exige que les RISQUES concernés par une exigence spécifique restent acceptables ou qu'aucun RISQUE inacceptable n'apparaisse en relation avec une exigence spécifique, la conformité est vérifiée par l'inspection du DOSSIER DE GESTION DES RISQUES pour les DANGERS ou SITUATIONS DANGEREUSES liés à cette exigence et pour la PREUVE TANGIBLE (par exemple, au moyen des calculs du FABRICANT, d'analyses ou de résultats d'essais) que les RISQUES correspondants sont jugés acceptables en se fondant sur les critères du fabricant pour l'acceptabilité du RISQUE. L'efficacité des mesures de MAITRISE DU RISQUE est évaluée conformément au paragraphe 6.3 de l'ISO 14971:2007.

– **Réduction du RISQUE:** Lorsqu'une exigence de la présente norme exige une mise en application de mesures de maitrise du risque spécifiques pour garantir que le RISQUE associé est acceptable, la conformité est vérifiée par l'une des deux actions suivantes:

  - soit en garantissant que les mesures spécifiques ont été mises en application, auquel cas aucune GESTION DES RISQUES ni aucune évaluation du RISQUE RESIDUEL ne sont exigées du fait que les RISQUES sont présumés être réduits à un niveau acceptable par la présence des mesures spécifiques (satisfaisant aux exigences objectives de la présente norme,
  - soit par l'inspection du DOSSIER DE GESTION DES RISQUES pour les DANGERS ou SITUATIONS DANGEREUSES identifiés dans l'exigence en l'absence des mesures spécifiées par l'exigence et pour la PREUVE TANGIBLE (par exemple, au moyen des calculs du FABRICANT, d'analyses ou de résultats d'essais) que les RISQUES correspondants sont jugés acceptables.

  Les paragraphes 7.2.2 pour les composants non fixés à demeure et 7.2.17 pour l'emballage de protection sont des exemples pour lesquels des marquages spéciaux sont exigés, à moins qu'aucun RISQUE inacceptable n'apparaisse. Ainsi, soit les marquages doivent être apposés, soit les RISQUES en l'absence de ces marquages doivent être évalués et jugés acceptables. Un autre exemple est 15.4.1 a), pour la conception et la construction des fiches des connecteurs.

– **Analyse des RISQUES/avantages:** Une analyse des RISQUES/avantages conformément au paragraphe 6.5 de l'ISO 14971:2007 n'est exigée que lorsque le RISQUE RESIDUEL associé à un DANGER ou SITUATION DANGEREUSE spécifique reste inacceptable en utilisant les critères d'acceptabilité du RISQUE mentionnés dans le plan de GESTION DES RISQUES et qu'une MAITRISE DU RISQUE supplémentaire n'est pas réalisable en pratique. De telles analyses des RISQUES/avantages ne sont pas exigées lorsque les RISQUES RESIDUELS sont jugés acceptables ou lorsque l'APPAREIL EM ou le SYSTEME EM est conforme aux exigences spécifiques de la présente norme. Le paragraphe 11.1.2 est l'un des quelques exemples dans lesquels une analyse des RISQUES/avantages est exigée lorsque des limites de température sont dépassées afin d'atteindre un objectif clinique (voir Tableau 24, note[b]).

Paragraphe 4.3 – PERFORMANCE ESSENTIELLE

~~Le concept de la "sécurité" a été élargi par rapport aux considérations de SECURITE DE BASE des première et deuxième éditions de la présente norme afin d'inclure les questions relatives à la PERFORMANCE ESSENTIELLE (par exemple la précision des appareils de surveillance physiologique). L'application de ce principe entraîne une modification du titre, qui passe de "Sécurité des appareils électromédicaux, Partie 1: Règles générales de sécurité" dans la seconde édition, à "Appareils électromédicaux, Partie 1: Exigences générales pour la sécurité de base et les performances essentielles".~~

~~Pour une explication de PERFORMANCE ESSENTIELLE, voir la justification de 3.27.~~

Au cours de l'ANALYSE DU RISQUE initiale, le FABRICANT identifie la performance des fonctions cliniques de l'APPAREIL EM ou du SYSTEME EM nécessaires pour atteindre l'UTILISATION PREVUE.

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Le FABRICANT identifie également d'autres caractéristiques qualitatives et quantitatives qui pourraient affecter la sécurité de l'APPAREIL EM ou du SYSTEME EM.

Les limites de performance spécifiées par le FABRICANT peuvent se trouver n'importe où dans la plage complète des performances prévues en CONDITION NORMALE et en CONDITION DE PREMIER DEFAUT, allant jusqu'à aucune performance.

Le FABRICANT détermine ensuite si la perte ou la défaillance de la performance dans les limites spécifiées entraînerait un RISQUE pour le PATIENT. L'estimation est souvent réalisée en supposant que la performance en question a été perdue ou dégradée au-delà des limites spécifiées (c.à.d. P_1 sur la Figure A.8 est égal à 100 %). Le FABRICANT tient compte de la probabilité d'une SITUATION DANGEREUSE conduisant à un DOMMAGE (P_2 sur la Figure A.8) ainsi que de la GRAVITE de ce DOMMAGE. Dans quelques cas, il arrive que P_2 soit aussi égal à 100 %, auquel cas l'estimation du RISQUE est basée entièrement sur la GRAVITE du DOMMAGE. Lorsque l'on considère le RISQUE associé à un niveau de performance dégradé, pouvant inclure une perte totale, il convient que l'analyse inclut les mesures prévues telles que prescrites dans les DOCUMENTS D'ACCOMPAGNEMENT, ce qui pourrait faire revenir tout ou partie de la performance après un délai incluant l'entretien de l'APPAREIL EM ou du SYSTEME EM, ou faire revenir tout ou partie des soins médicaux du PATIENT à l'aide de mesures de soins médicaux de secours.

Le FABRICANT évalue ensuite le RISQUE au moyen de ses critères d'acceptation de RISQUE établis. Si le RISQUE est inacceptable, alors la performance identifiée est une PERFORMANCE ESSENTIELLE puisque la réduction du RISQUE est requise pour obtenir un niveau acceptable du RISQUE RESIDUEL.

Lorsque la PERFORMANCE ESSENTIELLE est identifiée, le FABRICANT met en place les mesures de MAITRISE DU RISQUE qui sont appropriées pour réduire le RISQUE à un niveau acceptable. Lorsqu'il choisit l'analyse de MAITRISE DU RISQUE, le FABRICANT doit suivre l'ordre de priorité indiqué dans l'ISO 14971, à savoir:

a) la sécurité intrinsèque de par la conception;

b) les mesures de protection;

c) les informations de sécurité.

Les mesures de MAITRISE DU RISQUE sélectionnées doivent être raisonnablement praticables et cohérentes avec la technologie généralement acceptée. Par exemple, il pourrait être possible de construire un insufflateur de soins critiques qui continue de fonctionner en présence de la défaillance d'un seul composant, mais, étant donnée la technologie généralement acceptée, ce n'est pas praticable. Par conséquent, le FABRICANT peut se fier à une mesure de protection, par exemple un SYSTEME D'ALARME, pour alerter l'OPERATEUR de la défaillance afin que l'OPERATEUR puisse entreprendre à temps les actions appropriées pour empêcher le début du DOMMAGE. Le SIGNAL D'ALARME couplé à la formation requise de l'OPERATEUR peut représenter une mesure de MAITRISE DU RISQUE adéquate pour réduire le RISQUE naissant de la perte ou de la dégradation de la performance identifiée à un niveau acceptable, c.à.d. pour que le RISQUE RESIDUEL soit acceptable. Ces mesures de MAITRISE DU RISQUE peuvent faire partie intégrante de la considération des PERFORMANCES ESSENTIELLES.

Bien entendu, la mesure de MAITRISE DU RISQUE doit être suffisamment indépendante pour que la condition qui entraîne la perte ou la dégradation de la performance identifiée ne compromette pas l'efficacité de la mesure de MAITRISE DU RISQUE. Ceci est cohérent avec la philosophie des deux MOYENS DE PROTECTION employée dans la série IEC 60601. Par exemple, un SYSTEME D'ALARME destiné à alerter l'OPERATEUR que le RESEAU D'ALIMENTATION est coupé ne peut pas dépendre du RESEAU D'ALIMENTATION comme seule source d'alimentation. Une batterie de secours peut être utilisée pour alimenter le SYSTEME D'ALARME si le RESEAU D'ALIMENTATION est coupé.

Dans la MAITRISE DU RISQUE, le temps est crucial. Si le temps à partir du début de l'événement (coupure du RESEAU D'ALIMENTATION) est insuffisant pour que l'OPERATEUR enregistre le fait

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qu'une CONDITION D'ALARME s'est produite et entreprenne les actions appropriées pour empêcher le début du DOMMAGE, alors le SYSTEME D'ALARME seul n'est pas une mesure de MAITRISE DU RISQUE efficace. Une source d'alimentation de secours pour conserver l'APPAREIL EM en état de marche suffisamment longtemps pour que l'OPERATEUR exécute l'action corrective nécessaire pourrait également être requise.

Comme pour tous les aspects du PROCESSUS de GESTION DES RISQUES, l'identification de la PERFORMANCE ESSENTIELLE peut être itérative. Le FABRICANT peut devoir réexaminer le processus de détermination de ce qu'est une PERFORMANCE ESSENTIELLE au cours de la durée de vie de l'APPAREIL EM ou du SYSTEME EM.

Voir également la justification de 3.27.

Paragraphe 4.4 – DUREE DE VIE PREVUE

La DUREE DE VIE PREVUE est la période pendant laquelle l'APPAREIL EM ou le SYSTEME EM est censé rester adapté à son UTILISATION PREVUE. C'est aussi la période pendant laquelle toutes les mesures de MAITRISE DU RISQUE doivent rester effectives afin d'assurer que les RISQUES restent acceptables.

La DUREE DE VIE PREVUE doit être déterminée par le FABRICANT, dans le cadre du PROCESSUS de GESTION DES RISQUES, comme une condition préalable à l'évaluation de la conformité à de nombreuses exigences de la présente norme, comme 4.5, 4.7, 7.1.3, 8.6.3, 9.8.2 et 11.6.6.

Dans les DOCUMENTS D'ACCOMPAGNEMENT, il convient que le FABRICANT fournisse des informations permettant à l'ORGANISME RESPONSABLE d'évaluer le moment où l'APPAREIL EM approche de la fin de sa vie. Il convient que de telles informations incluent la DUREE DE VIE PREVUE telle qu'elle est déterminée par le FABRICANT (par exemple en termes d'années de service ou de nombre d'utilisations) mais elles pourraient aussi inclure des essais à effectuer dans le cadre de la maintenance préventive ou d'autres critères pour permettre à L'ORGANISME RESPONSABLE de réaliser une détermination appropriée. Il convient de traiter le besoin d'informations de ce type et la méthode de présentation appropriée dans le cadre du PROCESSUS de GESTION DES RISQUES.

En définissant la DUREE DE VIE PREVUE, il convient que le FABRICANT présume que l'ORGANISME RESPONSABLE suivra les instructions du FABRICANT pour les opérations d'entretien. Voir 7.9.2.13.

Paragraphe 4.5 – ~~Sécurité équivalente~~ Mesures de MAITRISE DU RISQUE ou méthodes d'essai alternatives pour les APPAREILS EM ~~et~~ ou les SYSTEMES EM

~~Ce paragraphe permet d'utiliser différents moyens de parvenir à un niveau équivalent de sécurité. Cela est important dans la mesure où cela permet à un FABRICANT d'utiliser des solutions innovantes, susceptibles d'être plus sûres ou qui pourraient avoir d'autres avantages, par exemple au niveau des coûts ou des performances.~~

~~Il convient que la documentation dans le DOSSIER DE GESTION DES RISQUES montre que le RISQUE RESIDUEL obtenu en utilisant les moyens alternatifs est acceptable car il est inférieur ou égal au RISQUE RESIDUEL obtenu en appliquant les exigences de la présente norme.~~

~~Si le RISQUE RESIDUEL est supérieur au RISQUE RESIDUEL obtenu en appliquant les exigences de la présente norme, les APPAREILS EM et les SYSTEMES EM ne peuvent pas être considérés comme conformes à la présente norme même si le RISQUE RESIDUEL est complètement justifié par d'autres considérations comme le bénéfice clinique pour le PATIENT.~~

Ce paragraphe permet que des moyens alternatifs à ceux qui sont spécifiés dans la présente norme servent à la sécurité. Ceci est important car cela permet à un FABRICANT d'utiliser des solutions innovantes qui sont sûres et qui peuvent présenter d'autres avantages, par exemple un coût moindre ou une meilleure capacité de fabrication.

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Du fait qu'il est souvent difficile de déterminer un sentiment d'acceptabilité du RISQUE pour une mesure individuelle de MAITRISE DU RISQUE ou une méthode d'essai, le FABRICANT est autorisé à utiliser des données scientifiques, des opinions cliniques ou des études comparatives au cas par cas pour établir que le RISQUE RESIDUEL résultant de l'application d'une mesure alternative reste acceptable.

Il convient que la documentation du DOSSIER DE GESTION DES RISQUES montre que le RISQUE RESIDUEL obtenu à l'aide des moyens alternatifs reste acceptable et est comparable à celui de la présente norme. Il convient que les études comparatives tiennent compte des études scientifiques référencées dans la présente norme et applicables aux moyens alternatifs.

Paragraphe 4.6 – Parties d'APPAREILS EM et SYSTEMES EM qui viennent au contact du PATIENT

Une partie qui entre involontairement en contact avec un PATIENT inconscient, anesthésié ou immobilisé peut présenter les mêmes RISQUES qu'une PARTIE APPLIQUEE qui vient nécessairement en contact avec le PATIENT. D'autre part, une partie pouvant être atteinte et touchée par un PATIENT actif peut ne pas présenter plus de RISQUE pour ce PATIENT que pour un OPERATEUR.

La définition de la PARTIE APPLIQUEE dans la première et la seconde éditions n'avait pas abordé ce problème. Le second amendement de la deuxième édition a élargi la définition pour inclure les parties qui peuvent venir en contact avec le PATIENT, mais la nouvelle définition posait toujours problème.

Dans la mesure où la présente norme exige maintenant l'application d'un PROCESSUS de GESTION DES RISQUES, il est approprié d'utiliser ce PROCESSUS pour déterminer s'il convient de soumettre ces parties aux exigences relatives aux PARTIES APPLIQUEES.

L'exclusion d'exigences relatives au marquage reflète la majorité des opinions des Comités nationaux ayant répondu à une enquête sur ce sujet au cours de l'élaboration de la présente édition. Les OPERATEURS pourraient être induits en erreur si des parties non destinées à être des PARTIES APPLIQUEES comportaient un marquage identique à celui des PARTIES APPLIQUEES.

Les parties identifiées comme devant être soumises aux exigences relatives aux PARTIES APPLIQUEES (excepté pour le marquage) seront généralement moins en contact avec les PATIENTS que les PARTIES APPLIQUEES, et les avantages d'une séparation électrique d'avec la terre seront donc moindres. Cependant, dans certains cas, ces parties peuvent devoir satisfaire aux exigences applicables aux PARTIES APPLIQUEES DE TYPE BF ou aux PARTIES APPLIQUEES DE TYPE CF afin de fournir un niveau approprié de sécurité.

Paragraphe 4.7 – CONDITION DE PREMIER DEFAUT pour les APPAREILS EM et SYSTEMES EM

L'exigence selon laquelle un APPAREIL EM est SECURISE EN PREMIER DEFAUT fixe effectivement une limite plus basse de probabilité de DOMMAGE provenant d'un DANGER. Si cette probabilité est tenue, le RISQUE présenté par le DANGER est acceptable. Dans tous les cas où cette discussion fait référence à la GRAVITE ou à la probabilité d'un DANGER particulier, cela se rapporte à la probabilité ou à la SEVERITE du DOMMAGE résultant de ce DANGER.

SECURISE EN PREMIER DEFAUT est un concept issu de l'approche de premier défaut décrite dans l'IEC/TR 60513 [12]. SECURISE EN PREMIER DEFAUT est une caractéristique de l'APPAREIL EM qui garantit la SECURITE DE BASE pendant sa DUREE DE VIE PREVUE. Pour un DOMMAGE de GRAVITE élevée, l'application du PROCESSUS de GESTION DES RISQUES peut mener à la conclusion selon laquelle le concept de premier défaut n'arrive pas à un RISQUE inacceptable.

La probabilité de l'apparition simultanée de deux défauts distincts est considérée comme assez faible pour être négligeable sous réserve

a) qu'un premier défaut provoque le fonctionnement d'un dispositif de protection (par exemple un fusible, un DISJONCTEUR, un écran de sécurité, etc.) qui empêche l'apparition d'un DANGER, ou

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b) qu'un premier défaut soit décelé à l'aide d'un signal nettement discernable, non susceptible d'une fausse interprétation et s'imposant avec évidence à l'OPERATEUR, ou

c) qu'un premier défaut soit décelé et réparé grâce à l'inspection périodique et à l'entretien prescrits dans les instructions d'utilisation. Il existe une probabilité finie qu'un deuxième défaut puisse survenir avant le prochain cycle d'inspection et de maintenance prévu. Comme dans le cas a) ci-dessus, pour que la probabilité de cette condition de double défaut soit négligeable, la probabilité de chaque défaut doit être faible. Cela signifie que la fréquence d'inspection et de maintenance doit être élevée par rapport à la probabilité d'apparition prévue du défaut. Plus longtemps une CONDITION DE PREMIER DEFAUT demeure présente avant d'être décelée et rectifiée, plus grande est la probabilité d'apparition d'un deuxième défaut. Par conséquent, le FABRICANT pourrait devoir considérer le temps de détection de manière explicite par rapport à l'apparition d'un deuxième défaut potentiel comme partie intégrante de l'ANALYSE DES RISQUES.

Exemples non exclusifs pour les catégories de a) à c):

– ISOLATION RENFORCEE ou DOUBLE ISOLATION;
– APPAREIL EM DE LA CLASSE I en cas de défaut dans l'ISOLATION PRINCIPALE;
– indications anormales des affichages, défaut dans un câble de suspension redondant provoquant un bruit ou une friction excessifs;
– détérioration d'un conducteur de terre de protection souple qui est déplacé en UTILISATION NORMALE.

Paragraphe 4.8 – Composants des APPAREILS EM

Résistances effectuant le contournement d'un MOYEN DE PROTECTION

Une résistance ou un groupe de résistances connectées en série (au moins deux) peuvent effectuer le contournement d'un ou deux MOYENS DE PROTECTION (MOOP ou MOPP), en stipulant que ce qui suit est observé:

– la résistance ou le groupe de résistances a une valeur nominale de tension de deux fois la valeur de la TENSION DE SERVICE à travers le MOYEN DE PROTECTION;
– la résistance ou le groupe de résistances peut supporter des essais de tension de tenue conformément à 8.8.3 et en considérant les tensions transitoires prévues auxquelles le(s) composant(s) sera(seront) soumis pendant une UTILISATION NORMALE au cours de la DUREE DE VIE PREVUE;
– la résistance ou le groupe de résistances a une valeur nominale de puissance de deux fois celle prévue en UTILISATION NORMALE;
– la résistance ou le groupe de résistances a une valeur de résistance telle que les exigences de COURANT DE CONTACT, de COURANT DE FUITE PATIENT et de COURANT AUXILIAIRE PATIENT ne sont pas dépassées;
– la résistance ou le groupe de résistances a une construction qui préserve les exigences de séparation de MOP pour la LIGNE DE FUITE et la DISTANCE DANS L'AIR (pour un groupe en série, la séparation au niveau de chaque composant est additive, ce qui réalise la séparation requise);
– la résistance ou le groupe de résistances est construit de telle manière que son inductance est faible;
– la résistance ou le groupe de résistances a une construction qui ne peut pas connaître de défaillance de court-circuit; et
– lorsqu'on utilise un groupe de résistances, elles ont toutes nécessairement la même valeur de résistance et l'exigence de doublement de la tension et de la puissance s'applique aussi à chaque composant sur la base de la TENSION DE SERVICE PREVUE à travers cette résistance en UTILISATION NORMALE.

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Paragraphe 4.9 – Usage de COMPOSANTS AUX CARACTERISTIQUES A HAUTE FIABILITE pour des APPAREILS EM

La première étape pour déterminer un COMPOSANT AUX CARACTERISTIQUES A HAUTE FIABILITE consiste à réaliser une ANALYSE DE RISQUES pour trouver les caractéristiques qui sont nécessaires pour maintenir la SECURITE DE BASE ou les PERFORMANCES ESSENTIELLES. Cela étant fait, le composant approprié peut être sélectionné. Il peut être fait référence aux normes IEC de composants comme élément de la détermination des caractéristiques nécessaires.

Les ESSAIS DE TYPE des COMPOSANTS AUX CARACTERISTIQUES A HAUTE FIABILITE ne constituent qu'une partie de la détermination d'adéquation exigée. Etant donné qu'un COMPOSANT AUX CARACTERISTIQUES A HAUTE FIABLITE particulier doit fonctionner comme prévu sous peine de DANGER, des considérations supplémentaires incluent, selon le cas:

– la surveillance continue dans le cadre du PROCESSUS de construction et également après assemblage dans le produit final;
– les caractéristiques particulières du dispositif concerné;
– les essais de lots;
– l'étalonnage;
– le contrôle des défauts de construction;
– la maintenance;
– la DUREE DE VIE PREVUE de l'appareil;
– l'utilisation des normes de composants applicables;
– les caractéristiques du mode de défaillance;
– les conditions d'environnement;
– la mauvaise utilisation prévue de l'appareil;
– l'interaction avec d'autres appareils.

Paragraphe 4.10 – Source d'alimentation

On considère en pratique qu'une tension alternative est sinusoïdale si toute valeur instantanée de la forme d'onde concernée diffère simultanément de la valeur instantanée de la forme d'onde idéale d'une valeur inférieure ou égale à ± 5 % de la valeur crête de la forme d'onde idéale.

On considère qu'un système de tensions polyphasées est symétrique lorsque, ni la grandeur de ses composantes de séquence négative, ni celle de ses composantes de séquence zéro ne dépasse de 2 % la grandeur de ses composantes de séquence positive.

On considère qu'un système d'alimentation polyphasé est symétrique si, lorsqu'il est alimenté par un système de tension symétrique, le système de courant produit est symétrique, c'est-à-dire que ni la grandeur des composantes du courant de séquence négative, ni celle de ses composantes de séquence zéro ne dépasse de 5 % la grandeur de ses composantes de séquence positive.

Article 5 – Exigences générales relatives aux essais des APPAREILS EM

Dans un APPAREIL EM, il pourrait y avoir plusieurs éléments d'isolation, composants (électriques et mécaniques) et caractéristiques de construction pour lesquels une défaillance ne créera pas un DANGER pour le PATIENT, l'OPERATEUR ou l'entourage, même si elle provoque une détérioration ou un fonctionnement défectueux de l'APPAREIL EM.

Paragraphe 5.1 – ESSAIS DE TYPE

Le PROCESSUS de GESTION DES RISQUES identifie les mesures de MAITRISE DU RISQUE nécessaires pour garantir que l'APPAREIL EM est sûr.

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Sauf spécification contraire dans la présente norme, il convient que les essais ne soient pas répétés. Cela s'applique notamment aux essais de tension de tenue effectués uniquement sur le site du FABRICANT ou en laboratoire.

Afin d'assurer la conformité de chaque APPAREIL EM produit individuellement avec la présente norme, il convient que le FABRICANT ou l'installateur prenne, en cours de montage, à la construction ou à l'installation, toutes les mesures permettant d'assurer que chaque appareil satisfait à toutes les exigences, même s'il n'est pas procédé à la totalité des essais sur chacun des appareils en cours de construction ou d'installation.

De telles mesures pourraient être:

a) des méthodes de production (pour assurer des résultats de fabrication corrects et une qualité constante), dans la mesure où cette qualité serait en rapport avec la sécurité;

b) des essais de production (essais individuels de série) effectués sur chaque appareil produit;

c) des essais de production effectués par prélèvement, dont les résultats justifieraient un degré de confiance suffisant.

Les essais de production n'ont pas à être identiques aux essais de type, mais peuvent être adaptés aux conditions de fabrication et éventuellement comporter moins de RISQUE pour la qualité de l'isolation ou d'autres caractéristiques importantes pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES.

Les essais de production seront bien entendu limités aux réglages (éventuellement déterminés au cours des ESSAIS DE TYPE) reproduisant les conditions les plus défavorables.

Selon la nature de l'APPAREIL EM, les méthodes de production ou les essais pourraient concerner l'isolation critique de la PARTIE REUEE AU RESEAU, des CONNEXIONS PATIENT et l'isolation ou la séparation entre ces parties.

Le COURANT DE FUITE et la tension de tenue peuvent être suggérés comme paramètres d'essai.

Si applicable, la continuité de la mise à la terre de protection peut être un paramètre d'essai essentiel.

Les lignes directrices relatives aux procédures d'essai générales qui peuvent être utilisées avec la présente norme sont données dans le IEC/TR 62354 [59].

La présente norme utilise plusieurs termes pour décrire les conditions de défaut qu'il est possible de rencontrer. Il s'agit de:

CONDITIONS DE PREMIER DEFAUT

La CONDITION DE PREMIER DEFAUT est définie en 3.116 pour décrire les conditions dans lesquelles "un seul moyen de réduction d'un RISQUE est défectueux" ou "une seule condition anormale est présente". Les CONDITIONS DE PREMIER DEFAUT possibles sont énumérées dans la présente norme et peuvent affecter des valeurs vérifiables telles que les LIGNES DE FUITE, les impédances des circuits de mise à la terre, les COURANTS DE FUITE, etc.

Défauts ne conduisant pas à une CONDITION DE PREMIER DEFAUT

Par comparaison avec les CONDITIONS DE PREMIER DEFAUT, la présente norme n'a pas d'exigences vérifiables pour les défauts ne conduisant pas à une CONDITION DE PREMIER DEFAUT. Cela signifie que la présente norme ne donne aucune ligne directrice sur la fiabilité de la prévention des défauts.

Combinaison de défauts indépendants simultanés

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Étant donné qu'il n'y a aucune exigence vérifiable fiable définie dans la présente norme pour la prévention des défauts, il convient d'envisager tous les défauts simultanés possibles conformément à 4.7.

Lorsqu'une CONDITION DE PREMIER DEFAUT reste indétectée (par exemple le contournement d'un MOYEN DE PROTECTION DE L'OPERATEUR), il convient d'envisager d'autres défauts simultanés conformément à 4.7.

NOTE Pour plus de directives, voir l'IEC 60513:1994.

Les cas les plus défavorables de défauts simultanés sont ceux qui produisent les résultats les plus dangereux. La formulation de la présente norme est utilisée pour éviter de mener tous les essais possibles de défauts simultanés, car beaucoup d'entre eux peuvent être couverts par les essais de conditions les plus défavorables.

Paragraphe 5.2 – Nombre de spécimens

Le ou les spécimens utilisés pour les ESSAIS DE TYPE doivent être représentatifs des unités destinées à l'ORGANISME RESPONSABLE.

Paragraphe 5.7 – Traitement en pré-conditionnement humide

Selon l'IEC 60529, l'ENVELOPPE d'APPAREILS EM de catégorie ASSIGNEE IPX8 empêche, dans des conditions définies, la pénétration d'un volume d'eau là où sa présence pourrait entraîner un DANGER.

Les conditions d'essai ainsi que le volume et la localisation acceptables de l'eau sont à définir dans les normes particulières. Si aucune entrée d'eau n'est tolérée (ENVELOPPES scellées), l'application du pré-conditionnement humide est inappropriée.

Les parties sensibles à l'humidité, normalement utilisées dans des environnements contrôlés et qui n'ont pas d'influence sur la ~~sécurité~~ SECURITE DE BASE et les PERFORMANCES ESSENTIELLES n'ont pas besoin d'être soumises à cet essai. Exemples: moyens de stockage à haute densité dans les systèmes informatisés, dispositifs d'entraînement des disques et bandes, etc.

Pour éviter une condensation lors de l'introduction de l'APPAREIL EM dans la chambre humide, il convient que la température de cette chambre soit égale ou légèrement inférieure à la température de l'APPAREIL EM. Pour éviter le recours à un système de stabilisation de la température de l'air ambiant, la température de l'air de la chambre durant le traitement est adaptée à celle de l'air ambiant dans les limites de la plage de +20 °C à +32 °C puis "stabilisée" à la valeur initiale. Bien que l'effet de la température de la chambre sur le degré d'absorption de l'humidité soit reconnu, on estime que la reproductibilité des résultats des essais n'est pas considérablement altérée et que l'économie correspondante est appréciable.

Paragraphe 5.9 – Détermination des PARTIES APPLIQUEES et des PARTIES ACCESSIBLES

Sauf dans des cas spéciaux, tels que les supports PATIENT et matelas à eau, le contact avec l'APPAREIL EM est supposé se faire avec:

– une main, simulée pour les mesures de COURANT DE FUITE par une feuille métallique de 10 cm x 20 cm (ou moins si l'ensemble de l'APPAREIL EM est plus petit);

– un doigt, tendu ou plié dans une position naturelle, simulé par un doigt d'essai pourvu d'une plaque d'arrêt;

– une lame ou tirette pouvant permettre, lorsqu'elle est sortie de son logement, d'y introduire le doigt, simulée par une combinaison du crochet et du doigt d'essai.

Paragraphe 5.9.2.1 – Doigt d'essai

Un CAPOT D'ACCES est une partie de l'ENVELOPPE qui peut être retirée pour permettre l'accès à des parties d'appareils électriques pour leur réglage, leur contrôle, leur remplacement ou leur réparation. On estime que les parties qui peuvent être retirées sans l'aide d'un OUTIL sont destinées à être remplacées par tout OPERATEUR, pas uniquement par le PERSONNEL

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D'ENTRETIEN, même si cela n'est pas décrit dans les instructions d'utilisation. Les OPERATEURS autres que ceux appartenant au PERSONNEL D'ENTRETIEN pourraient ne pas être aussi bien formés ou aussi expérimentés en matière de bonne pratique de sécurité que le PERSONNEL D'ENTRETIEN. C'est la raison pour laquelle des précautions supplémentaires de sécurité sont nécessaires pour éviter tout contact accidentel avec des tensions dangereuses. C'est pourquoi des parties comme les lampes, les fusibles et les portes fusibles qui peuvent être retirées sans l'aide d'un OUTIL doivent être retirées avant de déterminer quelles parties à l'intérieur du CAPOT D'ACCES doivent être considérées comme des PARTIES ACCESSIBLES.

Les portes fusibles dont l'élément de remplacement est maintenu dans un culot qui peut être retiré sans l'aide d'un outil font l'objet d'une attention particulière. Si l'élément de remplacement ne sort pas lorsque le culot est retiré, l'OPERATEUR pourrait être tenté de le retirer en prenant l'extrémité de l'élément avec les doigts. L'OPERATEUR pourrait essayer d'insérer un nouvel élément de remplacement dans l'ensemble porteur sans l'insérer d'abord dans le culot. Ces deux cas peuvent être considérés comme des MAUVAIS USAGES RAISONNABLEMENT PREVISIBLES. Il convient d'en tenir compte pour déterminer les parties qui sont accessibles.

Le lecteur se reportera à l'IEC 60127-6 [7] pour avoir plus d'informations concernant les portes fusibles.

Article 6 – Classification des APPAREILS EM et des SYSTEMES EM

Les APPAREILS EM peuvent avoir plusieurs classifications.

Paragraphe 6.2 – Protection contre les chocs électriques

Le terme “appareil de classe III” est utilisé dans d'autres normes pour identifier les appareils alimentés à partir d'un système d'alimentation réseau à très basse tension de sécurité (TBTS). Le terme "appareil de classe III" n'est pas formellement utilisé dans la présente norme. La SECURITE DE BASE des appareils de la classe III est étroitement conditionnée par l'installation et par les autres appareils de la classe III qui y sont reliés. Ces facteurs échappent au contrôle de l'OPERATEUR, ce qui est considéré comme non acceptable pour un APPAREIL EM. En outre, la limitation de la tension est insuffisante pour assurer la SECURITE du PATIENT. Pour ces raisons, la présente norme exclut les appareils de la classe III.

Paragraphe 6.3 – Protection contre la pénétration dangereuse d'eau ou de particules solides

Il convient de noter que la conformité aux exigences de la présente norme autorisent automatiquement les FABRICANTS à spécifier les APPAREILS EM comme étant classés IP2X car les exigences de l'IEC 60529 pour ces caractéristiques sont les mêmes que les exigences d'accessibilité (voir 5.9).

Paragraphe 6.6 – Mode de fonctionnement

Le SERVICE CONTINU et le service autre que le SERVICE CONTINU couvrent la plage des modes de fonctionnement de pratiquement tous les appareils. Il convient que les APPAREILS EM qui demeurent reliés au RESEAU D'ALIMENTATION de manière continue mais qui fonctionnent de manière intermittente soient ASSIGNES pour un fonctionnement autre qu'en SERVICE CONTINU comportent une indication appropriée des temps de marche/arrêt dans les DOCUMENTS D'ACCOMPAGNEMENT ainsi qu'un marquage approprié (voir 7.2.11).

Paragraphe 7.1.1 – APTITUDE A L'UTILISATION de l'identification, des marquages et DOCUMENTS D'ACCOMPAGNEMENT

Pour qu'un APPAREIL EM soit bien conçu, il convient que ses marquages et ses DOCUMENTS D'ACCOMPAGNEMENT soient clairs, cohérents et aident à réduire les erreurs d'utilisation potentielles. C'est pourquoi il convient que les marquages et les DOCUMENTS D'ACCOMPAGNEMENT subissent la même évaluation rigoureuse que d'autres éléments de l'INTERFACE OPERATEUR-APPAREIL EM.

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Paragraphe 7.1.2 – Lisibilité des marquages

Les marquages des APPAREILS EM sont sensés être CLAIREMENT LISIBLES par L'OPERATEUR pour toute la plage des niveaux d'éclairage normal dans lesquels les APPAREILS EM sont normalement utilisés. Les niveaux utilisés pour cet essai proviennent des niveaux d'éclairage recommandés pour utilisation dans la conception des éclairages intérieurs [51].

– Une valeur de 100 lx à 200 lx est recommandée pour les espaces de travail où des tâches visuelles ne sont réalisées qu'occasionnellement.
– Une valeur de 500 lx à 1 000 lx est recommandée pour les tâches visuelles de faible importance ou pour la lecture d'une écriture manuelle au crayon à pointe moyenne.
– Une valeur de 1 000 lx à 2 000 lx est recommandée pour les tâches visuelles de faible contraste ou de faible importance: par exemple lecture d'une écriture au crayon à pointe forte sur un papier de qualité médiocre.

Si les marquages ne sont pas lisibles par L'OPERATEUR dans les conditions attendues d'utilisation, il existerait un RISQUE inacceptable.

L'angle minimal de résolution (MAR) est une méthode de mesure de l'acuité visuelle développée comme une amélioration de l'échelle de Snellen qui est utilisée depuis longtemps. Les valeurs sont exprimées comme un logarithme de l'angle minimal de résolution. Log MAR peut être calculé à partir de l'échelle de Snellen, c'est-à-dire log MAR = log(6/6) = 0 pour une acuité visuelle normale.

La carte de Jaeger est utilisée pour déterminer la vision de près. N6 correspond à la lecture à une distance de 0,87 m du visage.

Un niveau de luminosité ambiante de 500 lx est recommandé pour effectuer l'examen de l'acuité visuelle.

Si une taille de police minimale recommandée doit être considérée, alors une taille de police lisible est une fonction de la distance de lecture et de l'angle visuel qui en résulte pour l'image de marquage présentée à la rétine de l'œil. Les calculs de l'angle visuel en minutes d'arc sont données dans ANSI/AAMI HE-75:2009 [59], paragraphe 6.2.2.6.5, Tableau 6.2. En utilisant un angle visuel acceptable minimal de 12 minutes d'arc, une taille de police de 9 serait recommandée pour une distance de lecture d'un mètre et une taille de police de 6 pour une distance de lecture typique de 0,7 m.

Paragraphe 7.1.3 – Résistance des marquages

L'essai de frottement est effectué avec de l'eau distillée, ~~des alcools dénaturés~~ de l'éthanol à 96 % et de l'alcool isopropylique.

L'éthanol à 96% est défini comme un réactif dans la Pharmacopée Européenne dans les termes suivants: C_2H_6O (MW46.07).

L'alcool isopropylique est défini comme un réactif dans la Pharmacopée Européenne dans les termes suivants: C_3H_8O (MW60.1).

Paragraphe 7.2.2 – Identification

Ce paragraphe est destiné à s'appliquer à tous les composants détachables lorsqu'une erreur d'identification pourrait ~~présenter un DANGER~~ entraîner une SITUATION DANGEREUSE. Par exemple, des consommables normaux devront probablement être identifiés mais ce ne sera pas nécessaire pour un couvercle de produit cosmétique.

Bien que la REFERENCE DU MODELE OU DU TYPE corresponde habituellement à une certaine spécification de caractéristiques, elle peut ne pas être complètement représentative du produit fini exact, y compris les composants et matériaux utilisés. ~~Si cela est nécessaire,~~ La REFERENCE DU MODELE OU DU TYPE ~~peut devoir être~~ est complétée par un numéro de série ou

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un identifiant de lot. Le numéro de série ou l'identifiant de lot peut être utilisé ~~pour d'autres buts~~ à d'autres fins, telles que la traçabilité au cas où le FABRICANT doit entreprendre une action corrective.

~~La seule indication d'une série de fabrication pourrait ne pas être suffisante si des exigences nationales stipulent une identification individuelle.~~

Il est courant pour un logiciel que différentes versions puissent tourner sur un SEMP. L'identification du logiciel se trouvera souvent sur l'interface utilisateur bien que cela puisse ne pas être possible par exemple lorsque le logiciel n'en possède pas. L'identification du logiciel pourrait nécessiter des outils spécifiques. Pour cette raison, l'exigence autorise que l'identification ne soit disponible qu'à des personnes désignées.

Paragraphe 7.2.3 – Consultation des DOCUMENTS D'ACCOMPAGNEMENT

Il n'est pas prévu qu'à chaque fois que les instructions d'utilisation contiennent des avertissements, l'APPAREIL EM soit marqué du signe ~~IEC 60878 Safety 01~~ ISO 7010-M002 (voir TABLEAU D.2, signe de sécurité 10). Des avertissements trop nombreux et qui ne sont pas nécessaires sont contre-productifs. Ce n'est que lorsque le FABRICANT décide, en tant que mesure de CONTROLE des RISQUES pour un RISQUE spécifique, de marquer l'APPAREIL EM pour indiquer à l'OPERATEUR de lire les instructions d'utilisation, qu'il convient d'utiliser le signe de sécurité ~~IEC 60878 Safety 01~~ ISO 7010-M002.

Paragraphe 7.2.4 – ACCESSOIRES

Les ORGANISMES RESPONSABLES et les OPERATEURS doivent pouvoir identifier les ACCESSOIRES afin de déterminer lesquels peuvent être utilisés sans nuire à la SECURITE DE BASE ou à la PERFORMANCE ESSENTIELLE. Une REFERENCE DU MODELE OU DU TYPE seule est insuffisante, étant donné que des FABRICANTS différents pourraient utiliser le même numéro. Le nom apposé sur l'ACCESSOIRE pourrait être celui du FABRICANT de l'APPAREIL EM ou un nom différent.

Paragraphe 7.2.10 – PARTIES APPLIQUEES

Selon la deuxième édition de la présente norme, le marquage pourrait être apposé, soit sur la PARTIE APPLIQUEE elle-même, soit à un endroit contigu au point de connexion. Aucun des deux emplacements n'est satisfaisant dans tous les cas.

Lorsqu'un conducteur qui n'est pas séparé des CONNEXIONS PATIENT se prolonge jusqu'au point interne de l'APPAREIL EM où se situe une barrière d'isolation, un marquage de TYPE BF ou TYPE CF sur la PARTIE APPLIQUEE elle-même pourrait amener l'ORGANISME RESPONSABLE et/ou l'OPERATEUR à croire que l'isolation est installée dans la PARTIE APPLIQUEE elle-même. D'autre part, si la classification dépend d'une PARTIE APPLIQUEE particulière en utilisation, un seul marquage sur le point de connexion serait inexact et plusieurs marquages prêteraient à confusion.

Dans le cas des PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION, si la protection contre l'effet de la décharge d'un défibrillateur cardiaque est en partie dans le câble PATIENT, un avertissement est nécessaire pour l'OPERATEUR car il existe des ~~dangers qui ne sont pas manifestes~~ SITUATIONS DANGEREUSES qui peuvent ne pas être manifestes si le mauvais câble est utilisé. Ces ~~DANGERS~~ SITUATIONS DANGEREUSES peuvent comprendre la diminution de l'énergie de défibrillation délivrée au PATIENT, les dommages affectant L'APPAREIL EM avec une perte importante des PERFORMANCES ESSENTIELLES ou un choc électrique sur L'OPERATEUR ou d'autres personnes.

Paragraphe 7.2.12 – Fusibles

Des exemples de marquage des fusibles conformes à l'IEC 60127-1 sont:

– T 315L, 250V
– T 315mAL, 250V
– F 1,25H, 250V

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– F 1,25AH, 250V

Il est admis de marquer la vitesse de fonctionnement avec les codes littéraux ou de couleurs de l'IEC 60127-1, comme suit:

– très rapide : FF ou noir ;
– rapide : F ou rouge ;
– temporisé moyen : M ou jaune ;
– temporisé : T ou bleu ;
– temporisé important : TT ou gris

Paragraphe 7.2.21 – Masse de l'APPAREIL EM MOBILE

Un APPAREIL EM MOBILE est destiné à être transporté d'un endroit à un autre sur ses propres roues ou par d'autres moyens équivalents. Pour la sécurité, il est important que l'OPERATEUR connaisse la masse totale de l'APPAREIL EM avec sa CHARGE DE FONCTIONNEMENT EN SECURITE installée. Ceci est important pour déplacer l'APPAREIL EM, et, pour les APPAREILS EM lourds, pour comprendre les éventuelles limitations sur les emplacements où l'APPAREIL EM peut être emmené. L'APPAREIL EM peut posséder des coffres, des étagères ou des tiroirs qui peuvent avoir leurs propres exigences en termes de charge maximale. Le marquage sur l'APPAREIL EM doit être suffisamment séparé et distinct de tout marquage sur les coffres, étagères ou tiroirs pour éviter de perturber l'OPERATEUR quant à l'objet auquel s'applique le marquage.

Paragraphe 7.3.2 – Parties HAUTE TENSION

Les parties HAUTE TENSION présentent un DANGER de choc électrique important pour le PERSONNEL D'ENTRETIEN et d'autres personnes qui pourraient avoir à travailler à l'intérieur de l'APPAREIL EM alors qu'il est sous tension. Du fait que des parties ~~soient~~ sont à l'intérieur de l'ENVELOPPE, le RISQUE est perçu comme substantiellement inférieur à celui des DISPOSITIFS DE RACCORDEMENT HAUTE TENSION situés à l'extérieur de l'APPAREIL EM. C'est pourquoi le symbole "tension dangereuse" (IEC 60417-5036) (~~DB:~~2002-10) (voir Tableau D.1, symbole 24) est autorisé comme marquage pour alerter le PERSONNEL D'ENTRETIEN et d'autres personnes de la présence potentielle de ces tensions dangereuses. Le FABRICANT est autorisé à utiliser ~~un~~ l'ISO 7010-W012 (voir Tableau D.3, signe de sécurité 3). Le PROCESSUS de GESTION DES RISQUES ~~pourrait~~ peut déterminer que le signe de sécurité est le choix le ~~mieux~~ plus approprié ~~si~~ lorsque le personnel exposé au DANGER a suivi une formation minimale ou pourrait sans cela ne pas savoir ~~connaissance qu'il y a présence de~~ qu'une HAUTE TENSION est présente.

Paragraphe 7.3.4 – Fusibles, COUPE-CIRCUITS THERMIQUES ET DISJONCTEURS

Voir la justification de 7.2.12.

Paragraphe 7.3.5 – BORNES DE PROTECTION DE MISE A LA TERRE

La présente norme n'exige pas le marquage des bornes des CONNEXIONS DE TERRE DE PROTECTION mais ne l'exclut pas.

Paragraphe 7.4.1 – Interrupteurs

Lorsqu'un marquage est utilisé pour un interrupteur à bascule, il convient d'utiliser les symboles pour "marche" (|) et "arrêt" (◯) [symboles 12 et 13 du Tableau D.1] pour indiquer qu'il se trouve dans la ou position MARCHE ou ARRET.

Pour un interrupteur à bouton-poussoir, le marquage approprié dépendra du type de l'interrupteur. Pour un interrupteur à bouton-poussoir avec positions bistables, il convient d'utiliser le symbole (⏽) [symbole 14 du Tableau D.1] pour indiquer que les deux positions MARCHE et ARRET sont stables.

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Pour un interrupteur à bouton-poussoir avec position MARCHE momentanée, il convient d'utiliser le symbole () [symbole 15 du Tableau D.1] pour indiquer que l'alimentation réseau n'est appliquée que lorsque le bouton-poussoir est enfoncé. Dès que le bouton est relâché, l'interrupteur repasse en position ARRET stable.

Paragraphe 7.4.2 – Dispositifs de commande

Il convient que les différentes positions des interrupteurs qui commandent les fonctionnalités de l'APPAREIL EM ou d'une partie de l'APPAREIL EM, mais qui ne commandent pas l'alimentation réseau vers l'APPAREIL EM ou une partie de l'APPAREIL EM soient également marquées de manière à indiquer clairement l'état de la fonction de commande. Tout moyen approprié, comprenant des chiffres, des lettres, des témoins lumineux, etc. peut être utilisé. Si le marquage inclut des symboles, les symboles "marche" pour une partie de l'appareil () et " arrêt" pour une partie de l'appareil () [symboles 16 et 17 du Tableau D.1] peuvent être utilisés pour indiquer les positions MARCHE et ARRET.

Un interrupteur ou une position d'interrupteur au moyen duquel ou de laquelle l'APPAREIL EM ou une partie de l'APPAREIL EM est allumé(e) pour le/la placer en état d' "attente" peut être indiqué(e) par le symbole d'attente () [symbole 29 du Tableau D.1]. Ce symbole est requis par l'IEC 60950-1 pour indiquer le mode attente de l'appareil de traitement de l'information couvert par cette norme.

Paragraphe 7.8 – Voyants lumineux et commandes

Voir aussi l'IEC 60073 [5] au sujet des couleurs des voyants lumineux.

Il convient de ne pas utiliser uniquement la couleur pour donner des informations importantes. Un moyen d'information redondant, tel que forme, emplacement, son ou marquage, est recommandé.

Paragraphe 7.9.1 – Généralités

Il est important qu'un APPAREIL EM ou un SYSTEME EM ne soit pas utilisé involontairement dans une application pour laquelle il n'a pas été prévu par son FABRICANT.

Le PROCESSUS D'INGENIERIE D'APTITUDE A L'UTILISATION exige que le fabricant développe des spécifications d'application incluant les environnements d'utilisation prévus. Le FABRICANT doit fournir un résumé de ces spécifications dans les DOCUMENTS D'ACCOMPAGNEMENT. Voir 12.2.

Paragraphe 7.9.2.1 – Généralités

Les ORGANISMES RESPONSABLES et les OPERATEURS doivent fréquemment utiliser différents types d'APPAREILS EM. Du fait de la complexité des APPAREILS EM modernes, les instructions d'utilisation représentent une partie importante de l'APPAREIL EM. Un certain caractère commun de la structure des instructions d'utilisation pourrait aider les OPERATEURS à trouver rapidement et aisément les informations dont ils ont besoin. Toutefois, en raison de la diversité des APPAREILS EM couverts par la présente norme, aucun format ne devra être appliqué de manière identique à l'ensemble des APPAREILS EM. ~~Par conséquent, le FABRICANT est encouragé, mais non contraint, à utiliser l'ordre des sujets de 7.9.2.2 à 7.9.2.16 comme plan d'ensemble pour la rédaction des instructions d'utilisation.~~

Si l'on considère que le PATIENT peut agir comme un OPERATEUR, le FABRICANT doit tenir compte du fait que le niveau de protection offert par la présente norme à l'OPERATEUR peut être différent de celui offert au PATIENT. Par exemple, les niveaux de COURANT DE FUITE acceptables et les valeurs de tension autorisées sont supérieures pour l'OPERATEUR à celles prévues pour le PATIENT. À la place du COURANT DE FUITE PATIENT, un COURANT DE CONTACT peut être appliqué. De plus, l'OPERATEUR peut avoir accès à des tensions allant jusqu'à 42,4 V en valeur de crête en courant alternatif ou 60 V en courant continu.

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Les autres conditions à prendre en compte comprennent les questions suivantes:

– L'APPAREIL EM est-il utilisé sous surveillance ou direction médicale?
– Quel est l'état de santé du PATIENT?
– Quel traitement est-il administré au PATIENT?
– Existe-t-il des considérations particulières d'APTITUDE A L'UTILISATION (voir l'IEC 60601-1-6)?
– L'APPAREIL EM doit-il être utilisé dans les environnements de soins professionnels, dans les environnements domestiques (voir l'IEC 60601-1-11 [59]) ou dans l'environnement des services médicaux d'urgence (voir l'IEC 60601-1-12 [59])?
– Le PATIENT a-t-il accès aux instructions d'utilisation?
– Existe-t-il une formation adéquate pour le PATIENT agissant comme un OPERATEUR?

Le problème des langues utilisées dans les marquages et dans les DOCUMENTS D'ACCOMPAGNEMENT ne peut pas être résolu par l'IEC. L'exigence spécifiant que les identifications et les DOCUMENTS D'ACCOMPAGNEMENT doivent être rédigés dans les langues nationales ne peut pas elle-même être affirmée universellement.

Paragraphe 7.9.2.2 – Avertissement et notices de sécurité

Pour un APPAREIL EM DE CLASSE I pour lequel le fonctionnement à partir d'un RESEAU D'ALIMENTATION ou d'une SOURCE ELECTRIQUE INTERNE est spécifié, il convient que les instructions d'utilisation indiquent que la SOURCE ELECTRIQUE INTERNE doit être utilisée si l'intégrité du CONDUCTEUR DE PROTECTION ou du système de mise à la terre de protection dans l'installation est douteuse.

Paragraphe 7.9.2.6 – Installation

Les instructions d'utilisation peuvent comporter une mention précisant que le FABRICANT, le monteur, l'installateur ou l'importateur ne se considère responsable des effets sur la SECURITE DE BASE, la fiabilité et les caractéristiques d'un APPAREIL EM ou d'un SYSTEME EM seulement si:

– les opérations de montage, les extensions, les réglages, les modifications ou réparations ont été effectués par des personnes correctement formées,
– l'installation électrique du local correspondant est conforme aux exigences appropriées, et si
– l'APPAREIL EM ou LE SYSTEME EM est utilisé conformément aux instructions d'utilisation.

Paragraphe 7.9.2.7 – Isolation du RESEAU D'ALIMENTATION

Une fiche et un socle fournissent un moyen d'isolation approprié par rapport au RESEAU D'ALIMENTATION pour satisfaire 8.11.1 a), mais ils ne seraient pas appropriés s'ils n'étaient pas directement accessibles en cas de nécessité.

Paragraphe 7.9.2.19 – Identifiant unique

Les FABRICANTS publient fréquemment de multiples révisions des instructions d'utilisation. Les ORGANISMES RESPONSABLES et les OPERATEURS doivent pouvoir déterminer si les instructions d'utilisation dont ils disposent sont à jour. Ceci est particulièrement important avec un logiciel SEMP qui peut être mis à jour dans l'environnement d'utilisation. L'indication d'une date de publication est une méthode largement acceptée d'identification des versions d'un document. Le FABRICANT décide du niveau de détails approprié et le mois et l'année sont couramment indiqués sur les documents imprimés. Une plus grande granularité peut toutefois être requise, en particulier pour les documents distribués sous forme électronique. Le FABRICANT peut inclure, le cas échéant, un numéro de révision.

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Paragraphe 7.9.3.1 – Généralités

Selon l'UTILISATION PREVUE de l'APPAREIL EM, il convient que le FABRICANT spécifie les conditions d'environnement admises qui n'entraînent pas de DANGER. Il est prévu de prendre en compte les conditions d'environnement suivantes, entre autres:

– l'effet de l'humidité;
– l'effet de la température;
– l'effet de la pression atmosphérique;
– l'effet des chocs et vibrations;
– l'effet des rayonnements ultraviolets;
– l'effet de la température de l'eau sur les APPAREILS EM refroidis par eau;
– l'effet de la pollution.

Il n'est pas possible de définir l'exactitude et la précision dans la présente norme. Ces notions sont à expliciter dans les normes particulières.

Les valeurs indiquées ci-dessous ont été utilisées dans la deuxième édition de l'IEC 60601-1 pour décrire la gamme des conditions d'environnement dans lesquelles les APPAREILS EM devaient être sûrs:

a) une plage de température ambiante de + 10 °C à + 40 °C;

b) une plage d'humidité relative de 30 % à 75 %;

c) une plage de pression atmosphérique de 70,0 kPa à 106,0 kPa;

d) une température d'eau à l'entrée d'un APPAREIL EM refroidi à l'eau ne dépassant pas 25 °C.

Ces conditions d'environnement étaient fondées sur les conditions qui prévalaient dans des bâtiments sans air conditionné sous des climats où la température ambiante atteignait parfois +40 °C.

Dans la deuxième édition de l'IEC 60601-1, les APPAREILS EM devaient être sûrs lorsqu'ils étaient utilisés dans les conditions ci-dessus mais il était seulement nécessaire qu'ils soient totalement opérationnels dans les conditions spécifiées par le FABRICANT telles qu'indiquées dans les DOCUMENTS D'ACCOMPAGNEMENT.

La présente édition spécifie des conditions d'environnement particulières pour certaines exigences et pour certains essais. Lorsque ce n'est pas le cas, l'APPAREIL EM doit rester sûr et fonctionner correctement sur la gamme des conditions environnementales spécifiées par le FABRICANT telles qu'indiquées dans les DOCUMENTS D'ACCOMPAGNEMENT.

L'attention est attirée sur le fait qu'il y a toujours eu un problème pour l'application de la condition d'environnement de 40 °C à un APPAREIL EM, dans les cas où la PARTIE APPLIQUEE devait fonctionner à des températures proches de la limite de 41 °C.

La deuxième édition de l'IEC 60601-1 spécifiait la plage suivante de conditions d'environnement pour le transport et le stockage des APPAREILS EM, sauf indication contraire du FABRICANT:

– une plage de températures ambiantes comprise entre – 40 °C et + 70 °C ;
– une plage d'humidité relative comprise entre 10 % et 100 %, y compris la condensation ;
– une plage de pression atmosphérique comprise entre 50 kPa et 106 kPa.

L'amendement 2 de la deuxième édition remplaçait la liste indiquée ci-dessus par une exigence stipulant que le FABRICANT indique les conditions de transport et de stockage admissibles. Toutefois, en l'absence d'autres informations, la liste ci-dessus peut servir de point de départ utile pour la détermination des limites admissibles.

Des informations sur les paramètres d'environnement et sur un nombre limité de sévérités associées correspondant à la plage des conditions rencontrées par les produits

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électrotechniques pendant leur transport, leur stockage, leur installation et leur utilisation peuvent être trouvées dans la série IEC 60721 [18].

Pour les APPAREILS EM de grande puissance INSTALLES DE MANIERE PERMANENTE, il pourrait être nécessaire de contrôler la chute de tension dans l'installation du client afin d'éviter que la tension d'entrée ne devienne inférieure à la tension normale minimale, en raison des conditions locales. Le contrôle peut être réalisé en spécifiant l'impédance apparente exigée du RESEAU D'ALIMENTATION.

Paragraphe 7.9.3.4 – Isolation réseau

Le PERSONNEL D'ENTRETIEN a besoin de savoir comment isoler l'APPAREIL EM du RESEAU. Cela n'est pas toujours évident, en particulier s'il existe un interrupteur dans la PARTIE RESEAU qui ne satisfait pas aux exigences de 8.11.

Article 8 – Protection contre les DANGERS d'origine électrique dus aux APPAREILS EM

Le principe fondamental de la protection contre les chocs électriques est que la tension ou le courant entre toute surface accessible et toute autre surface accessible ou la terre soit suffisamment faible de façon à ~~ne présenter aucun DANGER~~ n'entraîner aucune SITUATION DANGEREUSE, dans toutes les circonstances appropriées y compris en CONDITION NORMALE et en CONDITION DE PREMIER DEFAUT.

Les exigences relatives à la réalisation de la protection ont été formulées de différentes façons dans les normes de sécurité fondamentales IEC, dans les éditions précédentes de la présente norme, et dans d'autres normes de produits IEC.

Afin de satisfaire au principe fondamental:

a) les parties “sous tension" (telles que définies dans la deuxième édition de la présente norme) ou "dangereuses sous tension" (telles que définies dans d'autres normes comme l'IEC 61140 [23] et l'IEC 61010-1 [22]) ne doivent pas être accessibles (voir toutefois ci-dessous en ce qui concerne les problèmes d'identification de ce qui est “sous tension”), et

b) les PARTIES ACCESSIBLES y compris les PARTIES APPLIQUEES ne doivent pas être “sous tension" ou dangereuses sous tension.

NOTE Le terme “sous tension” a été défini dans la deuxième édition de la présente norme comme, “l'était d'une pièce qui, lorsqu'une connexion est réalisée avec cette pièce, peut causer un courant dépassant le COURANT DE FUITE admissible (spécifié au paragraphe 19.3) pour la pièce concernée allant de cette pièce à la terre ou de cette pièce à une PARTIE ACCESSIBLE du même APPAREIL.

Ces deux exigences sont en principe équivalentes mais certaines normes les mentionnent toutes les deux.

Ces exigences impliquent à leur tour que:

c) les PARTIES ACCESSIBLES y compris les PARTIES APPLIQUEES doivent être séparées de certaines parties internes sous tension: généralement deux MOYENS DE PROTECTION sont nécessaires, l'un pour garantir la séparation en CONDITION NORMALE et l'autre pour maintenir la SECURITE DE BASE en CONDITION DE PREMIER DEFAUT, et

d) les COURANTS DE FUITE (et si possible également les tensions et les énergies) doivent être inférieurs aux limites acceptables.

La plupart des normes incluent des exigences explicites couvrant chacun de ces aspects de protection. Par exemple, les première et deuxième éditions de la présente norme traitaient du point a) à l'Article 16, des points b) et d) à l'Article 19 et du point c) aux Articles 17, 18 et 20.

La formulation de l'exigence a) est typiquement celle d'une exigence relative à la disposition d'ENVELOPPES ou de barrières afin de prévenir tout contact avec les parties internes sous tensions dangereuses. Elle peut toutefois être également formulée en termes de détermination des parties accessibles. Le caractère approprié de l'adéquation des

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ENVELOPPES ou des barrières est de toute façon déterminé à l'aide de doigts et de sondes d'essai appropriés.

L'application de la méthode susmentionnée aux APPAREILS EM présente quelques difficultés. Les limites de tension et de courant dépendent de la façon, si toutefois elle existe, dont la ou les parties concernées peuvent être reliées à un PATIENT, par exemple directement au cœur, directement à d'autres parties du corps, ou indirectement via l'OPERATEUR. Tout cela entraîne des difficultés d'identification des parties "sous tension".

La définition du terme "sous tension" dans la deuxième édition de la présente norme fait référence au COURANT DE FUITE admissible. La définition est par conséquent difficile à appliquer aux parties internes pour lesquelles aucune limite particulière de COURANT DE FUITE n'est spécifiée.

Certaines parties pourraient être considérées "sous tension" (d'après la définition de la deuxième édition de la présente norme) pour certaines applications tout en étant considérées comme n'étant pas "sous tension" pour d'autres applications. Par exemple, une partie interne qui peut fournir un courant d'environ 200 µA doit être séparée de toutes les PARTIES ACCESSIBLES, y compris les CONNEXIONS PATIENT en CONDITION NORMALE.

La séparation des CONNEXIONS PATIENT, des PARTIES APPLIQUEES DU TYPE CF, doit demeurer effective en CONDITION DE PREMIER DEFAUT, dans la mesure où un courant de 200 µA fourni par ces parties n'est pas admissible. La même partie peut toutefois être reliée aux autres PARTIES ACCESSIBLES et aux CONNEXIONS PATIENT en CONDITION DE PREMIER DEFAUT.

Ainsi, deux MOYENS DE PROTECTION (DOUBLE ISOLATION ou ISOLATION RENFORCEE) seraient nécessaires entre une partie de ce type et les CONNEXIONS PATIENT des PARTIES APPLIQUEES DU TYPE CF, mais un seul MOYEN DE PROTECTION (tel que l'ISOLATION PRINCIPALE seule) serait acceptable entre une partie de ce type et une autre PARTIE ACCESSIBLE.

Par ailleurs, les exigences qui spécifient la séparation nécessaire entre les parties qui sont accessibles et les parties "sous tension" ne tiennent pas facilement compte des parties qui ne sont pas "sous tension" mais qui peuvent le devenir, telles que les parties d'un circuit flottant qui deviennent "sous tension" lorsqu'un raccordement est effectué avec une autre partie du même circuit.

Soit, par exemple, la situation simple présentée dans la Figure A.10.

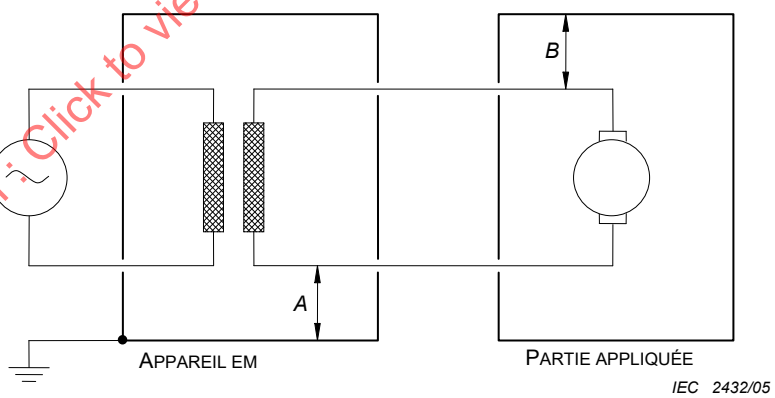


Figure A.10 – Circuit flottant

La PARTIE APPLIQUEE a une ENVELOPPE métallique qui n'est pas PROTEGEE PAR MISE A LA TERRE. S'il existe une connexion directe au point A, alors l'autre extrémité du CIRCUIT SECONDAIRE est "sous tension", et même la première édition de la présente norme aurait requis une DOUBLE ISOLATION ou une ISOLATION RENFORCEE au point B.

Si, au contraire, il existe une connexion directe au point B, la première édition aurait requis uniquement une ISOLATION PRINCIPALE au point A; mais cela a fait l'objet de la deuxième édition par l'ajout du Paragraphe 20.2 B-e, qui requiert une DOUBLE ISOLATION ou une ISOLATION RENFORCEE au point A.

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Si toutefois il existe une certaine forme d'isolation aux points A et B, alors aucune partie du CIRCUIT SECONDAIRE est “sous tension” selon la définition de la deuxième édition ; cette dernière ne spécifie alors aucune exigence relative à cette isolation, qui peut ainsi être minimale. Le comité national allemand de l'IEC a identifié ce problème en 1993, malheureusement trop tard pour qu'il soit traité dans le deuxième (et dernier) amendement de la deuxième édition de la présente norme. La méthode adoptée dans le présent projet est destinée à résoudre ce problème.

La formulation proposée pour la troisième édition de la présente norme doit préciser:

1) comment déterminer les parties devant être considérées comme PARTIES ACCESSIBLES (par examen et si nécessaire par l'utilisation de sondes et de doigts d'essai appropriés);
2) les limites admissibles de tension/courant/énergie en CONDITION NORMALE et dans les CONDITIONS DE PREMIER DEFAUT appropriées; ces limites dépendent des circonstances potentielles de raccordement à un PATIENT ou à un OPERATEUR;
3) que la CONDITION NORMALE inclut la mise en court-circuit de toute isolation, DISTANCE DANS L'AIR, LIGNE DE FUITE ou impédance qui n'est pas conforme aux exigences spécifiées relatives à la TENSION DE SERVICE correspondante, ainsi que le circuit ouvert de toute mise à la terre qui n'est pas conforme aux exigences relatives aux LIAISONS DE TERRE DE PROTECTION; et
4) que les CONDITIONS DE PREMIER DEFAUT incluent la mise en court-circuit de toute isolation, DISTANCE DANS L'AIR, LIGNE DE FUITE qui est conforme aux exigences spécifiées relatives à la TENSION DE SERVICE correspondante, la mise en court-circuit de tout composant approprié ainsi que le circuit ouvert de toute mise à la terre qui est conforme aux exigences relatives aux LIAISONS DE TERRE DE PROTECTION.

Cette méthode permet de ne pas inclure des exigences séparées explicites relatives aux moyens de protection particuliers, tel que spécifié dans les normes IEC existantes. On peut soutenir le fait qu'elle pourrait même éviter la formulation d'une exigence générale relative à la nécessité de deux MOYENS DE PROTECTION, spécifiés ici, mais le Groupe de travail a considéré qu'une telle exigence est souhaitable.

Lorsque les exigences utilisant le terme défini "sous tension" ont été conservées, elles ont été reformulées de manière à ne pas utiliser ce terme.

On obtient généralement cette protection par une combinaison des mesures suivantes:

– limitation de la tension ou de l'énergie, ou mise à la terre de protection (voir 8.4 et 8.6);
– mise sous enveloppe ou garde des circuits sous tension (voir 5.9);
– isolation de qualité et de construction appropriées (voir 8.5).

Les exigences de tension de tenue sont incluses afin de vérifier la qualité du matériau isolant utilisé à différents endroits dans l'APPAREIL EM.

Paragraphe 8.1 – Règles fondamentales de protection contre les chocs électriques

Paragraphe 8.1 a)

Une isolation non conforme à 8.8, un espacement inférieur à celui spécifié en 8.9, etc. ne sont pas des MOYENS DE PROTECTION, mais ils pourraient néanmoins influencer les tensions ou les COURANTS DE FUITE apparaissant sur les PARTIES ACCESSIBLES y compris LES PARTIES APPLIQUEES. Des mesures pourraient donc être effectuées avec ces parties intactes ou mises en dérivation, en choisissant le cas le plus défavorable.

Dans la mesure où il n'existe généralement aucune exigence d'intégrité relative aux raccordements de signalisation, la coupure d'une mise à la terre fonctionnelle doit être considérée comme une CONDITION NORMALE.

Paragraphe 8.1 b)

Les COURANTS DE FUITE ne sont généralement pas mesurés dans la CONDITION DE PREMIER DEFAUT de la coupure de l'ISOLATION PRINCIPALE des APPAREILS DE LA CLASSE I dans la mesure

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où les COURANTS DE FUITE dans ce cas s'écoulent uniquement pendant la période précédant le fonctionnement d'un fusible ou d'un DISJONCTEUR ou l'utilisation d'une alimentation isolée permettant de limiter les COURANTS DE FUITE à des valeurs sûres. Exceptionnellement, les COURANTS DE FUITE sont mesurés lors de la mise en court-circuit de l'ISOLATION PRINCIPALE lorsqu'il est fait état de doutes en ce qui concerne l'efficacité des LIAISONS DE TERRE DE PROTECTION à l'intérieur de l'APPAREIL EM (voir 8.6.4 b)).

Dans certaines circonstances, la condition de court-circuit n'est pas nécessairement le cas le plus défavorable. Par exemple, un dispositif de protection contre les surtensions qui est destiné à empêcher tout dommage sur l'isolation pourrait connaître une défaillance dans une condition de circuit ouvert en n'assurant plus sa fonction de sécurité. Cela pourrait entraîner un endommagement de l'isolation. Il est reconnu que dans la plupart des cas de ce paragraphe, la condition de circuit ouvert est superflue mais pour des composants sélectionnés, il a été reconnu que la condition de circuit ouvert est un mode de défaillance valable. Les composants des APPAREILS EM sont également traités en 4.8.

S'agissant de la présence de la TENSION RESEAU MAXIMALE sur une PARTIE ACCESSIBLE non reliée à la terre y compris les PARTIES APPLIQUEES, voir les justifications de 8.5.2.2 et 8.7.4.7 d).

Si la configuration de l'APPAREIL EM était celle représentée à la Figure A.11, la coupure du raccordement provoquerait un COURANT DE CONTACT excessif. Cette situation illustre par conséquent l'une des CONDITIONS DE PREMIER DEFAUT qu'il convient d'examiner.

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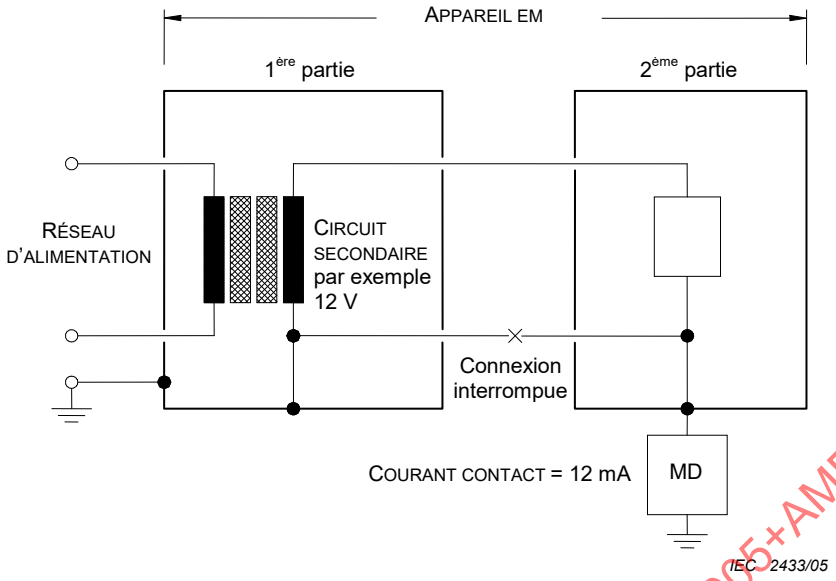


Figure A.11 – Interruption d'un conducteur d'alimentation entre des parties de l'APPAREIL EM dans des ENVELOPPES séparées

Paragraphe 8.3 – Classification des PARTIES APPLIQUEES

Paragraphe 8.3 a)

Un APPAREIL EM destiné à une APPLICATION CARDIAQUE DIRECTE ayant une ou plusieurs PARTIES APPLIQUEES DU TYPE CF peut avoir une ou plusieurs PARTIES APPLIQUEES DE TYPE B ou DE TYPE BF additionnelles qui peuvent être appliquées simultanément (voir aussi 7.2.10).

De la même façon, un APPAREIL EM pourrait comporter un mélange de PARTIES APPLIQUEES DE TYPE B et DE TYPE BF.

Paragraphe 8.3 b)

La plupart des normes particulières conçues pour les types d'APPAREILS EM ayant des électrodes côté PATIENT requièrent que les PARTIES APPLIQUEES soient du TYPE BF ou du TYPE CF. Pour les types D'APPAREILS EM similaires pour lesquels il n'existe aucune norme particulière, il vaut mieux inclure une telle exigence dans la présente norme générale que d'admettre que de telles PARTIES APPLIQUEES soient des PARTIES APPLIQUEES du TYPE B. La classification des PARTIES APPLIQUEES DU TYPE B est principalement utilisée, dans la pratique, pour les APPAREILS EM d'assistance au PATIENT tels que des tables de radiologie, et non pour des électrodes PATIENT.

~~**Paragraphe 8.3 d)**~~

~~Les parties identifiées selon 4.6 comme devant être soumises aux exigences relatives aux PARTIES APPLIQUEES (excepté pour le marquage) seront généralement moins en contact avec les PATIENTS que les PARTIES APPLIQUEES, et les avantages d'une séparation électrique d'avec la terre seront donc moindres. Toutefois, dans certains cas, le PROCESSUS de GESTION DES RISQUES pourrait identifier la nécessité de respecter les exigences relatives aux PARTIES APPLIQUEES DU TYPE BF ou du TYPE CF pour ces parties. Cette exigence reflète la majorité des opinions des Comités nationaux ayant répondu à une enquête sur ce sujet au cours de la préparation de la présente édition.~~

Paragraphe 8.4.1 – CONNEXIONS PATIENT prévues pour délivrer un courant

La présente norme ne spécifie aucune limite pour les courants destinés à produire un effet physiologique sur le PATIENT, mais ce peut être le cas de normes particulières. Tous les

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autres courants circulant entre les CONNEXIONS PATIENT sont soumis aux limites spécifiées pour le COURANT AUXILIAIRE PATIENT.

Paragraphe 8.4.2 – PARTIES ACCESSIBLES comprenant des PARTIES APPLIQUEES

Paragraphe 8.4.2 b)

Il est supposé qu'un COURANT DE CONTACT peut atteindre le PATIENT par hasard par différents chemins, y compris par l'intermédiaire de l'OPERATEUR. Les limites relatives au COURANT DE CONTACT s'appliquent donc à toutes les PARTIES ACCESSIBLES, à l'exception des CONNEXIONS PATIENT, qui sont couvertes par 8.4.2 a), et des parties qui respectent les conditions spécifiées en 8.4.2 c).

Paragraphe 8.4.2 c)

La différence observée dans la deuxième édition entre les cas où il existe un capot démontable sans l'aide d'un OUTIL et où il n'existe aucun capot n'est pas ou peu justifiée. Les valeurs limites ont été harmonisées avec l'IEC 60950-1:~~2001~~2005 car les appareils relevant de la technologie de l'information (IT) sont couramment utilisés dans les SYSTEMES EM et les valeurs données dans l'IEC 60950-1 ne sont guère différentes de celles données dans la deuxième édition de la présente norme (60 V courant continu est identique et la valeur de crête de 42,4 V n'est pas très différente de 25 V valeur efficace.).

La protection de l'OPERATEUR est essentiellement basée sur l'IEC 60950-1 et, par conséquent, nous avons besoin d'incorporer les exigences de protection de cette norme. Auparavant, l'IEC 60601-1 ne contenait pas d'exigence pour la protection contre l'énergie dangereuse mais il existe un RISQUE défini de brûlure, d'incendie et de débris volants. Cet aspect est maintenant couvert en utilisant l'exigence de l'IEC 60950-1:~~2001~~2005. Les valeurs limites ont été établies depuis de nombreuses années dans l'IEC 60950 et les normes qui l'ont précédée. L'énergie disponible maximale est autorisée à dépasser 240 VA au cours des premières 60 s qui suivent le contact avec la PARTIE ACCESSIBLE (par exemple, le circuit de limitation de courant d'une alimentation a besoin de temps pour fonctionner et au cours de cette période, le niveau d'énergie dangereuse peut être dépassé).

Paragraphe 8.4.2 d)

A l'instar des parties déterminées comme étant des PARTIES ACCESSIBLES selon 5.9, le contact électrique avec des parties internes est supposé réalisé avec:

– un crayon ou une plume, tenu(e) dans une main, simulé(e) par une broche d'essai guidée;

– un collier ou un pendentif similaire, simulé par une tige métallique suspendue au-dessus des ouvertures d'un couvercle;

– un tournevis pour l'ajustement par l'OPERATEUR d'une commande préréglée, simulé par une tige métallique insérée dans un manche.

Paragraphe 8.4.3 – APPAREIL EM prévu pour être connecté à une source d'énergie par l'intermédiaire d'une prise

La limite de 45 μC est identique à celle spécifiée dans l'IEC 60335-1, qui est basée sur les limites de l'IEC 60479-1 [11]. Elle est comparable (mais pas exactement équivalente) à la limite de 100 nF spécifiée dans la seconde édition de la présente norme. En ce qui concerne la SECURITE DE BASE, il n'est pas nécessaire de spécifier une limite plus rigoureuse entre la ligne et les broches de terre, comme dans la seconde édition.

Paragraphe 8.4.4 – Circuits internes capacitifs

La limite est passée de la valeur de 2 mJ spécifiée dans la seconde édition de la présente norme à la même valeur que celle spécifiée dans le paragraphe précédent, dans la mesure où ce qui est sûr pour un OPERATEUR ou même un PATIENT qui touche les broches d'une FICHE RESEAU est également sûr pour quelqu'un qui ouvre un PANNEAU D'ACCES pour accéder à l'intérieur de l'APPAREIL EM.

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Paragraphe 8.5.1 – MOYENS DE PROTECTION

Deux MOYENS DE PROTECTION peuvent être fournis de différentes façons. Ce qui suit en donne des exemples.

1) Les CONNEXIONS PATIENT et les autres PARTIES ACCESSIBLES sont séparées des parties n'étant pas au potentiel de masse uniquement par l'ISOLATION PRINCIPALE, tout en étant PROTEGEES PAR MISE A LA TERRE et en ayant une impédance interne par rapport à la terre si faible que les COURANTS DE FUITE ne dépassent pas les valeurs admissibles en CONDITION NORMALE et en CONDITION DE PREMIER DEFAUT.
2) Les CONNEXIONS PATIENT et les autres PARTIES ACCESSIBLES sont séparées des parties n'étant pas au potentiel de masse par L'ISOLATION PRINCIPALE et par une partie métallique PROTEGEE PAR MISE A LA TERRE intermédiaire qui pourrait être un écran métallique intégral.
3) Les CONNEXIONS PATIENT et les autres PARTIES ACCESSIBLES sont séparées des parties n'étant pas au potentiel de masse uniquement par une DOUBLE ISOLATION ou par une ISOLATION RENFORCEE.
4) Les impédances des composants préviennent toute circulation de COURANTS DE FUITE et de COURANTS AUXILIAIRES PATIENT, dépassant les valeurs admissibles, vers les CONNEXIONS PATIENT et les autres PARTIES ACCESSIBLES.

Une étude des chemins d'isolation est présentée à l'Annexe J.

Les éditions précédentes de la présente norme reconnaissaient également la possibilité de réaliser la séparation au moyen d'un circuit intermédiaire PROTEGE PAR MISE A LA TERRE. Toutefois, il est généralement impossible de connecter l'ensemble du circuit à la BORNE DE TERRE DE PROTECTION, avec une impédance très basse. En outre, si une partie d'un circuit est reliée à la terre, les autres parties du circuit sont alors à un potentiel différent du potentiel de masse et doivent donc être séparées des CONNEXIONS PATIENT et des autres PARTIES ACCESSIBLES.

L'air peut constituer une partie ou la totalité de l'ISOLATION PRINCIPALE ou de l'ISOLATION SUPPLEMENTAIRE.

En général, LA DOUBLE ISOLATION est préférable à l'ISOLATION RENFORCEE.

La première édition de la présente norme spécifiait de nombreuses parties qu'il était nécessaire de séparer, mais la liste était incomplète. Elle a été étendue dans la deuxième édition mais était toujours incomplète, par exemple concernant le cas illustré dans la Figure A.10.

Les discussions du groupe de travail qui se sont tenues au début de l'élaboration de la présente édition ont permis d'établir que les laboratoires d'essai doivent identifier les différents circuits dans les APPAREILS EM et les différents points au niveau desquels une séparation pourrait être nécessaire. Cette édition spécifie donc cette PROCEDURE de manière explicite.

La distinction entre les MOYENS DE PROTECTION DE L'OPERATEUR et les MOYENS DE PROTECTION DU PATIENT a été ajoutée pour répondre aux préoccupations selon lesquelles les exigences des éditions précédentes de la présente norme relatives aux essais, aux LIGNES DE FUITE et aux DISTANCES DANS L'AIR étaient trop rigoureuses.

De nombreux SYSTEMES EM incorporent des appareils conformes à l'IEC 60950-1. De nombreux types d'APPAREIL EM incorporent également des parties, comme l'alimentation électrique, qui ont été conçues à l'origine pour être utilisées avec des appareils conformes à l'IEC 60950-1. Certains experts et Comités nationaux ont donc proposé que les exigences de la présente norme soient harmonisées autant que possible avec l'IEC 60950-1.

Toutefois, les tensions d'essai et les valeurs minimales des LIGNES DE FUITE et des DISTANCES DANS L'AIR spécifiées dans l'IEC 60950-1 sont issues de l'IEC 60664-1 et s'appuient sur des hypothèses concernant des surtensions éventuelles dans le réseau et dans d'autres circuits, notamment la fréquence d'occurrence de différents niveaux de surtension. Selon les experts du groupe de travail qui ont révisé les exigences correspondantes de la présente norme, la

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conformité aux exigences de l'IEC 60664-1 ou de l'IEC 60950-1 implique le RISQUE qu'une défaillance transitoire de l'isolation se produise avec une fréquence proche d'une fois par an environ.

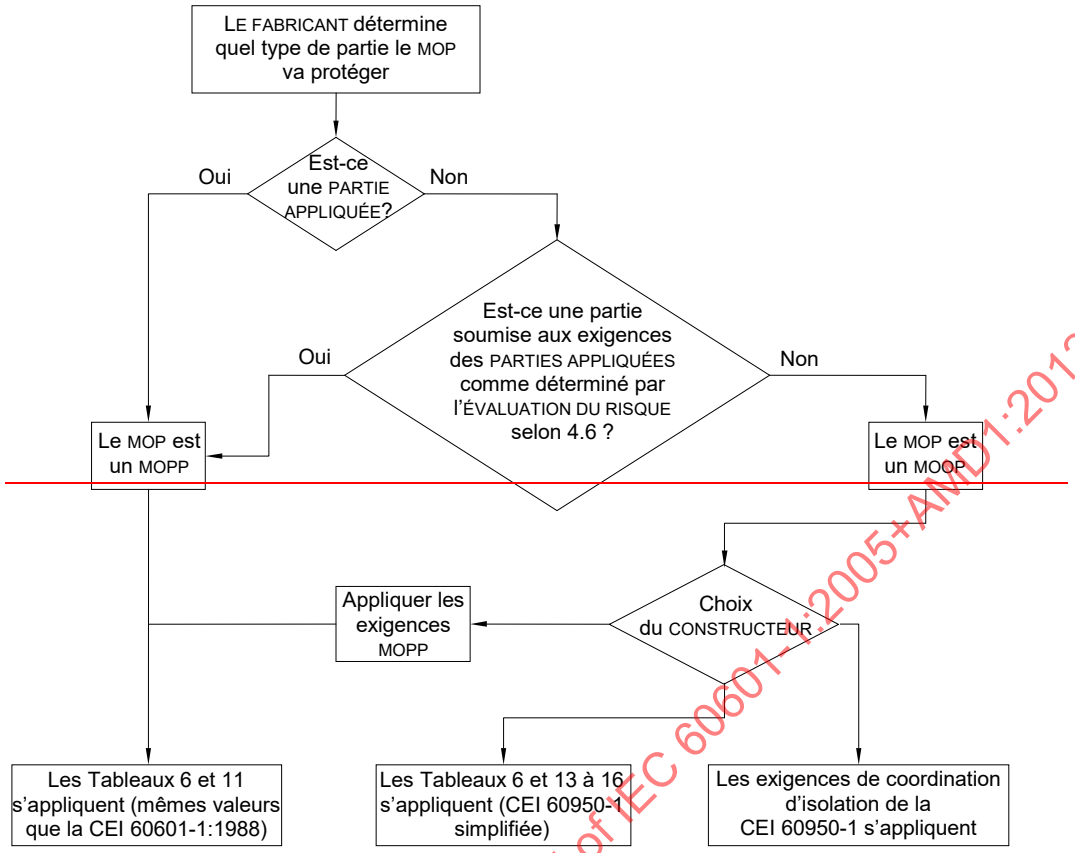
La probabilité qu'un OPERATEUR entre en contact avec une partie concernée et avec la terre au moment de la défaillance est faible, le RISQUE RESIDUEL est donc acceptable pour les APPAREILS EM, comme pour les appareils informatiques. La probabilité qu'un PATIENT soit en contact avec une PARTIE APPLIQUEE et avec la terre est cependant bien plus élevée. Le groupe de travail a donc décidé qu'une marge de sécurité plus importante devrait être appliquée lorsque la sécurité du PATIENT est concernée. Toutefois, il n'existait pas de base fiable sur laquelle s'appuyer pour déterminer quelle marge supplémentaire pourrait être appliquée aux valeurs de l'IEC 60664-1, les valeurs spécifiées dans la seconde édition de la présente norme ont donc été retenues pour les MOYENS DE PROTECTION DU PATIENT.

Pour les MOYENS DE PROTECTION DE L'OPERATEUR, la présente révision de la norme laisse trois options au FABRICANT (voir Figure A.12). L'une des options consiste à appliquer les exigences de l'IEC 60950-1 et à identifier la catégorie d'installation et le degré de pollution appropriés. Le FABRICANT peut également appliquer les valeurs des tableaux, qui sont extraits de l'IEC 60950-1, sur la base d'hypothèses raisonnables sur la catégorie d'installation et le degré de pollution. La troisième option consiste à traiter les MOYENS DE PROTECTION DE L'OPERATEUR comme s'il s'agissait de MOYENS DE PROTECTION DU PATIENT.

Les condensateurs Y sont utilisés pour réduire le brouillage radioélectrique en offrant un chemin de faible impédance à la terre pour les hautes fréquences en courant alternatif. Ils sont utilisés pour ponter l'ISOLATION DOUBLE ou RENFORCEE comme élément du régime de suppression du brouillage. Il existe quatre types: Y1, Y2, Y3 et Y4. Les condensateurs Y1 sont conçus pour être utilisés en triphasé et ont une TENSION DE SERVICE jusqu'à 500 V en courant alternatif et une tension de tenue de 4 000 V en courant alternatif. Les condensateurs Y2 sont conçus pour être utilisés en monophasé et ont une TENSION DE SERVICE jusqu'à 300 V en courant alternatif et une tension de tenue de ~~2 500~~ 1 500 V en courant alternatif. Les condensateurs Y3 sont similaires aux condensateurs Y2 mais ils ont une TENSION DE SERVICE jusqu'à 250 V en courant alternatif. Les condensateurs Y4 sont conçus pour être utilisés en basse tension et une TENSION DE SERVICE jusqu'à 150 V en courant alternatif et une tension de tenue de 1 000 V en courant alternatif. Ces condensateurs sont critiques pour la sécurité dans la mesure où ils fournissent un chemin de fuite à la terre ou à travers une barrière. C'est pourquoi il faut qu'ils soient certifiés et surveillés par un organisme d'essai reconnu selon l'IEC 60384-14, qui sert au contrôle de leur fabrication.

~~Un condensateur Y1 peut être utilisé pour fournir deux MOOP mais un seul MOPP (les PATIENTS ont besoin d'un niveau plus élevé de protection que les OPERATEURS). Un condensateur Y2 peut être utilisé pour fournir un MOOP uniquement.~~

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MOP MOYENS DE PROTECTION
MOPP MOYENS DE PROTECTION DU PATIENT
MOOP MOYENS DE PROTECTION DE L'OPÉRATEUR

IEC 2434/05

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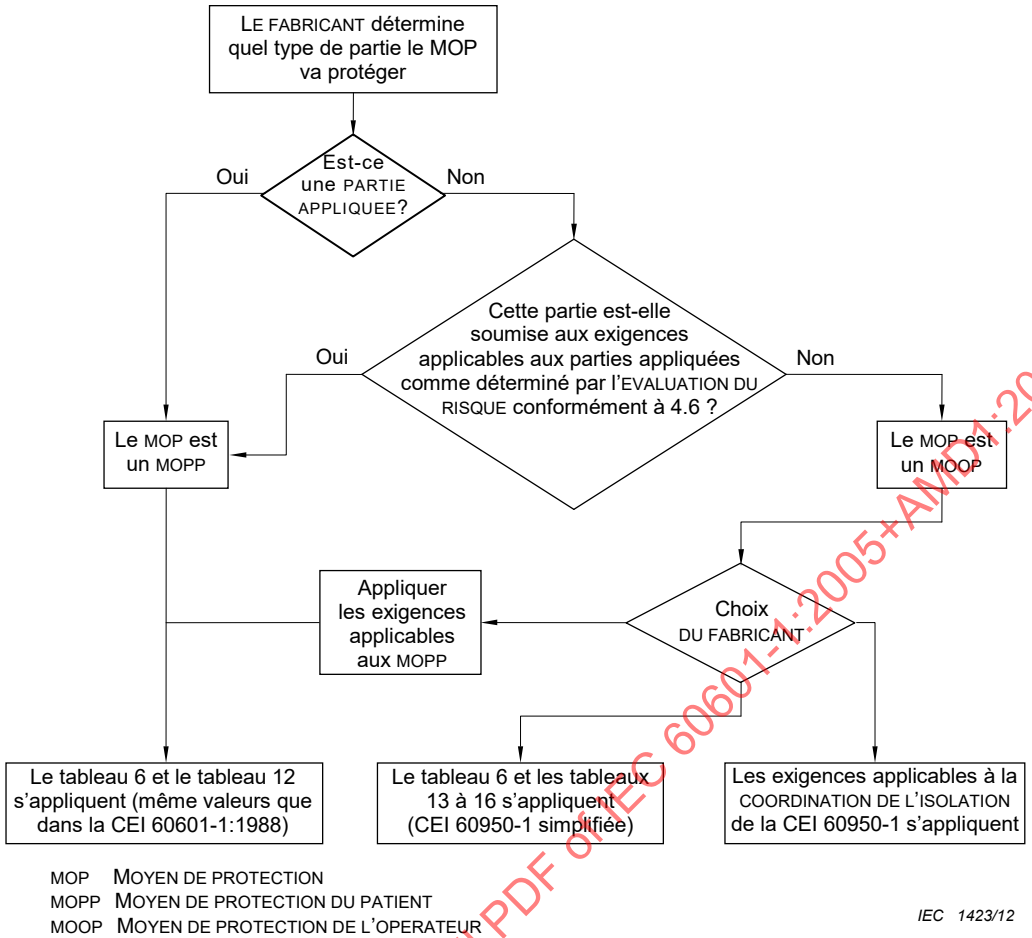


Figure A.12 – Identification des MOYENS DE PROTECTION DU PATIENT et des MOYENS DE PROTECTION DE L'OPERATEUR

Paragraphe 8.5.1.2 – MOYENS DE PROTECTION DU PATIENT (MOPP)

Lors du raccordement de condensateurs Y à travers des barrières, l'exigence de tension de tenue doit être prise en considération. Par exemple, pour des tensions dans la plage de 212 V crête à 354 V crête, deux MOYENS DE PROTECTION DU PATIENT sont requis pour être soumis à l'essai à 4 000 V en courant alternatif. Ceci exigerait l'utilisation de condensateurs Y1. Deux condensateurs Y2 en série ne supporteraient pas cette tension, puisqu'ils sont assignés à 1 500 V en courant alternatif chacun. Pour des tensions inférieures à 212 V crête, deux condensateurs Y2 suffiraient, puisque l'exigence de tension de tenue est 3 000 V en courant alternatif.

Paragraphe 8.5.2.1 – PARTIES APPLIQUEES de TYPE F

La caractéristique essentielle d'une PARTIE APPLIQUEE DE TYPE F est la séparation de cette partie des autres parties. Ce paragraphe spécifie et quantifie le degré de séparation nécessaire.

Les fonctions multiples peuvent être considérées comme des PARTIES APPLIQUEES multiples (qui doivent être séparées les unes des autres par un MOYEN DE PROTECTION PATIENT) ou comme une PARTIE APPLIQUEE. Cela est décidé par le FABRICANT après évaluation du RISQUE qu'une mise à la terre d'une ou de plusieurs CONNEXION(S) PATIENT d'une fonction pourrait donner lieu à un COURANT DE FUITE excessif à travers la ou les CONNEXION(S) PATIENT d'une autre fonction, dans la condition dans laquelle une tension imprévue provenant d'une source extérieure devient connectée au PATIENT.

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La limite de 500 V en valeur efficace pour les dispositifs de protection était déjà spécifiée dans la première édition de la présente norme. La justification initiale n'est pas connue mais cette tension correspond à la tension ASSIGNEE la plus élevée spécifiée en 4.10.

Paragraphe 8.5.2.2 – PARTIES APPLIQUEES de TYPE B

Cette exigence aborde la possibilité selon laquelle une tension non prévue issue d'une source externe vienne en contact avec une partie de l'APPAREIL EM. En l'absence de séparation appropriée entre une telle partie et les CONNEXIONS PATIENT, il pourrait se produire un COURANT DE FUITE PATIENT excessif.

Selon le point c) de l'Article 17 de la seconde édition de la présente norme, cette exigence s'appliquait à toutes les PARTIES APPLIQUEES, mais elle ne s'applique plus dans de nombreux cas:

– Pour les PARTIES APPLIQUEES DU TYPE F, l'isolation requise par 8.5.2.1 couvre également ce cas (mais les PARTIES APPLIQUEES DU TYPE BF exigent un essai supplémentaire, comme expliqué dans la justification de 8.7.4.7 d)).

– ~~Le RISQUE ne peut pas survenir~~ Une SITUATION DANGEREUSE ne peut pas se développer si la partie de l'APPAREIL EM concernée ou les CONNEXIONS PATIENT d'une PARTIE APPLIQUEE DE TYPE B sont PROTEGEES PAR MISE A LA TERRE. (Une défaillance de la LIAISON DE TERRE DE PROTECTION, ajoutée à l'apparition d'une tension non prévue correspondrait à une condition de double défaut).

– Si la partie concernée de l'APPAREIL EM jouxte physiquement la PARTIE APPLIQUEE (par exemple, une pièce à main dentaire), l'exigence ne s'applique pas si le RISQUE de contact avec une source de tension ou un COURANT DE FUITE au-dessus des limites autorisées est suffisamment faible pour être acceptable.

Paragraphe 8.5.2.3 – ~~Liaisons PATIENT~~ Conducteurs PATIENT ou câbles PATIENT

Il y a deux sortes de circonstances dont il faut se protéger:

– en premier lieu, pour les PARTIES APPLIQUEES DU TYPE BF et du TYPE CF, il convient qu'il n'existe aucune possibilité de liaison accidentelle du PATIENT avec la terre par l'intermédiaire de tout conducteur qui pourrait se détacher de l'APPAREIL EM ; même pour une PARTIE APPLIQUEE DE TYPE B, une liaison indésirable avec la terre peut avoir un effet néfaste sur le fonctionnement de l'APPAREIL EM;

– en second lieu, pour tous les types de PARTIE APPLIQUEE, il ne devrait y avoir aucune possibilité pour que le PATIENT puisse être relié accidentellement à des parties de l'APPAREIL EM ou à d'autres parties conductrices qui sont proches de lui dans lesquelles un courant excédant le COURANT DE FUITE admissible pourrait circuler.

Un cas extrême de ce dernier DANGER serait une connexion directe au RESEAU D'ALIMENTATION, résultant de l'insertion du connecteur dans une prise réseau ou dans l'extrémité d'une prise de courant d'un CABLE D'ALIMENTATION NON FIXE A DEMEURE. Il est essentiel d'empêcher cette situation.

Pour certaines combinaisons de connecteurs PATIENT et de CONNECTEURS RESEAU, il sera possible d'enficher accidentellement le connecteur PATIENT dans le socle de prise de courant réseau.

Cette possibilité ne peut raisonnablement pas être évitée par des exigences dimensionnelles, car réaliser cela conduirait à des connecteurs à fiche unique excessivement grands. Dans cette éventualité, on assure la sécurité par une exigence stipulant de protéger le connecteur PATIENT par une isolation ayant une LIGNE DE FUITE d'au moins 1,0 mm et une tension de tenue d'au moins 1 500 V. Cette dernière exigence ne suffirait pas à elle seule, car une protection de 1 500 V pourrait facilement être réalisée à l'aide d'une fine feuille de plastique qui ne résisterait pas à une usure journalière normale ou à des poussées, vraisemblablement répétées, dans une prise de courant réseau. Egalement pour cette raison, on peut se rendre compte qu'il convient que l'isolation soit solide et rigide.

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La formulation de cette exigence a été modifiée par rapport à la seconde édition de la présente norme pour éviter l'utilisation des expressions “liaison conductrice”, qui a été éliminée en tant que terme défini. Cette modification résulte directement des commentaires des Comités nationaux pendant la préparation de la présente édition.

Selon la justification de la seconde édition de la présente norme, l'essai dans lequel le doigt d'essai est appliqué avec une force de 10 N était destiné à “vérifier la résistance du matériau isolant”. Cela a maintenant été remplacé par une référence croisée explicite à 8.8.4.1.

Suite à une enquête, l'un des comités nationaux a déclaré que cet essai est un "essai mécanique du couvercle de protection sur la broche", en suggérant que l'essai était destiné à s'appliquer spécifiquement à une conception de connecteur particulière, dans laquelle le contact est entouré d'une gaine mobile conçue pour permettre le contact avec le connecteur correspondant adéquat mais pas avec d'autres parties.

Au cours de l'élaboration de cette édition de la norme, la question s'est posée de savoir si cet essai devait être limité aux connecteurs à fiche unique, comme c'était le cas dans la seconde édition, ou s'il pouvait également s'appliquer à des connecteurs à plusieurs fiches. Certains connecteurs à plusieurs fiches ont une forme similaire aux connecteurs à fiche unique et pourraient être insérés dans une PRISE RESEAU de la même façon ; les mêmes considérations sur l'adéquation de l'isolation s'appliquent donc aux deux types de connecteur. D'autre part, certains connecteurs à plusieurs fiches types d'utilisation courante ne peuvent pas être insérés dans une PRISE RESEAU, mais échoueraient à cet essai dans la mesure où le doigt d'essai peut facilement toucher leurs contacts, même sans appliquer une force de 10 N.

Une autre enquête réalisée auprès des comités nationaux a permis de dégager un consensus raisonnable sur certains points mais pas sur la question de savoir s’il convenait d’appliquer cet essai à tous les connecteurs ou se limiter aux connecteurs à fiche unique.

Il convient probablement que cet essai s'applique aux connecteurs à plusieurs fiches dont la forme et les dimensions permettent de les insérer dans une prise de courant réseau. Dans ce cas, le RISQUE est le même qu'avec un connecteur à fiche unique.

L'application de cet essai à certains connecteurs à plusieurs fiches permet également de pallier le fait que cet essai avec la plaque plane n'évalue pas entièrement la possibilité de contact avec les parties conductrices à proximité de la zone dans laquelle un courant excédant le COURANT DE FUITE admissible pourrait s'écouler. Pratiquement tous les types de connecteurs, s'ils sont détachés de l'APPAREIL EM ou s'ils tombent, pourraient entrer en contact avec quelque chose à proximité du connecteur correspondant, mais le RISQUE dépend de la forme du connecteur et des circonstances. Dans la plupart des cas, ce RISQUE est faible. Par exemple, un connecteur de type "D" n'est susceptible d'entrer en contact avec un objet relié à la terre que pendant quelques instants alors qu'une broche droite pourrait entrer en contact pendant une période prolongée. Toutefois, même un contact prolongé avec un objet métallique ne peut entraîner ~~un DANGER~~ une SITUATION DANGEREUSE que s'il se produit en même temps qu'un défaut ou qu'une situation anormale permettant à un courant excessif de s'écouler à travers le PATIENT. Le RISQUE est dans tous les cas bien moins grand que le RISQUE encouru si le connecteur entre en contact avec la prise de courant réseau. Il convient de formuler les exigences de la présente norme en fonction des RISQUES. Il est souhaitable que la norme permette de réduire au minimum le RISQUE pour le PATIENT, tout en laissant aux FABRICANTS un choix de connecteurs raisonnable.

Il y a lieu d'entendre “tout connecteur” en y comprenant des connecteurs à contacts multiples, plusieurs connecteurs ou des connecteurs en série.

La dimension de 100 mm de diamètre n'est pas en elle-même importante, elle sert seulement à indiquer l'ordre de grandeur de la surface plane. Toute feuille d'un matériau conducteur de dimension plus grande conviendrait.

Paragraphe 8.5.3 – TENSION D'ALIMENTATION RESEAU MAXIMALE

Plusieurs exigences et essais de la présente norme renvoient à la possibilité qu'une tension non prévue provenant d'une source externe soit connectée au PATIENT ou à certaines parties de l'APPAREIL EM. L'amplitude réelle d'une telle tension n'est pas connue ; mais, dans la

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deuxième édition de cette norme, elle était prise comme étant la TENSION RESEAU ASSIGNEE la plus élevée ou pour les appareils polyphasés comme la tension d'alimentation phase-neutre. Ces valeurs reflétaient une hypothèse raisonnable de cas le plus défavorable selon laquelle la tension externe réelle ne dépassera probablement pas la tension du RESEAU D'ALIMENTATION à l'endroit où l'APPAREIL EM est utilisé et l'APPAREIL EM ne sera probablement pas utilisé dans un endroit où le RESEAU D'ALIMENTATION présente une tension supérieure à sa TENSION RESEAU ASSIGNEE la plus élevée. Pour les APPAREILS EM A SOURCE ELECTRIQUE INTERNE, la valeur spécifiée était (et demeure) 250 V, étant donné qu'il s'agit de la tension phase-neutre la plus communément rencontrée dans les endroits où les APPAREILS EM sont utilisés.

Lors des premiers projets de la présente édition, la formulation correspondante ne mentionnait que le RESEAU D'ALIMENTATION en courant alternatif. Cette erreur a été relevée pendant la période des commentaires. Les discussions menées sur ce commentaire ont confirmé qu'il ne convenait pas que les exigences dépendent uniquement de savoir si le RESEAU D'ALIMENTATION était en courant continu ou alternatif, mais elles ont révélé une autre anomalie. Si l'APPAREIL EM est spécifié pour une liaison avec le RESEAU D'ALIMENTATION à très basse tension TBT (par exemple, 12 V dans une ambulance) mais qu'il n'est spécifié pour aucun autre RESEAU D'ALIMENTATION, de tension plus élevée, la tension externe supposée pour les besoins de l'essai uniquement serait la TBT. Un tel APPAREIL EM pourrait néanmoins être utilisé dans des endroits où un RESEAU D'ALIMENTATION de tension plus élevée est également installé. La rédaction a donc été révisée pour supprimer cette anomalie.

Si l'APPAREIL EM présente une tension d'alimentation ASSIGNEE maximale inférieure à 100 V, il sera forcément utilisé dans un endroit spécial dans lequel cette alimentation est disponible et nous ne savons pas quelles autres alimentations pourraient être également présentes. La tension externe supposée pour des essais pertinents est donc de 250 V, comme pour les APPAREILS EM A SOURCE ELECTRIQUE INTERNE.

Toutefois, un APPAREIL EM ayant une TENSION RESEAU ASSIGNEE maximale d'environ 115 V ne sera probablement pas utilisé dans des endroits présentant un RESEAU D'ALIMENTATION de tension plus élevée, la tension externe supposée pour des essais pertinents est donc égale à la TENSION RESEAU ASSIGNEE maximale, comme dans la seconde édition de la présente norme.

Paragraphe 8.5.4 – TENSION DE SERVICE

Les tensions d'essai de tenue spécifiées au Tableau 6 sont appropriées pour une isolation qui est normalement soumise à une TENSION DE SERVICE continue et à des surtensions transitoires.

La TENSION DE SERVICE pour chaque MOYEN DE PROTECTION formant une DOUBLE ISOLATION est la tension à laquelle la DOUBLE ISOLATION est soumise dans son ensemble, car tout MOYEN DE PROTECTION peut être soumis à cette tension si l'autre MOYEN DE PROTECTION connaît une défaillance.

Pour l'isolation entre deux parties isolées ou entre une partie isolée et une partie reliée à la terre, la TENSION DE SERVICE pourrait dans certains cas être égale à la somme arithmétique des tensions maximales entre deux points dans les deux parties.

Pour les PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION, une tension d'essai ayant pour base la TENSION DE SERVICE égale à la tension de crête de défibrillation serait beaucoup trop élevée pour une isolation qui, en UTILISATION NORMALE, est soumise seulement de manière occasionnelle à des tensions de choc, de durée normalement inférieure à ~~10~~ 1 s et sans surtension additionnelle.

Paragraphe 8.5.5 – PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION

L'essai spécial décrit en 8.5.5 est considéré comme pouvant assurer une protection suffisante contre l'exposition à des chocs de défibrillation, sans qu'aucun essai de tension de tenue séparé soit nécessaire.

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Paragraphe 8.5.5.1 – Protection contre les chocs de défibrillation

L'une ou l'autre des électrodes de défibrillation, en vertu de son application clinique, pourrait être reliée à la terre ou au moins être référencée à la terre.

Quand un défibrillateur est utilisé sur le PATIENT, une TENSION ELEVEE peut ainsi se trouver appliquée soit entre une partie de l'APPAREIL EM et une autre, soit entre de telles parties ensemble et la terre. Il convient que les PARTIES ACCESSIBLES soient convenablement isolées des CONNEXIONS PATIENT ou protégées d'une autre façon. L'isolation des CONNEXIONS PATIENT ne peut pas être protégée par des dispositifs de limitation de la tension reposant sur des connexions reliées à la terre.

Le marquage des PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION indique qu'une PARTIE APPLIQUEE peut rester en toute sécurité fixée à un PATIENT qui est défibrillé sans effet défavorable pour l'utilisation ultérieure de l'APPAREIL EM.

Les essais assurent:

a) que toutes les PARTIES ACCESSIBLES de l'APPAREIL EM, les câbles PATIENT, les connecteurs des câbles, etc. qui ne sont pas PROTEGES PAR MISE A LA TERRE ne produiront pas un niveau dangereux de charge ou d'énergie du fait d'un amorçage dû à la tension de défibrillation ; et

b) que l'APPAREIL EM continuera d'assurer sa fonction (au moins concernant la SECURITE DE BASE ET LA PERFORMANCE ESSENTIELLE) après avoir été soumis à la tension de défibrillation.

L'exigence et la PROCEDURE d'essai se réfèrent à l'expression “toute durée nécessaire” indiquée dans les DOCUMENTS D'ACCOMPAGNEMENT. Il n'est pas obligatoire d'inclure une déclaration concernant le temps de récupération dans les DOCUMENTS D'ACCOMPAGNEMENT mais s'il n'y a pas de déclaration, l'APPAREIL EM doit alors récupérer et fournir sa SECURITE DE BASE et sa PERFORMANCE ESSENTIELLE immédiatement.

Les essais sont conduits avec L'APPAREIL EM connecté au RESEAU D'ALIMENTATION et en fonctionnement conformément aux instructions d'utilisation, car les essais ne traitent pas uniquement de l'effet de l'énergie de défibrillation sur la SECURITE DE base mais également de la capacité de l'APPAREIL EM à délivrer sa PERFORMANCE ESSENTIELLE après le temps de reprise indiqué.

L'UTILISATION NORMALE comprend la situation dans laquelle on défibrille le PATIENT tandis qu'il est relié à l'APPAREIL EM et, en même temps, l'OPERATEUR ou une autre personne se trouve en contact avec l'ENVELOPPE. La possibilité que cela se produise en même temps qu'une CONDITION DE PREMIER DEFAUT due à une LIAISON DE TERRE DE PROTECTION défectueuse est très faible et, par suite, on n'en tient pas compte. Toutefois, la coupure des connexions de terre fonctionnelles est plus probable, et en conséquence, elle est requise pour ces essais.

La GRAVITE du choc électrique qu'une personne reçoit lorsqu'elle touche des PARTIES ACCESSIBLES pendant la décharge d'un défibrillateur est limitée à une valeur (correspondant à une charge de 100 μC) produisant une sensation désagréable mais non dangereuse.

Les ENTREES/SORTIES DE SIGNAUX sont incluses, car les conducteurs de signaux reliés à un APPAREIL EM éloigné pourraient sans cela être porteurs d'énergies qui pourraient être dangereuses.

Les circuits d'essai de la Figure 9 et de la Figure 10 de la présente norme sont conçus pour simplifier l'essai en tenant compte de la tension apparaissant sur la résistance d'essai (R_1).

La valeur de l'inductance L dans les circuits d'essai de la Figure 9 et de la Figure 10 est choisie pour fournir un temps de montée plus court que la normale pour soumettre correctement aux essais les moyens de protection incorporés.

Si l'APPAREIL EM était conçu conformément à 8.5.2.1 et 8.5.5.1, il pourrait disposer de deux fonctions différentes sur un circuit commun de PARTIE APPLIQUEE. Considérons l'exemple de la Figure A.21. Dans cet exemple, l'ECG et un cathéter invasif de régulation de la pression

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artérielle (IBP) partagent un circuit commun de PARTIE APPLIQUEE. En utilisation réelle à l'hôpital, quelquefois une seule fonction (ECG) est utilisée pendant que l'autre fonction (IBP) n'est pas connectée. Si le PATIENT a besoin d'être défibrillé, il existe la possibilité qu'un deuxième OPERATEUR subisse un choc électrique sur les socles non utilisés de l'IBP pendant la sélection des réglages corrects de l'APPAREIL EM (moniteur patient multi-paramètres par exemple). Il convient de souligner qu'en principe, les 5 KV peuvent se produire sur chaque connecteur déconnecté ne disposant pas de broches de renfoncement. Toutefois, dans la pratique, la probabilité d'un DOMMAGE est bien plus élevée sur les socles de la PARTIE APPLIQUEE non utilisée de l'APPAREIL EM que sur tout connecteur des câbles de l'adaptateur. Les câbles de l'adaptateur ne sont normalement pas touchés par l'OPERATEUR pendant une défibrillation, car la commande "ne pas s'approcher" est donnée avant la défibrillation. Même dans le cas où un câble de l'adaptateur débranché serait touché par un OPERATEUR pendant une défibrillation, le plus probable est qu'il soit touché au niveau des parties en plastique isolées et non sur les broches internes.

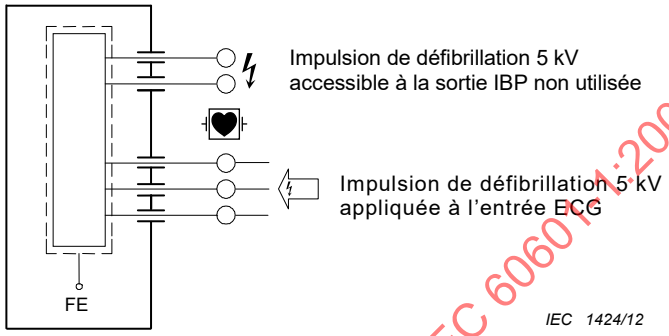


Figure A.21 – Exemple d'APPAREIL EM disposant de deux fonctions différentes sur un circuit commun de PARTIE APPLIQUEE

Justification pour la tension d'essai de choc

Lorsqu'une tension de défibrillation est appliquée au thorax d'un PATIENT, par l'intermédiaire de palpateurs (ou électrodes de défibrillation) appliqués de manière externe, le tissu corporel du PATIENT au voisinage des palpateurs et entre ceux-ci devient un système diviseur de tension.

La distribution de tension peut être évaluée approximativement en utilisant la théorie des champs à trois dimensions mais elle est modifiée par la conductivité locale des tissus qui est loin d'être uniforme.

Si l'électrode d'un autre élément d'APPAREIL EM est appliquée au PATIENT, approximativement dans l'entourage des palpateurs du défibrillateur, la tension à laquelle une telle électrode est soumise dépend de sa position mais elle est généralement inférieure à la tension en charge de défibrillation.

Il est malheureusement impossible de dire de combien elle le sera puisque l'ELECTRODE en question peut être placée n'importe où dans cette zone comprenant la partie immédiatement jointive à un des palpateurs du défibrillateur. En l'absence de norme particulière applicable, il est exigé qu'une telle électrode et l'APPAREIL EM auquel elle est connectée soient capables de résister à la tension de défibrillation complète. Cette tension est la tension hors charge, puisque l'un des palpateurs du défibrillateur pourrait ne pas avoir un bon contact avec le PATIENT.

La présente norme spécifie en conséquence 5 kV en courant continu comme tension d'essai appropriée en l'absence d'une norme particulière applicable.

En appliquant le Paragraphe 4.5, un FABRICANT est autorisé à utiliser des moyens alternatifs pour traiter un RISQUE couvert par la présente norme si le RISQUE RESIDUEL après application des moyens alternatifs est égal ou inférieur au RISQUE RESIDUEL après application des exigences de la présente norme. Il est possible pour un FABRICANT de déterminer qu'une

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tension d'essai inférieure est appropriée en fonction de l'UTILISATION PREVUE de l'APPAREIL EM et de l'emplacement des PARTIES APPLIQUEES sur le PATIENT s'il peut être démontré que la tension d'essai choisie est la tension maximale qui peut apparaître sur la PARTIE APPLIQUEE avec 5 kV appliqués sur la poitrine. De telles parties peuvent être classées et marquées PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION.

Paragraphe 8.6 – Protection par mise à la terre, mise à la terre fonctionnelle et égalisation des potentiels des APPAREILS EM

Normalement, les PARTIES ACCESSIBLES métalliques des APPAREILS EM de la CLASSE I sont PROTEGEES PAR MISE A LA TERRE. Toutefois, elles pourraient être séparées par d'autres MOYENS DE PROTECTION, conformément à 8.5. Ainsi, certaines PARTIES ACCESSIBLES métalliques pourraient être mise à la terre incidemment, ni par une CONNEXTION DE TERRE DE PROTECTION ni dans des buts fonctionnels. Par exemple, une telle partie pourrait être en contact avec une autre partie qui est PROTEGEE PAR MISE A LA TERRE mais qui n'a pas besoin elle même d'être PROTEGEE PAR MISE A LA TERRE.

Paragraphe 8.6.1 – Application des exigences

Les LIAISONS DE TERRE DE PROTECTION qui concernent uniquement la sécurité des OPERATEURS peuvent satisfaire aux exigences de la présente norme ou à celles de l'IEC 60950-1, mais cette dernière option n'est pas autorisée pour les LIAISONS DE TERRE DE PROTECTION qui concernent la sécurité des OPERATEURS et des PATIENTS.

Paragraphe 8.6.2 – BORNE DE TERRE DE PROTECTION

Ces exigences sont destinées à assurer une liaison fiable entre l'APPAREIL EM et le système de mise à la terre de protection de l'installation électrique.

Paragraphe 8.6.3 – Mise à la terre de protection des parties en mouvement

Les liaisons aux parties mobiles, que ce soit par contacts glissants, par fils flexibles ou par tout autre moyen, pourraient être plus susceptibles de se détériorer que les liaisons FIXES ordinaires pendant la DUREE DE VIE PREVUE de l'APPAREIL EM. Par conséquent, elles ne sont pas acceptables en tant que LIAISONS DE TERRE DE PROTECTION à moins que leur fiabilité ne soit démontrée.

Paragraphe 8.6.4 a)

Les LIAISONS DE TERRE DE PROTECTION ne peuvent remplir leur fonction de protection que si elles peuvent supporter le courant de défaut résultant d'une défaillance de l'ISOLATION PRINCIPALE.

Un tel courant est supposé avoir une valeur suffisante pour faire déclencher les dispositifs de protection de l'installation électrique (fusibles, disjoncteurs, coupe-circuit de fuites à la terre et autres dispositifs du même genre) en un temps suffisamment court.

Il est donc nécessaire de vérifier à la fois l'impédance et la capacité sous tension des LIAISONS DE TERRE DE PROTECTION.

Le temps minimal exigé pour le passage du courant d'essai est destiné à mettre en évidence toute surchauffe des parties du raccordement due à un amincissement des conducteurs ou à un mauvais contact. Un tel “point faible” pourrait en effet ne pas être découvert par seulement une mesure de résistance.

Les LIAISONS DE TERRE DE PROTECTION peuvent comporter des zones d'impédance plus élevée, par exemple en raison de l'oxydation des matériaux. L'utilisation d'une source de courant avec une tension illimitée pourrait prévenir toute détection de zones de ce type en raison de leur capacité d'amorçage. On détermine donc en premier lieu l'impédance en utilisant une tension limitée.

Si cette tension est suffisante pour faire circuler le courant d'essai spécifié à travers l'impédance totale, alors cet essai unique sert également à démontrer la capacité sous tension du raccordement. Dans le cas contraire, un essai supplémentaire est nécessaire, en

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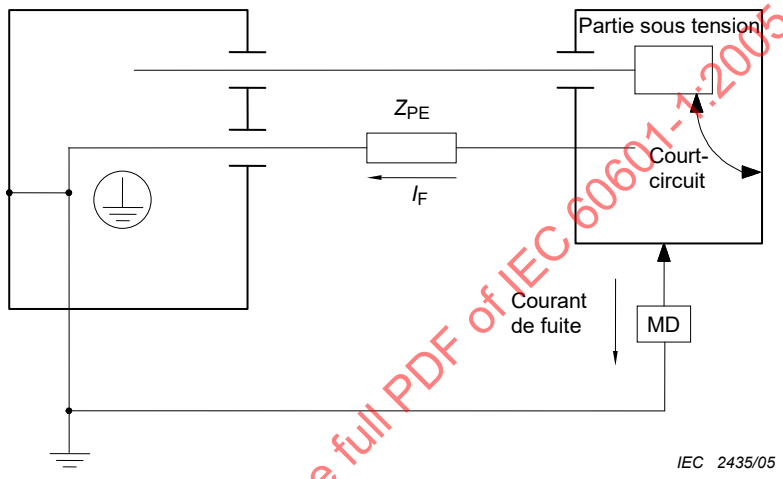
faisant appel à une tension plus élevée ou en évaluant la section de raccordement par examen.

Lorsqu'un long CABLE D'ALIMENTATION NON FIXE A DEMEURE (> 3 m) est fourni, spécifié ou utilisé, l'exigence du circuit total de mise à la terre de protection de 200 mΩ s'applique toujours. Il pourrait donc être nécessaire d'utiliser un CABLE D'ALIMENTATION NON FIXE A DEMEURE ayant des conducteurs d'une section supérieure au minimum requis en 8.11.3.3.

Paragraphe 8.6.4 b)

Le courant de défaut pourrait être limité à une valeur relativement faible, en raison de l'impédance propre ou de la caractéristique de la source d'alimentation, par exemple lorsque le système d'alimentation n'est pas relié à la terre ou s'il est relié à la terre par l'intermédiaire d'une impédance élevée (voir Figure A.13).

Dans de tels cas, la section de la LIAISON DE TERRE DE PROTECTION peut être déterminée essentiellement par des considérations mécaniques.



Légende

Z_{PE} = Impédance de la LIAISON DE TERRE DE PROTECTION en ohms (dépassant la limite spécifiée en 8.6.4 a))

I_F = Courant de défaut continu maximal présumé, en ampères, dans la LIAISON DE TERRE DE PROTECTION provoqué par une seule défaillance de l'isolation par rapport à la terre

MD Exemple de dispositif de mesure et de ses caractéristiques de fréquence (voir Figure 12)

NOTE La figure montre un APPAREIL EM avec une ENVELOPPE principale et une partie distante dans une ENVELOPPE séparée, exemple d'un cas où l'impédance d'une LIAISON DE TERRE DE PROTECTION pourrait dépasser la limite spécifiée en 8.6.4 a): cette situation pourrait toutefois se produire également dans un APPAREIL EM ayant une seule ENVELOPPE.

Figure A.13 – Impédance de terre de protection admissible avec courant de défaut limité

Paragraphe 8.6.7 – CONDUCTEUR D'EGALISATION DES POTENTIELS

Les locaux à usage médical dans la plupart des pays ne disposent pas d'installations pour l'utilisation de CONDUCTEURS D'EGALISATION DES POTENTIELS détachables. La présente norme ne nécessite donc pas de moyens pour le raccordement d'un CONDUCTEUR D'EGALISATION DES POTENTIELS sur l'APPAREIL EM. Si toutefois l'APPAREIL EM ne comporte pas ces moyens, pour une utilisation dans des locaux où des CONDUCTEURS D'EGALISATION DES POTENTIELS sont utilisés, les exigences appropriées doivent être respectées.

Paragraphe 8.6.9 – APPAREIL EM de CLASSE II

Cette exigence permet de relier un APPAREIL EM DE CLASSE II à une borne de terre de protection uniquement pour des raisons fonctionnelles. Vert/jaune est exigé pour éviter toute confusion pendant l'installation. Cette tolérance n'altère pas le degré de protection contre les chocs électriques.

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Le courant circulant à travers le CONDUCTEUR DE TERRE FONCTIONNELLE doit être limité de la même manière que le courant dans le CONDUCTEUR DE TERRE DE PROTECTION. Pour empêcher le CONDUCTEUR DE TERRE FONCTIONNELLE de devenir un CONDUCTEUR DE TERRE DE PROTECTION, l'isolation entre les écrans internes, y compris le câblage interne connecté entre ces écrans et les PARTIES ACCESSIBLES, doit fournir deux MOYENS DE PROTECTION.

Paragraphe 8.7.2 – CONDITION DE PREMIER DEFAUT

Un court-circuit d'une des parties de la DOUBLE ISOLATION augmenterait probablement le COURANT DE FUITE d'un facteur d'environ 2. Dans certains cas, l'essai pourrait être difficile à mener, dans la mesure où les valeurs admissibles pour la CONDITION DE PREMIER DEFAUT correspondent à cinq fois celles en CONDITION NORMALE, l'essai ne fournirait pas d'informations utiles.

Paragraphe 8.7.3 – Valeurs admissibles et Tableau 3 et Tableau 4

La valeur du courant électrique s'écoulant dans le corps humain ou de l'animal qui peut provoquer un certain degré de stimulation varie d'un individu à l'autre, selon la façon dont est réalisée la liaison avec le corps et la fréquence du courant appliqué ainsi que sa durée.

Les courants de faible fréquence s'écoulant directement dans ou à travers le cœur augmentent considérablement le danger d'une fibrillation ventriculaire. Pour les courants de fréquence moyenne ou élevée, le RISQUE de choc électrique est moindre ou quantité négligeable, mais le RISQUE de brûlure demeure.

La sensibilité du corps de l'être humain ou de l'animal aux courants électriques, dépendant du degré et de la nature du contact avec les APPAREILS EM, conduit à un système de classification reflétant le degré et la qualité de la protection assurés par les PARTIES APPLIQUEES (classées en PARTIES APPLIQUEES DU TYPE B, PARTIES APPLIQUEES DU TYPE BF et en PARTIES APPLIQUEES DU TYPE CF). Les PARTIES APPLIQUEES des TYPES B et BF conviennent généralement à des applications impliquant un contact interne ou externe avec le PATIENT, à l'exclusion du cœur. Les PARTIES APPLIQUEES DU TYPE CF conviennent pour les APPLICATIONS CARDIAQUES DIRECTES en ce qui concerne le COURANT DE FUITE.

Conjointement à cette classification, les exigences relatives au COURANT DE FUITE admissible ont été formulées. L'absence de données scientifiques suffisantes concernant la sensibilité du cœur humain aux courants provoquant une fibrillation ventriculaire pose toujours problème.

Néanmoins, la publication de la première édition de la présente norme en 1977 a permis aux ingénieurs de disposer de données leur permettant de concevoir les APPAREILS EM ; et il a été démontré depuis lors que ces exigences permettaient d'assurer un niveau de RISQUE très faible sans être trop onéreux pour les concepteurs.

Les exigences relatives au COURANT DE FUITE ont été formulées en tenant compte du fait:

– que la possibilité de fibrillation ventriculaire est influencée par des facteurs autres que les seuls paramètres électriques ;

– qu'il convient que les valeurs applicables aux COURANTS DE FUITE admissibles en CONDITION DE PREMIER DEFAUT soient aussi élevées que ce qui est considéré sûr, compte tenu des considérations d'ordre statistique, afin d'éviter de confronter les concepteurs à des difficultés inutiles, et

– que les valeurs applicables à la CONDITION NORMALE sont nécessaires pour créer une condition sûre en toutes situations en fournissant un facteur de SECURITE suffisamment élevé eu égard aux CONDITIONS DE PREMIER DEFAUT.

La mesure des COURANTS DE FUITE est décrite d'une façon qui permet l'utilisation d'instruments simples, évitant ainsi différentes interprétations d'un cas donné et indiquant les possibilités d'un contrôle périodique par l'ORGANISME RESPONSABLE.

Les valeurs admissibles des COURANTS DE FUITE permanents et du COURANT AUXILIAIRE PATIENT pour des formes d'ondes complexes en courant alternatif et en courant continu avec des fréquences inférieures ou égales à 1 kHz tiennent compte des considérations suivantes.

~~d~~a) En général, le RISQUE de fibrillation ventriculaire ou de défaillance de la pompe cardiaque augmente avec la valeur ou la durée, allant jusqu'à quelques secondes, du courant traversant le cœur. Certaines parties du cœur sont plus sensibles que d'autres.

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En d'autres termes, un courant qui provoque une fibrillation ventriculaire lorsqu'il est appliqué à une partie du cœur pourrait n'avoir aucun effet lorsqu'il est appliqué à une autre partie du cœur.

~~e~~b) Le RISQUE est plus élevé et ~~à peu près le même~~ approximativement identique pour ~~des~~ les fréquences comprises entre 10 Hz et 200 Hz. Il est plus faible dans un rapport voisin de 5, en courant continu, et dans un rapport d'approximativement 1,5 à une fréquence de 1 kHz. Au-delà de 1 kHz, le RISQUE décroît rapidement [45]. Toutefois, des valeurs inférieures sont nécessaires pour le courant continu pour empêcher la nécrose des tissus lors d'applications de longue durée.

Les valeurs des Tableaux 3 et 4 s'appliquent aux courants mesurés avec le dispositif de mesure représenté à la Figure 12 a), qui permet automatiquement une sensibilité réduire à des fréquences plus élevées. Les fréquences du RESEAU D'ALIMENTATION de 50 Hz et de 60 Hz sont dans la plage du RISQUE le plus élevé.

~~f~~c) Bien que, en règle générale, les exigences d'une norme générale sont moins restrictives que celles des normes particulières, certaines valeurs admissibles des Tableaux 3 et 4 ont été fixées à des valeurs telles que:

– la majorité des types d'APPAREILS EM puissent s'y conformer, et
– elles puissent s'appliquer à la plupart des types d'APPAREILS (existants ou futurs) pour lesquels aucune norme particulière n'existe.

COURANT DE FUITE A LA TERRE

Le COURANT DE FUITE A LA TERRE s'écoulant dans le CONDUCTEUR DE PROTECTION ne présente pas en soi un DANGER. Le PATIENT et l'OPERATEUR sont protégés en spécifiant des valeurs suffisamment basses pour le COURANT DE FUITE PATIENT et le COURANT DE CONTACT en CONDITION NORMALE et en CONDITIONS DE PREMIER DEFAUT, y compris l'interruption du CONDUCTEUR DE PROTECTION. Toutefois, un COURANT DE FUITE A LA TERRE excessif pourrait poser un éventuel problème pour le réseau de terre de l'installation et à tous les disjoncteurs actionnés par des détecteurs de déséquilibre de courant.

Voir aussi l'IEC 60364-7-710 [10].

COURANT DE CONTACT

Les limites sont basées sur les considérations suivantes:

~~g~~d) Le COURANT DE CONTACT des APPAREILS EM est soumis aux mêmes valeurs indépendamment du ou des types de PARTIES APPLIQUEES, si elles existent, dans la mesure où même un APPAREIL EM qui ne comporte pas lui-même de PARTIE APPLIQUEE DE TYPE CF pourrait être utilisé dans des situations où des PROCEDURES intracardiaques sont appliquées.

~~h~~e) Bien que le COURANT DE CONTACT s'écoule à partir de parties autres que des CONNEXIONS PATIENT, il peut atteindre le PATIENT par un contact fortuit par divers chemins, y compris par l'intermédiaire de l'OPERATEUR.

~~i~~f) La densité de courant produite au niveau du cœur par un courant pénétrant dans la poitrine est de 50 μA/mm^2 par ampère [46]. La densité de courant au niveau du cœur produite par un courant de 500 μA (valeur maximale admissible en CONDITION DE PREMIER DEFAUT) pénétrant dans la poitrine est de 0,025 μA/mm^2, bien au-dessous du niveau considéré.

~~j~~g) La probabilité pour que le COURANT DE CONTACT s'écoulant au travers du cœur provoque la fibrillation ventriculaire ou la défaillance de la pompe cardiaque.

Le COURANT DE CONTACT pourrait d'une façon concevable atteindre un site intracardiaque si les PROCEDURES utilisées lors de la manipulation de conducteurs intracardiaques ou de cathéters remplis de liquide sont effectuées sans précaution. Il convient que ces dispositifs soient toujours manipulés avec beaucoup de soin et toujours avec des gants de caoutchouc secs. L'ANALYSE DES RISQUES suivante est fondée sur des hypothèses pessimistes concernant le degré de précaution appliqué.

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On considère que la probabilité d'un contact direct entre un dispositif intracardiaque et l'ENVELOPPE de l'APPAREIL EM est très faible, peut-être 1 procédure médicale sur 100. La probabilité d'un contact indirect par l'intermédiaire du personnel médical est en revanche plus élevée, disons 1 procédure médicale sur 10. Le COURANT DE FUITE maximal admissible en CONDITION NORMALE est de 100 µA et a lui-même une probabilité de provoquer une fibrillation ventriculaire de 0,05. Si la probabilité de contact indirect est de 0,1, la probabilité totale est de 0,005. Bien que cette probabilité apparaisse indésirablement élevée, il convient de rappeler qu'en manipulant correctement le dispositif intracardiaque, cette probabilité peut être réduite au niveau de celle de la stimulation mécanique seule, c'est-à-dire 0,001.

La probabilité pour que le COURANT DE CONTACT s'élève au niveau maximal admissible de 500 µA (CONDITION DE PREMIER DEFAUT) est considérée être de 0,1 dans les services comportant des PROCEDURES de maintenance médiocres. La probabilité pour que ce courant provoque une fibrillation ventriculaire est prise égale à 1.

La probabilité d'un contact accidentel direct avec l'ENVELOPPE est, comme précédemment, considérée égale à 0,01, ce qui donne une probabilité totale de 0,001, égale à la probabilité due à la stimulation mécanique seule.

La probabilité pour qu'un COURANT DE CONTACT au niveau maximal admissible de 500 µA (CONDITION DE PREMIER DEFAUT) s'écoule dans un dispositif intracardiaque par l'intermédiaire du personnel médical est de 0,01 (0,1 pour la CONDITION DE PREMIER DEFAUT; 0,1 pour le contact accidentel). Puisque la probabilité de ce courant de provoquer une fibrillation ventriculaire est de 1, la probabilité totale est également de 0,01. Comme il est dit ci-dessus, cette probabilité totale est élevée; elle peut toutefois être abaissée à la probabilité de stimulation mécanique seule de 0,001 en utilisant des PROCEDURES médicales appropriées.

~~k~~h) La probabilité pour que le COURANT DE CONTACT devienne perceptible par le patient.

La probabilité pour qu'un courant de 500 µA devienne perceptible est de 0,01 pour les hommes et de 0,014 pour les femmes lorsque l'on utilise des électrodes à pinces sur une peau intacte [45] [48]. Cette perceptibilité est plus élevée lorsque le courant passe à travers les muqueuses ou des perforations de la peau [48]. Même avec une distribution normale, il y aura une possibilité que certains PATIENTS perçoivent des courants très faibles. On rapporte qu'une personne a ressenti un courant de 4 µA, traversant une de ses muqueuses [48].

COURANT DE FUITE PATIENT

La valeur admissible du COURANT DE FUITE PATIENT pour les APPAREILS EM dont les PARTIES APPLIQUEES sont de TYPE CF en CONDITION NORMALE est de 10 µA, avec une probabilité de 0,002 de provoquer une fibrillation ventriculaire ou une défaillance de la pompe cardiaque lorsqu'il est appliqué au travers de petites zones d'un site intracardiaque.

Même avec un courant nul, il a été observé qu'une irritation mécanique peut produire une fibrillation ventriculaire [50]. Une limite de 10 µA peut être facilement atteinte et n'augmente pas de façon significative le RISQUE de fibrillation ventriculaire pendant les interventions intracardiaques.

La valeur maximale de 50 µA admissible en CONDITION DE PREMIER DEFAUT pour les APPAREILS EM avec des PARTIES APPLIQUEES DE TYPE CF est basée sur une valeur du courant qui, dans les conditions cliniques, a été trouvée avoir une très faible probabilité de provoquer une fibrillation ventriculaire ou de nuire à l'action hémodynamique du cœur.

Pour les cathéters de 1,25 mm à 2 mm de diamètre susceptibles de toucher le myocarde, la probabilité qu'un courant de 50 µA provoque une fibrillation ventriculaire est voisine de 0,01 (voir la Figure A.14 et sa légende). Les cathéters de petite surface (0,22 mm^2 et 0,93 mm^2) utilisés en angiographie ont de plus fortes probabilités de provoquer une fibrillation ventriculaire ou une défaillance de la pompe cardiaque s'ils sont placés directement sur des zones sensibles du cœur.

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La probabilité totale qu'une fibrillation ventriculaire soit provoquée par le COURANT DE FUITE PATIENT, en CONDITION DE PREMIER DEFAUT, est de 0,001 (0,1 pour la probabilité de PREMIER DEFAUT, 0,01 pour la probabilité que 50 μA provoque une fibrillation ventriculaire), égale à la probabilité due à la stimulation mécanique seule.

Il est peu probable que le courant de 50 μA admissible en CONDITION DE PREMIER DEFAUT conduise à une densité de courant suffisante pour stimuler les tissus neuromusculaires et, dans le cas d'un courant continu, provoquer une nécrose.

Pour les APPAREILS EM ayant des PARTIES APPLIQUEES DE TYPE B et BF avec lesquels le COURANT DE FUITE PATIENT maximal admissible en CONDITION DE PREMIER DEFAUT est égal à 500 μA, les mêmes justifications s'appliquent que celles valables pour le COURANT DE CONTACT dans la mesure où ce courant ne s'écoule pas directement à travers le cœur.

Comme l'existence d'une liaison à la terre du PATIENT est une CONDITION NORMALE, non seulement le COURANT AUXILIAIRE PATIENT mais aussi le COURANT DE FUITE PATIENT peuvent s'écouler pendant une période prolongée. Une très faible valeur du courant continu est donc nécessaire pour éviter la nécrose des tissus, quelle que soit la classification de la PARTIE APPLIQUEE.

L'apparition d'une TENSION RESEAU, à partir d'une faible source d'impédance, sur les CONNEXIONS PATIENT d'une PARTIE APPLIQUEE DE TYPE F serait provoquée par une double défaillance d'un moyen de protection des autres APPAREILS EM, simultanément reliés au PATIENT et conformes à la présente norme ou à une autre norme IEC, ou par une seule défaillance d'un moyen de protection des appareils non conformes à la présente norme. Telle quelle, cette condition est très improbable en bonne pratique médicale.

Toutefois, l'apparition d'une tension moins élevée, ou d'un COURANT DE FUITE d'une source ayant une tension de circuit ouvert de l'ordre de la TENSION RESEAU, est possible.

Du fait que la caractéristique de SECURITE principale des APPAREILS EM avec une PARTIE APPLIQUEE DE TYPE F est que le PATIENT n'est pas mis à la terre par la liaison avec L'APPAREIL EM, la séparation électrique d'une PARTIE APPLIQUEE DE TYPE F de la terre doit présenter une qualité minimale. Cela est assuré par l'exigence prévoyant que, même si une tension hypothétique à la fréquence d'alimentation, et égale à la tension d'alimentation la plus grande par rapport à la terre, présente dans le lieu où l'APPAREIL EM est utilisé apparaît sur les CONNEXIONS PATIENT, la limite du COURANT DE FUITE PATIENT ne sera pas dépassée.

Pour les PARTIES APPLIQUEES de TYPE CF, le COURANT DE FUITE PATIENT sera limité à 50 μA, ce qui n'est pas pire que dans la CONDITION DE PREMIER DEFAUT examinée précédemment.

Pour les PARTIES APPLIQUEES de TYPE BF, le COURANT DE FUITE PATIENT maximal dans ces conditions est de 5 mA. Même une telle valeur de courant pénétrant dans la poitrine ne conduirait qu'à une densité de courant au niveau du cœur du PATIENT de 0,25 μA/mm^2. Ce courant serait très perceptible par le PATIENT; cependant, la probabilité d'un tel événement est très faible. Le RISQUE d'effets physiologiques dangereux est faible et la TENSION RESEAU MAXIMALE utilisée pour cet essai représente le cas le plus défavorable, plus grave que ce qui est susceptible de se produire dans la pratique.

COURANT DE FUITE PATIENT total

Les valeurs du COURANT DE FUITE PATIENT dans la présente norme sont pour une seule fonction d'une PARTIE APPLIQUEE DE TYPE B ou d'une PARTIE APPLIQUEE DE TYPE BF ou une seule CONNEXION PATIENT d'une PARTIE APPLIQUEE DE TYPE CF. Avec des fonctions multiples ou des PARTIES APPLIQUEES multiples, le COURANT DE FUITE PATIENT total pourrait être bien plus élevé. Ce COURANT DE FUITE PATIENT total est la somme vectorielle des COURANTS DE FUITE PATIENT individuels. C'est pourquoi il est nécessaire de spécifier des limites pour le COURANT DE FUITE PATIENT total. Ces exigences sont tirées de l'IEC 60601-2-49:2001 [16].

La présente norme ne fixe pas le nombre des PARTIES APPLIQUEES connectées à un seul PATIENT. Il a été estimé que le nombre de PARTIES APPLIQUEES connectées à un seul PATIENT était compris entre une et cinq.

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COURANT DE FUITE PATIENT total pour les PARTIES APPLIQUEES DU TYPE CF

Pour les PARTIES APPLIQUEES de TYPE CF, le COURANT DE FUITE PATIENT pour la CONDITION NORMALE est de 10 µA. Les éléments suivants doivent être pris en compte pour les fonctions PATIENT multiple.

~~i~~) Le courant qui pénètre dans le cœur est réparti sur toutes les CONNEXIONS PATIENT et il n'est pas appliqué à la même petite zone sensible du tissu cardiaque.

~~m~~j) Le nombre de CONNEXIONS PATIENT connectées directement au tissu cardiaque n'est pas susceptible de dépasser le nombre de trois. Ainsi, le COURANT DE FUITE qui pénètre dans une seule petite zone du cœur est inférieur à 50 µA et il est proche de 15 µA à 20 µA pour une somme algébrique des courants. Le courant serait inférieur pour une somme vectorielle. La probabilité de fibrillation ventriculaire, selon la justification du COURANT DE FUITE PATIENT, se situe dans la plage de 0,003 même si les CONNEXIONS PATIENT sont très proches les unes des autres. Ce n'est pas très différent de la probabilité de 0,002 qui est acceptée pour une PARTIE APPLIQUEE unique connectée directement au cœur.

~~n~~k) Le COURANT DE FUITE provenant des PARTIES APPLIQUEES sur la surface du corps s'écoule de manière répartie à travers le corps. Selon la justification du COURANT DE FUITE PATIENT, 5 mA pénétrant dans la poitrine produit une densité de courant au niveau du cœur de 0,025 µA/mm^2.

C'est pourquoi la valeur de 50 µA est considérée comme acceptable pour la CONDITION NORMALE pour le COURANT DE FUITE PATIENT total.

Pour la CONDITION DE PREMIER DEFAUT, le COURANT DE FUITE pour ~~l'APPAREIL~~ les PARTIES APPLIQUEES DE TYPE CF a été porté à 0,1 mA. La justification donnée pour le COURANT DE FUITE PATIENT donne une probabilité de 0,07 pour la fibrillation ventriculaire pour le courant entrant directement dans le cœur. La probabilité d'une CONDITION DE PREMIER DEFAUT a été donnée comme étant 0,1. C'était il y a plus d'une dizaine d'années. En raison des améliorations intervenues dans la conception, des composants plus fiables, des matières de meilleure qualité, de l'utilisation de la GESTION DES RISQUES conformément à l'ISO 14971 et de l'utilisation liée d'outils associés, comme le DANGER lié à l'ANALYSE DES RISQUES, la probabilité d'une CONDITION DE PREMIER DEFAUT devrait être très inférieure. Elle est désormais estimée proche d'au moins 0,02. La probabilité d'une fibrillation ventriculaire est de 0,07 × 0,02, ou 0,0014, et proche de celle acceptée pour une seule PARTIE APPLIQUEE DE TYPE CF.

COURANT DE FUITE PATIENT total pour les PARTIES APPLIQUEES DU TYPE BF

Le COURANT DE FUITE PATIENT total a été porté à 500 µA pour la CONDITION NORMALE et à 1 000 µA pour la CONDITION DE PREMIER DEFAUT. Comme cela est expliqué au point ~~c~~ k) ci-dessus, la densité de courant au niveau du cœur pour le courant de 5 000 µA est assez faible. Il ne devrait pas y avoir de problème ni pour la CONDITION NORMALE ni pour la CONDITION DE PREMIER DEFAUT.

COURANT DE FUITE PATIENT total causé par une tension externe sur la CONNEXION PATIENT

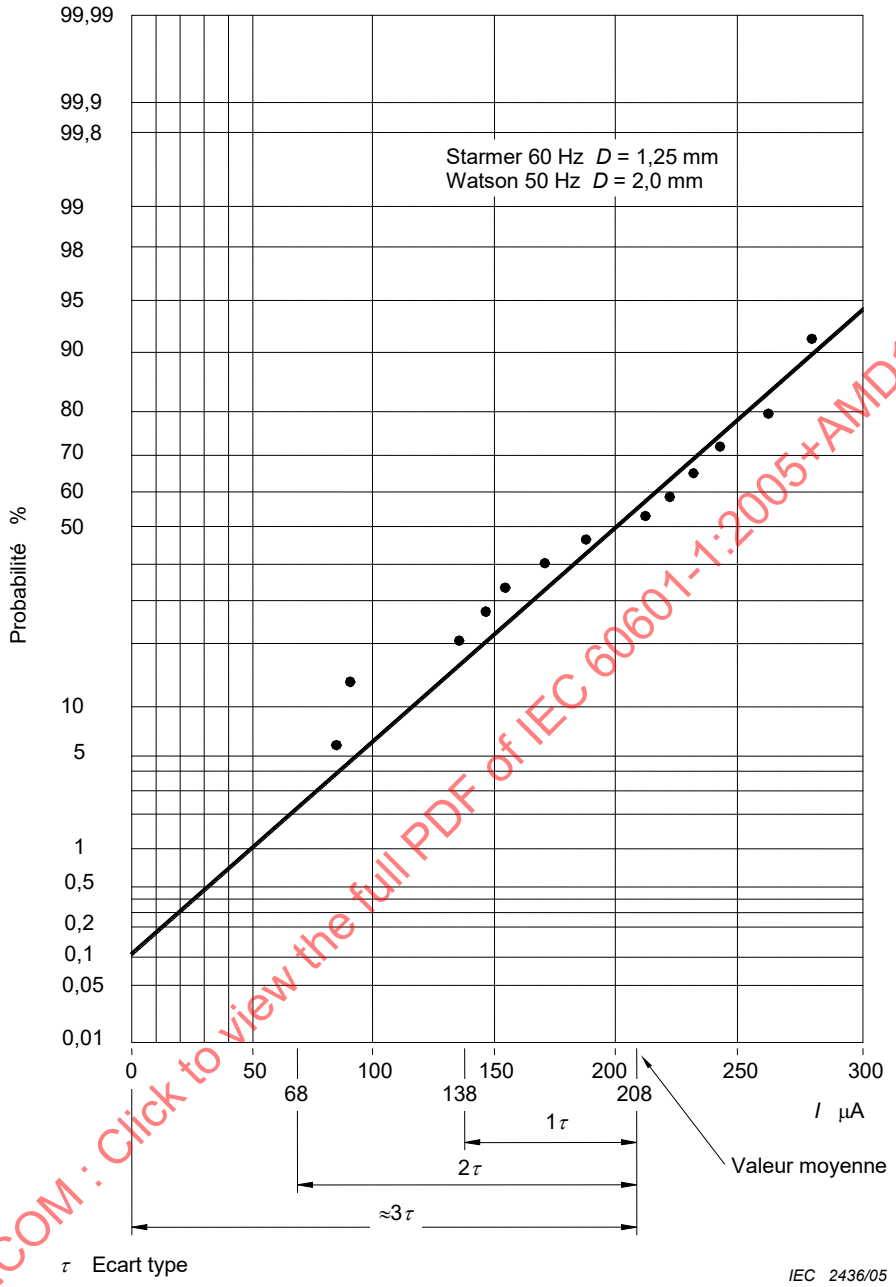
Pour les PARTIES APPLIQUEES DE TYPE CF, la limite a été portée à 100 µA. La justification pour le COURANT DE FUITE PATIENT indique que la probabilité de défaillance de la mise à la terre de protection des APPAREILS EM de la CLASSE I est de 0,1 et que la probabilité d'un défaut dans un MOP est inférieure à 0,1. Cela s'est passé il y a une dizaine d'années. Comme expliqué plus avant, ces probabilités devraient être bien inférieures à l'heure actuelle et elles sont considérées comme n'étant pas plus mauvaises que 0,02. La probabilité d'apparition de la TENSION RESEAU sur le PATIENT est de 0,02 × 0,02, ou 0,0004. Cette valeur est inférieure à la probabilité de 0,001 acceptée dans la deuxième édition de l'IEC 60601-1.

COURANT AUXILIAIRE PATIENT

Les valeurs admissibles pour le COURANT AUXILIAIRE PATIENT sont basées sur des considérations similaires à celles relatives au COURANT DE FUITE PATIENT. Elles s'appliquent, que le COURANT AUXILIAIRE PATIENT soit ou non nécessaire au fonctionnement de l'APPAREIL EM

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(par exemple pléthysmographes par impédance). Des valeurs inférieures sont données pour le courant continu pour empêcher la nécrose des tissus lors d'applications de longue durée.



NOTE Se référer aux documents originaux de Starmer [53] et Watson [54] pour l'interprétation des données.

Figure A.14 – Probabilité de fibrillation ventriculaire

Explication de la Figure A.14

Les articles de Starmer [53] et Watson [54] fournissent des données sur la fibrillation ventriculaire provoquée par des courants de fréquence 50 Hz et 60 Hz appliqués directement sur les cœurs des personnes faisant partie des populations humaines ayant des maladies cardiaques. La probabilité de la fibrillation a été obtenue en prenant en compte le diamètre des électrodes et l'intensité du courant. Pour des électrodes de diamètre 1,25 mm et 2 mm et des courants inférieurs ou égaux à 0,3 mA, la distribution apparaît normale. En conséquence, elle a été extrapolée pour y inclure les valeurs couramment utilisées pour évaluer le RISQUE PATIENT (valeurs notées sur la Figure A.14). A partir de cette extrapolation, il apparaît que:

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- une quelconque valeur de courant, même faible, entraîne une certaine probabilité de provoquer une fibrillation ventriculaire, et
- les valeurs couramment utilisées comportent toutes de faibles probabilités, comprises entre 0,002 et 0,01 approximativement.

Etant donné que la fibrillation ventriculaire est influencée par de nombreux facteurs (état du PATIENT, probabilité qu'un courant pénètre dans une zone plus sensible du myocarde, probabilité d'une fibrillation en fonction du courant ou de la densité de courant, physiologie, champ électrique, etc.), il est raisonnable d'utiliser les statistiques pour déterminer la possibilité de RISQUE pour des conditions variées.

Effets de chauffe des COURANTS DE FUITE

Un courant de 10 mA ne produit aucune sensation de chauffe avec une CONNEXION PATIENT type et une zone de contact de l'ordre de 1 cm^2, mais un courant quelques fois plus élevé provoquerait une brûlure. Le RISQUE de brûlure dépend de l'intensité du courant mais pas de sa fréquence, le courant doit donc être mesuré avec un dispositif non pondéré en fréquence, tel que celui illustré à la Figure 12 a) mais sans C_1 et R_1.

Paragraphe 8.7.3 f)

Les COURANTS DE FUITE peuvent circuler à travers un CONDUCTEUR DE TERRE FONCTIONNELLE. Ceci peut entraîner un RISQUE inattendu si un APPAREIL EM DE CLASSE II est combiné avec un APPAREIL EM DE CLASSE I ou avec un trolley mis à la terre, par exemple utilisant un MSO. Même si une application appropriée des 'règles' de montage d'un SYSTEME EM élimine ce RISQUE, le RISQUE causal peut être atténué en limitant le COURANT DE FUITE autorisé dans un CONDUCTEUR DE TERRE FONCTIONNELLE.

Paragraphe 8.7.4.2 – Circuits de mesure de l'alimentation

Pour des résultats corrects des mesurages du COURANT DE FUITE, il est essentiel que le circuit de mesure ait un point de référence commun. Le point doit également être référencé électriquement par rapport à l'ensemble des parties du circuit. Le COURANT DE FUITE mesuré pourrait également être différent selon la configuration d'alimentation. Par exemple, si un APPAREIL EM spécifié pour être raccordé à une alimentation ayant un côté au niveau du potentiel de la masse est en fait raccordé à une alimentation ayant deux phases symétriques (telle qu'une alimentation 230 V aux USA), le COURANT DE FUITE mesuré sera très inférieur au cas le plus défavorable. Si le RESEAU D'ALIMENTATION installé dans la salle où ont lieu les mesurages ne représente pas le cas le plus défavorable, un circuit d'alimentation spécifique doit être établi. Cela peut être effectué à l'aide d'un transformateur de séparation avec le point approprié du CIRCUIT SECONDAIRE relié au point de référence. Les mesurages du COURANT DE FUITE peuvent également permettre d'obtenir des résultats précis et reproductibles sans transformateur de séparation. Toutefois, cela dépendra de la qualité du RESEAU D'ALIMENTATION utilisé pour les mesurages. Les facteurs devant être pris en compte sont les tensions transitoires, les signaux d'interférence et les différences de tension entre le neutre et la terre dans le circuit de mesure.

Les symboles de masse donnés dans les figures représentent ce point de référence commun, qui n'est pas relié à la borne de terre de protection du RESEAU D'ALIMENTATION. Un point de référence indépendant de ce type peut assurer une protection supplémentaire pour la personne effectuant les mesurages.

La présence d'un transformateur de tension variable est nécessaire pour fournir 110 % de la tension d'alimentation ASSIGNEE aux APPAREILS EM. Bien qu'il soit possible d'effectuer un essai avec la TENSION RESEAU normalement présente dans la salle d'essai et de multiplier les valeurs mesurées du COURANT DE FUITE par le facteur approprié, cela ne produit pas toujours le même résultat qu'un essai effectué avec 110 % de la tension d'alimentation ASSIGNEE, particulièrement avec les APPAREILS EM qui comportent une alimentation à découpage.

Les commutateurs S_1 ou $S_1 + S_2$ ou $S_1 + S_2 + S_3$ dans les Figures F.1 à F.4 (incluse) peuvent être omis et les coupures des conducteurs correspondants peuvent être obtenues par d'autres moyens.

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Les transformateurs de séparation mono- ou polyphasés à la tension ou aux tensions de sortie réglables, représentés aux Figures F.1 à F.5 (incluse), peuvent être remplacés par une combinaison comprenant un transformateur de séparation à tension de sortie fixe et un autotransformateur à tension de sortie réglable.

Paragraphe 8.7.4.3 – Connexion au circuit de mesure de l'alimentation

Bien qu'il ne soit pas improbable que les APPAREILS EM soient utilisés en étant placés sur ou dans un environnement métallique mis à la terre, une telle situation serait plutôt difficile à décrire de manière telle que les résultats d'essai deviendraient reproductibles. Le conseil dans la note en 8.7.4.3 d) 1) doit donc être considéré comme une convention.

Le fait que les câbles PATIENT puissent avoir une capacité significative par rapport à la terre est généralement importante et a une influence considérable sur les résultats d'essais. Une disposition donnant des résultats reproductibles est, en conséquence, prescrite.

Le transformateur de séparation du circuit d'alimentation de mesure fournit une protection complémentaire pour la personne qui réalise les mesures et augmente la précision des mesures du COURANT DE FUITE. Toutefois, il n'est pas absolument nécessaire d'utiliser un isolateur de séparation lors des mesures du COURANT DE FUITE. Dans certains cas, comme pour les APPAREILS EM et SYSTEMES EM à forte puissance, l'utilisation d'un transformateur de séparation n'est pas réalisable en pratique. Lorsqu'on réalise des mesures du COURANT DE FUITE sans transformateur de séparation, le FABRICANT doit prendre en compte ce qui suit:

– est-il possible d'extrapoler les COURANTS DE SUITE à 110 % de la tension d'alimentation ASSIGNEE;
– l'influence des courants qui sont entraînés par des différences de tension entre la terre de protection et le neutre du réseau d'alimentation de L'APPAREIL EM ou pour les SYSTEMES EM avec des CONNEXIONS DE TERRE DE PROTECTION multiples.

Mesurer sans transformateur de séparation peut produire des valeurs lues de COURANT DE FUITE supérieures aux mesures du COURANT DE FUITE avec un transformateur de séparation.

Paragraphe 8.7.4.5 – Mesure du COURANT DE FUITE A LA TERRE et du courant dans la CONNEXION DE TERRE FONCTIONNELLE

Le dispositif de mesure représente une méthode de mesure prenant en compte l'effet physiologique d'un courant à travers le corps humain, y compris le cœur, ainsi que la possibilité d'un contact par impédance faible entre une CONNEXION PATIENT et le PATIENT. Bien que l'IEC 60990 [20] spécifie certains dispositifs de mesure pour une utilisation générale, aucun de ceux-ci ne serait approprié pour mesurer le COURANT DE FUITE PATIENT. Etant donné que l'instrument de mesure de la seconde édition est retenu dans ce but, il semble pratique d'utiliser le même instrument pour toutes les mesures de COURANT DE FUITE, exceptées les mesures de courants ou de composantes de courant avec des fréquences supérieures à 1 kHz par rapport à la limite de 10 mA spécifiée en 8.7.3 d).

Paragraphe 8.7.4.6 – Mesure du COURANT DE CONTACT

Lorsqu'une feuille de métal doit être appliquée sur une ENVELOPPE composée de matériau isolant, un contact strict peut être effectué en appliquant la feuille contre le matériau isolant en exerçant une pression d'environ 5 kPa (0,5 N/cm^2).

Paragraphe 8.7.4.7 – Mesure du COURANT DE FUITE PATIENT

Paragraphe 8.7.4.7 b)

Cet essai permet de confirmer que la séparation entre les CONNEXIONS PATIENT et les autres parties est adéquate pour limiter le COURANT DE FUITE PATIENT à la valeur admissible en cas de tension externe.

Si la PARTIE APPLIQUEE peut être déconnectée de l'APPAREIL EM, il est possible que les contacts du connecteur touchent un objet relié à la terre, mais cette situation est couverte par

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les essais de 8.5.2.3, et non par 8.7.4.7 b), qui s'applique à l'APPAREIL EM et à la PARTIE APPLIQUEE ensemble.

La feuille métallique de 20 cm × 10 cm représente la taille d'une main humaine. Pour certains APPAREILS EM, la zone de contact est de taille supérieure à celle de la main. Dans ce cas, la taille de la feuille peut être augmentée.

Paragraphe 8.7.4.7 c)

Certains des essais spécifiés dans la seconde édition de la présente norme relatifs à la présence éventuelle d'une TENSION RESEAU sur une ENTREE DE SIGNAL ou une SORTIE DE SIGNAL (comme défini dans cette édition, maintenant regroupé dans l'expression ENTREE/SORTIE DE SIGNAL). Il existe plusieurs exclusions, mais aucune des exclusions appliquées à cette condition n'était considérée comme une CONDITION DE PREMIER DEFAUT. L'hypothèse choisie dans la troisième édition est que, si les DOCUMENTS D'ACCOMPAGNEMENT ne comportent pas de restrictions sur le raccordement des autres appareils sur l'ENTREE/SORTIE DE SIGNAL, il convient de considérer la présence de la TENSION RESEAU MAXIMALE comme une CONDITION NORMALE.

A la place d'un transformateur de séparation T_2 avec une tension de sortie réglable, une combinaison d'un transformateur de séparation avec une tension de sortie réglée et un auto-transformateur avec une tension de sortie peut être utilisée.

Paragraphe 8.7.4.7 d)

L'essai avec une tension externe appliquée à des PARTIES METALLIQUES ACCESSIBLES non reliées à la terre reflète l'exigence présentée en 8.5.2.2 pour l'isolation entre ces parties et des CONNEXIONS PATIENT non reliées à la terre de PARTIES APPLIQUEES DU TYPE B.

Pour les PARTIES APPLIQUEES DU TYPE BF, cet essai s'applique, ainsi que l'essai de 8.7.4.7 b), même si les deux portent sur l'isolation entre les CONNEXIONS PATIENT et d'autres parties, dans la mesure où le COURANT DE FUITE PATIENT peut ne pas être le même dans les deux situations avec des valeurs limites différentes.

A la place d'un transformateur de séparation T_2 avec une tension de sortie réglable, une combinaison d'un transformateur de séparation avec une tension de sortie réglée et un auto-transformateur avec une tension de sortie peut être utilisée.

Il convient de veiller à ce que la capacité du dispositif de mesure et de ses conducteurs de connexion à la terre et à la masse de l'APPAREIL EM soit maintenue à un niveau aussi faible que possible.

Comme indiqué dans la justification de 8.7.3, la présence de la TENSION RESEAU MAXIMALE sur un PATIENT représente un des cas les plus défavorables, il est plus grave que ce qui pourrait se produire dans la pratique, et le COURANT DE FUITE PATIENT admissible pour une PARTIE APPLIQUEE DE TYPE BF dans cette situation est de 5 mA. Il a été souligné que l'application de la TENSION RESEAU sur une PARTIE ACCESSIBLE non reliée à la terre pourrait donc entraîner un COURANT DE FUITE PATIENT jusqu'à 5 mA s'écoulant à partir des CONNEXIONS PATIENT d'une PARTIE APPLIQUEE DE TYPE BF ; alors que dans la même situation, une PARTIE APPLIQUEE DE TYPE B (qui offre en général un niveau de sécurité inférieur) était admissible à 500 µA uniquement. Pour résoudre cette anomalie, l'essai de 8.7.4.7 d), avec 110 % de la TENSION RESEAU MAXIMALE sur des PARTIES ACCESSIBLES non reliées à la terre, s'applique également aux PARTIES APPLIQUEES DU TYPE BF, et, dans cette condition, le COURANT DE FUITE PATIENT admissible est la valeur générale de 500 µA pour la CONDITION DE PREMIER DEFAUT.

Il n'est pas nécessaire d'effectuer les essais de 8.7.4.7 d) sur les PARTIES APPLIQUEES DU TYPE CF car pour celles-ci, la même valeur admissible de 50 µA s'applique comme dans l'essai de 8.7.4.7 b).

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Paragraphe 8.7.4.7 h)

Cette exigence représente un compromis entre une exigence d'essais extensifs qui, avec la plupart des APPAREILS EM, donnerait des informations inutiles et l'absence d'exigence particulière pour traiter de ce RISQUE.

La plupart des PARTIES APPLIQUEES DE TYPE B sont mises à la terre, si bien que la mesure selon 8.7.4.7 g) (toutes les CONNEXIONS PATIENT d'une fonction unique connectées directement ensemble) donnera le même résultat que la mesure selon 8.7.4.7 h) (toutes les CONNEXIONS PATIENT de toutes les PARTIES APPLIQUEES du même type connectées ensemble). Si ce résultat se situe dans les limites du COURANT DE FUITE PATIENT, ce sera certainement dans les limites du COURANT DE FUITE PATIENT total. Toutefois, il est possible d'avoir des PARTIES APPLIQUEES DE TYPE B qui ne sont pas directement reliées à la terre et, dans ce cas, les valeurs mesurées peuvent être différentes.

Paragraphe 8.7.4.9 – APPAREIL EM avec des CONNEXIONS PATIENT multiples

Cette exigence a été introduite dans le second amendement de la deuxième édition de la présente norme. Elle concerne un RISQUE qui peut se produire, par exemple avec un instrument de mesure des signaux physiologiques lorsqu'un amplificateur pilote une électrode pour réduire les interférences en mode commun. Si l'une des électrodes sensibles est déconnectée du PATIENT et capte une tension élevée à la fréquence du réseau, l'amplificateur pourrait envoyer un courant élevé dans le PATIENT dans un effort inutile pour supprimer l'interférence.

Cette exigence représente un compromis entre des essais extensifs, qui pour la plupart des APPAREILS EM n'apporteraient pas d'informations utiles, et l'absence d'exigence spécifique sur ce RISQUE.

Ainsi, l'IEC 60601-2-49:2001 [16] a introduit un ensemble complet d'essais à effectuer sur tous les appareils relevant du domaine d'application de cette norme. Ils comprennent la mesure de ce qui est appelé "COURANT DE FUITE DE PARTIE" dans cette norme: il s'agit du courant qui s'écoule entre les CONNEXIONS PATIENT d'une fonction et les CONNEXIONS PATIENT d'une autre ou d'autres fonctions, qui est couvert dans la présente édition de la norme générale par la définition révisée de COURANT AUXILIAIRE PATIENT.

L'incorporation de ces essais dans la norme générale a été envisagée mais il a été décidé que ces essais spécifiques devraient être laissés à des normes particulières. Les scénarios auxquels ils se rattachent, tels que les CONNEXIONS PATIENT d'une fonction utilisées et reliées au PATIENT alors que les CONNEXIONS PATIENT d'une autre fonction ne sont pas utilisées et pourraient être en contact avec d'autres objets, sont susceptibles de se produire avec des appareils multifonction de surveillance des PATIENTS mais peu probables avec la plupart des autres types d'APPAREILS EM.

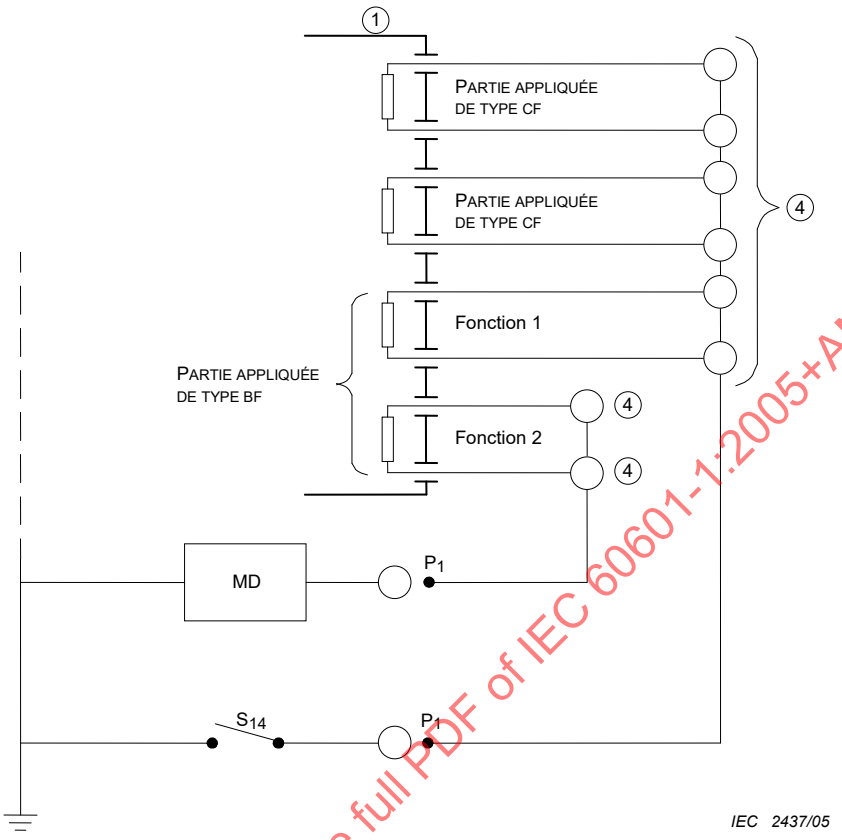
La Figure A.15, basée sur la Figure KK.101 de l'IEC 60601-2-49:2001 [16], illustre un exemple de mesure du COURANT DE FUITE PATIENT à partir d'une fonction d'une PARTIE APPLIQUEE DE TYPE BF alors que les CONNEXIONS PATIENT d'une autre fonction de la même PARTIE APPLIQUEE et de deux PARTIES APPLIQUEES DU TYPE CF sont flottantes ou reliées à la terre.

Paragraphe 8.8.1 – Généralités

Il convient de veiller à ce que la tension appliquée sur une ISOLATION RENFORCEE ne soumette aucun des MOYENS DE PROTECTION de l'APPAREIL EM à un effort trop important. S'il existe plusieurs chemins entre les mêmes points, il peut être nécessaire de les soumettre aux essais séparément. Par exemple, il pourrait y avoir un chemin à partir de la PARTIE RELIEE AU RESEAU vers une CONNEXION PATIENT qui comporte une ISOLATION PRINCIPALE plus une LIAISON DE TERRE DE PROTECTION et une isolation des CONNEXIONS PATIENT, comme requis par 8.5.2.1, ainsi qu'un chemin parallèle comportant une ISOLATION RENFORCEE. Certaines parties de l'APPAREIL EM pourraient devoir être déconnectées pour pouvoir soumettre l'ISOLATION RENFORCEE à essai sans surcharger l'isolation séparée de la PARTIE RELIEE AU RESEAU ou des CONNEXIONS PATIENT.

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Cela pourrait être évité, par exemple dans le cas d'un transformateur, en utilisant un diviseur de tension ayant une prise intermédiaire reliée au noyau ou à quelque autre point de raccordement approprié pour assurer une division correcte de la tension sur les isolations en présence, ou en utilisant deux transformateurs d'essai, correctement mis en place.



Pour les légendes, voir le Tableau 5.

Indication

Toutes les mesures sont effectuées avec S_{14} fermé et de nouveau avec S_{14} ouvert.

Figure A.15 – Exemple d'un circuit de mesure pour le COURANT DE FUITE PATIENT entre une CONNEXION PATIENT et la terre pour un APPAREIL EM avec CONNEXIONS PATIENT multiples

Paragraphe 8.8.2 – Distance au travers d'une isolation solide ou usage d'un matériau de feuille fine

La seconde édition de la présente norme ne comportait pas de restriction sur l'épaisseur de l'isolation solide, à l'exception de celle spécifiée en 57.9.4 e) pour les transformateurs et de la nécessité pour toutes les isolations couvertes par l'Article 20 d'être suffisamment épaisses pour réussir l'essai de tension de tenue. Un film de matériau isolant très fin pourrait réussir cet essai mais pourrait ne pas fournir une isolation fiable pour tous les éléments de production pendant la DUREE DE VIE PREVUE.

Certains Comités nationaux ont proposé au cours de l'élaboration de la présente édition d'introduire des exigences correspondantes issues de l'IEC 60950-1 pour réparer cette omission. Les groupes de travail WG 14 (essais) comme WG 16 (risques électriques) ont recommandé d'accepter ces propositions.

Ces exigences sont incluses dans l'IEC 60950-1 depuis de nombreuses années sans problèmes. Elles ne devraient pas être onéreuses dans la pratique pour les APPAREILS EM, et la plupart des APPAREILS EM conçus selon les précédentes éditions de la présente norme les auraient d'ailleurs respectées.

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Les exigences qui ont été introduites sont destinées à être techniquement équivalentes à celles de l'IEC 60950-1, mais la structure rédactionnelle a été modifiée comme suit pour plus de clarté.

– L'IEC 60950-1 spécifie une exigence générale pour la distance à travers l'isolation, à l'exception des tensions jusqu'à 71 V. Cela a été modifié pour indiquer explicitement que l'exigence s'applique au-dessus de 71 V.

– L'IEC 60950-1 spécifie une exception pour l'exigence relative à la distance à travers l'isolation selon laquelle les exigences pour les matériaux de feuille fine s'appliquent comme indiqué dans un autre paragraphe, mais ce paragraphe ne mentionne pas explicitement la limite de 71 V. Cela a été indiqué de manière explicite en précisant les exigences pour les matériaux de feuille fine en tant qu'alternative à l'exigence relative à l'épaisseur, selon la même formulation d'introduction.

– L'IEC 60950-1 spécifie que "l'isolation en matériaux de feuille fine est admise... à condition de" remplir certaines conditions. Cela a été modifié en une exigence explicite selon laquelle l'isolation en matériaux de feuille fine doit remplir ces conditions.

– L'IEC 60950-1 exige que l'isolation en matériaux de feuille fine "soit utilisée dans l'ENVELOPPE de l'appareil". Toutefois, l'ENVELOPPE telle que définie dans la présente norme inclut toutes les surfaces extérieures, y compris les surfaces des câbles, les PARTIES APPLIQUEES, etc. L'exigence a donc été reformulée.

Ailleurs dans la présente norme, les termes ISOLATION SUPPLEMENTAIRE et ISOLATION RENFORCEE ont pour la plupart été remplacés par des références aux MOYENS DE PROTECTION, mais ils ont été conservés ici car, comme dans l'IEC 60950-1, les exigences relatives à la distance à travers l'isolation et l'utilisation de matériaux de feuille fine s'appliquent à l'ISOLATION SUPPLEMENTAIRE et à l'ISOLATION RENFORCEE, mais pas à l'ISOLATION PRINCIPALE. Ces exigences ne s'appliquent donc pas lorsque l'ISOLATION PRINCIPALE, en tant que MOYEN DE PROTECTION, est utilisée en association avec une LIAISON DE TERRE DE PROTECTION en tant que second MOYEN DE PROTECTION. Lorsqu'une DOUBLE ISOLATION est utilisée, ces exigences s'appliquent quelle que soit sa composante considérée comme l'ISOLATION SUPPLEMENTAIRE.

Paragraphe 8.8.3 – Tension de tenue

Les composantes conçues pour limiter la tension pourraient devoir être retirées afin de pouvoir appliquer la tension d'essai maximale sur l'isolation soumise à l'essai.

L'objectif de cet essai est de vérifier toute l'isolation solide en condition du cas le plus défavorable après avoir atteint la température de fonctionnement. Pour les éléments de chauffage, le cas le plus défavorable est atteint lorsque les appareils de chauffage restent alimentés pendant le mesurage.

Les tensions d'essai spécifiées sont appropriées pour la seule isolation solide. Les espacements (LIGNES DE FUITE et DISTANCES DANS L'AIR) sont évalués par 8.9. L'IEC 60664-1 donne des informations détaillées sur les méthodes d'essais électriques des distances d'isolement en utilisant les essais de tension de tenue de tension de choc. Ces essais peuvent être utilisés selon l'IEC 60950-1 pour les MOOP, mais ils ne sont pas spécifiés pour les MOPP. L'IEC 60664-1 indique que l'essai de tension de tenue de type 2U + 1 000 V “n'est pas approprié pour les essais des distances d'isolement”.

Puisque l'essai de tension de tenue est appliqué immédiatement après le traitement de pré-conditionnement humide, l'APPAREIL EM étant toujours dans l'enceinte d'épreuve hygroscopique, des précautions suffisantes pour la protection du personnel de laboratoire pourraient être nécessaires.

Dans le Tableau 6, les valeurs pour la protection de l'OPERATEUR sont tirées de la IEC 60950-1 et celles pour la protection du PATIENT de la deuxième édition de l'IEC 60601-1. Trois principes ont été appliqués pour la construction du tableau.

– Les MOPP sont toujours à une valeur plus élevée que les MOOP.

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– Les circuits réseau sont affectés par des surtensions transitoires comme cela est précisé au Tableau 10. Dans les CIRCUITS SECONDAIRES, le niveau de surtension transitoire est au moins inférieur d'un niveau aux circuits réseau.

– La valeur de la tension d'essai est essentiellement déterminée par la tension transitoire sur le RESEAU qui est généralement d'ordres d'amplitude supérieurs à la TENSION DE SERVICE.

Dans un but d'alignement avec la deuxième édition de l'IEC 60601-1 pour la TENSION DE SERVICE commune de 220 V à 240 V en valeur efficace, la tension d'essai de 4 000 V en valeur efficace a été retenue même si cette valeur est supérieure à deux fois la tension d'essai pour un MOPP. Toutefois, chaque MOPP individuel doit satisfaire l'exigence minimale de 1 500 V en valeur efficace.

Paragraphe 8.8.3 a)

La tension d'essai peut être fournie par un transformateur, par une source en courant continu ou en utilisant le ou les transformateurs de l'APPAREIL EM. Dans ce dernier cas, pour empêcher l'échauffement, la tension d'essai peut avoir une fréquence supérieure à la fréquence ASSIGNEE de l'APPAREIL EM.

La PROCEDURE et la durée de l'essai pour des TENSIONS DE SERVICE supérieures ou égales à 1 000 V en courant alternatif ou 1 500 V en courant continu ou des valeurs de crête peuvent être spécifiées d'autre part dans les normes particulières.

Paragraphe 8.8.4.1 – Solidité mécanique et résistance à la chaleur

Les essais concernant l'inflammabilité des matériaux sont décrits dans l'IEC 60695-11-10.

Paragraphe 8.9 – DISTANCE DANS L'AIR et LIGNES DE FUITE

Pour les APPAREILS EM destinés à être alimentés à partir du RESEAU D'ALIMENTATION, les exigences relatives à la DISTANCE DANS L'AIR et la tension de tenue sont fondées sur les surtensions transitoires attendues qui pourraient entrer dans l'appareil à partir du RESEAU D'ALIMENTATION. Selon l'IEC 60664-1, l'intensité de ces surtensions transitoires est déterminée par la tension d'alimentation normale et le dispositif d'alimentation. Ces surtensions transitoires sont classées selon l'IEC 60664-1 en quatre groupes désignés catégories de surtension I à IV (également appelées catégories d'installation I à IV). Ailleurs dans la présente norme, la catégorie de surtension est présumée être la catégorie II.

Il convient de coordonner la conception de l'isolation solide et des DISTANCES DANS L'AIR de sorte que, si une surtension transitoire fortuite dépasse les limites de la catégorie de surtension II, l'isolation solide peut supporter une tension supérieure aux DISTANCES DANS L'AIR.

Les valeurs indiquées dans les Tableaux 13 à 15 correspondent à celles de l'IEC 60950-1 pour la catégorie de surtension II pour les PARTIES RELIEES AU RESEAU et la catégorie de surtension I pour les CIRCUITS SECONDAIRES. Si l'APPAREIL EM est destiné à être utilisé dans des lieux où le RESEAU D'ALIMENTATION correspond à la catégorie de surtension III ou IV, ces valeurs seront inappropriées.

UN CIRCUIT SECONDAIRE issu du RESEAU D'ALIMENTATION appartiendra normalement à la catégorie de surtension I si le RESEAU D'ALIMENTATION appartient à la catégorie de surtension II ; les surtensions transitoires maximales pour diverses tensions du RESEAU D'ALIMENTATION dans la catégorie de surtension I sont indiquées dans les titres de colonnes du Tableau 13.

Certaines règles s'appliquent à l'isolation entre l'ENVELOPPE et la CONNEXION PATIENT d'une PARTIE APPLIQUEE DE TYPE F:

1) Dans le cas d'une PARTIE APPLIQUEE DE TYPE F ne comportant pas de différence de potentiel, l'isolation entre les CONNEXIONS PATIENT et l'ENVELOPPE ne recevra une charge égale à la TENSION RESEAU que dans le cas d'un défaut se produisant dans un autre appareil relié au PATIENT.

   Ce cas survient rarement et en outre cette isolation n'est normalement pas soumise aux surtensions transitoires se manifestant dans la PARTIE RELIEE AU RESEAU. Compte tenu

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de ce qui précède, l'isolation requise entre la PARTIE APPLIQUEE et l'ENVELOPPE pour le cas cité doit uniquement satisfaire aux exigences relatives à L'ISOLATION PRINCIPALE.

2) Dans le cas d'une PARTIE APPLIQUEE DE TYPE F comportant des éléments affectés d'une différence de potentiel, le raccordement d'une CONNEXION PATIENT à la terre via un PATIENT relié lui-même à la terre (CONDITION NORMALE) peut soumettre l'isolation entre d'autres parties et l'ENVELOPPE à la totalité de la tension au sein de la PARTIE APPLIQUEE.

   Etant donné que cette tension se manifeste en CONDITION NORMALE, bien que rarement, l'isolation correspondante devrait satisfaire aux exigences relatives à la DOUBLE ISOLATION ou à l'ISOLATION RENFORCEE. ~~Eu égard à la faible probabilité que cette situation a de se produire, les LIGNES DE FUITE et les DISTANCES DANS L'AIR figurant dans le Tableau 11 sont jugées adéquates.~~

3) La valeur applicable est la plus grande valeur obtenue selon 1) et 2) ci-dessus.

En l'absence d'arrière plan théorique de référence, il a été décidé que les valeurs supérieures à 1 000 V seraient tirées du Tableau 7 de l'IEC 61010-1:2001 [22] pour les LIGNES DE FUITE en utilisant la colonne Groupe de matériau IIIa-b, degré de pollution 3, qui correspond aux valeurs existant dans la deuxième édition de l'IEC 60601-1 ou qui est légèrement plus forte. Pour les DISTANCES DANS L'AIR, les valeurs ont été estimées sur la base de la relation entre la LIGNE DE FUITE et la DISTANCE DANS L'AIR pour les valeurs inférieures à 1 000 V en valeur efficace à partir des valeurs du Tableau 12. Ces valeurs obtenues sont données au Tableau A.1.

Le Tableau 16 de la deuxième édition de l'IEC 60601-1 a été éclaté en deux tableaux dans la présente norme (Tableaux 9 et 10). Pour l'aligner avec les tableaux tirés d'autres normes comme l'IEC 60950-1, le facteur entre les tensions en courant alternatif et les tensions en courant continu a été modifié pour passer de 1,2 à environ 1,4. Cette modification a été acceptée dans la mesure où il s'agit d'une approche commune dans d'autres normes et que cela empêche d'avoir des LIGNES DE FUITE et des DISTANCES DANS L'AIR différentes dans des circuits où il existe une tension en courant continu provenant d'une tension en courant alternatif.

Tableau A.1 – Valeurs de la DISTANCE DANS L'AIR et de la LIGNE DE FUITE tirées du Tableau 7 de l'IEC 61010-1:2001 et du Tableau 12

TENSION DE SERVICE V courant continu. jusqu'à inclus	TENSION DE SERVICE V valeur efficace jusqu'à inclus	Espacement assurant un MOYEN DE PROTECTION AU PATIENT		Espacement assurant deux MOYENS DE PROTECTION AU PATIENT	
		DISTANCE DANS L'AIR mm	LIGNE DE FUITE mm	DISTANCE DANS L'AIR mm	LIGNE DE FUITE mm
1 500	1 250	11,5	20	23,0	40
1 920	1 600	14,5	25	29,0	50
2 400	2 000	18,5	32	37,0	64
3 000	2 500	23,0	40	46,0	80
3 840	3 200	29,0	50	58,0	100
4 800	4 000	36,0	63	72,0	126
6 000	5 000	46,0	80	92,0	160
7 560	6 300	57,0	100	114,0	200
9 600	8 000	71,5	125	143,0	250
12 000	10 000	91,5	160	183,0	320

Le Tableau A.2 contient les LIGNES DE FUITE pour TENSION DE SERVICE supérieure à 1 000 V provenant de l'IEC 60664-1:2007, Tableau ~~4~~ F.4.

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Paragraphe 8.9.1 – Valeurs

Lorsqu'on utilise les valeurs de LIGNE DE FUITE et de DISTANCE DANS L'AIR, il convient de noter que les valeurs de crête, en courant continu et en valeur efficace sont toutes utilisées. Il est important de lire les tableaux avec soin.

Les tableaux pour les MOOP utilisent les valeurs de l'IEC 60950-1 qui représentent les principes de base suivants pris dans l'IEC 60664-1.

– "La base pour la détermination d'une LIGNE DE FUITE est la valeur efficace à long terme de la tension qui existe à travers elle".

– Les "DISTANCES ~~D'ISOLEMENT~~ DANS L'AIR" doivent être dimensionnées pour supporter la tension de tenue aux chocs prescrite". La tension de tenue aux chocs est la "valeur de crête la plus élevée de la tension de tenue ...".

Toutefois, les tableaux pour les MOPP sont tirés de la deuxième édition de l'IEC 60601-1 où à la fois les lignes de fuite et les distances dans l'air sont liées aux tensions efficaces ou en courant continu.

Tableau A.2 – LIGNES DE FUITE pour éviter les défaillances dues au cheminement de l'IEC 60664-1

TENSION DE SERVICE V valeur efficace ou courant continu	Espacement assurant un MOYEN DE PROTECTION DE L'OPERATEUR						
	Degré de pollution 1	Degré de pollution 2			Degré de pollution 3		
	Groupe de matériau	Groupe de matériau			Groupe de matériau		
	I, II, IIIa, IIIb	I	II	IIIa ou IIIb	I	II	IIIa ou IIIb
1 250	Utiliser la DISTANCE DANS L'AIR du tableau approprié	6,3	9,0	12,5	16,0	18,0	20,0
1 600		8,0	11,0	16,0	20,0	22,0	25,0
2 000		10,0	14,0	20,0	25,0	28,0	32,0
2 500		12,5	18,0	25,0	32,0	36,0	40,0
3 200		16,0	22,0	32,0	40,0	45,0	50,0
4 000		20,0	28,0	40,0	50,0	56,0	63,0
5 000		25,0	36,0	50,0	63,0	71,0	80,0
6 300		32,0	45,0	63,0	80,0	90,0	100,0
8 000		40,0	56,0	80,0	100,0	110,0	125,0
10 000		50,0	71,0	100,0	125,0	140,0	160,0

Paragraphe 8.9.1.6 – Interpolation

L'interpolation est autorisée pour les LIGNES DE FUITE mais non pour les DISTANCES DANS L'AIR, excepté lorsque la TENSION DE SERVICE est supérieure à 2 kV en valeur efficace ou 2,8 kV en courant continu. Cette approche est globalement cohérente avec l'IEC 60950-1 et l'IEC 61010-1 [22].

Paragraphe 8.9.1.15 – DISTANCE DANS L'AIR et LIGNES DE FUITE pour les PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION

Le Tableau F.2 de l'IEC 60664-1:2007 indique qu'une distance de 4 mm est adéquate pour les tensions de choc de 5 kV ayant une durée courte de moins de 10 ms, de telles tensions provenant typiquement de l'utilisation d'un défibrillateur.

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Paragraphe 8.9.2 – Application

Paragraphe 8.9.2 a)

Selon l'UTILISATION PREVUE de l'APPAREIL EM, le fonctionnement du fusible ou du DISJONCTEUR peut comporter un RISQUE. L'ouverture d'un disjoncteur de branche n'est pas acceptable. Le Paragraphe 8.9.2 a) est fondé sur le fait qu'il y a un dispositif à maximum de courant à l'entrée de L'APPAREIL EM avant la partie du circuit où le paragraphe s'applique. Avant ce dispositif à maximum de courant, les espacements doivent être conformes à l'exigence de base pour les parties de polarité opposée à l'intérieur de la PARTIE RELIEE AU RESEAU.

Paragraphe 8.9.3 – Espaces remplis par un mélange isolant

Les LIGNES DE FUITE sont mesurées jusqu'au joint entre deux parties d'une barrière d'isolation, excepté pour les joints collés, c'est-à-dire ceux dans lesquels:

– les deux parties formant le joint sont liées par thermoscellage ou autre moyen à l'endroit concerné; ou

– le joint est entièrement rempli d'adhésif aux endroits concernés et l'adhésif relie les surfaces de la barrière d'isolation de sorte que l'humidité ne peut pas s'infiltrer dans le joint.

Dans la deuxième édition de la présente norme, les titres des Figures 43 à 45 mentionnaient des "joints non collés". Le point 7 des légendes de ces figures renvoyait à 57.9.4 f), second tiret, “pour une description des joints collés” mais ne spécifiait aucune méthode d'essai autre que l'examen. Au cours de l'élaboration de la présente édition, il a été proposé d'introduire des exigences correspondantes issues de l'IEC 60950-1 pour traiter le sujet connexe de l'enrobage.

Les exigences qui ont été introduites sont étroitement liées à celles de l'IEC 60950-1 et couvrent l'enrobage, l'encapsulation, les joints collés, etc. La structure rédactionnelle a été quelque peu révisée d'après celle de l'IEC 60950-1 pour plus de clarté. Ces exigences ont été incluses en 8.9 plutôt qu'en 8.8 car elles spécifient des circonstances qui permettent l'exemption des LIGNES DE FUITE et des DISTANCES DANS L'AIR des exigences plutôt que des exigences supplémentaires s'appliquant à l'isolation solide.

Paragraphe 8.9.4 – Mesure des DISTANCES DANS L'AIR et des LIGNES DE FUITE

Il convient d'éviter autant que possible les interstices étroits en direction d'un chemin de fuite possible et ne mesurant que quelques dixièmes de mm, dans la mesure où des saletés et de l'humidité peuvent s'y déposer.

Paragraphe 8.10.1 – Fixation des composants

Dans de nombreux cas, il apparaîtra évident que les composants et le câblage sont fixés de manière sûre (par exemple petits composants soudés sur une carte à circuit imprimé) sans qu'il y ait besoin d'une justification spécifique dans le FICHIER DE GESTION DES RISQUES ; mais si des informations pertinentes sont incluses dans le FICHIER DE GESTION DES RISQUES, il convient d'en tenir compte lors de l'évaluation de la conformité à ces exigences.

Paragraphe 8.10.2 – Fixation du câblage

Il est généralement accepté que les connexions de câblage soient soumises à la CONDITION DE PREMIER DEFAUT. Celles qui possèdent un seul moyen de fixation qui empêcherait qu'un fil cassé ou desserré cause une ~~DANGER~~ SITUATION DANGEREUSE, comme le retrait d'une CONNEXION DE TERRE DE PROTECTION ou le pontage d'un MOYEN DE PROTECTION, sont considérées comme n'étant pas conformes.

Les exemples suivants pourraient être conformes à la CONDITION DE PREMIER DEFAUT:

– double sertissage à la fois du fil et de l'isolation du fil ;

– sécurité mécanique du fil et du soudage ;

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– sécurité mécanique du fil et des dispositifs de blocage des fils comme les bandes de fixation, les serre-fils, les brides de faisceau ;

– les mécanismes de compensation de traction et la sécurité mécanique.

Paragraphe 8.10.4 – Parties PORTATIVES et dispositifs de commande à pieds reliées par un câble de connexion

Les commutateurs A MAIN et au pied sont exposés à des conditions sévères dans la pratique. Cette exigence permet d'assurer que, même dans le cas le plus défavorable, lorsque l'ENVELOPPE d'un commutateur de ce type est complètement cassée, seules les parties présentant des tensions dans les limites spécifiées en 8.4.2 c), dont le contact est sûr, peuvent être exposées.

Paragraphe 8.10.5 – Protection mécanique du câblage

Il n'y a pas d'exigence relative à une justification spécifique à inclure dans le FICHIER DE GESTION DES RISQUES, mais si des informations pertinentes sont incluses dans le FICHIER DE GESTION DES RISQUES, il convient d'en tenir compte lors de l'évaluation de la conformité à ces exigences.

Paragraphe 8.10.7 – Isolation du câblage interne

Les conducteurs peuvent être acheminés dans des câbles gainés séparément, d'une valeur nominale adéquate. Lorsqu'on doit faire passer des conducteurs appartenant à diverses catégories de circuits par des câbles communs, des rainures de câblage, des conduits ou des dispositifs de raccordement, une séparation adéquate est obtenue par une isolation nominale suffisante des conducteurs et en prévoyant des DISTANCES DANS L'AIR et des LIGNES DE FUITE suffisantes, conformes aux exigences de 8.9, entre les parties conductrices des dispositifs de raccordement.

Paragraphe 8.11.1 – Isolation depuis le RESEAU D'ALIMENTATION

Paragraphe 8.11.1 a)

Les personnes qualifiées, telles que le PERSONNEL D'ENTRETIEN, qui doivent avoir accès aux parties d'APPAREILS EM internes, éventuellement dangereuses, doivent disposer d'un moyen permettant d'isoler l'APPAREIL EM du RESEAU D'ALIMENTATION.

Un sectionneur de réseau, lorsqu'il existe, pourrait également servir de hors circuit fonctionnel pour une utilisation régulière ou pour désactiver toute sortie dangereuse pour une urgence. Ce type de sectionneur n'est pas nécessairement utilisé à ces fins, de même que la présente norme ne spécifie aucune exigence générale relative à un hors circuit d'urgence.

Paragraphe 8.11.1 c)

Dans la deuxième édition de la présente norme, l'exigence pour une séparation minimale des contacts des interrupteurs utilisés pour assurer l'isolation par rapport au RESEAU D'ALIMENTATION a été spécifiée dans l'IEC 328. L'IEC 61058-1 a remplacé l'IEC 328 en 1990. La première édition de l'IEC 61058-1 exigeait 3 mm de séparation entre contacts pour une déconnexion complète du RESEAU D'ALIMENTATION. Il n'a pas été fait mention de catégorie de surtension. La troisième édition de l'IEC 61058-1 a introduit le concept de catégorie de surtension conformément à l'IEC 60664-1. Pour une TENSION du RESEAU D'ALIMENTATION de 230 V dans la catégorie de surtension II, le Tableau 22 de l'IEC 61058-1:2000 autorise une séparation minimale des contacts de 1,5 mm. Alors que les exigences de la présente norme font généralement référence à la catégorie de surtension II (voir 8.9.1.11), il a été considéré qu'il était prudent de rester avec l'exigence de 3 mm associée à la TENSION du RESEAU D'ALIMENTATION de 230 V dans la catégorie de surtension III pour tous les interrupteurs destinés à assurer une isolation par rapport au RESEAU D'ALIMENTATION. Cela n'est pas seulement cohérent avec l'exigence de la deuxième édition de l'IEC 60601-1 mais c'est aussi en harmonie avec les exigences des IEC 60065 et IEC 60950-1, qui exigent toutes les deux une séparation minimale de contact de 3 mm pour les interrupteurs destinés à assurer l'isolation par rapport au RESEAU D'ALIMENTATION.

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Paragraphe 8.11.1 h)

Un dispositif de protection de ce type, qu'il provoque ou non le fonctionnement d'un dispositif de protection de surintensité intégré à l'APPAREIL EM, provoquerait vraisemblablement également le fonctionnement d'un fusible ou du disjoncteur de l'installation, interrompant de ce fait l'alimentation de tout autre APPAREIL EM, comprenant éventuellement l'APPAREIL EM d'assistance vitale. Un dispositif de ce type pourrait également occasionner des effets thermiques indésirables à l'intérieur de l'APPAREIL EM et ne pourrait de toute façon pas être une méthode de protection fiable contre les RISQUES correspondants.

Paragraphe 8.11.1 i)

Les parties qui ne peuvent pas être déconnectées de l'alimentation peuvent inclure par exemple un circuit pour l'éclairage des locaux ou un circuit pour la télécommande du commutateur réseau. Ces parties pourraient devenir accessibles lorsqu'un couvercle est ouvert, par exemple pour des besoins de maintenance.

Un montage avec espaces de séparation est un montage dans lequel les parties qui doivent être accessibles pour l'entretien sont situées de manière que le PERSONNEL D'ENTRETIEN ne soit pas susceptible d'entrer en contact avec les parties qui possèdent des tensions supérieures à celles spécifiées dans la présente norme en réalisant la tâche d'entretien exigée. Dans ce cas, un avertissement est considéré assurer la sécurité appropriée pour le PERSONNEL D'ENTRETIEN.

Paragraphe 8.11.2 – SOCLE A PRISES MULTIPLES

Cette exigence réduit la probabilité de branchement d'un autre appareil, ce qui pourrait conduire à un COURANT DE FUITE excessif.

Paragraphe 8.11.3.4 – CONNECTEURS D'APPAREIL

Un CABLE D'ALIMENTATION relié à ~~la~~ une PRISE RESEAU est soumis à des contraintes similaires à celles d'un CABLE D'ALIMENTATION NON FIXE A DEMEURE. S'il n'est pas correctement protégé contre une flexion excessive, cela peut entraîner une ~~DANGER~~ SITUATION DANGEREUSE.

Paragraphe 8.11.3.5 – Dispositif d'arrêt de traction

Si un câble d'alimentation n'était pas correctement protégé contre la déformation et l'abrasion, il y aurait une forte probabilité d'endommagement de l'isolation fournissant les MOYENS DE PROTECTION et, avec les APPAREILS EM DE CLASSE I, une forte probabilité de rupture ou de déconnexion du CONDUCTEUR DE PROTECTION.

Paragraphe 8.11.3.6 – Protections du câble d'alimentation

Si un câble d'alimentation n'est pas correctement protégé contre la flexion, il y aurait une forte probabilité de rupture des conducteurs électriques, entraînant un RISQUE d'incendie, et, avec les APPAREILS EM DE CLASSE I, une forte probabilité de rupture du CONDUCTEUR DE PROTECTION.

L'essai de pliage décrit est identique à celui spécifié en ~~3.29~~ 3.2.8 de l'IEC 60950-1:~~2001~~2005. La deuxième édition de l'IEC 60601-1 précisait: "Les dispositifs de protection ne satisfaisant pas à l'essai dimensionnel ci-dessus doivent subir avec succès l'essai décrit dans l'IEC 60335-1, Amendement 6, 1988, Paragraphe 25.10." Cette alternative a été retenue mais la référence concerne maintenant une version plus récente de l'IEC 60335-1. L'exigence d'effectuer un essai dans tous les cas puis d'effectuer l'autre essai si l'APPAREIL EM échoue au premier essai a été en outre modifiée pour permettre d'effectuer l'un ou l'autre essai en premier, car cela ne fait aucune différence en ce qui concerne la conformité de l'APPAREIL EM.

Paragraphe 8.11.4.1 – Exigences générales applicables aux DISPOSITIFS DE RACCORDEMENT AU RESEAU D'ALIMENTATION

Il convient que les bornes du réseau assurent des connexions de résistance suffisamment basse pour éviter la surchauffe et réduire au minimum le RISQUE de déconnexion. Une

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connexion fiable peut être effectuée par des vis, écrous, soudure, serrage, sertissage des conducteurs ou autre méthode également efficace.

L'utilisation de bornes de composants autres que les répartiteurs comme organes de raccordement des conducteurs externes est autorisée dans des cas particuliers lorsque la disposition des bornes est appropriée (accessible et clairement marquée) et conforme à la présente norme. Les bornes de raccordement de certains types de composants ont souvent des caractéristiques prévues pour les installations sur le terrain. Cela englobe les ensembles porteurs, les filtre CEM, les disjoncteurs, les contacteurs, les bandes de câblage, les régulateurs de moteur et les détecteurs de phase. Chacun peut être un des composants raccordés en premier, ce qui les place en bonne position pour accepter les premières connexions de câblage.

Paragraphe 8.11.4.2 – Agencement des DISPOSITIFS DE RACCORDEMENT AU RESEAU D'ALIMENTATION

Paragraphe 8.11.4.2 a)

On s'attend naturellement à voir regroupées toutes les bornes de connexion des câbles externes ou des CABLES D'ALIMENTATION. L'éventualité d'une connexion incorrecte peut augmenter si les bornes ne sont pas regroupées.

Paragraphe 8.11.4.4 – Connexion aux bornes de raccordement au réseau

L'expression "préparation spéciale du conducteur" comprend le soudage des brins, l'emploi de cosses, la confection d'œillets, etc., par le PERSONNEL D'ENTRETIEN (c'est-à-dire sur le terrain) mais non le reformage du conducteur avant son introduction dans la borne ou la torsion d'un conducteur torsadé destinée à affermir son extrémité. Lorsque le conducteur est préparé par le FABRICANT et que le câble souple est fourni comme la seule pièce de rechange acceptable, une telle partie est considérée comme satisfaisant à cette exigence.

Paragraphe 8.11.5 – Fusibles et DISJONCTEURS

L'installation de fusibles ou de DISJONCTEURS sur l'APPAREIL EM réduit le RISQUE de voir un défaut de l'APPAREIL EM entraîner le fonctionnement d'un dispositif de protection de l'installation, interrompant de ce fait l'alimentation de tout autre APPAREIL EM, comprenant éventuellement l'APPAREIL EM.

Il est évident que la pose d'un fusible dans une LIAISON DE TERRE DE PROTECTION serait inappropriée.

Mettre un fusible sur le conducteur neutre d'un APPAREIL INSTALLE DE FAÇON PERMANENTE ne servirait à rien et, avec les appareils triphasés, cela pourrait causer une surcharge de l'isolation si un tel fusible fonctionnait alors que les connexions au réseau restent intactes. Toutefois, un DISJONCTEUR qui interrompt simultanément tous les pôles, y compris le neutre, est acceptable.

L'exemption pour le cas où la DOUBLE ISOLATION ou l'ISOLATION RENFORCEE est présente entre toutes les parties de polarité opposée dans la PARTIE RELIEE AU RESEAU a été confirmée par les présente édition. Elle pourrait s'appliquer lorsque l'installation d'un fusible ou d'un DISJONCTEUR ne conviendrait pas, par exemple dans une petite alimentation enfichable.

Article 9 – Protection contre les DANGERS MECANIQUES des APPAREILS EM et SYSTEMES EM

Les exigences de l'Article 9 décrivent les DANGERS de nature mécanique provoqués par l'APPAREIL EM (DOMMAGE causé par des parties en mouvement, des surfaces rugueuses, des arêtes et angles vifs, l'instabilité, des projections d'objets, des vibrations et du bruit et par la rupture des supports du PATIENT et des moyens de suspension de parties d'APPAREIL EM). Les exigences qui décrivent des DANGERS engendrés par dommage ou détérioration des APPAREILS EM (contrainte mécanique) ont été regroupées en 15.3.

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L'APPAREIL EM peut devenir dangereux du fait de parties endommagées ou détériorées par des contraintes mécaniques telles que souffles, pressions, chocs, vibrations, par la pénétration de particules solides, poussières, fluides, humidité et gaz nocifs, par des contraintes thermiques et dynamiques, par la corrosion, par le relâchement des moyens de fixation d'une partie en mouvement ou d'une masse suspendue et par les rayonnements.

Les effets des surcharges, la défectuosité des matériaux ou leur usure peuvent être évités par:

– des moyens qui interrompent ou rendent non dangereux le fonctionnement ou l'alimentation en énergie (par exemple, fusibles, vannes de limitation de la pression) dès qu'une surcharge se produit; ou

– des moyens qui protègent contre ou interceptent des parties qui sont projetées ou qui tombent (en raison de la défectuosité de matériaux, de l'usure ou de la surcharge) et qui pourraient constituer un DANGER MECANIQUE.

La protection contre la rupture des supports du PATIENT et des suspensions peut être assurée par la redondance des moyens ou par la mise en place d'arrêts de sécurité.

Les parties D'APPAREIL EM destinées à être tenues à la main ou disposées sur un lit doivent être suffisamment robustes pour supporter une chute. Les instruments peuvent être soumis à des vibrations ou à des chocs, non seulement lorsqu'ils sont transportés mais aussi lorsqu'ils sont utilisés dans des véhicules.

Paragraphe 9.2 – DANGERS MECANIQUES associés aux parties en mouvement

Les OPERATEURS, les PATIENTS et les autres personnes doivent être protégés contre les DANGERS MECANIQUES. Cela peut être réalisé de plusieurs façons, par exemple:

– en prévoyant une distance suffisante entre les personnes et les DANGER(S) MECANIQUE(S);

– en limitant l'accès aux zones qui comportent des DANGER(S) MECANIQUE(S);

– en installant une barrière, mécanique ou non, entre les personnes et les DANGER(S) MECANIQUE(S);

– en réduisant le RISQUE associé aux DANGER(S) MECANIQUE(S);

– en assurant un meilleur contrôle de l'OPERATEUR sur les mouvements entraînant un DANGER MECANIQUE; ou

– en installant des systèmes de sauvegarde de manière à assurer un RISQUE RESIDUEL acceptable lorsque le système de contrôle initial est défectueux.

Lorsqu'il est fait référence, dans ce paragraphe, au RISQUE concernant les personnes, plutôt que le PATIENT ou l'OPERATEUR, il convient de noter qu'il peut y avoir d'autres personnes, en plus du PATIENT ou de l'OPERATEUR à proximité de l'APPAREIL EM. En fonction de L'APPAREIL EM, les visiteurs, les membres de la famille et d'autres personnes sans qualification pourraient se trouver à proximité.

Paragraphe 9.2.1 – Généralités

Les exigences concernant les parties en mouvement ont été basées sur celles des autres normes qui s'appliquent à des appareils non médicaux et des machines non médicales, mais elles ont été modifiées pour tenir compte de la nécessité pour les APPAREILS EM d'être en contact le PATIENT ou d'en être très proches.

En raison de la diversité des situations, il n'est pas possible dans la présente norme d'indiquer les endroits où il convient de placer les avertissements concernant les RISQUES RESIDUELS. Selon l'application et le niveau de RISQUE RESIDUEL, il pourrait être important de placer un avertissement sur le produit. Il pourrait cependant être acceptable de placer l'avertissement uniquement sur les DOCUMENTS D'ACCOMPAGNEMENT.

Paragraphe 9.2.2.4 – BARRIERES et autres mesures de ~~protection~~ MAITRISE DU RISQUE

Le degré de protection exigé pour les ENVELOPPES ou DISPOSITIFS PROTECTEURS des parties en mouvement dépend de la conception générale et de l'UTILISATION PREVUE de l'APPAREIL EM. Les facteurs à prendre en considération pour l'acceptation des parties découvertes en

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mouvement incluent le degré d'exposition, la forme des parties en mouvement, la probabilité d'un contact accidentel, la vitesse du mouvement et la probabilité de happer des doigts, des bras ou des vêtements (par exemple en présence d'engrenages, de courroies passant sur une poulie, de parties se refermant en pinçant ou en coupant).

Ces facteurs peuvent être pris en considération en UTILISATION NORMALE comme en cours de réglage ou pendant le remplacement ou l'adaptation d'un ACCESSOIRE, et en tenant éventuellement compte de l'installation, car les DISPOSITIFS PROTECTEURS peuvent être fournis lors de l'installation et ne pas faire partie d'un APPAREIL FIXE donné.

Les caractéristiques des DISPOSITIFS PROTECTEURS qui peuvent être prises en considération comprennent:

– l'aptitude au démontage seulement à l'aide d'OUTILS;
– l'aptitude au démontage pour entretien ou déplacement;
– la résistance et la rigidité;
– les parties constitutives;
– l'apparition de DANGERS supplémentaires tels que des points de pincement, et la nécessité de manipulation supplémentaire occasionnée par des besoins accrus d'entretien tel que le nettoyage.

~~Les mesures de protection abordées dans cet article sont aussi destinées à inclure des systèmes de détection de collision tels que ceux utilisant des barrières de lumière.~~

~~Des mesures de protection peuvent être utilisées à la place de commandes de type à activation continue. Les mesures de protection doivent fournir un contrôle en retour.~~

Paragraphe 9.2.2.5 – Activation continue

Les systèmes de commande de mouvement lorsque l'OPERATEUR est dans la boucle de retour doivent utiliser une activation continue (par exemple contact momentané, commutateur d'homme mort). Des facteurs comme la vitesse de mouvement et le retour visible vers L'OPERATEUR doivent également être appropriés.

Dans certaines circonstances, la formation de l'OPERATEUR et d'autres qualifications sont nécessaires pour obtenir un contrôle approprié de l'OPERATEUR. Dans de tels cas, il pourrait être souhaitable d'utiliser des "commandes de verrouillage" exigeant une action intentionnelle pour permettre le mouvement. De telles commandes peuvent être:

– un interrupteur équipé d'une clé avec une fonction de "déverrouillage";
– un interrupteur à empreinte digitale d'une clé avec une fonction de "déverrouillage";
– une carte mot de passe.

Dans d'autres circonstances, le contrôle des accidents peut constituer une préoccupation. Dans un tel cas, les commandes pourraient utiliser des techniques de construction comme:

– une commande avec fonction de "déverrouillage" avant que tout mouvement ne soit possible;
– des commandes avec organes de manœuvre en retrait; cela pourrait empêcher tout mouvement si une main ou une jambe heurte involontairement l'organe de manœuvre.

Si l'OPERATEUR pouvait avoir accès aux parties en mouvement qui sont dangereuses, des commandes pourraient être conçues pour empêcher l'accès à la ZONE DE PIEGEAGE par l'emplacement des commandes OPERATEUR. Un système de commande exigeant deux activations manuelles est un exemple possible.

Pour les systèmes de commande OPERATEUR sans activation continue, il peut y avoir une réduction acceptable des RISQUES ; toutefois, il est nécessaire d'évaluer le système avec les autres options de 9.2.2.1.

Cet article traite des systèmes électroniques de commande de mouvement. Pour les systèmes manuels, voir d'autres options en 9.2.2.1.

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Paragraphe 9.2.2.6 – Vitesse des mouvements

Pour certains appareils médicaux, il subsistera des DANGERS inévitables dus aux parties mobiles.

Paragraphe 9.2.3 – Autres DANGERS MECANIQUES associés aux parties en mouvement

Le Paragraphe 9.2.2.1 traite des DANGERS MECANIQUES causés par les ZONES DE PIEGEAGE. Le mouvement pourrait donner lieu à d'autres DANGERS MECANIQUES, par exemple impacts, perforation, etc.

Paragraphe 9.2.4 – Dispositifs d'arrêt d'urgence

Les dispositifs d'arrêt d'urgence sont conçus pour éviter des dommages accidentels en empêchant ou en stoppant les mouvements des parties des APPAREILS EM. Il pourrait y avoir plusieurs dispositifs d'arrêt d'urgence sur un APPAREIL EM. Les APPAREILS EM peuvent également inclure des dispositifs de coupure d'urgence destinés à couper toute l'alimentation de l'installation. Les dispositifs de coupure d'urgence ne sont pas soumis aux exigences de ce paragraphe à moins qu'ils ne soient destinés à assurer la fonction d'arrêt d'urgence. Les dispositifs d'arrêt d'urgence pourraient ne représenter qu'une partie de la fonction d'interruption d'urgence.

Paragraphe 9.2.5 – Libération du PATIENT

Cette exigence tient compte de l'effet possible d'une interruption de l'alimentation créant des mouvements non voulus et du besoin potentiel, dans cette situation, de suppression de forces de compression ou du retrait des PATIENTS d'un emplacement dangereux.

Paragraphe 9.3 – DANGERS MECANIQUES associés aux surfaces, coins et bords

Le RISQUE associé à un angle vif dépend de la position de l'angle vif et de l'application de l'APPAREIL EM. Pour cette raison, la conformité à ce paragraphe est vérifiée par examen. En cas de doute, l'essai pour les angles vifs, décrit dans la norme UL 1439 [43], peut être utilisé comme guide.

Ce paragraphe s'applique aux surfaces accessibles en UTILISATION NORMALE. Il convient de veiller à assurer la protection du PERSONNEL D'ENTRETIEN ou autres systèmes internes, dans lesquels des dommages pourraient entraîner un RISQUE inacceptable (par exemple des systèmes de fluides).

Paragraphe 9.4 – DANGERS d'instabilité

En UTILISATION NORMALE, de nombreux types d'APPAREILS EM sont exposés à de multiples conditions pendant le transport (mouvement de pièce en pièce en UTILISATION NORMALE). Bien que les exigences de la présente norme essaient de représenter les RISQUES susceptibles de se produire, il convient que le PROCESSUS de GESTION DES RISQUES évalue les conditions dans lesquelles l'APPAREIL EM est destiné à être utilisé et comment ces conditions pourraient influer sur la SECURITE DE BASE et la PERFORMANCE ESSENTIELLE.

Lorsque l'absence de stabilité pendant ces essais pourrait causer des DOMMAGES à l'OPERATEUR, au PATIENT et à d'autres personnes (par exemple par écrasement ou chute), ou entraîner l'échec de l'APPAREIL EM à respecter les exigences de SECURITE DE BASE applicables de la présente norme (telles que: exposition à des tensions dangereuses, réduction des LIGNES DE FUITE ou des DISTANCES DANS L'AIR ou création de brèches dans les ENVELOPPES à l'épreuve du feu qui ne sont pas évidentes) ou perte de PERFORMANCE ESSENTIELLE. Il convient de considérer que l'instabilité donne lieu à un RISQUE inacceptable.

Tous les APPAREILS EM sont soumis à l'essai de basculement avec une inclinaison de 5°, une inclinaison de 10°, et une poussée en 9.4.2.1, 9.4.2.2, 9.4.2.3 a) et b). Dans 9.4.3.1 a), b) et c), et 9.4.3.2 a) et b), seuls les APPAREILS EM MOBILES sont soumis à l'essai, puisque ce sont des exigences relatives aux roues et à leurs freins.

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Paragraphe 9.4.2 – Instabilité due au basculement

Pour aider à mieux comprendre, le Tableau A.3 et la Figure A.16 illustrent la logique des exigences de l'essai de stabilité.

Tableau A.3 – Conditions de l'essai d'instabilité

Avertissement de transport	Angle du plan d'essai	
	Plan 10°	Plan 5°
Pas d'avertissement pour le transport	Doit passer dans toutes les positions	Non applicable (représenté par l'essai à 10°)
Avertissement pour le transport fourni	~~Doit passer en position de transport (seulement) Doit passer dans toutes les positions sauf de transport~~ Doit passer dans la position de transport (uniquement)	Doit passer dans toutes les positions sauf de transport

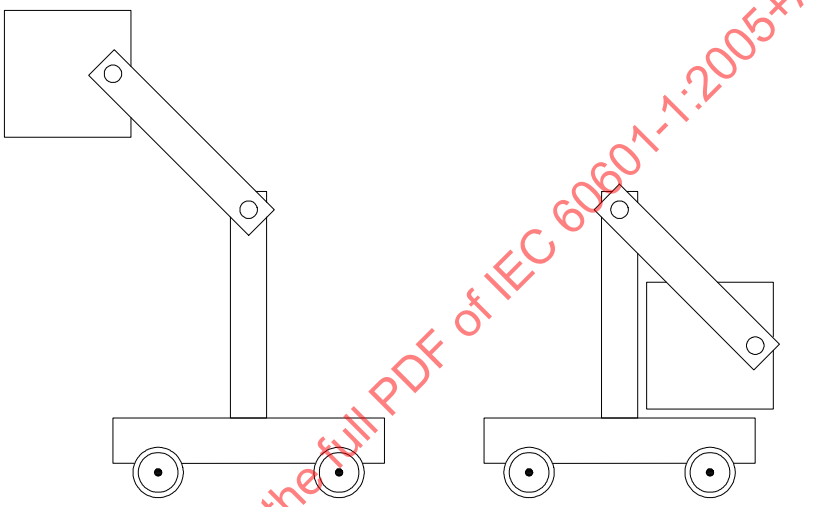


Figure A.16 – Conditions de l'essai d'instabilité

Paragraphe 9.4.2.3 a)

La force de poussée de 15 % du poids de l'APPAREIL EM ou un maximum de 150 N a été sélectionné(e) afin de représenter le mauvais usage prévisible pour un APPAREIL EM typique, sur la base des données des FABRICANTS d'APPAREILS EM. L'option de marquage pour un APPAREIL EM qui bascule sous cette force de poussée est considérée comme procurant un bénéfice en termes de soins médicaux, et, avec le marquage indiquant de ne pas pousser, le comité suppose que le RISQUE serait acceptable, mais le FABRICANT doit se déterminer en fonction de ses propres analyses, qui peuvent comprendre des études d'aptitude à l'utilisation, y compris pour l'emplacement du marquage.

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Paragraphe 9.4.2.4 – Roulettes et roues

La conformité avec le présent paragraphe est exigée ~~pas uniquement~~ non seulement pour éviter un RISQUE manifeste Inacceptable ~~évident~~ mais également pour assurer le mouvement en grande partie opérationnel comme une PERFORMANCE ESSENTIELLE. ~~Pour les APPAREILS EM à considérer comme MOBILES, il faut qu'il puisse être déplacé d'une pièce à une autre.~~ Un APPAREIL EM MOBILE est défini comme un appareil destiné à être déplacé d'un endroit à un autre.

Paragraphe 9.4.2.4.3 – Franchissement d'un seuil

La hauteur de seuil de 10 mm provient de la réflexion sur la représentation des câbles par une hauteur de 8 mm à 10 mm. Le comité pensait que l'alignement d'un ascenseur est maintenant plus proche de 10 mm (4 mm par exemple) que de 20 mm. Normalement les portes des hôpitaux n'ont pas de seuil.

Une vitesse manuelle de 0,8 m/s a été choisie dans une plage prévue comprise entre 0,4 m/s et 1,5 m/s en UTILISATION NORMALE, en fonction des données des FABRICANTS d'APPAREILS EM. Une vitesse de 0,8 m/s a été choisie comme la plus représentative d'une UTILISATION NORMALE et d'une vitesse de marche normale. Elle représente un juste milieu entre une vitesse trop faible à laquelle l'APPAREIL EM ne peut pas franchir le seuil et une vitesse trop rapide entraînant l'instabilité de l'APPAREIL EM. Une seule vitesse a été sélectionnée pour l'essai, car il semblait que c'était nécessaire à la reproductibilité de l'essai.

Certains APPAREILS EM MOBILES sont munis de roulettes par commodité mais non dans le but de franchir des seuils ni des obstacles du même type. Lorsque le FABRICANT indique clairement que cette utilisation n'est pas prévue, il convient que l'essai de franchissement de seuil ne soit pas nécessaire. Des exemples d'appareils ne devant pas nécessairement subir un essai de franchissement de seuil comprennent les trolleys et les tables d'examen, qui sont équipés de roulettes leur permettant d'être déplacés facilement pour nettoyer le sol ou faire de la place.

Paragraphe 9.4.3 – Instabilité provoquée par un mouvement latéral involontaire (y compris un glissement)

Les essais de vérification fonctionnelle du freinage permettent d'évaluer la conformité du système de freinage en supposant le RISQUE acceptable. Les critères d'essai supposent généralement que tout mouvement élastique initial et ultérieur jusqu'à 50 mm est acceptable. Conformément à 4.2, si ces mouvements pour une partie spécifique de l'APPAREIL EM et son UTILISATION PREVUE semblent inappropriés, il convient que le RISQUE soit réduit à l'aide de mesures de MAITRISE DU RISQUE supplémentaires.

La force de poussée du freinage de 15 % ou le maximum de 150 N ont été choisis pour représenter un mauvais usage raisonnablement prévisible d'un APPAREIL EM typique, en fonction des données des FABRICANTS d'APPAREILS EM.

L'objectif des exigences de freinage est de fournir un essai générique pour les APPAREILS EM généraux. Les critères de conformité sont donc noirs et blancs. Il est reconnu qu'un mouvement lent indésirable de chariots de poids faible (moment faible) pourrait être considéré comme un RISQUE acceptable.

Il est accepté que pour de nombreux chariots à 4 roues, prévoir 2 freins soit une mesure raisonnable de MAITRISE DU RISQUE pour atténuer un mouvement indésirable dû à un freinage inapproprié. Placer 4 freins sur un grand nombre de chariots n'entraînera pas une plus grande utilisation des freins, puisque certaines des roues vont généralement pivoter en étant hors de portée.

L'Article 4.5 est toujours applicable et permet au FABRICANT d'utiliser des mesures alternatives de MAITRISE DU RISQUE, ou des variantes de la méthode d'essai ou des critères de conformité d'essai, avec une justification.

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Paragraphe 9.4.3.1 c) – Instabilité pendant le transport

Il convient que la surface plate et dure utilisée dans cet essai reflète les conditions les plus défavorables d'UTILISATION PREVUE. Le glissement des roues sur la surface plate dure est un préoccupation secondaire. Si un glissement est détecté, il convient de déterminer s'il est recommandé de choisir une surface plus appropriée pour l'essai ou si le matériau des roues est inapproprié.

Paragraphe 9.5 – DANGER de projection d'objets

Les projections d'objets sont des parties ou des fragments de parties d'APPAREILS EM, telles que des parties d'écran d'un appareil à vide endommagé, un ressort mécanique, un cylindre de compression de gaz, un volant ou une batterie au lithium éclatée, qui pourraient être projetés par collision, détente, etc.

Le degré de protection contre les "projections d'objets" dépend de la probabilité d'occurrence et de la GRAVITE du DOMMAGE. Des mesures de protection peuvent se composer d'une ENVELOPPE, d'une barrière ou de moyens électroniques (par exemple moyens redondants pour empêcher le courant de charge de la batterie au lithium).

Paragraphe 9.6.1 – Généralités

Un bruit excessif peut provoquer de la fatigue, des interférences avec la parole et les signaux acoustiques, voire des troubles de l'ouïe. Les limites susceptibles de prévenir de tels dommages font l'objet de normes ISO.

Dans les locaux à usage médical, des limites beaucoup plus basses sont nécessaires au confort des PATIENTS et du personnel médical. L'effet réel provoqué par le bruit d'un APPAREIL EM dépend étroitement des propriétés acoustiques du local, de l'isolation entre salles et de l'interaction des parties de l'APPAREIL EM.

Des vibrations excessives provoqueront l'inconfort du PATIENT, de l'OPERATEUR et des autres personnes. Une exposition prolongée peut entraîner des troubles vasculaires, neurologiques ou ostéo-articulaires. Des vibrations excessives peuvent également endommager l'APPAREIL EM ou un décalage de l'étalonnage.

La plupart des APPAREILS EM couverts par la présente norme exposent le PATIENT et l'OPERATEUR ou d'autres personnes à des niveaux de bruit et de vibration négligeables. Il convient que le PROCESSUS de GESTION DES RISQUES permette d'identifier clairement les cas dans lesquels des mesures sont nécessaires.

Paragraphe 9.6.2 – Energie acoustique

Ces valeurs sont fondées sur la probabilité de déficience auditive à long terme. La valeur généralement utilisée au niveau mondial pour des besoins de réglementation est actuellement de 90 dBA avec un écart de 5 dBA. Toutefois les dernières recherches donnent une valeur de 85 dBA pour 8 h sur une période de 24 h avec un décalage de 3 dBA lorsque la durée est multipliée ou divisée par deux [34].

Toutefois, les critères pour estimer si un bruit est considéré comme un bruit d'impact ne sont volontairement pas donnés, il convient de juger de la situation. Exemples de bruit d'impacts: bruit d'inclinaison des appareils à résonance magnétique et impulsions de lithotritie.

Paragraphe 9.6.3 – Vibrations transmises par la main

Les valeurs de seuil pour les vibrations sont moins précises que celles relatives à l'énergie a acoustique (bruit). La valeur utilisée ici est issue de la *Directive du Parlement Européen et du Conseil sur les exigences minimales de santé et de sécurité concernant l'exposition des travailleurs aux risques dus aux agents physiques (vibrations)* (seizième Directive au sens de l'Article 16(1) de la Directive 89/391/CEE). Elle correspond à une incidence d'environ 10 % de blanchiment (indicateur de troubles neurologiques) après 8 ans d'exposition régulière, selon l'ISO 5349-1. Il est encore plus difficile d'établir les valeurs de seuil pour les vibrations sur l'ensemble du corps. C'est la raison pour laquelle cette norme ne spécifie pas de valeurs de seuil. Les points d'extrémité, tels que les douleurs dans le dos et autres effets nocifs sur la

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santé, ne sont pas facilement quantifiables, aucune norme convenue sur les expositions de l'ensemble du corps aux vibrations n'a donc pu être élaborée. Des informations pertinentes sur ce sujet peuvent être consultées dans des normes telles que l'ISO 5805 [28] et l'ISO 8041 [29].

Lorsqu'une personne est exposée à différentes niveaux d'accélération sur une période de 24 h, l'exposition cumulée admissible peut être déterminée comme suit. Prendre en compte tout d'abord le Tableau A.4 de durée d'exposition admissible sur une période de 24 h pour chaque niveau d'accélération.

Tableau A.4 – Durée d'exposition admissible pour le niveau d'accélération

Durée d'exposition admissible sur une période de 24 h h	Accélération m/s^2
1	7,07
2	5,00
3	4,08
4	3,54
5	3,16
6	2,89
7	2,67
8	2,50
9	2,36
12	2,04
16	1,77
24	1,44

Quelques exemples d'exposition cumulée admissible sont donnés ci-dessous.

Si une personne avait été exposée à une accélération de 5 m/s^2 pendant 1 h (ce qui représente 1/2 de la durée quotidienne d'exposition admissible pour cette accélération), suivie d'une exposition à une accélération de 1,44 m/s^2 pendant 12 h (ce qui représente 1/2 de la durée d'exposition quotidienne admissible pour cette accélération), cela représenterait une exposition cumulée acceptable sur une période de 24 h.

Si une personne avait été exposée à une accélération de 4,08 m/s^2 pendant 1 h (ce qui représente 1/3 de la durée quotidienne d'exposition admissible pour cette accélération), suivie d'une exposition à une accélération de 2,36 m/s^2 pendant 3 h (ce qui représente 1/3 de la durée d'exposition quotidienne admissible pour cette accélération), suivie par une exposition à une accélération de 1,44 m/s^2 pendant 8 h (ce qui représente 1/3 de la durée quotidienne d'exposition pour cette accélération), cela représenterait une exposition cumulée acceptable sur une période de 24 h.

Si une personne avait été exposée à une accélération de 5 m/s^2 pendant 1 h (ce qui représente 1/2 de la durée quotidienne d'exposition admissible pour cette accélération), suivie d'une exposition à une accélération de 4,08 m/s^2 pendant 1 h (ce qui représente 1/3 de la durée d'exposition quotidienne admissible pour cette accélération), suivie par une exposition à une accélération de 2,04 m/s^2 pendant 2 h (ce qui représente 1/6 de la durée quotidienne d'exposition pour cette accélération), cela représenterait une exposition cumulée acceptable sur une période de 24 h.

En résumé, pour chaque accélération, déterminer la valeur d'ionisation de l'exposition quotidienne admissible en divisant la durée d'exposition réelle pour une accélération donnée par la durée d'exposition quotidienne admissible pour cette accélération. La somme des valeurs d'ionisation pour chaque accélération ne doit pas être supérieure à 1.

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Paragraphe 9.7 – Réservoirs et parties soumises à pression pneumatique et hydraulique

Les exigences de ce paragraphe ne constituent pas la combinaison la plus sévère des réglementations ou des normes nationales.

Dans certains pays, de telles réglementations ou normes s'appliquent.

Type de systèmes considérés comme comprenant des systèmes à pression pneumatique, systèmes à pression hydrauliques, systèmes à vapeur sous pression et combinaisons de tels systèmes. Ces systèmes pourraient ou non inclure des réservoirs sous pression.

DANGERS

a) Rupture ou fracture mécanique (DOMMAGE: lacérations, plaie par perforation)

Les exigences de l'Article 45 de la deuxième édition, qui traitent de ce DANGER, ont été déplacées dans ce paragraphe et restent inchangées.

Les exigences ont été clarifiées pour indiquer que toutes les parties qui présentent une PRESSION MAXIMALE ADMISSIBLE DE FONCTIONNEMENT qui n'est pas inférieure à la pression en CONDITION NORMALE ou en CONDITION DE PREMIER DEFAUT. En principe, il devrait exister un facteur de sécurité adapté entre la PRESSION MAXIMALE ADMISSIBLE DE FONCTIONNEMENT et la pression d'éclatement lorsque la pression d'éclatement est la pression à laquelle une partie souffre d'une déformation (plastique) ou d'une fuite permanente. Les normes de l'industrie concernant les parties sous pression varient mais les facteurs de sécurité adaptés sont 3 ×, 4 ×, et parfois 5 ×, (ISO, ASME, SAE). Etant donné qu'un facteur de sécurité peut varier, en fonction des facteurs associés à l'application finale et au RISQUE, il a été considéré comme inapproprié de spécifier un facteur de sécurité minimal dans la définition de la PRESSION MAXIMALE ADMISSIBLE DE FONCTIONNEMENT mais cela a été au contraire laissé à la responsabilité de déclaration de la part du FABRICANT d'une telle partie. On estime que les déclarations de PRESSION MAXIMALE ADMISSIBLE DE FONCTIONNEMENT seront fondées sur des normes nationales ou internationales reconnues et par conséquent inférieures aux pressions d'éclatement au moins en phase avec le facteur de multiplication de la Figure 32 (3 ×, réduit après 1 MPa jusqu'à 1,3 × après 30 MPa).

Pour les réservoirs sous pression qui dépassent à la fois une limite d'énergie (pression × volume) et une limite maximale de pression, l'exigence prévoit de réaliser un essai de surpression hydrostatique basé sur la déclaration de PRESSION MAXIMALE ADMISSIBLE DE FONCTIONNEMENT et sur le facteur de multiplication présenté dans la Figure 32 (3 ×, réduit après 1 MPa jusqu'à 1,3 × après 30 MPa).

b) Perte mécanique de support (DOMMAGE: écrasement et plaies par perforation)

Les exigences ont été clarifiées afin d'indiquer que les composants d'un système sous pression, tels que les composants d'un système élévateur hydraulique, dont l'intégrité est destinée à réduire le RISQUE de blessure par perte de support, doivent se conformer aux FACTEURS DE TRACTION DE SECURITE en CONDITION NORMALE spécifiés en 9.8. Le FACTEUR DE TRACTION DE SECURITE est généralement de 4 × pour les parties non altérées par l'usure, et de 8 × pour les parties altérées par l'usure (Cas B). Ainsi les parties soumises à la pression dont la défaillance pourrait donner lieu à une rupture mécanique et à une perte de support doivent avoir une PRESSION MAXIMALE ADMISSIBLE DE FONCTIONNEMENT basée sur la pression la plus élevée de la CONDITION DE PREMIER DEFAUT et sur la déclaration du FABRICANT pour chaque composante de système comme spécifié en 9.7, ou la pression en CONDITION NORMALE et le FACTEUR DE TRACTION DE SECURITE comme spécifié en 9.8.

c) Fuite de gaz ou de liquide toxique (DOMMAGE: détérioration cellulaire chimique ou biologique)

Les exigences de l'Article 45 de la deuxième édition, qui traitent de ce DANGER, ont été déplacées dans ce paragraphe et restent inchangées.

Les exigences ont été clarifiées pour indiquer que tous les composants du système de pression doivent avoir leur PRESSION MAXIMALE ADMISSIBLE DE FONCTIONNEMENT basée sur la pression de CONDITION DE PREMIER DEFAUT et la déclaration du FABRICANT pour chaque composant du système.

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d) Fuite de gaz ou de liquide inflammable (DOMMAGE: incendie entraînant des brûlures ou des dommages matériels).

Les exigences de l'Article 45 de la deuxième édition, qui traitent de ce DANGER, ont été déplacées dans ce paragraphe et restent inchangées.

Les exigences ont été clarifiées pour indiquer que tous les composants du système de pression doivent avoir leur PRESSION MAXIMALE ADMISSIBLE DE FONCTIONNEMENT basée sur la pression de CONDITION DE PREMIER DEFAUT et la déclaration du FABRICANT pour chaque composant du système.

Paragraphe 9.7.5 – Réservoirs sous pression

Le dictionnaire Oxford définit un réservoir sous pression comme "un récipient conçu pour maintenir des substances à des pressions élevées". Il s'agit de l'utilisation prévue par la présente norme.

On suppose que si la pression est inférieure ou égale à 50 kPa ou si le produit de la pression et du volume est inférieur ou égal à 200 kPa · l, un essai hydraulique n'est pas nécessaire.

Les facteurs de sécurité impliqués par la Figure 32 sont supérieurs à ceux généralement appliqués dans les essais des réservoirs sous pression. Cependant, tandis que l'essai hydraulique est normalement utilisé pour vérifier qu'un réservoir sous pression ne présente pas de défaut de fabrication ou de détérioration grave, la validité de la conception étant déterminée d'autres façons, le présent essai hydraulique est destiné à vérifier la validité de la conception lorsqu'elle ne peut pas être établie d'autres façons.

La suppression des références nationales dans le texte amendé évite toute subordination des exigences de la norme aux exigences des réglementations locales. Les APPAREILS EM doivent parfois satisfaire aux deux types d'exigences, ou aux exigences les plus rigoureuses, en supposant qu'il n'existe aucune réglementation locale en contradiction avec la présente norme.

Un essai hydraulique est spécifié même pour les récipients pneumatiques, ce qui est plus sûr pour la personne qui effectue les essais. En atteignant la pression d'essai avec un gaz, celui-ci se comprime, le récipient d'essai emmagasine donc plus d'énergie qu'avec une méthode d'essai hydraulique. Les deux méthodes aboutissent à la même pression d'essai, ce qui est l'objectif de l'essai.

Paragraphe 9.8 – DANGERS MECANIQUES associés aux systèmes support

Le terme "support" est utilisé pour inclure la notion de "suspension" et les charges peuvent inclure les PATIENTS, les OPERATEURS et les autres personnes.

Les systèmes de support peuvent être globalement classés comme suit.

– Un système de suspension est un système qui contient des éléments flexibles ou rigides conçus pour suspendre des masses, y compris des PATIENTS et des OPERATEURS en UTILISATION NORMALE.

– Les éléments flexibles incluent des cordes, câbles, ceintures, bandes et ressorts. En outre, un contre-écrou est considéré comme sujet à l'usure, de sorte qu'il exige un FACTEUR DE TRACTION DE SECURITE plus élevé.

– Un système d'actionnement est un système qui contient des éléments tels que des actionneurs électriques, pneumatiques ou hydrauliques, des moteurs, des boîtes de vitesses, axes, paliers, poulies, molettes, volants et guides.

– Une structure de support est généralement constituée d'un dispositif rigide qui peut être fixe ou mobile et qui supporte les charges externes de l'APPAREIL EM et, si nécessaire, les PATIENTS et les OPERATEURS.

Paragraphe 9.8.2 – FACTEUR DE SECURITE EN TRACTION

Des FACTEURS DE TRACTION DE SECURITE sont appliqués afin de fournir une marge de sécurité dans la conception, après avoir prévu toutes les tolérances raisonnables pour les conditions de fonctionnement et les variables de matières et de fabrication, etc.

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Il est nécessaire de connaître avec certitude la résistance de matériau pour appliquer les valeurs du cas A afin de déterminer si on doit utiliser le cas A ou B à partir du Tableau 21. De plus, il est nécessaire d'avoir confiance dans la détermination de la CHARGE TOTALE pour appliquer les valeurs du cas A. La charge totale est constituée à partir des composantes "force statique" et "force dynamique". La force statique est normalement claire. Mais la force/charge dynamique est parfois incertaine. Lorsque les forces dynamiques sont connues ainsi que les forces statiques, le FACTEUR DE TRACTION DE SECURITE est déterminé avec le cas A. Lorsque les forces dynamiques ne sont pas claires et que les forces statiques sont connues, le FACTEUR DE TRACTION DE SECURITE est déterminé avec le cas B.

Les forces extérieures pour les supports PATIENT peuvent inclure celles qui sont générées par l'application de CPR, etc.

L'allongement à la rupture de 5 % est basé sur l'expérience historique avec les matériaux métalliques, en particulier l'acier et la fonte. Les matériaux dont l'allongement à la rupture est inférieur à 5 % sont considérés comme fragiles et leur défaillance est susceptible d'être catastrophique et c'est la raison pour laquelle un facteur de sécurité supérieur est considéré comme étant approprié. Pour les matériaux non métalliques:

– En l'absence d'autre expérience, et si le mode de défaillance est susceptible d'être catastrophique, ce facteur d'élongation est considéré comme étant approprié et c'est pourquoi un FACTEUR DE TRACTION DE SECURITE est considéré comme approprié.

– Lorsque l'expérience et les essais montrent d'autres valeurs, un allongement à la rupture de moins de 5 % peut être approprié avant qu'un FACTEUR DE TRACTION DE SECURITE ne soit justifié.

Par exemple, les tables PATIENT des systèmes à rayons X/CT/RM sont souvent conçues en matières plastiques laminées ou renforcées avec des toiles/tissus en fibres de carbone ou en fibres de verre, dans la mesure où ces tables PATIENT doivent être optimisées pour une faible absorption des rayonnements X (équivalence aluminium), une compatibilité RM (signal proton faible), ainsi que pour une stabilité structurelle. Bien que ces matières plastiques renforcées par des fibres/tissus de carbone puissent avoir un allongement à la rupture de moins de 5 %, de nombreuses années d'expérience, l'expérience acquise et la surveillance après mise sur le marché peuvent donner suffisamment de preuves que la stabilité structurelle adaptée des tables PATIENT est obtenue en appliquant le FACTEUR DE TRACTION DE SECURITE du Tableau 21, situation 1 (de préférence à situation 2).

A la fin du cycle de vie ou du cycle de maintenance périodique, les APPAREILS EM doivent maintenir leur intégrité structurelle. La ligne 1 du Tableau 21 est normalement appropriée pour la fin de vie ou de maintenance périodique dans la mesure où l'usure n'est plus prise en compte.

Les systèmes de suspension et d'actionnement ont des FACTEURS DE TRACTION DE SECURITE qui sont nécessairement élevés pour réduire les effets de détérioration par l'usure et la fatigue.

Il convient de porter une attention particulière à la fixation des structures sur les sols, les plafonds, etc. qui sont soumises à des FACTEURS DE TRACTION DE SECURITE variables.

Un défaut caché est un défaut qui n'apparaît pas pendant la fabrication, l'entretien ou le fonctionnement normal de l'APPAREIL EM mais qui pourrait entraîner une défaillance d'une partie et donc un DANGER MECANIQUE. On trouve par exemple des contraintes internes élevées dans les parties traitées thermiquement telles que les ressorts, des fibres de fils cassées à l'intérieur des câbles et des zones poreuses à l'intérieur des moulages.

La Figure A.17 contient un exemple de détermination du FACTEUR DE TRACTION DE SECURITE utilisant le Tableau 21. La Figure A.18 contient un exemple de détermination de la conception et des charges d'essai. Ces exemples ne sont pas destinés à couvrir tous les cas possibles. Pour une conception particulière, ces FACTEURS DE TRACTION DE SECURITE et charges de calcul /d'essai peuvent varier selon les matériaux utilisés, leurs caractéristiques d'usure, les conditions de charge, etc.

Ce paragraphe se concentre sur les facteurs de sécurité comme l'approche suggérée de confiance dans l'intégrité structurelle maintenue des appareils au cours de la DUREE DE VIE PREVUE. Dans certains cas, les facteurs de sécurité spécifiés sont plus que nécessaires et

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dans certains cas même des facteurs plus importants pourraient être considérés comme appropriés. Les critères de conformité peuvent être satisfaits par la GESTION DES RISQUES plutôt que par l'utilisation de la voie du facteur de sécurité. Pour les nouveaux matériaux ou pour les structures avec surveillance sophistiquée des contraintes, les facteurs de sécurité pourraient ne pas être nécessaires.

Si on estime que le mode de défaillance de la partie ne donne pas lieu à un RISQUE inacceptable, les FACTEURS DE TRACTION DE SECURITE spécifiés dans le Tableau 21 ne s'appliquent pas. Par exemple, pour les composants propriétaire comme les paliers, il est acceptable de se reposer sur les données du FABRICANT du composant pour l'espérance de charge et de vie sans appliquer un FACTEUR DE TRACTION DE SECURITE.

Un contre-écrou considéré comme sujet à l'usure est généralement réalisé volontairement en un matériau plus tendre que la vis. L'objectif est qu'une exigence générique soit fournie pour les APPAREILS EM en général.

De nouvelles conceptions de vis peuvent présenter moins de frottement que des conceptions classiques et, par exemple, peuvent inclure plusieurs roulements à billes. De telles conceptions peuvent être considérées comme moins "sujettes à l'usure", comme indiqué par les affirmations des vendeurs et par une EVALUATION DES RISQUES du FABRICANT .

Le paragraphe 4.5 est toujours applicable et permet au FABRICANT d'utiliser des mesures alternatives de MAITRISE DU RISQUE, ou des variantes de la méthode d'essai ou des critères de conformité d'essai, avec une justification.

Paragraphe 9.8.3 – Résistance des supports PATIENT ou OPERATEUR, ou des systèmes de suspension

Ce paragraphe s'applique aux forces appliquées aux parties de suspension ou de support des APPAREILS EM destinées à supporter ou à suspendre toute ou partie de la masse d'un corps humain et des ACCESSOIRES utilisés sur ces parties de support ou de suspension. Pour les PATIENTS adultes ou les OPERATEURS, la masse de 135 kg représente le 99ème percentile de la population. Pour des populations spécifiques, une masse supérieure ou inférieure peut être utilisée (personne lourde ou application pédiatrique).

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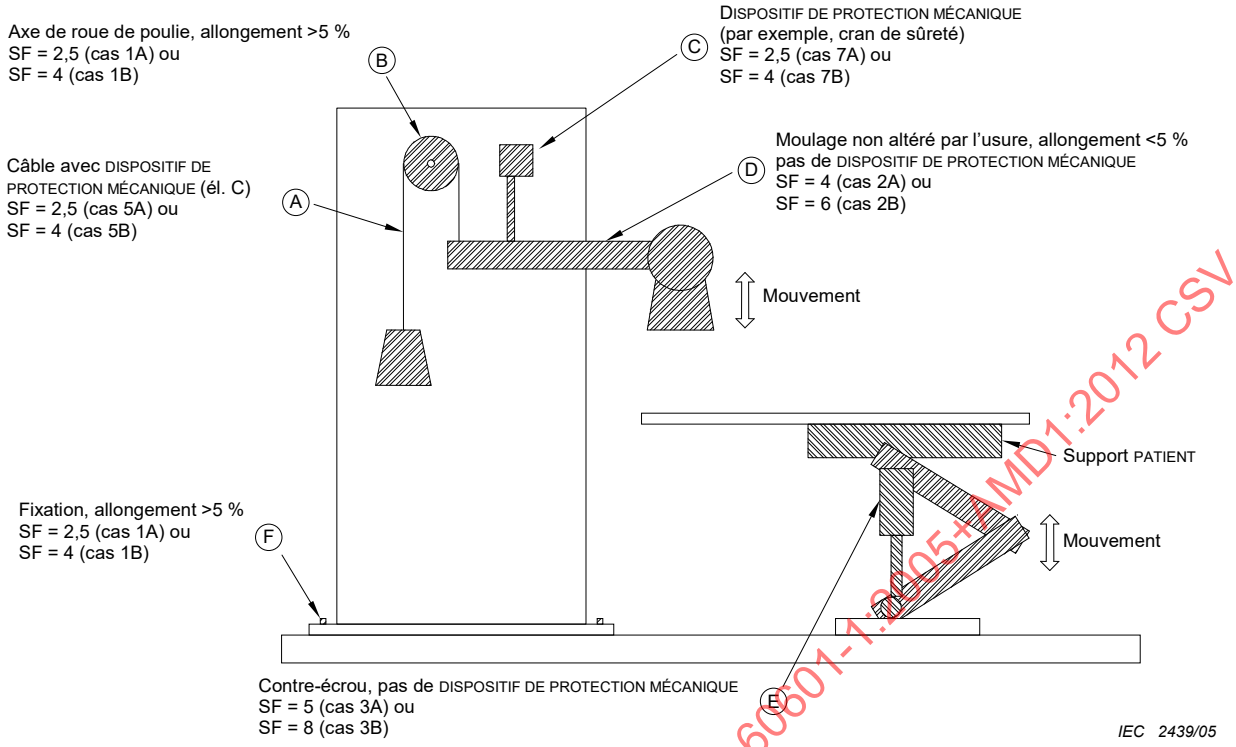
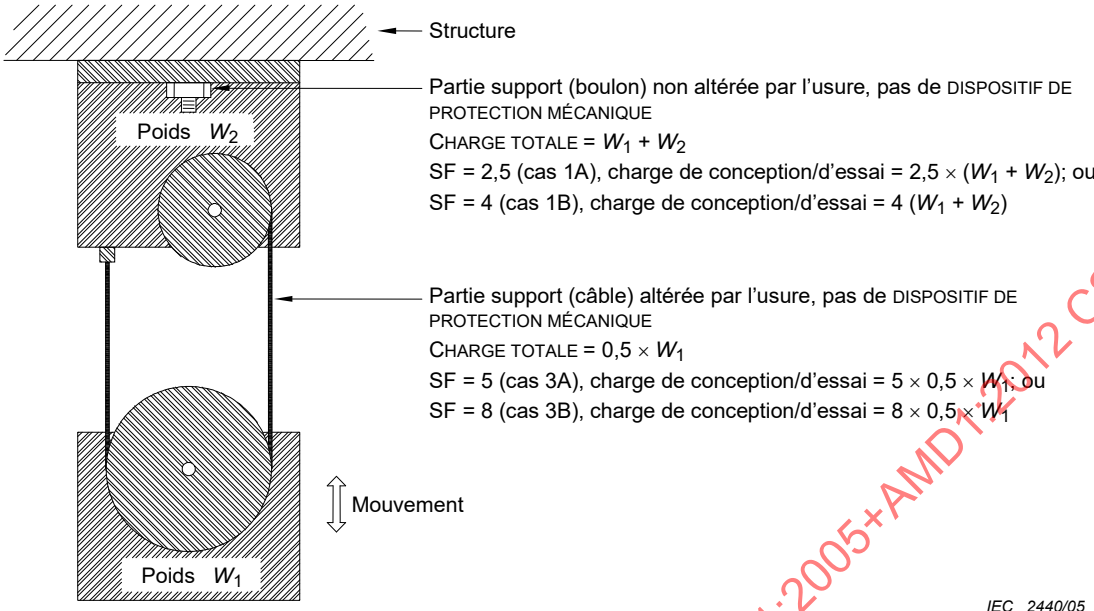


Figure A.17 – Exemple de détermination du FACTEUR DE TRACTION DE SECURITE au moyen du Tableau 21

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NOTE La CHARGE TOTALE est montrée sur la base des seules forces statiques, pour obtenir les charges totales réelles, les forces dynamiques doivent aussi être incluses.

Figure A.18 – Exemple de détermination des charges de calcul et d'essai

Paragraphe 9.8.3.2 – Forces statiques dues à la charge des personnes

La Figure A.19 illustre un exemple de distribution de masse d'un corps humain pour les surfaces de support du PATIENT.

Dimensions en millimètres

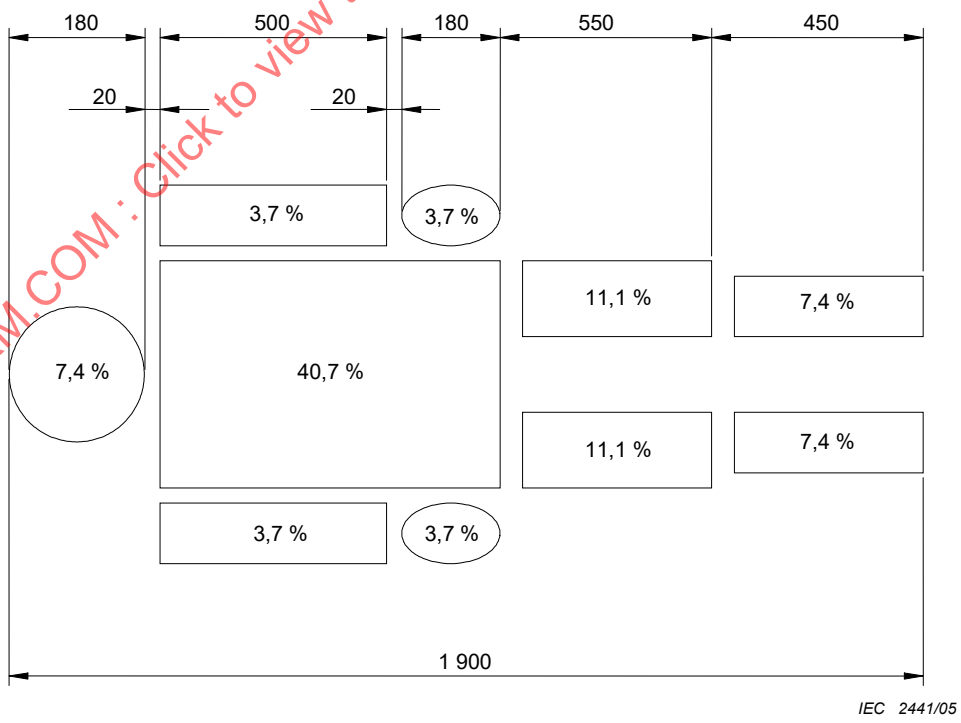


Figure A.19 – Exemple de distribution de masse du corps humain

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La distribution de masse d'un diagramme d'un corps correspond à une distribution moyenne basée sur des données anthropométriques. Elle peut varier en raison de la variété des populations ou des catégories spécifiques d'âge. Pour des personnes sédentaires n'ayant pas d'activité physique, la masse de la partie supérieure du corps peut représenter un pourcentage plus important.

La diversité des APPAREILS EM ne permet pas plus de précision dans la présente norme générale. Il appartient aux normes particulières de définir plus précisément la zone de distribution ou la position du cas le plus défavorable, plutôt que des essais dynamiques.

Un repose-pied est essayé pour le double de sa charge normale, plutôt que pour une charge basée sur une valeur de FACTEUR DE TRACTION DE SECURITE du Tableau 21, car il est destiné à supporter le poids d'un PATIENT seulement pendant une courte période.

L'essai avec une masse de 80 kg placée à 60 mm du bord extérieur est destiné à simuler le centre de gravité d'un PATIENT assis ou s'appuyant sur le bord de la surface de support.

Pendant les essais de charge statique, il est prévu de vérifier tout effet négatif d'un fléchissement élastique temporaire (pendant l'essai) et d'un fléchissement plastique permanent (après l'essai) sur la SECURITE DE BASE ou les PERFORMANCES ESSENTIELLES.

Pour l'essai de variation de charge, le comité pensait qu'un fléchissement de 5 ° procurerait une quantité mesurable représentant une limite d'acceptation raisonnable. Le facteur de charge 2X est un précédent de la 2ème édition de l'IEC 60601-1 et semble reconnaître la charge temporaire représentée par les variations.

Pour l'essai de charge sur surface d'assise, aucune limite linéaire spécifique n'est précisée. L'objectif est d'évaluer tout fléchissement élastique temporaire ou plastique permanent pour déterminer un effet négatif sur la SECURITE DE BASE ou les PERFORMANCES ESSENTIELLES. Un facteur de charge d'assise de 60 % a été considéré comme représentatif d'une charge d'assise réelle, lorsque les jambes se balancent au bord de la surface d'assise. La perte de fonction n'est considérée comme inacceptable qu'associée aux PERFORMANCES ESSENTIELLES. L'objectif est le suivant: il convient que la détérioration n'entraîne aucune blessure aux personnes ni aucune perte des mesures de MAITRISE DU RISQUE. La conformité des surfaces destinées à soutenir l'assise et, à d'autres moments, une charge complète de patient est également évaluée par rapport aux) facteur(s) de charge appropriés en 9.8.2.

Paragraphe 9.8.3.3 – Forces dynamiques dues à la charge des personnes

Un essai dynamique général est défini pour représenter des situations communes avec une personne en train de s'asseoir ou de se mettre debout.

L'exigence de ce paragraphe est destinée à s'appliquer aux fauteuils pour la chirurgie dentaire, aux tables pour rayonnements X et à de nombreux autres types similaires D'APPAREILS EM. Il convient que l'APPAREIL EM soit placé dans tous les modes et toutes les positions de fonctionnement où les charges des PATIENTS peuvent être raisonnablement attendues. Par exemple, lorsqu'une table PATIENT est positionnée dans la zone d'une structure CAT ou magnétique, l'essai dynamique n'est pas applicable dans la mesure où la charge dynamique causée par un PATIENT est négligeable.

Il convient que les APPAREILS EM soient conçus pour supporter une force répétitive en tenant compte des FACTEURS DE SECURITE DE TRACTION et des résultats des calculs de fatigue. Les FACTEURS DE TRACTION DE SECURITE existent pour montrer la fiabilité des appareils sans véritables essais.

La partie inférieure de l'appareillage de masse d'essai du corps humain représentée à la Figure 33 est de la mousse et il convient de simuler le contact par la partie PATIENT appropriée.

Paragraphe 9.8.4 – Systèmes avec DISPOSITIFS DE PROTECTION MECANIQUE

L'objectif d'un DISPOSITIF DE PROTECTION MECANIQUE est d'agir pour prévenir tout DOMMAGE en cas de défaillance du moyen de support primaire soumis à l'usure.

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La défaillance du moyen de support primaire soumis à l'usure est considérée comme une CONDITION DE PREMIER DEFAUT si elle présente un FACTEUR DE TRACTION DE SECURITE conforme au Tableau 21, lignes 5 et 6. Pour protéger contre les DOMMAGES dans cette CONDITION DE PREMIER DEFAUT, le DISPOSITIF DE PROTECTION MECANIQUE agit comme un dispositif de sauvegarde et doit avoir le FACTEUR DE TRACTION DE SECURITE indiqué au Tableau 21, ligne 7. Il est considéré comme une bonne pratique d'ingénierie de construire un DISPOSITIF DE PROTECTION MECANIQUE à partir de matériaux non cassants, et c'est la raison pour laquelle la ligne 7 ne comporte pas de colonne élongation.

Pour soumettre un DISPOSITIF DE PROTECTION MECANIQUE à essai, le moyen de support primaire soumis à l'usure doit être mis en échec. Par exemple, si le système de support primaire est un câble, il doit être coupé.

Article 10 Protection contre les DANGERS dus aux rayonnements non désirés et excessifs

Les rayonnements provenant d'un APPAREIL EM peuvent se présenter sous toutes les formes connues en physique. Les exigences de SECURITE DE BASE concernent les rayonnements indésirables. Des mesures de protection sont nécessaires pour un APPAREIL EM et son environnement et les méthodes déterminant les niveaux de rayonnement doivent être normalisées.

Cet article est destiné à traiter les rayonnements résiduels (tels que les rayonnements diffusés provenant des appareils radiologiques) et les rayonnements non essentiels (tels que les rayons X émis par les tubes cathodiques). L'exigence relative à la quantité de rayons involontaire ou excessive que l'APPAREIL EM peut fournir au PATIENT est couverte en 12.4.5.

En ce qui concerne les rayonnements ionisants, les exigences de l'IEC satisfont généralement aux recommandations de la Commission internationale de protection radiologique (CIPR). Leur but est de fournir des éléments d'information immédiatement utilisables par le FABRICANT et l'ORGANISME RESPONSABLE.

Leur évaluation n'est possible que par l'étude adéquate des méthodes et des durées de fonctionnement de l'APPAREIL EM et de la position de l'OPERATEUR et de ses assistants, car l'application des conditions les plus défavorables conduirait à des situations pouvant faire obstacle à un diagnostic ou à un traitement correct.

Les récentes publications CIPR indiquent également à l'OPERATEUR les méthodes propres à réduire les irradiations intentionnelles.

Paragraphe 10.1.1 – APPAREILS EM non prévus pour délivrer des rayonnements X à des fins de diagnostic ou de thérapie

Les rayonnements X parasites provenant des composants comme les unités d'affichage vidéo (VDU) sont une source potentielle de préoccupation concernant les APPAREILS EM, dont beaucoup contiennent des VDU. L'Annexe H de l'IEC 60950-1:2001 contient une PROCEDURE bien acceptée de mesure des émissions parasites pour les appareils de traitement de l'information. Les limites de cette annexe sont basées sur la ICRP 60 [39]. Les exigences provenant de l'Annexe H de l'IEC 60950-1:2001 ont été incorporées dans le corps de la présente norme parce qu'il s'agissait de la seule référence normative qui exigeait l'utilisation de l'IEC 60950-1. D'autres références normatives à l'IEC 60950-1 constituent des moyens alternatifs pour traiter d'aspects comme les LIGNES DE FUITE et les DISTANCES DANS L'AIR. Un utilisateur de la présente norme n'a pas à se référer à la 60950-1 sauf s'il désire utiliser les méthodes de coordination de l'isolement de ce document.

Paragraphe 10.3 – Rayonnements à micro-ondes

Le présent paragraphe spécifie une limite de densité de puissance des micro-ondes dans le but d'atténuer un dommage thermique aux tissus corporels dans leur ensemble. L'objectif est de pouvoir déterminer la conformité de façon appropriée au moyen d'un jugement d'ingénierie plutôt que d'un essai, lorsqu'il est évident que les émissions ne s'approchent en aucun cas de la limite de densité de puissance de 10 W/m^2. La connaissance des spécifications de transmission des appareils et du jugement d'ingénierie peut être utilisée pour déterminer la

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conformité. Le seuil de sécurité de 10 W/m^2 dépasse de beaucoup le seuil autorisé pour les communications sans fil, où les limites de DAS (W/kg) sont applicables. Par exemple, un appareil équipé d'oscillateurs d'horloge ou des radios de transmission intentionnelle tels les appareils Wi-Fi™, Bluetooth®, GPS ou cellulaires sont conformes à ce seuil car ils satisfont à ces limites plus rigoureuses pour leur bande passante applicable. Lorsque cette confiance n'existe pas, il convient d'effectuer des mesures appropriées de densité de puissance.

Paragraphe 10.4 – Lasers ~~et diodes électroluminescentes (DEL)~~

~~Une référence datée à l'IEC 60825-1 a été utilisée car au moment de la publication de cette norme, le CE 76 de l'IEC avait commencé les travaux préliminaires à l'élaboration de la troisième édition de l'IEC 60825-1 et était en train d'envisager de retirer les exigences concernant les DEL de l'IEC 60825-1.~~

L'IEC 60825-1 est applicable à la sécurité des produits laser émettant des rayonnements laser dans la plage de longueurs d'onde comprise entre 180 nm et 1 mm. Un produit laser peut être constitué d'un seul laser avec ou sans alimentation séparée, ou bien il peut incorporer un ou plusieurs lasers dans un système optique, électrique ou mécanique complexe.

Tout produit laser est exempt de toutes les exigences supplémentaires de l'IEC 60825-1 si la classification de ce produit par le fabricant conformément aux Articles 3, 8 et 9 de l'IEC 60825-1 montre que le niveau d'émission ne dépasse pas la LEA (Limite d'Emission Accessible) de Classe 1 dans toutes les conditions de fonctionnement, de maintenance, de service et de défaillance.

Dans les éditions précédentes de l'IEC 60825-1, les DEL étaient incluses dans le domaine d'application de la norme et elles peuvent toujours être incluses dans d'autres parties de la série IEC 60825. Cependant, avec le développement des normes de sécurité sur les lampes, la sécurité en matière de rayonnements optiques des DEL en général peut être couverte de façon plus appropriée par les normes de sécurité sur les lampes. La suppression des DEL du domaine d'application de l'IEC 60825-1 n'exclut pas la présence des DEL dans d'autres normes dès lors qu'elles se réfèrent aux lasers. L'IEC 62471 [67] peut être appliquée pour déterminer la classe de groupe de risque d'une DEL ou d'un produit intégrant une ou plusieurs DEL.

L'IEC 62471 donne des directives pour évaluer la sécurité photobiologique des lampes et des systèmes lumineux, y compris les luminaires. Plus précisément, elle spécifie les limites d'exposition, la technique de mesure de référence et le schéma de classification pour l'évaluation et la maîtrise des dangers photobiologiques de toutes les sources électriques de rayonnements optiques en large bande incohérentes, y compris les DEL mais à l'exclusion des lasers, dans la plage de longueurs d'onde comprise entre 200 nm et 3 000 nm. L'IEC 62471 a été préparée à l'origine comme Norme CIE S 009:2002 par la Commission Internationale sur l'Eclairage.

Paragraphe 11.1 –Températures excessives à l'intérieur des APPAREILS EM

Les limites de température sont prescrites pour prévenir les ~~DANGERS~~ SITUATIONS DANGEREUSES pour presque tous les types d'APPAREILS EM afin d'éviter le vieillissement rapide de l'isolation et l'inconfort lorsque l'APPAREIL EM est touché ou manipulé, ou les blessures lorsque les PATIENTS peuvent entrer en contact avec des parties de l'APPAREIL EM.

Des parties d'APPAREIL EM pourraient être introduites dans les cavités du corps, habituellement de façon temporaire mais quelquefois de façon permanente.

Pour les contacts avec le PATIENT, des limites de température spéciales ont été établies.

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Paragraphe 11.1.1 – Températures maximales en UTILISATION NORMALE

Le Tableau 22 traite des limites applicables aux parties des composants susceptibles d'affecter la conformité de l'APPAREIL EM avec la présente norme en général (par exemple SECURITE électrique DE BASE).

Il n'est pas prévu que les parties des APPAREIL EM soient soumises aux essais dans chaque configuration possible en UTILISATION NORMALE tant que le FABRICANT peut déterminer les conditions du cas le plus défavorable. Le “cas le plus défavorable” inclura presque toujours la température ambiante la plus élevée admissible et le fonctionnement de l'APPAREIL EM au CYCLE D'UTILISATION maximal, mais il convient que d'autres aspects particuliers de la configuration de l'APPAREIL EM (comme la fixation des ACCESSOIRES) soient déterminés par le FABRICANT à partir d'une compréhension complète de la conception de l'APPAREIL EM.

Paragraphe 11.1.2 – Température des PARTIES APPLIQUEES

Les Tableaux 23 et 24 traitent des DANGERS susceptibles de se produire du fait d'un contact de l'homme avec des températures élevées. Les températures relatives à un contact humain sont fondées sur l'expertise et la littérature cliniques [52] et l'expérimentation. Les valeurs sont en outre conformes à la norme européenne EN 563 [38].

Bien que la température de surface maximale d'une PARTIE APPLIQUEE passe de 41 °C à 43 °C en réponse à l'intervention clinique susmentionnée, l'intervention pratiquée par certains médecins cliniciens révèle que les petits enfants ainsi que certains autres groupes présentant un RISQUE élevé pourraient être davantage sujets à subir des DOMMAGES provoqués par des surfaces chauffées à une température de 43 °C.

En situation idéale, les normes particulières applicables aux APPAREILS EM utilisés pour ces groupes de PATIENTS stipuleraient des exigences (si nécessaire) relatives à des températures de contact moins élevées. Afin de traiter les cas pour lesquels de telles normes particulières n'existent pas, le groupe de travail a constaté que la notification de l'ORGANISME RESPONSABLE lorsque les températures dépassent la seconde limite de 41 °C est appropriée. Toutefois, la nouvelle limite de 43 °C doit être considérée comme limite maximale absolue.

Lorsqu'on mesure les températures des PARTIES APPLIQUEES, il convient que la méthode utilisée simule la configuration du cas le plus défavorable lorsque cela est possible en utilisant la peau humaine réelle ou simulée. Il convient que la détermination de la configuration du cas le plus défavorable prenne en compte les aspects comme la température probable du corps et si la partie du corps ou de la PARTIE APPLIQUEE elle-même est couverte (par exemple par une couverture). La peau humaine simulée dans ce but pourrait inclure des matières comme le caoutchouc au silicone.

Paragraphe 11.1.2.2 – PARTIES APPLIQUEES non destinées à fournir de la chaleur à un PATIENT

Le Tableau A.5 est présenté à titre indicatif pour les APPAREILS EM qui génèrent des températures basses (fraîches) pour des besoins thérapeutiques ou dans le cadre de leur fonctionnement. Aucune exigence normative n'a été incluse dans la présente norme dans la mesure où ces APPAREILS EM sont rares.

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Tableau A.5 – Conseils sur les températures de surface pour les APPAREILS EM qui génèrent des températures basses (fraîches) pour des besoins thérapeutiques ou dans le cadre de leur fonctionnement

APPAREILS EM et ses parties		Température minimale [a] °C	
		Aluminium	Acier
La surface externe de l'APPAREIL EM et de ses parties est susceptible d'être touchée pendant un temps "*t*".[b]	*t* < 1 s	–20	–20
	1 s ≤ *t* < 10 s	–10	–15
	10 s ≤ *t* < 60 s	–2	–7

[a] Les valeurs limites de température minimale admissible pour les surfaces externes susceptibles d'être touchées par le PATIENT, L'OPERATEUR et les autres personnes sont basées sur les valeurs de seuil de congélation d'un doigt touchant différents matériaux (seuil de gelure).

[b] Il convient de déterminer et de documenter la probabilité d'apparition d'un contact et la durée du contact dans le FICHIER de GESTION DES RISQUES.

Paragraphe 11.1.3 – Mesures

L'utilisation correcte de couples thermoélectriques est reconnue dans d'autres normes comme technique d'essai valide. Les limites de température sont réduites pour compenser les erreurs susceptibles de se produire dans la construction et la disposition du couple thermoélectrique.

Durant le développement des exigences de 11.1.3, le groupe de travail a examiné la question de savoir s'il serait approprié de réduire la température autorisée maximale pour les surfaces et les PARTIES APPLIQUEES aux altitudes supérieures. En réponse à cette question, une évaluation approfondie a été réalisée par le Dr. Joachim Kohl, membre expert du groupe. Ce qui suit résume les résultats de cette évaluation (voir Figure A.22).

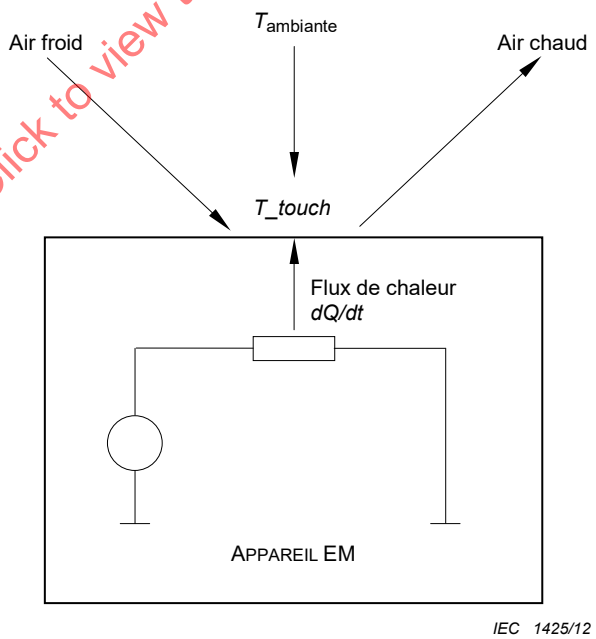


Figure A.22 – Température autorisée maximale pour les surfaces et les PARTIES APPLIQUEES à des altitudes plus élevées

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Les variables et symboles suivants sont utilisés dans l'évaluation:

T_touch	température de contact à la surface de l'APPAREIL EM
DeltaT	différence entre la température de la zone touchée et la température ambiante
R_thermal	résistance thermique de l'APPAREIL EM soumis à l'essai à température ambiante
Q	chaleur
dQ/dt	flux de chaleur
Pambiant	pression de l'air ambiant
alpha	coefficient de transfert thermique = *dQ/dt / (DeltaT * surface)*
L	longueur caractéristique de la surface de transfert thermique
surface	surface de refroidissement de l'appareil
lambda	conductance thermique
eta	viscosité dynamique
rho	densité du gaz
Nu	nombre de Nusselt
Re	nombre de Reynolds
Gr	nombre de Grashof
sqrt	racine carrée
~	proportionnelle

Évaluation des effets de l'altitude sur le transfert thermique:

L'équation standard du transfert thermique est la suivante:

$$DeltaT = R_thermique * dQ/dt$$

Pour *R_thermique,* l'on peut estimer*:*

$$R_thermique \sim 1 / Pambiant^{m}$$

avec l'exposant *m* = 0,6 … 0,8, nous supposerons 1.

Équations de proportionnalité à 1 / *Pambiant*^{m}:

En conséquence:

$$R_thermique \sim 1 / alpha$$

où le facteur de proportionnalité contient des données géométriques.

Définition de *Nu*:

$$Nu = alpha * L / lambda$$

Résultats des investigations théoriques:

$$Nu \sim Re^{m}$$

Le facteur de proportionnalité dépend de la géométrie, du type de gaz et de la circulation de l'air, mais non de la température, de la pression ou de la densité.

L'exposant m est déterminé par la géométrie et par la circulation de l'air. Pour une convection naturelle due à un gradient de température, *Re* est donné par:

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$$Re = sqrt\ (0{,}4 * Gr)$$

La définition de *Gr* entraîne:

$$Gr \sim (rho / eta)^2$$

de sorte que:

$$Re \sim rho / eta.$$

Cette dernière relation est vraie également pour la convection forcée.

D'après l'équation générale pour le gaz, nous voyons que:

$$rho \sim Pambiant$$

Lambda et *eta* ne dépendent pas de la pression (selon les manuels de physique classiques). Le rassemblement de toutes ces informations conduit à la proportionnalité indiquée ci-dessus entre *R_thermique* et *Pambiant*.

Paragraphe 11.2 – Prévention du feu

Dans la plupart des environnements où les APPAREILS EM sont utilisés, d'autres sources de "carburant" ou de combustion sont généralement bien plus importantes que celles générées par l'APPAREIL EM lui-même. Les exigences qui concernent les incendies dans la présente norme s'attachent à éviter que l'APPAREIL EM soit une source de combustion. Pour cette raison, ces exigences se concentrent sur les APPAREILS EM qui contiennent ou qui sont utilisés dans des ATMOSPHERES ENRICHIES EN OXYGENE. Ces exigences tentent d'assurer que toute source potentielle d'inflammation reste isolée des ATMOSPHERES ENRICHIES EN OXYGENE en UTILISATION NORMALE et en CONDITIONS DE PREMIER DEFAUT.

Lorsque l'APPAREIL EM n'est pas utilisé dans ces atmosphères, il convient de considérer comme adéquat d'assurer que les limites des températures de fonctionnement et les exigences sur la protection contre les surcharges sont respectées.

Pour les APPAREILS EM qui pourraient fournir une source de carburant importante (comparé à des environnements de fonctionnement normaux), il convient de définir des exigences supplémentaires dans des normes particulières. Lorsqu'il n'existe pas de norme particulière, il convient de traiter ces questions de manière spécifique en appliquant le PROCESSUS de GESTION DES RISQUES tel que requis en 4.2.

Paragraphe 11.2.1 – Solidité et rigidité exigées pour la prévention des DANGERS liés au feu dans les APPAREILS EM

Il convient d'envelopper au moins toutes les parties électriques qui pourraient entraîner une ~~DANGER~~ SITUATION DANGEREUSE, à l'exception des CABLES D'ALIMENTATION et des autres câbles d'interconnexion, par des matériaux n'entretenant pas la combustion.

Cela n'exclut pas l'emploi d'un capot extérieur d'un autre matériau, couvrant l'enceinte intérieure conforme à la recommandation précitée.

Pour obtenir des ~~conseils~~ lignes directrices sur l'évaluation des DANGERS ~~d'incendie~~ D'INCENDIE, voir l'IEC 60695-1-1 [17].

Paragraphe 11.2.2 – APPAREILS ET SYSTEMES EM utilisés avec des ENVIRONNEMENTS RICHES EN OXYGENE

Bien qu'il ne s'agisse pas d'un mélange inflammable, la présence d'une ATMOSPHERE ENRICHIE EN OXYGENE accroît l'inflammabilité de nombreuses substances. Les rapports faisant état d'incendie dans des ATMOSPHERES ENRICHIES EN OXYGENE avec des APPAREILS EM ne sont pas courants. Toutefois, lorsque de tels incendies se produisent en milieu hospitalier, ils peuvent avoir des conséquences tragiques.

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Il convient de concevoir les APPAREILS EM destinés à fonctionner dans des ATMOSPHERES ENRICHIES EN OXYGENE de manière à minimiser la probabilité d'inflammation des matériaux inflammables.

Le cas échéant, il convient que des normes particulières spécifient les exigences correspondantes.

Paragraphe 11.2.2.1 a)

Le coton est considéré comme le matériau ayant la température et l'énergie d'inflammation les plus faibles comparé aux circuits électroniques et il est estimé qu'on peut le trouver à l'intérieur d'un dispositif sous forme de poussière.

La limite maximale de la température de surface est fondée sur la température minimale d'inflammation de la plaque chaude pour le coton ignifuge dans un volume de 100 % d'oxygène, que la NFPA 53 [41] fixe à 310 °C. L'hypothèse ainsi formulée repose sur le fait que 300 °C est une limite de température acceptable pour les APPAREILS EM opérant dans des ATMOSPHERES ENRICHIES EN OXYGENE.

Les conditions les plus défavorables décrites dans le texte permettent de fournir des chiffres simples pour limites.

Les valeurs relatives à la formation d'étincelles sont issues de Kohl, H.-J. *et al.*, ASTM STP 1395 [37].

Ce paragraphe permet d'utiliser des circuits électroniques dans des ATMOSPHERES ENRICHIES EN OXYGENE uniquement lorsque leur alimentation électrique est limitée. La limitation résistive de la puissance absorbée est nécessaire pour la CONDITION DE PREMIER DEFAUT d'un joint à brasure tendre ouvert pouvant former une étincelle. La même raison s'applique à la limitation de l'énergie des condensateurs et des inductances. Dans la plupart des cas, la limitation donnée au point 4) à 300 °C est plus restrictive. Pour la plupart des petits composants comme par exemple les condensateurs de découplage, ou lorsque la défaillance d'un composant entraîne la génération de la puissance maximale possible de la source, il est nécessaire de limiter la puissance à environ 1 W. La PROCEDURE utilisée pour déterminer la valeur permettant de limiter la puissance de sorte que la limite de 300 °C ne soit pas dépassée peut être la suivante:

– rechercher le plus petit composant qui peut correspondre à la source de puissance dans une CONDITION DE PREMIER DEFAUT;
– estimer sa résistance thermique;
– calculer la limitation de puissance = 200 °C / résistance thermique.

Paragraphe 11.2.2.1 b) 2)

Ce point traite de la condition où il se produit une fuite d'oxygène qui n'est pas détectée. Conformément à la définition de l'expression EXEMPT DE PREMIER DEFAUT, une telle fuite (dans la mesure où elle n'est pas détectée) est considérée comme une CONDITION NORMALE (voir 4.7). De même, seule la défaillance de ventilation, qui n'est pas détectée, doit être considérée comme une CONDITION NORMALE. Lorsque la conception d'un système de ventilation rend improbable le fait qu'il soit complètement bloqué en UTILISATION NORMALE, il convient que de tels blocages ne soient pas pris en compte. Le seul moyen de déterminer le taux de fuite maximal qui doit être pris en compte est de trouver le taux de fuite qui peut être détecté par l'ORGANISME RESPONSABLE en toute sécurité.

Paragraphe 11.2.2.1 b) 3)

La cause de la SITUATION DANGEREUSE est la suivante: une fuite se produit et n'est pas détectée, peu après une panne électrique se produit et provoque une inflammation. L'intervalle de temps t_c de vérification des joints peut être calculé de la manière suivante:

– estimer la probabilité par le temps p_e d'une panne électrique supérieure aux valeurs données en 11.2.2.1 a);

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– estimer la probabilité par le temps de la fuite d'oxygène p_o;

– déterminer la probabilité acceptée de pannes dangereuses par temps r ;

– calculer: $t_c = r / (0,5 \times p_e \times p_o)$.

Paragraphe 11.2.2.2 – Sorties d'évacuation extérieures pour un ENVIRONNEMENT RICHE EN OXYGENE

On a signalé des feux importants par injection d'oxygène dont la source d'inflammation est un connecteur électrique défectueux au voisinage d'une prise d'oxygène.

Paragraphe 11.3 – Exigences de construction pour les ENVELOPPES à l'épreuve du feu des APPAREILS EM

Les exigences relatives aux ENVELOPPES pare-feu de l'IEC 61010-1 [22] ont été tout d'abord incluses en tant qu'alternative aux essais sur les CONDITIONS DE PREMIER DEFAUT (associées à la combustion et ses conséquences) énumérées dans l'Article 13). Avec l'exigence selon laquelle l'ENVELOPPE et les matériaux qu'elle contient doivent être résistants à l'inflammation, la probabilité que le feu s'échappe de ces ENVELOPPES est considérée comme minimale. Lorsque l'ENVELOPPE pare-feu constitue la seule partie de l'APPAREIL EM, il convient de réaliser une analyse rigoureuse pour s'assurer de la présence d'une barrière fiable contre la propagation du feu.

Les composants de l'IEC 60950-1:2005 (c'est-à-dire, alimentations, modems, routeurs de réseau, etc) peuvent être intégrés dans des APPAREILS EM lorsque l'isolation des MOOP a été déterminée comme étant adéquate et que les limites du COURANT DE CONTACT ont été satisfaites.

Les exigences de résistance à l'inflammation pour l'isolation des fils, lors d'une utilisation à l'intérieur d'une ENVELOPPE à l'épreuve du feu conformément à l'IEC 60950-1:2005, paragraphe 4.7.3.4, sont:

– un minimum de FV-2 lorsqu'ils sont soumis à l'essai conformément à l'IEC 60695-11-10, ou

– une isolation en PVC, TFE, PTFE, FEP, polychloroprène ou polyimide.

Alors que l'exigence de résistance à l'inflammation des APPAREILS EM de FV-1 pour l'isolation des fils lors d'une utilisation à l'intérieur d'une ENVELOPPE à l'épreuve du feu est légèrement plus rigoureuse que l'exigence de l'IEC 60950-1:2005, paragraphe 4.7.3.4, il semblerait raisonnable d'aboutir à un niveau équivalent de risque, si un fil conforme à l'IEC 60950-1 était intégré dans l'APPAREIL EM ou le SYSTEME EM:

– soit indirectement lorsque les composants de l'IEC 60950-1 ont été intégrés dans l'APPAREIL EM ou le SYSTEME EM,

– soit directement, dans le cadre d'une décision de sélection de fil pour l'APPAREIL EM ou le SYSTEME EM.

L'IEC 61010-1:2010 [22], paragraphe 9.3.2, exige que l'isolation des fils lors d'une utilisation à l'intérieur d'une ENVELOPPE à l'épreuve du feu ait une valeur assignée UL 2556 [72] de VW-1, ou qu'elle soit conforme aux exigences applicables de l'IEC 60332-1-2 [55] ou de l'IEC 60332-2-2 [56]. Ces exigences de résistance à l'inflammation des fils sont considérées comme acceptables pour les APPAREILS EM et les SYSTEMES EM.

Paragraphe 11.4 – APPAREILS EM et SYSTEMES EM destinés à être utilisés avec des produits anesthésiques inflammables

Bien que l'utilisation d'anesthésiques inflammables soit peut répandue, il a été convenu lors de la rédaction de cette édition que certains FABRICANTS pourraient vouloir classer leurs APPAREILS EM dans les CATEGORIES AP ou APG. Afin de rendre cette édition plus pratique (en supprimant la section sur ce sujet rarement utilisée) tout en conservant les VALEURS ASSIGNEES relatives aux CATEGORIES AP et APG, le texte a été déplacé dans une annexe et seule cette brève référence demeure dans la norme.

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Il convient que le FABRICANT détermine si l'APPAREIL EM doit être classé en CATEGORIE AP ou APG, en fonction de l'UTILISATION PREVUE. Les exigences relatives aux CATEGORIES AP et APG sont présentées à l'Annexe G (voir également la justification pour l'Annexe G).

Paragraphe 11.5 – APPAREILS EM ET SYSTEMES EM destinés à être utilisés avec des produits inflammables

Bien qu'il ait été nécessaire de traiter des cas où les APPAREILS EM sont utilisés avec des agents inflammables (tels que les désinfectants) ou dans des zones dans lesquelles ils sont fréquemment utilisés et lorsque le FABRICANT de l'APPAREIL EM n'a donné aucune instruction ou précaution spéciale, la diversité de ces agents, leur volatilité ainsi que beaucoup d'autres facteurs déterminants empêchent de donner des instructions spécifiques. La seule solution raisonnable dans ces cas est d'assurer que le FABRICANT évalue et traite le RISQUE associé.

Un mélange de vapeurs inflammables dégagées par un agent de désinfection ou de nettoyage et d'air peut être traité comme un MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'AIR sous réserve des réglementations nationales ou locales.

Paragraphe 11.6.2 – Débordements dans les APPAREILS EM

Cet essai est destiné à évaluer non seulement si le liquide mouille réellement des parties d'une manière qui affecterait un MOYEN DE PROTECTION ou engendrerait un DANGER mais également si une quantité similaire de liquide qui pourrait déborder à une autre occasion et atteindre les mêmes parties de l'APPAREIL EM, sans éventuellement les toucher exactement de la même façon, affecterait un MOYEN DE PROTECTION ou donnerait lieu à un DANGER. Il convient que les résultats de l'essai soient évalués pour assurer qu'ils représentent de manière réaliste les conditions qui seront expérimentées lorsque l'APPAREIL EM sera utilisé.

Paragraphe 11.6.3 – Renversement sur un APPAREIL EM OU UN SYSTEME EM

~~Outre les APPAREILS EM qui nécessitent l'utilisation de fluides, de nombreux types d'appareils sont exposés au déversement accidentel de fluides comme partie intégrante de leur MAUVAIS USAGE RAISONNABLEMENT PREVISIBLE. Dans ce genre de cas (ainsi que pour les APPAREILS EM requérant l'emploi de fluides), le volume et le lieu géographique où peuvent se produire ces fuites varient fortement. Seule une évaluation correcte de l'APPAREIL EM soumis à essai peut déterminer une application appropriée de l'exigence. Cette évaluation est de la responsabilité du FABRICANT et les résultats doivent être communiqués aux personnes effectuant l'essai (généralement dans le FICHIER DE GESTION DES RISQUES). Cette exigence constituerait un domaine d'évaluation approprié que pourraient stipuler les rédacteurs des normes particulières.~~

Outre les APPAREILS EM qui nécessitent l'utilisation de fluides, certains APPAREILS EM sont exposés au déversement accidentel de fluides comme partie intégrante de leur mauvais usage raisonnablement prévisible. Dans de tels cas, le renversement est considéré comme une UTILISATION NORMALE et les RISQUES associés sont traités par les exigences du présent paragraphe. De plus, comme décrit en 9.4.2, l'inclinaison d'un APPAREIL EM TRANSPORTABLE d'un angle de 10° est considérée comme une UTILISATION NORMALE. Dans ce genre de cas (ainsi que pour les APPAREILS EM requérant l'emploi de fluides), le volume et le lieu géographique où peuvent se produire ces fuites varient fortement. Seule une évaluation correcte de l'APPAREIL EM soumis à l'essai peut déterminer une application appropriée de l'exigence. Cette évaluation est de la responsabilité du FABRICANT et les résultats doivent être communiqués aux personnes effectuant l'essai (généralement dans le DOSSIER DE GESTION DES RISQUES). Cette exigence constituerait un domaine d'évaluation approprié que pourraient stipuler les rédacteurs des normes particulières.

En accord avec les principes soulignés dans l'IEC 62366, lorsque sont donnés des avertissements et des notices de sécurité explicites (validés comme décrit dans l'IEC 62366), le non respect de ces avertissements ou notices de sécurité est considéré comme une utilisation incorrecte de l'APPAREIL EM qui est au-delà de la responsabilité du FABRICANT. Par conséquent, lorsque ces avertissements ou notices de sécurité sont donnés, le réservoir de liquide n'est rempli que jusqu'au niveau de remplissage prévu avant d'être incliné de 10°. Lorsqu'ils ne sont pas donnés, le réservoir de liquide est rempli à 15 % au-dessus du niveau prévu.

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Il convient que l'examen de l'UTILISATION NORMALE de l'APPAREIL EM donne une estimation appropriée de la quantité de fluide susceptible d'y être déversée.

Le renversement dans le cas d'un appareil qui ne nécessite pas l'utilisation de fluides est considéré comme une CONDITION DE PREMIER DEFAUT.

Paragraphe 11.6.4 – Fuite

Une fuite est considérée comme une CONDITION DE PREMIER DEFAUT.

Paragraphe 11.6.5 – Pénétration d'eau et de corps solides dans les APPAREILS EM ET LES SYSTEMES EM

Bien qu'il soit peu vraisemblable que les APPAREILS EM fassent l'objet d'une EVALUATION pour la protection contre les corps solides, l'IEC 60529 traite de cette possibilité et il convient de la considérer comme une option valide. La présence d'eau ou de corps solides à l'intérieur de l'ENVELOPPE après des essais conformes à sa classification IEC 60529 est considérée comme une CONDITION NORMALE. L'exigence consiste par conséquent à évaluer la possibilité d'une SITUATION DANGEREUSE due à une telle pénétration en combinaison avec une CONDITION DE PREMIER DEFAUT possible (telle une CONNEXION DE TERRE DE PROTECTION interrompue).

Paragraphe 11.6.8 – Compatibilité avec les substances utilisées avec l'APPAREIL EM

Il convient que l'APPAREIL EM, les ACCESSOIRES et les parties de ceux-ci soient conçus pour être utilisés en toute sécurité avec les substances avec lesquelles ils sont destinés à entrer en contact en UTILISATION NORMALE.

Le cas échéant, il convient que des normes particulières spécifient les exigences correspondantes.

Paragraphe 11.8 – * Coupure de l'alimentation / du RESEAU D'ALIMENTATION vers L'APPAREIL EM

L'interruption de l'alimentation pourrait donner lieu à une ~~DANGER~~ SITUATION DANGEREUSE dû à la perte de fonctionnalité. Cette ~~DANGER~~ SITUATION DANGEREUSE est traité en 7.9.2.4. La restauration de la source de puissance peut aussi donner lieu à des SITUATIONS DANGEREUSES. Des exemples pourraient être une activation involontaire de parties en mouvement ou le rétablissement de valeurs de sortie dangereuses. Cette situation potentiellement dangereuse et la durée de l'interruption de l'alimentation qui pourraient engendrer des ~~DANGERS~~ SITUATIONS DANGEREUSES doivent être considérées comme une partie du PROCESSUS de GESTION DES RISQUES.

L'IEC 61000-4-11 [21] définit des conditions générales et reproductibles pour le fonctionnement des appareils électriques et électroniques s'ils subissent des chutes de tension, de brèves interruptions et des variations de tension. Le niveau de tension et la durée des interruptions de courte durée sont définis aux Tableaux 210 et 211 de l'IEC 60601-1-2: 2001. L'IEC 60601-1-2 traite ces interruptions de faible durée comme une CONDITION NORMALE.

Pour les APPAREILS EM avec lesquels la sécurité du PATIENT dépend de la continuité de l'alimentation, il convient que des normes particulières comportent des exigences relatives à des alarmes de défaut d'alimentation ou à d'autres précautions.

Article 12 – Précision des commandes, des instruments et protection contre les caractéristiques de sortie présentant des risques

L'IEC 60601-1 sert de guide pour toutes les normes particulières et doit donc contenir des exigences ayant le caractère le plus général afin de parvenir à ce but. Pour cette raison, il est donc nécessaire qu'elle contienne des exigences formulées de manière générale à l'Article 12.

Les organismes de normalisation, y compris ceux étrangers à l'IEC, ont adopté le système de la présente Publication IEC afin de disposer d'un système unique et uniforme de normes. Dans de tels cas, il est très important de donner des lignes directrices dans cet article.

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Cet article introduit le concept d'APTITUDE A L'UTILISATION. Ce terme a été choisi de préférence aux termes plus courants de “erreur utilisateur” ou “erreur humaine” parce que toutes les erreurs n'arrivent pas par mégarde ou négligence du fait de l'OPERATEUR de l'APPAREIL EM. Bien trop fréquemment, les erreurs d'utilisation sont la conséquence directe d'une mauvaise conception de l'interface avec l'homme qui conduit l'OPERATEUR à prendre une décision incorrecte. Les erreurs d'utilisation dues à une APTITUDE A L'UTILISATION inadéquate sont devenues une préoccupation majeure. Le PROCESSUS D'INGENIERIE D' APTITUDE A L'UTILISATION décrit dans l'IEC 60601-1-6 est destiné à obtenir une APTITUDE A L'UTILISATION raisonnable qui, a son tour, est destinée à minimiser les erreurs d'utilisation et à minimiser l'utilisation des RISQUES associés.

Paragraphe 12.4.1 – Dépassement intentionnel des limites de sécurité

Si l'étendue de commande de l'APPAREIL EM est telle que la puissance délivrée dans une partie de cette étendue diffère considérablement de la puissance qui est considérée comme ne générant pas de danger, il convient que l'on dispose de moyens permettant d'empêcher l'atteinte d'une telle valeur ou indiquant à l'OPERATEUR (par exemple au moyen d'une résistance additionnelle perceptible lorsque la commande est actionnée ou par le contournement d'un verrouillage) que le réglage retenu dépasse la limite de sécurité.

Le cas échéant, il convient que des normes particulières spécifient les niveaux de sortie respectant la sécurité.

Paragraphe 12.4.3 – Sélection accidentelle de valeurs excessives des caractéristiques de sortie

La protection contre la sélection accidentelle de valeurs de sortie excessives peut être obtenue par des étapes appropriées pour réduire la possibilité de sélection accidentelle de valeurs de sortie excessives, par exemple par des verrouillages de manière à obtenir une action délibérée ou par des bornes de sortie séparées. Dans l'étude des mesures de protection, la norme sur les facteurs humains pourrait être prise en compte.

Article 13 – SITUATIONS DANGEREUSES et conditions de défaut

L'APPAREIL EM ou ses parties pourraient engendrer des ~~DANGERS~~ SITUATIONS DANGEREUSES en raison d'un fonctionnement anormal ou de conditions de défaut qui doivent donc être examinés. Alors que cet article identifie des conditions de défaut spécifiques, le Paragraphe 4.7 exige que l'ANALYSE DES RISQUES soit utilisée pour identifier d'autres défaillances qu'il convient d'examiner.

Paragraphe 13.1.1 – Généralités

Alors que les exigences de séparation (LIGNES DE FUITE et DISTANCES DANS L'AIR) et les exigences d'isolation sont détaillées à l'Article 8, il convient de ne pas voir ces exigences comme étant applicables uniquement aux RISQUES associés aux DANGERS électriques. Si les courants électriques peuvent causer une fibrillation (due au choc électrique), ils peuvent aussi être à l'origine de blessures qui ne sont pas directement liées au choc électrique.

Des exemples de ces autres DANGERS (liés à une isolation inadéquate ou présentant des défauts ou à des courts-circuits à travers l'espace physique utilisé comme isolation) pourraient inclure les étincelles qui pourraient devenir une source d'inflammation de matériaux inflammables (comme indiqué à l'Article 11) ou des défaillances fonctionnelles qui pourraient causer une perte de PERFORMANCE ESSENTIELLE. Dans ces cas, il convient de toujours considérer que la conformité avec les exigences d'isolation de l'Article 8 est une preuve que les RISQUES provenant de la défaillance de l'isolation ou de l'espacement ont été traités de manière appropriée lors de l'évaluation de la sécurité de l'APPAREIL EM.

Finalement, il convient de noter que les exigences pour les LIGNES DE FUITE et les DISTANCES DANS L'AIR ne sont pas destinées à être exigées au niveau de la carte du circuit où il n'existe pas de RISQUE significatif que les espacements soient compromis (coupés) par des contaminants (en UTILISATION NORMALE ou au cours du PROCESSUS de fabrication) comme des fluides ou des matières solides (voir aussi l'IEC 60529). Dans la plupart des applications, l'espace entre (par exemple) les pistes de carte de circuit et les fils de composants n'est pas considéré comme susceptible de connaître une défaillance. Dans les cas où il y a un doute

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concernant une éventuelle défaillance de l'espace (lorsque les exigences de LIGNE DE FUITE et de DISTANCE DANS L'AIR de 8.9 ne sont pas satisfaites), il convient que l'ANALYSE DE RISQUES DU FABRICANT évalue la probabilité de court-circuit à travers de tels espaces, mais uniquement lorsqu'un tel court-circuit pourrait directement donner lieu à des RISQUES inacceptables. Lorsque le court-circuit à travers les espaces ou lorsque les défaillances de l'isolation sont clairement non susceptibles de donner lieu à des RISQUES inacceptables, il convient qu'une telle analyse ne soit pas exigée.

Paragraphe 13.1.2 – Emissions, déformation d'ENVELOPPE ou dépassement de température maximale

Le fait de délivrer de manière involontaire des quantités dangereuses d'énergie ou de matière au PATIENT ou à son environnement naturel pourrait être traité dans des normes particulières.

Les quantités dangereuses de gaz toxiques ou inflammables dépendent du type de gaz, de la concentration, de l'endroit de l'émission, etc.

Les CONDITIONS DE PREMIER DEFAUT qui pourraient engendrer un feu de faible ampleur, mais pour lesquelles le feu resterait contenu dans l'ENVELOPPE pare-feu, sont acceptables car ce confinement limitera les effets à la zone située à l'intérieur de la dite ENVELOPPE.

~~Avec une dissipation de puissance inférieure à 15 W en l'absence de concentration d'oxygène accrue (voir 11.2.2), il n'existe pas de DANGERS d'incendie. Lorsque des circuits peuvent dissiper 15 W ou plus, il convient de démontrer que des composants dans ces circuits ne provoqueront pas d'incendie, de métal fondu, etc. se propageant de manière à engendrer un DANGER (en mettant les alentours en feu par exemple). Toutefois, comme dans la IEC 61010-1 [22], il est considéré que lorsque ces composants sont enfermés dans une ENVELOPPE pare-feu telle que définie en 11.3, une protection adéquate contre cette propagation est fournie.~~

Le niveau de puissance (15 Watts) cité dans la publication originale de la présente norme comme seuil sous lequel aucune inflammation ne se produit dans des conditions de concentration en oxygène ambiante normales s'est révélé très inférieur au niveau utilisé dans l'IEC 61010-1 [22]. La valeur originale de 15 W n'était basée sur aucun essai ni aucune recherche scientifique mais provenait d'une "pratique commune" dans certains corps de certification (valeur seulement anecdotique).

L'IEC 60950-1 donne toutefois une variété de niveaux d'énergie fondés sur la tension allant de 100 VA à 150 VA. A des fins de simplicité, la plus faible de ces valeurs (100 VA), jointe à des restrictions minimales sur la construction, était utilisée comme alternative à la limite de 15 W (sans restriction sur la construction) utilisée à l'origine dans la présente norme pour les APPAREILS EM en général.

L'application directe des exigences applicables aux circuits à énergie limitée dans l'IEC 60950-1 peut également être envisagée pour assurer que le RISQUE d'incendie est réduit à des niveaux acceptables aux énergies plus élevées, également pour démontrer la sécurité équivalente.

Etant donné que les installations où des APPAREILS EM conformes à la présente norme sont utilisés contiennent également des appareils de traitement de l'information (conformes à l'IEC 60950-1) et que ces appareils peuvent faire partie des APPAREILS EM ou des SYSTEMES EM, il serait déraisonnable d'exiger que les APPAREILS EM offrent un niveau de protection contre l'inflammation plus élevé que celui offert par les autres appareils utilisés dans le même environnement.

On estime qu'il est approprié de limiter les températures maximales pour les PARTIES APPLIQUEES en ce qui concerne les valeurs en CONDITION NORMALE dans la mesure où des valeurs supérieures entraînent des DOMMAGES et que le PATIENT est souvent incapable de se sortir de difficulté.

Les restrictions du présent paragraphe sont considérées comme suffisantes pour éviter un incendie durable. Un incendie non seulement est dangereux en lui-même mais a des effets secondaires tels que la destruction des barrières d'isolation ou la perte de la stabilité

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mécanique. Ces effets ne peuvent pas être pris en compte par les limitations données ci-dessus. Le FABRICANT doit donc tenir compte de ce qui suit pour prendre une décision:

– Une limitation de 10 VA ne peut évidemment pas garantir 'zéro inflammation'. Des composants plus petits, tels que résistances, semi-conducteurs, etc, peuvent être exposés à des niveaux de puissance qui pourraient entraîner une inflammation. Toutefois, des normes telles que l'IEC 60950-1 et l'IEC 61010-1 et l'expérience montrent que lorsque de telles situations surviennent, si les composants sont montés sur un matériau assigné FV1, il est très improbable qu'un incendie durable se produise.

– Une inflammation pourrait détruire les barrières d'isolation et exposer des tensions dangereuses. Il convient qu'un appareil conçu selon les exigences du présent paragraphe soit contrôlé pour déterminer si ces barrières seraient affectées et s'il convient de prendre des précautions supplémentaires appropriées indépendantes des exigences du présent paragraphe.

  Étant donné qu'aucun incendie durable ne peut se produire, la stabilité mécanique est considérée comme préservée.

Paragraphe 13.2.9 – Interruption et court-circuit des condensateurs de moteurs

Les effets de fonctionnement d'interrupteurs centrifuges peuvent être pris en considération. On spécifie une condition de rotor calé car certains moteurs à condensateur démarraient ou ne démarreraient pas avec diverses conséquences. La tension des condensateurs est vérifiée afin de s'assurer que leur diélectrique ne sera pas renforcé, provoquant l'accumulation de gaz dangereux y compris l'hydrogène.

Alors qu'un court-circuit ou un circuit ouvert de condensateur est une CONDITION DE PREMIER DEFAUT et que le blocage du rotor est aussi une CONDITION DE PREMIER DEFAUT (voir 13.2.8), cela est considéré comme un exemple de situation indiquée en 4.7, où une CONDITION DE PREMIER DEFAUT peut donner lieu inévitablement à une autre CONDITION DE PREMIER DEFAUT et les deux défaillances sont considérées comme une CONDITION DE PREMIER DEFAUT.

Paragraphe 13.2.10 – Critères d'essai complémentaires pour les APPAREILS EM fonctionnant avec un moteur et le Tableau 26, dernière ligne

Les limites de température des enroulements de moteurs d'APPAREIL EM sont déterminées après la première heure par une moyenne arithmétique, car l'expérience ~~du~~ des laboratoires d'essais a montré que les APPAREILS EM prévus pour un SERVICE NON CONTINU atteignent des valeurs variables qui pourraient temporairement être différentes des valeurs maximales. C'est pourquoi ~~une~~ des limites de température plus faibles ~~est~~ sont prescrites. Les valeurs du Tableau 26 sont fondées sur les exigences de l'IEC 60950-1:~~2001~~2005.

Paragraphe 13.2.13.1 – Conditions générales d'essai de surcharge

L'essai à la bille n'est pas destiné à représenter les conditions exactes expérimentées en utilisation. L'essai est réalisé à des températures élevées pour mettre à l'essai la robustesse (facteur de sécurité adapté) des propriétés mécaniques de l'isolation. Le principe n'est pas différent de l'essai de résistance diélectrique qui soumet l'isolation à des tensions bien supérieures à celles observées en utilisation.

Paragraphe 13.2.13.4 – APPAREILS EM à caractéristiques ASSIGNEES POUR SERVICE non CONTINU

Lorsque l'APPAREIL EM ou des parties de celui-ci sont ASSIGNES pour un SERVICE NON CONTINU mais que les commandes permettent aux OPERATEURS de le laisser en service (en cas d'urgence médicale ou autre), le SERVICE CONTINU de l'APPAREIL EM est considéré comme un MAUVAIS USAGE RAISONNABLEMENT PREVISIBLE. Lorsque la sécurité dépend de l'interruption de l'APPAREIL EM ou de parties de celui-ci après une période donnée, il convient de s'assurer qu'aucune action intentionnelle n'est nécessaire pour ce faire.

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Article 14 – SYSTEMES ELECTROMEDICAUX PROGRAMMABLES (SEMP)

Les ordinateurs sont de plus en plus utilisés dans les APPAREILS EM souvent dans des fonctions critiques pour la sécurité. L'utilisation de technologies informatiques augmente le niveau de complexité dans les APPAREILS EM. Cette complexité signifie que des défaillances systématiques peuvent échapper aux limites pratiques des essais. Par conséquent, cet article va au-delà des essais et des mesures classiques de l'APPAREIL EM fini et inclut des exigences relatives aux PROCESSUS de développement de l'APPAREIL EM. Les essais du produit fini ne sont pas adéquats pour évaluer la sécurité ~~d'APPAREILS EM~~ de SYSTEMES ELECTROMEDICAUX PROGRAMMABLES.

C'est pourquoi cet article exige qu'un PROCESSUS comportant des éléments spécifiques soit établi et suivi. L'objectif est de déterminer ces éléments spécifiques du PROCESSUS en laissant l'utilisateur de cet article déterminer en détail comment les mettre en œuvre. Cela est similaire à l'approche adoptée dans la série des ISO 9000. Etant donné que les utilisateurs de cet article sont supposés qualifiés pour effectuer les activités identifiées, les détails ont été limités au niveau minimal.

Bien que la répétition de certains éléments du PROCESSUS soit prévisible, aucune exigence spécifique sur ce point n'a été incluse. Ces exigences ont été omises dans la mesure où la nécessité de répéter des PROCESSUS ou des portions de PROCESSUS est propre à chaque dispositif. La nécessité de répétition se fera en outre sentir à mesure que le PROCESSUS de conception permettra une compréhension plus fine du projet.

Dans la mesure où les utilisateurs de la présente norme doivent établir, tenir à jour et appliquer un PROCESSUS de GESTION DES RISQUES dans le cadre de la conformité, cet article définit les caractéristiques propres aux systèmes programmables qu'il convient d'intégrer dans le PROCESSUS. Les exigences applicables au développement et à la modification de logiciels d'appareils médicaux ont été spécifiées dans l'IEC 62304. Les exigences de l'IEC 62304 qui s'appliquent au développement avant la mise en service d'un produit sont incluses par référence au logiciel SEMP.

Certaines des exigences de l'IEC 62304 s'appliquent à la maintenance du logiciel après la mise en service du produit. Ces exigences n'ont pas été incluses dans la référence.

L'application efficace de l'Article 14 nécessitera, selon la tâche, des compétences pour les points suivants:

– application de l'APPAREIL EM spécifique en mettant l'accent sur les questions de sécurité;
– PROCESSUS de développement de l'APPAREIL EM;
– méthodes par lesquelles la sécurité est assurée;
– techniques d'ANALYSE DES RISQUES et de MAITRISE DU RISQUE.

Les exigences ont été réduites à celles qui sont essentielles pour assurer la SECURITE DE BASE et la PERFORMANCE ESSENTIELLE. Cela reflète la multiplication des documents relatifs à l'assurance des logiciels et aux techniques d'évaluation des RISQUES ainsi que la rapide évolution de la discipline.

Paragraphe 14.1 – Généralités

La présente norme requiert l'application d'un PROCESSUS de GESTION DES RISQUES conformément à l'ISO 14971. Cela est particulièrement important dans le cas du SEMP, dans la mesure où il est difficile de montrer le caractère correct des logiciels ou de matériel complexe. La conception d'un SEMP doit donc être menée dans le cadre d'un PROCESSUS DE GESTION DES RISQUES dans lequel les mesures de MAITRISE DU RISQUE sont liées aux RISQUES maîtrisés. Pour un SSEP logiciel, les exigences de sécurité logicielle du paragraphe 4.3 de l'IEC 62304:2006 et les exigences de GESTION DES RISQUES de l'article 7 de l'IEC 62304:2006 sont incluses. Si l'application de ~~l'ISO 14971~~ la GESTION DES RISQUES montre qu'un SSEP peut contribuer à engendrer une SITUATION DANGEREUSE et des mesures de MAITRISE DU RISQUE externes au SEEP non logicielles n'ont pas ramené le RISQUE à un niveau acceptable, l'Article 14 ajoute des PROCESSUS de GESTION DES RISQUES et de CYCLE DE VIE pour le SSEP.

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La VERIFICATION de la conformité implique que l'évaluation interne du FABRICANT couvre non seulement les exigences de cet article mais aussi celles de ~~l'ISO 14971~~ l'IEC 62304 qui ont été incluses par référence.

La conformité aux exigences de l'Article 14 est évaluée en examinant la documentation fournie par les PROCESSUS requis dans les divers paragraphes. ~~Il convient d'appliquer l'Article 14 dans son ensemble et non de manière sélective. Toute cette documentation doit figurer dans le FICHIER DE GESTION DES RISQUES.~~

Le concept d'évaluation a été introduit dans la déclaration de conformité pour autoriser des méthodes autres que le contrôle si nécessaire, par exemple un audit. Ainsi, bien qu'il n'y ait pas d'exigence générale imposant au FABRICANT d'appliquer un système de management de la qualité conforme à l'ISO 13485 [30], certaines caractéristiques de ce système sont nécessaires. L'une des caractéristiques communément considérée comme essentielle pour l'efficacité d'un système de management de la qualité est un PROCESSUS d'audit et de revue effectué au sein de l'organisme pour confirmer qu'il suit réellement ses propres PROCEDURES ; cela est différent des évaluations externes qui pourraient être effectuées pour démontrer la conformité à des normes ou des exigences réglementaires. La présente norme exige donc non seulement que le FABRICANT documente certains aspects du PROCESSUS de conception mais qu'il effectue également une évaluation pour confirmer que les exigences de cet article ont été respectées.

Paragraphe 14.2 – Documentation

Le moyen par lequel la conformité aux exigences du PROCESSUS peut être déterminée consiste à assurer que la documentation requise pour chaque étape du PROCESSUS a été créée. Bien que la plupart des exigences de ~~l'ISO 14971~~ 4.2 soient des éléments essentiels d'un cycle de vie de logiciel adéquat, l'Article 14 contient beaucoup d'autres étapes de PROCESSUS non exigées par ~~cette norme~~ 4.2. Par conséquent, la documentation impliquée par ces étapes de PROCESSUS supplémentaires (à l'Article 14) est nécessaire pour qu'un organisme de certification détermine que les étapes du PROCESSUS ont été effectuées. ~~Dans la mesure où l'Article 14 aborde les RISQUES associés au SEMP, cette documentation doit être incluse dans le FICHIER DE GESTION DES RISQUES.~~

Dans la mesure où l'Article 14 aborde les RISQUES associés au SEMP, cette documentation fait partie du DOSSIER DE GESTION DES RISQUES.

Etant donné que la conformité à l'Article 14 est déterminée par examen et évaluation afin d'assurer que la documentation requise a été générée, la qualité et l'exactitude de ces documents sont importantes. Dans la mesure où la démonstration de la SECURITE d'un SEMP dépend essentiellement de la documentation, un système efficace est nécessaire pour assurer l'intégrité de la documentation et, si différentes versions d'un document existent, d'identifier l'applicabilité de chaque version. Il est donc nécessaire que ces documents soient générés, révisés et tenus à jour dans un système formel de maîtrise des documents. Il convient que les FABRICANTS s'assurent que cette documentation est claire et complète afin de soutenir le PROCESSUS d'évaluation.

Paragraphe 14.3 – Plan de GESTION DES RISQUES

~~L'ISO 14971~~ Le paragraphe 4.2.2 exige de préparer et de tenir à jour un plan de GESTION DES RISQUES dans le FICHIER DE GESTION DES RISQUES.

Outre les éléments du plan de GESTION DES RISQUES exigé par ~~l'ISO 14971~~ 4.2.2, un plan de VALIDATION de SEMP est nécessaire dans la mesure où la validation est considérée comme une activité nécessaire dans le cadre du développement d'un SEMP.

Paragraphe 14.4 – CYCLE DE DEVELOPPEMENT DE SEMP

Un cycle de vie documenté contribue à assurer que les questions de sécurité sont prises en compte pendant toute l'élaboration d'un produit. Cela est important pour tous les produits et c'est essentiel pour les SEMP. La sécurité ne peut pas être ajoutée à un SEMP après son développement, et cela pour deux raisons:

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a) Les PROCESSUS effectivement utilisés dans l'élaboration d'un SEMP et la qualité et la rigueur de ces PROCESSUS sont décidés en fonction de l'EVALUATION DES RISQUES. Si l'on découvre ensuite que des PROCESSUS inappropriés ont été utilisés ou qu'une qualité et une rigueur inadéquates ont été appliquées, le développement devra alors été répété avec des PROCESSUS corrects;

b) des modifications effectuées tardivement dans le CYCLE DE DEVELOPPEMENT d'un SEMP sont susceptibles d'être onéreuses (en temps comme en argent). Cela est particulièrement vrai si une exigence relative au système est incorrecte ou manquante. L'architecture du système peut également être vulnérable aux changements tardifs. L'architecture fait souvent partie de la sécurité. Des modifications tardives peuvent impliquer un travail de reprise important afin de préserver l'intégrité de la solution architecturale adoptée.

Cadre

Un cycle de développement d'un produit fournit un cadre qui permet de mener les activités de sécurité nécessaires rapidement et systématiquement. Il ne convient pas que ce cadre impose des restrictions inutiles mais qu'il assure que toutes les activités de sécurité nécessaires sont menées. Le cycle de vie doit être décidé au début du projet. Plusieurs modèles de cycle de vie sont acceptables. L'Article H.2 explique le CYCLE DE DEVELOPPEMENT DE SEMP de manière plus détaillée. ~~L'IEC 62304 [26] décrit~~ Les Articles 5, 7, 8 et 9 de l'IEC 62304:2006 décrivent les PROCESSUS à inclure dans le cycle de vie de développement du logiciel pour le développement d'un logiciel sûr pour les appareils médicaux.

Etapes et activités

Les exigences d'étapes et d'activités qui fournissent des valeurs en entrée et en sortie assurent qu'il est dûment tenu compte:

– des activités,

– de ce qu'il est nécessaire de réaliser avant que l'activité puisse être lancée, et

– de ce que l'activité doit fournir,

de manière que la VERIFICATION des résultats puisse être réalisée.

L'ordre des activités dans le cycle de vie doit être défini en termes d'étapes car cela offre la plus grande souplesse au FABRICANT. Aucune exigence n'est donnée en ce qui concerne le nombre et la nature des étapes et il n'y a pas non plus d'implication prévoyant que toutes les activités du projet doivent passer par les étapes simultanément. La présente norme n'a pas utilisé le terme "phases" bien que celui-ci ait été utilisé dans l'IEC 60601-1-4 [14]. Ce terme a été évité car il est difficile d'exprimer la collatéralité et le chevauchement dans un modèle avec des phases.

Dans un cycle de vie de bonne qualité:

– les activités nécessaires sont définies avant leur performance;

– les PROCESSUS utilisés dans les activités de développement pourraient être spécifiés comme un résultat de la GESTION DES RISQUES;

– l'ordre des activités est défini de manière à assurer que les entrées nécessaires d'une activité sont disponibles avant que l'activité ne débute;

– les critères sont définis pour décider si l'activité a été terminée de manière satisfaisante; et

– l'imputabilité est facilitée.

Les activités sont définies en termes d'entrées et de sorties car il est simple de mesurer si ces entrées et sorties existent. Le FABRICANT est responsable de décider de la manière dont les étapes sont passées et dont la documentation exigée est produite.

Pour déterminer si chaque activité a été terminée de manière satisfaisante, il est exigé que les critères de VERIFICATION de chaque activité soient définis. La VERIFICATION consiste à examiner si les entrées ont été complètement transformées en sorties, correctement et

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conformément au PROCESSUS exigé. Aucune exigence n'est donnée concernant le type ou l'étendue de VERIFICATION, à l'exception de la VERIFICATION des mesures de MAITRISE DU RISQUE et de PERFORMANCE ESSENTIELLE (voir 14.10).

Paragraphe 14.5 – Résolution de problème

S'il y a lieu, un système documenté de résolution des problèmes est requis par la présente norme.

Des problèmes peuvent apparaître:

– avec le produit;

– dans un PROCESSUS;

– entre des PROCESSUS.

Les problèmes sont par exemple:

– des exigences contradictoires;

– des exigences ambiguës;

– des spécifications manquantes;

– des erreurs de codage;

– un fonctionnement incorrect du SEMP.

Un système de résolution de problèmes est nécessaire pour assurer que, lorsqu'un problème survient, son impact sur les DANGERS et leurs RISQUES correspondants est géré. Des méthodes ad hoc de résolution de problèmes peuvent contrecarrer les avantages d'une approche systématique du cycle de vie. Le CYCLE DE DEVELOPPEMENT DU SEMP est un cadre adéquat pour documenter le système de résolution de problèmes.

Paragraphe 14.6.1 – Identification des DANGERS connus et prévisibles

Les SEMP comportent des causes de DANGER supplémentaires.

Paragraphe 14.6.2 – MAITRISE DU RISQUE

Dans la mesure où le choix des PROCEDURES et des outils utilisés par un FABRICANT pour le développement d'un SEMP sera influencé par de nombreux facteurs, ce paragraphe exige que l'un de ces facteurs soit la réduction du RISQUE requise pour la mesure de MAITRISE DU RISQUE. Une mesure de MAITRISE DU RISQUE établie au moyen de PROCEDURES et d'outils dont l'efficacité est avérée est davantage susceptible de remplir ses fonctions qu'une mesure élaborée au moyen de PROCEDURES et d'outils de qualité inconnue.

Paragraphe 14.7 – Spécification des exigences

Les mesures de MAITRISE DU RISQUE sont utilisées pour maîtriser le RISQUE associé à des DANGERS identifiés. Les exigences relatives à ces mesures sont documentées dans les spécifications d'exigences. Il convient que l'exigence spécifie ce que fait la mesure et comment elle le fait. ~~L'ISO 14971~~ Le paragraphe 4.2 ne requiert pas de spécification d'exigences.

Exigences vérifiables

Il convient que les exigences soient vérifiables. Cela s'applique à la fonction de la mesure de MAITRISE DU RISQUE comme à la probabilité selon laquelle elle est susceptible de fonctionner correctement. Une VERIFICATION quantitative des taux de défaillance est généralement impossible pour les logiciels. La VERIFICATION d'une approche qualitative se ferait en vérifiant que les PROCESSUS appropriés sont utilisés.

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Exigences de sécurité identifiables

L'exigence qui prévoit de distinguer les mesures de MAITRISE DU RISQUE et la PERFORMANCE ESSENTIELLE est nécessaire pour assurer qu'elles sont mises en œuvre et pour assurer que s'il est nécessaire de modifier la PERFORMANCE ESSENTIELLE ou une mesure de MAITRISE DU RISQUE, l'impact de la modification sur le RISQUE RESIDUEL puisse être évalué.

Décomposition

Des exemples de structure de SEMP sont présentés à l'Annexe H. Il convient de spécifier les exigences de mise en œuvre des mesures de MAITRISE DU RISQUE pour les SEMP et pour tout SSEP qui applique entièrement ou partiellement une ou plusieurs mesures de MAITRISE DU RISQUE. Cela peut figurer dans un seul ou dans plusieurs documents.

***Paragraphe* 14.8 – Architecture**

Une spécification sur l'architecture n'est pas requise par ~~l'ISO 14971~~ 4.2. C'est une exigence supplémentaire pour les SEMP car:

– souvent l'architecture choisie fera partie d'une mesure de MAITRISE DU RISQUE. Les mesures de MAITRISE DU RISQUE doivent être explicites pour les systèmes complexes tels que les SEMP;

– il est reconnu que les spécifications d'architecture sont un élément essentiel d'un bon PROCESSUS de développement de logiciel tel que requis pour un SEMP.

Il existe une liste des caractéristiques d'architecture qui doivent être incorporées dans la spécification le cas échéant. Cette liste a été choisie car dans des cas particuliers, une ou plusieurs caractéristiques pourraient être utilisées pour maîtriser le RISQUE associé à un DANGER. Par exemple, l'utilisation d'un COMPOSANT AUX CARACTERISTIQUES A HAUTE FIABILITE supprimera réellement tout RISQUE résultant d'une défaillance de ce composant.

***Paragraphe* 14.8 e)**

Le partitionnement de fonctionnalité peut être utile lorsqu'il est absolument nécessaire d'effectuer une validation rigoureuse de la sécurité d'un SEMP.

Le logiciel (micrologiciel et couches d'application) est distinctement divisé en sections critiques, non critiques et de supervision. Le partitionnement est utilisé de manière que les instructions et les données des sections critiques, non critiques et de supervision n'interfèrent pas entre elles et qu'il y a séparation des tâches parmi les sections du logiciel. S'il n'y a pas séparation des tâches parmi les sections du logiciel, il convient de définir tout le logiciel comme critique afin d'assurer que l'analyse a pris en compte la section critique du logiciel.

Les exigences relatives à la séparation des codes critiques et non critiques incluent l'EVALUATION DU RISQUE de l'ensemble du système, les stratégies de MAITRISE DU RISQUE employées, l'analyse des ressources physiques et l'analyse des propriétés logiques (par exemple le couplage du contrôle et des données). Il convient généralement que le partitionnement sépare et isole les fonctions relatives à la sécurité de celles non relatives à la sécurité dans la conception et dans la mise en œuvre. Ce PROCESSUS peut minimiser, ou du moins réduire, la VERIFICATION nécessaire pour assurer que les données partagées ou transmises à la section critique n'affectent pas le fonctionnement spécifié du code critique de sécurité.

Le partitionnement comprend les étapes suivantes:

a) identification des sections critiques, non critiques et de supervision. Un moyen d'identification dépend de la modularité du code, du langage de programmation, de la conception du code et d'autres attributs de spécification;

b) description des interfaces entre les sections critiques et non critiques:

   1) identification des données ou des variables globales relatives aux sections, critiques et non critiques, modules, etc., identifiées dans l'étape a);

   2) identification de tous les paramètres transmis entre les sections critiques et non critiques, modules, etc., identifiés dans l'étape a);

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3) description du flux de données, des variables ou des paramètres identifiés dans les étapes b) 1) et b) 2);

4) description du mécanisme utilisé pour empêcher la corruption des données, la réécriture ou autres erreurs des données, variables et/ou paramètres identifiés ci-dessus affectant les performances critiques en matière de sécurité;

c) validation de l'intégrité du partitionnement. Cela peut être réalisé par des essais fonctionnels et des techniques d'essai de contrainte.

Paragraphe 14.8 g) à n)

Il existe une liste des éléments à prendre en compte dans la spécification de l'architecture. Cette liste a été choisie car chacun de ces éléments pourrait influencer le choix de l'architecture.

Paragraphe 14.9 – Conception et réalisation

Les solutions techniques choisies doivent être définies. Il est souvent approprié de décomposer un SEMP en sous-systèmes. La Figure H.1 montre des exemples de structures de SEMP/SSEP avec différentes importances de décomposition. Les raisons qui engagent à décomposer un SEMP pourraient inclure ce qui suit.

Maintenir la complexité des sous-systèmes à un niveau gérable

Moins le système est complexe, plus il sera facile de comprendre et donc de concevoir puis de mettre à jour. La conception qui en résulte est davantage susceptible d'être correcte et facile à tester. Il convient que les normes de codage spécifient des limites de complexité.

Architecture

L'architecture du système pourrait contribuer à rendre logique la séparation des systèmes, par exemple, si plusieurs systèmes sont nécessaires, il convient de les mettre en œuvre en tant que sous-systèmes distincts.

Modularité

La modularité peut faciliter le choix de différentes options, la réutilisation d'un sous-système existant éprouvé et l'extension des fonctionnalités du système.

Composants physiques

Une division pertinente des sous-systèmes physiques contribuera à déceler et à réparer des défauts de matériel.

Technologies différentes

La mise en œuvre et la conception du matériel et des logiciels seront souvent réalisées par des ingénieurs différents. Dans ce cas, la séparation des sous-systèmes permettra de mettre chacun d'entre eux en œuvre de manière indépendante.

Le système global ne fonctionnera correctement que si chacun de ses sous-systèmes a été spécifié de manière adéquate. Ce qui implique l'exigence relative à la spécification de conception pour chaque sous-système. Une spécification de conception pour un sous-système inclura généralement une spécification d'interface détaillée et pourrait inclure des détails de mise en œuvre, par exemple, des algorithmes.

Il convient de soumettre chaque sous-système à essai pour démontrer que la spécification de conception a été correctement mise en œuvre. Cela implique l'exigence relative à la spécification d'essai pour chaque sous-système.

Les spécifications de conception et d'essai peuvent être documentées sous quelque forme que ce soit, elles peuvent par exemple se présenter sous forme de documents séparés ou être réunies dans un document plus grand. Il convient que les spécifications de conception et d'essai de chaque sous-système soient identifiables.

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Des exemples des éléments de l'environnement de conception sont donnés en H.4 a). Ces éléments auront une influence sur la qualité et l'exactitude de la conception. Certains éléments auront été identifiés comme des outils ou des PROCEDURES correctement validés (voir 14.6.2). Les données descriptives concernant l'environnement de conception contribuent à vérifier que les outils et PROCEDURSE correctement validés ont été utilisés.

Paragraphe 14.10 – VERIFICATION

~~L'ISO 14971~~ Le paragraphe 4.2 exige la VERIFICATION des mesures de MAITRISE DU RISQUE. Il existe des exigences supplémentaires pour les SEMP. A savoir:

– la PERFORMANCE ESSENTIELLE est vérifiée; et

– il existe un plan de VERIFICATION.

La PERFORMANCE ESSENTIELLE est importante pour les SEMP car les SEMP utilisent un SSEP pour contrôler les fonctions. La PERFORMANCE ESSENTIELLE dépendra souvent des fonctions des SEMP qui sont réalisées correctement.

Un plan de VERIFICATION laisse au FABRICANT le choix de la manière de satisfaire les exigences de cet article. Cette approche est meilleure et plus souple que celle qui consiste à vérifier un SEMP dans cet article. Le FABRICANT est responsable de la planification de la VERIFICATION pour qu'elle soit complète et adéquate et ensuite de la mise en œuvre du plan.

L'exigence donne la liste des activités qui affectent le caractère complet de la VERIFICATION et le besoin à planifier.

Paragraphe 14.11 – VALIDATION DE SEMP

La phase finale de tout modèle de CYCLE DE DEVELOPPEMENT DE SEMP est la VALIDATION DU SEMP. La VALIDATION DU SEMP est destinée à assurer que le bon produit est fabriqué. La validation est importante pour les SEMP dans la mesure où des interactions imprévues entre des fonctions ne peuvent être découvertes que par la validation.

La VALIDATION des SEMP peut inclure des essais pour un volume de données important, des charges élevées de contraintes des facteurs humains, la sûreté, les performances, la compatibilité des configurations, les essais de défaut, la documentation et la sécurité.

L'indépendance est nécessaire pour éviter les conflits d'intérêt et dans la mesure où il ne convient pas que les hypothèses du concepteur influencent ou limitent le domaine d'application de la VALIDATION DU SEMP. Le niveau d'indépendance inclut par exemple:

– une autre personne;

– une gestion séparée;

– un autre organisme.

Paragraphe 14.12 – Modification

Généralement, la conception d'un SEMP n'est pas complètement nouvelle mais est partiellement ou largement inspirée d'une ou de plusieurs conceptions précédentes. Il pourrait néanmoins être possible de considérer la conception comme si elle était totalement nouvelle et d'établir le rapport de GESTION DES RISQUES et de démontrer la conformité aux exigences de la présente norme sans mentionner la documentation précédente. Si, toutefois, il n'est pas nécessaire que le rapport de GESTION DES RISQUES inclue certaines informations de la documentation de la ou des conceptions précédentes, il est alors nécessaire de confirmer que toutes ces informations demeurent valides malgré les modifications apportées à la nouvelle conception.

Paragraphe 14.13 – ~~Connexion de SEMP par un COUPLAGE DE RESEAUX/ DONNEES à d'autres appareils~~ SEMP destiné à être incorporé dans un RESEAU INFORMATIQUE

Aujourd'hui, de nombreux hôpitaux utilisent des APPAREILS EM en réseau. A l'origine, ces ~~réseaux~~ RESEAUX INFORMATIQUES étaient installés pour optimiser la zone économique et

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technique concernée. Pour cela, il est nécessaire de disposer d'échanges de données électroniques rapides. Ces ~~réseaux~~ RESEAUX INFORMATIQUES sont maintenant utilisés pour des applications médicales au sein de l'hôpital, entre des hôpitaux et depuis le domicile.

Au départ, ces échanges de données se limitaient aux laboratoires. Aujourd'hui, de grandes quantités de données sont transportées sur les ~~réseaux~~ RESEAUX INFORMATIQUES, par exemple les données d'imagerie médicale. L'utilisateur souhaite en outre davantage de solutions "en temps réel" (par exemple contrôle de robots d'intervention par ~~réseau~~ RESEAU INFORMATIQUE).

~~Des lignes directrices supplémentaires sur le COUPLAGE RESEAUX / DONNEES sont disponibles à l'Annexe H.~~

On trouve des directives supplémentaires sur l'incorporation d'un SEMP à un RESEAU INFORMATIQUE en Annexe H.

Paragraphe 15.1 – Groupements des commandes et indicateurs des APPAREILS EM

Il convient de regrouper les commandes, les instruments, les voyants lumineux, etc., qui sont associés à une fonction spécifique de l'APPAREIL EM.

Paragraphe 15.2 – Aptitude à l'entretien

L'échange de ces parties doit être facile à effectuer, de préférence sans OUTILS spéciaux. De plus, le démontage de la partie usée ou de la partie remplacée préventivement et le montage de la pièce de rechange ne devraient pas ~~créer de DANGER~~ entraîner de SITUATION DANGEREUSE. Pour cela, les instructions correspondantes doivent être faciles à comprendre et à suivre, en évitant tout RISQUE de confusion.

Paragraphe 15.3.2 – Essai de poussée

Les ENVELOPPES doivent avoir une rigidité adéquate pour conserver un niveau de protection correct par rapport aux PARTIES SOUS TENSION internes. Cette exigence est harmonisée avec l'essai de force de l'IEC 60950-1. La force dépend de la personne qui manipule les APPAREILS EM, et non du poids de l'APPAREIL EM. Dans la plupart des cas, l'application d'une force de 250 N est considérée comme raisonnablement prévisible. Toutefois, il peut y avoir des cas où une EVALUATION DU RISQUE établit que la force de 45 N appliquée sur une surface de 625 mm^2, comme cela est exigé par la deuxième édition de la présente norme, continuerait à constituer une méthode de VERIFICATION acceptable pour la détermination d'un niveau acceptable de RISQUE. Par exemple, des transducteurs à ultrasons et d'autres petites PARTIES APPLIQUEES similaires TENUES A LA MAIN, qui équilibrent les besoins de résistance avec d'autres besoins liés à l'efficacité et la biocompatibilité, ont établi des ENREGISTREMENTS de sécurité et d'efficacité sur de nombreuses années et pour cela pourraient continuer à utiliser l'ancien essai de VERIFICATION.

Les composants internes ne sont pas soumis à l'essai de force de l'IEC 60950-1 car leur robustesse est vérifiée par les essais de 15.3.4 et 15.3.5.

Paragraphe 15.3.3 – Essai d'impact

La résistance d'une ENVELOPPE aux impacts est nécessaire pour éviter tout RISQUE inacceptable au cours d'un MAUVAIS USAGE RAISONNABLEMENT PREVISIBLE. L'énergie de l'impact d'essai se rapproche d'un APPAREIL EM heurté accidentellement par un objet tenu à la main d'un passant, par un manche à balai ou par le manche d'une brosse pendant le nettoyage du sol. L'appareil d'essai a été simplifié et harmonisé avec d'autres normes contenant des exigences relatives aux impacts sur les ENVELOPPES, y compris l'IEC 60950-1.

Lorsqu'un FABRICANT considère que les exigences de ce paragraphe ne sont pas nécessaires pour atténuer un RISQUE inacceptable, la justification est documentée dans le FICHIER DE GESTION DES RISQUES selon 4.5, avec l'identification des exigences alternatives respectées. Par exemple, un des côtés de l'ENVELOPPE d'un APPAREIL EM FIXE peut être protégé par le sol, le mur ou le plafond. Le FABRICANT documente l'évaluation de la probabilité selon laquelle L'APPAREIL EM peut être déplacé ou installé de manière incorrecte. Le FABRICANT doit également évaluer et identifier, dans le cadre du PROCESSUS de GESTION DES RISQUES, la

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résistance à l'impact que doit avoir le côté protégé de l'ENVELOPPE pour assurer qu'aucun RISQUE inacceptable n'est généré par la non-conformité aux exigences d'origine de ce paragraphe.

Paragraphe 15.3.4 – Essai de chute

Les essais pour les APPAREILS EM ou parties d'APPAREILS EM TENUS A LA MAIN sont différents de ceux pour les APPAREILS EM PORTABLES et MOBILES du fait de la différence des applications pratiques.

Une surface de chute en bois de densité supérieure à 600 kg/m^3 permet de choisir la plupart des bois de feuillus communs. Le chêne, le hêtre, le bouleau, le frêne et l'érable sont acceptables. Ces variétés ont une dureté similaire alors que les feuillus de densité inférieure à 600 kg/m^3 (par exemple l'acajou, l'orme, le liquidambar, le cerisier) et les résineux présentent une dureté très inférieure en comparaison.

Paragraphe 15.3.4.2 – APPAREILS EM PORTABLES

Cet essai représente l'UTILISATION NORMALE, comme expliqué dans la justification de 15.3.5. Cet essai n'est pas destiné à représenter un MAUVAIS USAGE RAISONNABLEMENT PREVISIBLE. Il n'existe pas actuellement d'essai qui concerne directement un MAUVAIS USAGE RAISONNABLEMENT PREVISIBLE de type chute libre ; toutefois, on estime que l'essai d'impact de balle de 15.3.3 représente un MAUVAIS USAGE RAISONNABLEMENT PREVISIBLE, même si c'est indirectement. Comme indiqué en 4.2, si le PROCESSUS de GESTION DES RISQUES conclut qu'un essai plus sévère est souhaitable, il convient de l'effectuer.

Paragraphe 15.3.5 – Essai de manipulations brutales

Contrairement à ce qui est souvent supposé, les APPAREILS EM peuvent être utilisés dans un environnement hostile. En cas d'urgence, les APPAREILS EM sont portés ou roulés sur des chariots montant des marches ou poussés dans des monte-charges et subissent des chocs et des vibrations. De telles conditions peuvent en fait représenter l'UTILISATION NORMALE de certains APPAREILS EM. Le fait de rencontrer des obstacles est considéré comme très commun et pratiquement comme un MAUVAIS USAGE RAISONNABLEMENT PREVISIBLE. Tous les obstacles ne sont pas clairement marqués et l'OPERATEUR ne peut pas toujours stopper l'APPAREIL EM à temps après avoir pris conscience de la présence d'un obstacle.

~~Les exigences d'essai de 15.3.5 sont destinées à juger de la résistance aux manipulations brutales, et non de la stabilité. Les exigences des essais de stabilité pour les APPAREILS EM MOBILES se trouvent en 9.4.~~

On considère que la vitesse de 0,8 m/s et la difficulté des obstacles choisis représentent pour les niveaux d'énergies de contrainte/de choc le cas le plus défavorable de mauvais usage raisonnablement prévisible. L'objectif de cet essai est de déterminer les risques à partir des dommages causés par les chocs/les contraintes des manipulations brutales. L'instabilité est évaluée en 9.4.

La signification de "dans sa direction normale de déplacement" correspond à la ou les directions dans lesquelles l'APPAREIL EM est susceptible de se déplacer à la vitesse normale maximale. Pour la plupart des cas, cela correspondrait à la direction vers l'avant. Certains APPAREILS EM, comme les lits, sont susceptibles d'être déplacés vers l'avant ou vers l'arrière, à vitesse normale, et c'est pourquoi il convient d'envisager chaque essai pour chaque direction.

Paragraphe 15.3.6 – Essai de suppression de la contrainte de moulage

Beaucoup de PROCESSUS de thermoformage peuvent laisser des contraintes résiduelles aux plastiques. Les chaînes polymères étant maintenues ensemble par des liaisons de van der Waals faibles, ces contraintes résiduelles peuvent engendrer un flux visqueux (déformation). Une température élevée affaiblit les liaisons de van de Waals et augmente le débit de flux visqueux. Les matières thermoplastiques à faibles températures de fusion, comme le polyéthylène et le polypropylène, sont plus susceptibles d'exercer des contraintes de

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déformation que les polymères dont les températures de fusion sont plus élevées, comme les polycarbonates et les polyéthéramides.

Il convient que la conformité soit vérifiée par l'analyse des propriétés polymères lorsque cela est possible. Il convient que cette VERIFICATION consiste à faire une comparaison documentée de la température maximale à laquelle le polymère sera exposé en UTILISATION NORMALE et la plage de températures d'utilisation recommandée par le FABRICANT du polymère.

Paragraphe 15.3.7 – Influences environnementales

a) Les APPAREILS EM sont souvent utilisés ou stockés dans des conditions ambiantes correspondant à l'UTILISATION PREVUE telle que décrite par le FABRICANT. Dans ces cas, aucun DANGER n'est attendu. Toutefois, les conditions ambiantes pourraient différer de celles déclarées et l'APPAREIL EM est toujours supposé rester en sécurité. Pour assurer cela, l'ORGANISME RESPONSABLE doit effectuer régulièrement le contrôle et la maintenance prescrits par le FABRICANT. Ces activités sont supposées empêcher toute détérioration du niveau de sécurité, elles permettent également de déceler les signes avant-coureurs de cette détérioration. Pour assurer cela, les instructions relatives à la maintenance préventive doivent être faciles à comprendre et à suivre, en évitant tout risque de confusion et sans négliger les symptômes pertinents pour la sécurité.

b) L'échange de ces parties doit être facile à effectuer, de préférence sans OUTILS spéciaux. De plus, le démontage de la partie usée ou de la partie remplacée préventivement et le montage de la pièce de rechange ne devraient pas créer de DANGER. Pour cela, les instructions correspondantes doivent être faciles à comprendre et à suivre, en évitant tout RISQUE de confusion.

c) Il convient que la corrosion des interfaces métal-métal soit prise en compte.

Paragraphe 15.4.3 – Batteries d'accumulateurs

Si une SITUATION DANGEREUSE peut survenir résultant de l'épuisement de la batterie d'accumulateurs, il convient que des moyens soient fournis pour prévenir cette situation.

Le cas échéant, il convient que des normes particulières spécifient l'exigence correspondante.

Paragraphe 15.4.3.5 – Protection contre les surintensités et les surtensions

Le paragraphe 4.7 exige que l'APPAREIL EM soit SECURISE EN PREMIER DEFAUT. Un défaut possible pourrait être le contournement d'une LIGNE DE FUITE entre les bornes positive et négative d'une ALIMENTATION ELECTRIQUE INTERNE dans la zone comprise entre l'ALIMENTATION ELECTRIQUE INTERNE et un éventuel dispositif de protection (voir Figure A.23).

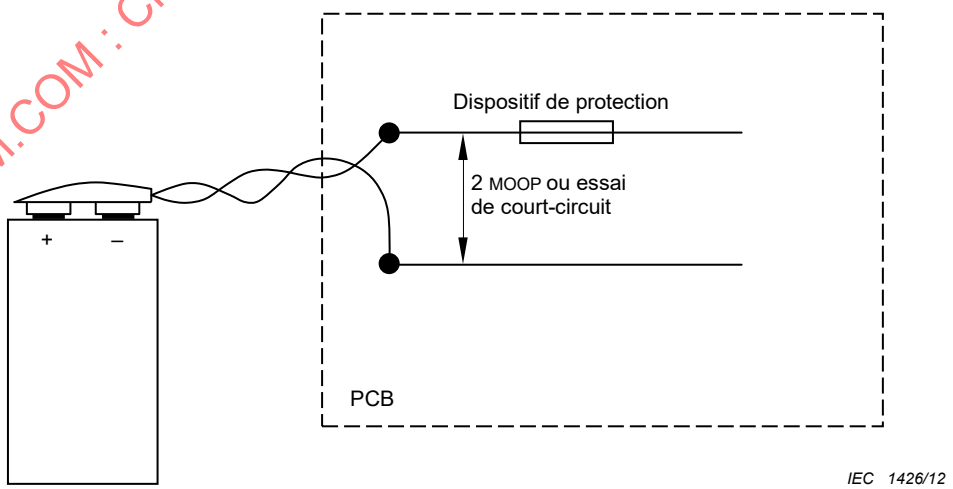


Figure A.23 – Exemple de MOYEN DE PROTECTION DE L'OPERATEUR nécessaire entre les bornes d'une ALIMENTATION ELECTRIQUE INTERNE et un dispositif de protection complémentaire

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Un essai de court-circuit serait requis pour démontrer que cette zone est SECURISEE EN PREMIER DEFAUT sauf si deux MOYENS DE PROTECTION DE L'OPERATEUR sont présents. Dans ce cas, l'essai peut être omis.

Paragraphe 15.4.4 – Voyants lumineux

Il est important que l'OPERATEUR et le PERSONNEL D'ENTRETIEN soient capables de déterminer l'état de fonctionnement de l'APPAREIL EM. En UTILISATION NORMALE, l'OPERATEUR doit être capable de distinguer un APPAREIL EM en attente d'un APPAREIL EM en marche. Certains APPAREILS EM ont une longue période de préchauffage. D'autres ont des modes d'attente ou de chargement de batterie.

Il peut être dangereux de laisser un APPAREIL EM sans surveillance dans un état inapproprié. Le PERSONNEL D'ENTRETIEN doit être capable de déterminer si l'APPAREIL EM est alimenté pour éviter les DANGERS.

Paragraphe 15.4.7.3 – Pénétration de liquides

La précédente exigence sur la catégorie assignée IPX8 pour les interrupteurs au pied se réduit à une "protection plus importante que pour IPX7". En définissant IPX6 comme la catégorie minimale, l'exigence permet d'établir un niveau de protection minimal défini tout en admettant des niveaux supérieurs selon le cas.

Pour les appareils utilisés sur le sol dans des zones où il se trouve généralement des liquides, l'exigence IPX1 est incluse car il est considéré comme extrêmement probable qu'un mouillage interviendra.

Paragraphe 15.5 – TRANSFORMATEURS D'ALIMENTATION RESEAU des APPAREILS EM et transformateurs assurant la séparation conformément à 8.5

L'ajout de "et de transformateurs garantissant une séparation conformément à 8.5" au titre original qui identifiait uniquement les "transformateurs réseau" est délibéré. Il est recommandé de faire appel aux essais des transformateurs chaque fois que le transformateur est utilisé pour établir une séparation entre les OPERATEURS, les PATIENTS, etc. et un DANGER.

Les révisions apportées au Paragraphe 15.5 ne modifient pas de manière significative les méthodes d'essai (y compris celles de la seconde édition de la présente norme) actuelles. Les méthodes et exigences ont été simplifiées et incluent dorénavant tous les différents types de protections utilisées, telles que: thermistances à coefficient de température positif, régulation (alimentations en mode commutation), dispositifs de protection primaires ou secondaires contre les surintensités, etc. Les transformateurs qui n'ont pas été soumis à l'essai conformément aux essais de fréquence et de tension 5X de 15.5.2 permettant d'établir l'adéquation de l'isolation entre les spires d'un enroulement sont court-circuités au niveau des bornes (plutôt qu'à l'extérieur du transformateur) afin de s'assurer que la défaillance de cette isolation n'entraînera pas le dépassement des températures maximales admissibles.

En raison des difficultés qui apparaîtraient si les transformateurs de caractéristiques ASSIGNEES pour de hautes fréquences (tels que les transformateurs utilisés avec des alimentations en mode commutation) étaient soumis à essai, les essais de fréquence et de tension 2X sont également spécifiés dans ces cas. La deuxième édition n'appliquait cet essai que lorsque la tension dépassait 500 V.

Paragraphe 15.5.1.1 – Transformateurs

Les enroulements de sortie doivent être soumis à essai l'un après l'autre car dans des conditions de surcharge, l'essai simultané de tous les enroulements peut entraîner le déclenchement de dispositifs de surchauffe qui ne fonctionneraient pas si un seul enroulement était mis en surcharge. Un seul enroulement de sortie en surcharge est en fait relativement probable. Cette combinaison de conditions est donc considérée comme le scénario le plus défavorable.

L'exigence est destinée à réaliser l'essai dans la condition du cas le plus défavorable (pratiquement toujours soit en pleine charge soit à vide). Un tel cas défavorable peut être déterminé par l'évaluation de la conception du transformateur ou en réalisant quelques essais

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rapides. Pour déterminer le cas le plus défavorable, il est généralement inutile de réaliser les essais pour toutes les conditions possibles.

Les limites indiquées dans le Tableau 31 sont appliquées à une température ambiante de 25 °C dans la mesure où il est impossible de réaliser les essais de surcharge et les essais courts à l'intérieur d'une chambre thermique.

Paragraphe 15.5.2 – Tension de tenue

Il est nécessaire d'augmenter la fréquence de la tension d'essai proportionnellement à la tension pour empêcher la saturation du cœur magnétique et le courant de forte valeur qui en résulte.

L'isolation électrique entre l'enroulement primaire et les autres enroulements, écrans et noyau d'un TRANSFORMATEUR D'ALIMENTATION RESEAU est supposée avoir été vérifiée au cours des essais de tension de tenue effectués sur l'APPAREIL EM monté comme cela est décrit en 8.8.3. Les essais de tension de tenue de 8.8.3 n'ont pas à être répétés.

Paragraphe 15.5.3 – Construction des transformateurs utilisés pour assurer la séparation par 8.5

~~Les exigences spécifiées en 5.12 de l'IEC 61558-1 sont globalement similaires à celles spécifiées dans la seconde édition de la présente norme mais les transformateurs conformes à ces exigences seront probablement plus rapidement disponibles.~~

La citation originale du paragraphe 5.12 de l'IEC 61558-1 est devenue incorrecte suite aux modifications de la série 61558. Lors de la revue des normes IEC 61558 révisées, il a été déterminé que la citation de la norme ne réduirait pas le coût des transformateurs ni n'entraînerait aucun bénéfice puisque les exigences diélectriques et concernant l'espacement de l'IEC 60601-1 s'appliqueraient nécessairement afin de procurer des MOYENS DE PROTECTION DU PATIENT. Pour cette raison, la citation a été supprimée et les principes de la deuxième édition de l'IEC 60601-1 ont été utilisés en référence aux exigences diélectriques et en matière d'espacement de la troisième édition. Lorsque seuls des MOYENS DE PROTECTION DE L'OPERATEUR sont requis, il convient que les transformateurs construits pour une utilisation dans un équipement selon l'IEC 60950-1 soient considérés comme acceptables.

De plus, l'Annexe U de l'IEC 60950-1:~~2001~~ 2005 inclut des exigences relatives à l'utilisation de fil d'enroulement à triple isolation dans les transformateurs, plutôt qu'une couche d'isolation séparée entre les enroulements (comme ce serait le cas des bobines, par exemple). Il convient de considérer que les transformateurs faisant appel à cette méthode de séparation entre les enroulements et qui satisfont à toutes les autres exigences de la présente norme présentent un niveau de SECURITE DE BASE adéquat.

Article 16 – SYSTEMES EM

De plus en plus, les APPAREILS EM sont combinés à d'autres appareils qui n'étaient pas forcément destinés à des applications médicales afin de créer des systèmes dont l'un ou plusieurs éléments entrent en contact avec le PATIENT. L'Article 16 donne des exigences pour assurer la sécurité du PATIENT qui pourrait entrer en contact avec les SYSTEMES EM.

L'Article 16 sur les SYSTEMES EM est destiné à être utilisé par les FABRICANTS des combinaisons d'appareils électriques qui incluent un ou plusieurs éléments D'APPAREILS EM. L'appareil peut être constitué d'éléments séparés ou d'une ENVELOPPE unique ou d'une combinaison de ces cas.

L'Article 16 est également destiné à être utilisé par le personnel d'institutions de pratique médicale qui assemblent ou adaptent ces SYSTEMES EM, dans la mesure où ils peuvent devenir les FABRICANTS par cette action. Dans ce cas, une expertise technique dans l'application des normes de conception des appareils électriques est nécessaire pour assurer que le SYSTEME EM satisfait à toutes les exigences de l'Article 16.

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De plus en plus, ces SYSTEMES EM comprennent des appareils construits à l'origine pour être utilisés dans différents domaines d'application spécifiques, pas nécessairement médicaux, liés entre eux de façon directe ou indirecte. Les APPAREILS EM conformes à la présente norme peuvent être connectés avec d'autres APPAREILS non EM. Ceux-ci pourraient satisfaire entièrement aux exigences indiquées dans les normes de sécurité applicables dans leur domaine d'application spécifique. Toutefois, ils ne satisfont pas toujours aux exigences de SECURITE pour les APPAREILS EM et influent donc sur la SECURITE de l'ensemble du SYSTEME EM. C'est la raison pour laquelle le FABRICANT doit appliquer la GESTION DES RISQUES au SYSTEME EM dans son ensemble. Un exemple de DANGER supplémentaire concerne le déclenchement d'un feu lorsqu'un SYSTEME EM contenant des APPAREILS non EM est utilisé dans une ATMOSPHERE ENRICHIE EN OXYGENE, éventuellement par accident.

L'appareil électrique peut être situé dans un local à usage médical destiné au diagnostic, au traitement ou à la surveillance des PATIENTS, ou dans un local à usage non médical dans lequel aucune pratique médicale n'est effectuée. Dans un local à usage médical, les appareils électriques pourraient être placés à l'intérieur ou à l'extérieur d'un volume défini comme l'ENVIRONNEMENT DU PATIENT.

Il y a deux situations possibles dans la pratique médicale.

a) Lorsque l'Article 16 ne s'applique pas

Des APPAREILS EM fonctionnant simultanément, c'est-à-dire plusieurs APPAREILS EM connectés en même temps au PATIENT mais non connectés entre eux. Ces APPAREILS EM peuvent avoir une influence les uns sur les autres. Par exemple, les appareils chirurgicaux à haute fréquence dans la zone de fonctionnement peuvent avoir un effet sur le dispositif de surveillance du PATIENT.

NOTE Il est possible d'obtenir une assistance à partir des instructions d'utilisation de chaque APPAREIL EM.

b) Lorsque l'Article 16 s'applique

Les SYSTEMES EM constitués d'APPAREILS EM et éventuellement d'APPAREILS non EM, interconnectés en permanence ou temporairement pour un objectif donné tel que le diagnostic ou le traitement d'un PATIENT. Exemples: SYSTEMES EM pour examen diagnostique par rayons X, endoscopes avec caméra vidéo, surveillance du PATIENT, appareil à ultrasons avec micro-ordinateur, tomographie informatique ou imagerie par résonance magnétique.

Les différentes parties d'un SYSTEME EM de ce type pourraient être situées dans l'ENVIRONNEMENT DU PATIENT ou en dehors mais toujours dans un local à usage médical, ou des parties du SYSTEME EM pourraient être situées dans un local à usage non médical qui contient par exemple des appareils de distribution électrique ou de traitement de données.

Paragraphe 16.1 – Exigences générales applicables aux SYSTEMES EM

L'exigence de base pour la sécurité des SYSTEMES EM est que, après installation ou modification ultérieure, un SYSTEME EM n'engendre pas un RISQUE inacceptable. La conformité avec les exigences imposées aux SYSTEMES EM dans la présente norme impliqueront que le RISQUE RESIDUEL est présumé acceptable à moins qu'il existe une PREUVE OBJECTIVE du contraire.

Il pourrait être demandé au FABRICANT de SYSTEMES EM qui peuvent être reconfigurés par l'OPERATEUR ou par l'ORGANISME RESPONSABLE de fournir des informations concernant toutes les combinaisons possibles d'appareils qui pourraient représenter une charge déraisonnable. Les méthodes de GESTION DES RISQUES fournissent un moyen très adapté pour déterminer quelle combinaison d'éléments constitue les RISQUES les plus importants et quelles mesures doivent être prises pour fournir le niveau de sécurité approprié. Enfin, les essais de conformité peuvent être réalisés après l'assemblage du SYSTEME EM.

Une documentation appropriée sur la conformité aux normes peut se composer d'une déclaration de conformité du FABRICANT ou d'un certificat délivré par un laboratoire d'essai.

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Les SYSTEMES EM, de par leur nature, peuvent être fréquemment modifiés; l'Article 0 ne s'applique pas à la modification des éléments individuels d'un SYSTEME EM.

Paragraphe 16.2 – DOCUMENTS D'ACCOMPAGNEMENT d'un SYSTEME EM

Il convient que les documents qui accompagnent un SYSTEME EM destiné à une APPLICATION CARDIAQUE DIRECTE fournissent des données sur des éléments tels que:

– l'utilisation de gants en caoutchouc;
– l'utilisation de robinets d'arrêt en matériau isolant;
– des distances minimales entre le PATIENT et les appareils faisant partie du SYSTEME EM (ENVIRONNEMENT DU PATIENT);
– des instructions sur la méthode d'utilisation de l'APPAREIL EM dans le cadre de l'application médicale type, par exemple utilisation d'un cathéter.

Pour des raisons de sécurité, il convient de porter une attention particulière aux différents niveaux de RISQUE lorsque, dans l'ENVIRONNEMENT DU PATIENT, des électrodes ou autres capteurs corporels sont utilisés sur le PATIENT, à l'extérieur et à l'intérieur, y compris connexions directes au cœur.

Il convient d'isoler les connexions éventuelles au cœur d'un PATIENT de l'appareil.

L'avertissement de ne pas placer des SOCLES DE PRISE DE COURANT MULTIPLE sur le sol est destiné à empêcher la pénétration de liquides et à prévenir tout dommage mécanique.

Il convient en outre de prendre des mesures pour assurer que, lors de l'assemblage ou la modification d'un SYSTEME EM qui contient des SOCLES DE PRISE DE COURANT MULTIPLE, ceux-ci doivent être montés de manière à empêcher la pénétration de liquides et à prévenir tout dommage mécanique en UTILISATION NORMALE et pendant le transport.

Les normes sur la sécurité pertinentes pour les APPAREILS non EM pourraient spécifier ou exiger la présentation d'informations sur les conditions ambiantes admissibles. Les conditions ambiantes admises pour les différents éléments d'un SYSTEME EM peuvent donc être différentes. Les conditions ambiantes admissibles pour le SYSTEME EM doivent être spécifiées de manière à ce qu'aucune ~~DANGER~~ SITUATION DANGEREUSE n'apparaisse lorsqu'il fonctionne dans les limites spécifiées.

Paragraphe 16.3 – Alimentation

Cette exigence permet d'assurer la sécurité selon l'IEC 60601-1 au niveau du SYSTEME EM.

La SECURITE DE BASE est par exemple préservée après le montage par l'une ou plusieurs des mesures suivantes:

– mesures intégrées à l'APPAREIL EM, par exemple séparation des circuits pertinents;
– DISPOSITIFS DE SEPARATION fournis en tant qu'ACCESSOIRES avec l'APPAREIL EM (voir 16.5);
– DISPOSITIFS DE SEPARATION fournis en tant qu'ACCESSOIRES avec le SYSTEME EM;
– transformateur de séparation;
– CONDUCTEURS DE PROTECTION supplémentaires.

Les APPAREILS non EM peuvent fournir l'alimentation spécifiée pour les APPAREILS EM conformément à 5.5 f), 7.9.2.14 et 8.2.1.

Paragraphe 16.5 – DISPOSITIFS DE SEPARATION

La SECURITE DE BASE de certains des APPAREILS EM dépend de la condition préalable selon laquelle toutes les ENTREES/SORTIES DE SIGNAL sont connectées uniquement à l'appareil spécifié à cet effet. Dans le cas contraire, les COURANTS DE FUITE pourraient être augmentés par des courants indésirables circulant par les câbles de signaux.

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Des SITUATIONS DANGEREUSES pourraient survenir si l'ENTREE/SORTIE DE SIGNAL de l'APPAREIL EM est connectée à un appareil en dehors du local à usage médical, éventuellement dans un autre bâtiment, et donc raccordée à un autre circuit d'alimentation réseau.

Un DISPOSITIF DE SEPARATION empêche une ~~DANGER~~ SITUATION DANGEREUSE pour le PATIENT ou l'OPERATEUR. De plus, l'inclusion du DISPOSITIF DE SEPARATION contribue à éviter les ~~DANGERS~~ SITUATIONS DANGEREUSES causés par le dysfonctionnement de l'appareil issu de courants indésirables circulant dans les câbles.

La nécessité d'installer un DISPOSITIF DE SEPARATION dépend de la configuration du SYSTEME EM.

Paragraphe 16.6 – COURANTS DE FUITE

Les normes pertinentes pour certains APPAREILS non EM peuvent comporter des limites pour des COURANTS DE CONTACT plus élevées que celles requises par l'Article 16 ; ces limites plus élevées sont acceptables uniquement en dehors de l'ENVIRONNEMENT DU PATIENT. Il est essentiel de réduire les COURANTS DE CONTACT lorsque des APPAREILS non EM sont utilisés dans l'ENVIRONNEMENT DU PATIENT. Les mesures de réduction du COURANT DE FUITE peuvent inclure:

– des parties PROTEGEES PAR MISE A LA TERRE supplémentaires;
– un transformateur de séparation;
– une ENVELOPPE non conductrice supplémentaire.

Les câbles d'interconnexion et leurs boîtiers de connecteurs font partie de l'ENVELOPPE, les limites du COURANT DE FUITE dans l'ENVIRONNEMENT DU PATIENT, comme requis en 16.6.1, sont donc applicables.

Si un SOCLE DE PRISE DE COURANT MULTIPLE sans transformateur de séparation est utilisé, l'interruption de sa mise à la terre de protection pourrait entraîner des COURANTS DE CONTACT correspondant à la somme des COURANTS DE FUITE A LA TERRE individuels.

Paragraphe 16.6.3 – COURANT DE FUITE PATIENT

Pour un APPAREIL EM, les valeurs maximales admises pour le COURANT DE FUITE PATIENT et le COURANT DE FUITE PATIENT total (applicable avec plusieurs PARTIES APPLIQUEES reliées à l'APPAREIL EM) sont données dans les Tableaux 3 et 4; voir également 8.7.3. Un SYSTEME EM doit fournir un niveau de sécurité équivalent à celui fourni par un APPAREIL EM, dans l'ENVIRONNEMENT DU PATIENT (voir 16.1). Par conséquent, les mêmes valeurs maximales que pour le COURANT DE FUITE PATIENT et le COURANT DE FUITE PATIENT total s'appliquent, que les PARTIES APPLIQUEES soient reliées ou non au même élément du SYSTEME EM. Cela est valable pour le fonctionnement du SYSTEME EM, en CONDITION NORMALE, dans la mesure où le concept du premier défaut n'est pas applicable à un SYSTEME EM.

Il convient de noter que les combinaisons d'appareils ou de PARTIES APPLIQUEES faites par l'ORGANISME RESPONSABLE ou l'OPERATEUR qui n'appartiennent pas à la gamme de combinaisons indiquée par le FABRICANT pourraient entraîner des conditions dangereuses. Cet avertissement vaut en particulier lorsque les combinaisons d'appareils sont utilisées à des fins médicales sur le même PATIENT et qu'elles n'ont pas été prévues par le ou les FABRICANTS.

Paragraphe 16.7 – Protection contre les DANGERS MECANIQUES

Il convient de porter une attention particulière aux effets d'interruptions entraînant des mouvements imprévus, la suppression des forces de compression et le retrait sûr de PATIENTS de l'ENVIRONNEMENT DU PATIENT lorsqu'une SITUATION DANGEREUSE apparaît.

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Paragraphe 16.9.2.1 – SOCLES DE PRISES MULTIPLES

La seconde édition de la présente norme utilisait le terme défini “socle auxiliaire de prise de courant réseau" pour décrire un socle de prise de courant destiné à la fourniture d'une alimentation réseau à d'autres APPAREILS EM ou à d'autres parties séparées de l'APPAREIL EM. La norme collatérale sur les systèmes, l'IEC 60601-1-1 [13], définissait un terme “socle de prise de courant multiple portable". Ces deux termes ont été combinés en un nouveau terme, “SOCLE DE PRISE DE COURANT MULTIPLE”. Le Paragraphe 57.2 e) de la deuxième édition exigeait qu'un socle auxiliaire de prise de courant réseau soit conçu de manière à ne pas pouvoir accepter une FICHE RESEAU. Une exception pour les ~~CHARIOTS D'URGENCE~~ chariots d'urgence était admise. La combinaison des deux définitions et la modification de 8.11.2 selon laquelle tout SOCLE DE PRISE DE COURANT MULTIPLE sur un APPAREIL EM doit respecter 16.9.2.1 concilie le besoin de rapidité d'échange en cas d'urgence et la nécessité de limiter le COURANT DE FUITE.

La redistribution du ~~CABLAGE RESEAU~~ câblage réseau du SYSTEME EM est une pratique dangereuse qui n'entre pas dans le domaine d'application de cet article. Voir 16.2 pour les exigences relatives à la présentation d'informations.

Des COURANTS DE CONTACT excessifs peuvent se produire à moins que l'accès fortuit à des liaisons d'appareils supplémentaires ne soit empêché.

~~**Paragraphe 16.9.2.1 c), 3ème tiret**~~

~~Les APPAREILS EM avec CABLE D'ALIMENTATION FIXE A DEMEURE ont une impédance entre la broche de terre dans la FICHE RESEAU et toute partie PROTEGEE PAR MISE A LA TERRE qui ne dépasse pas 200 mΩ. De même, le SOCLE DE PRISE DE COURANT MULTIPLE a une impédance qui ne dépasse pas 200 mΩ entre sa FICHE RESEAU et ses socles de prise de courant. Cela entraîne une impédance qui ne dépasse pas 400 mΩ entre la FICHE RESEAU du SOCLE DE PRISE DE COURANT MULTIPLE et toute partie de l'APPAREIL EM PROTEGEE PAR MISE A LA TERRE.~~

~~L'impédance des LIAISONS DE TERRE DE PROTECTION peut dépasser 200 mΩ lorsque les circuits correspondants ont une capacité de courant limitée (voir 8.6.4b)). Dans ces cas, cela entraîne dans l'APPAREIL EM une impédance entre la broche de terre et la FICHE RESEAU et toute partie PROTEGEE PAR MISE A LA TERRE qui dépasse 400 mΩ.~~

Paragraphe 16.9.2.1 d)

Il faut que le COURANT DE CONTACT du SYSTEME EM soit inférieur à 500 µA dans les CONDITIONS DE PREMIER DEFAUT. Un transformateur de séparation peut être utilisé comme une mesure pour réduire ce COURANT DE CONTACT. C'est pourquoi un transformateur de séparation avec une ISOLATION PRINCIPALE est suffisant. L'isolation DOUBLE ou RENFORCEE telle qu'elle est exigée pour les transformateurs d'isolation n'est pas nécessaire.

L'exigence relative à la CLASSE I pour l'ensemble transformateur est nécessaire pour munir les appareils reliés d'une LIAISON DE TERRE DE PROTECTION.

La surveillance de l'isolation du transformateur de séparation n'est pas nécessaire. La CONDITION DE PREMIER DEFAUT peut être détectée pendant la maintenance de routine et l'apparition de deux CONDITIONS DE PREMIER DEFAUT indépendantes est sans objet. La structure de transformateur peut être avec ou sans secondaire à prise médiane PROTEGE PAR MISE A LA TERRE.

Les transformateurs fournissant un degré de sécurité plus élevé, par exemple ceux construits selon les exigences de l'IEC 60601-1 ou selon les exigences des transformateurs d'isolation présentes dans d'autres parties de la série IEC 61558, telles que l'IEC 61558-2-4 [63], ou l'IEC 61558-2-23 [64], sont également acceptables.

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Paragraphe 16.9.2.2 – CONNEXIONS DE TERRE DE PROTECTION dans les SYSTEMES EM

Il convient d'acheminer tous les CONDUCTEURS DE PROTECTION et les CABLES D'ALIMENTATION ensemble.

Lorsqu'un SOCLE DE PRISES MULTIPLES est utilisé pour construire un SYSTEME EM, chaque élément individuel de l'appareil branché sur le SOCLE DE PRISES MULTIPLES doit satisfaire aux exigences des APPAREILS EM ou des APPAREILS non EM concernés. L'impédance totale de terre de protection, lorsqu'ils sont soumis à l'essai en tant que système complet conformément à 8.6.4, doit satisfaire à l'exigence d'impédance la plus élevée provenant de 8.6.4 a) (c'est-à-dire ne doit pas dépasser 200 mΩ). Ceci peut nécessiter des mesures telles que l'utilisation de câbles d'alimentation courts dans le SYSTEME EM et l'utilisation d'un système de CABLES D'ALIMENTATION de section plus grande qu'il n'est nécessaire aux fins de transport du courant afin de réduire l'impédance de terre de protection. La pratique consistant à connecter des SOCLES DE PRISES MULTIPLES en série est inacceptable.

Il est important de limiter les différences de potentiel au sein de l'ENVIRONNEMENT DU PATIENT entre différentes parties d'un SYSTEME EM, et une liaison adéquate avec le système de protection par mise à la terre joue un rôle important dans la réduction de cette différence de potentiel. Il est donc important d'empêcher l'interruption des moyens de protection de toute partie du SYSTEME EM.

– La mise à la terre de protection supplémentaire pourrait être utilisée lorsque le COURANT DE CONTACT en CONDITION DE PREMIER DEFAUT dépasse les limites admissibles.
– La mise à la terre de protection supplémentaire n'est pas nécessaire pour les APPAREILS EM conformes à la présente norme. Toutefois, pour les APPAREILS non EM, cela permet d'empêcher les COURANTS DE CONTACT de dépasser les limites admissibles.
– L'utilisation d'un OUTIL n'est pas nécessaire pour déconnecter la FICHE RESEAU car elle déconnectera à la fois le réseau et la borne de terre de protection.

Article 17 – Compatibilité électromagnétique des APPAREILS et des SYSTEMES EM

L'IEC 60601-1-2 spécifie des niveaux d'essai d'immunité électromagnétique pour réduire au minimum l'effet de l'environnement électromagnétique sur les APPAREILS EM et les SYSTEMES EM couverts par la présente norme. Elle spécifie des limites d'émissions électromagnétiques pour réduire au minimum l'effet, sur les autres appareils, de perturbations électromagnétiques qui peuvent être émises, intentionnellement ou non, par les APPAREILS EM et SYSTEMES EM. Elle spécifie également les exigences relatives à l'identification, le marquage et les documents de manière que le FABRICANT de l'APPAREIL EM ou du SYSTEME EM fournisse à l'ORGANISME RESPONABLE les informations essentielles pour déterminer l'adéquation de L'APPAREIL EM ou du SYSTEME EM à l'environnement électromagnétique d'utilisation et maîtriser l'environnement électromagnétique d'utilisation afin que l'APPAREIL EM ou le SYSTEME EM assure la SECURITE DE BASE et fournisse ses PERFORMANCES ESSENTIELLES sans perturber d'autres appareils

Les exigences en matière d'émissions électromagnétiques sont nécessaires pour la protection des:

– services de sécurité (par exemple communication de la police, des pompiers et des ambulances);
– autres APPAREILS EM et SYSTEMES EM;
– APPAREILS non EM (par exemple, ordinateurs);
– télécommunications (par exemple radio/TV, téléphone, radionavigation).

Plus important encore, les exigences en matière d'immunité électromagnétique sont nécessaires pour assurer que les APPAREILS EM et les SYSTEMES EM maintiennent la sécurité de base et continuent de fournir leurs PERFORMANCES ESSENTIELLES en présence des perturbations électromagnétiques auxquelles ils sont susceptibles d'être exposés pendant leur UTILISATION NORMALE.

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Annexe G – Protection contre les RISQUES de combustion des mélanges anesthésiques inflammables (voir également la justification de 11.4)

La section six de la deuxième édition de cette norme a été transformée en annexe normative. Cela a été effectué en reconnaissant le fait que les anesthésiques inflammables sont rarement utilisés, et qu'il est prévu de mettre un terme définitif à leur utilisation à court terme. Toutefois, il est également admis que la pratique médicale change fréquemment et que, même à l'heure actuelle, certains FABRICANTS pourraient encore vouloir proposer des APPAREILS EM pour de telles applications. Pour assurer que le contenu de la section six et les CLASSIFICATIONS des CATEGORIE AP et APG restent disponibles tout en améliorant la lisibilité de la norme pour la majorité des utilisateurs, le texte a été déplacé à l'Annexe G.

Paragraphe G.1.3 – Exigences pour les APPAREILS EM

Les accidents les plus dévastateurs dans le cas des agents anesthésiques inflammables se produisent lorsque le mélange de l'agent avec l'oxygène normalement utilisé est celui qui causera la combustion la plus rapide, un état qui est parfois décrit comme "l'état optimal de détonation". Le pire exemple d'un tel agent est le cyclopropane, alors que le mélange oxygène/éther normalement utilisé est bien loin de ce point.

Paragraphe G.5.3 – Circuits de faible énergie

Les graphiques de la Figure G.1, la Figure G.2 et la Figure G.3 sont donnés pour aider la conception des circuits qui satisfont aux exigences relatives aux limites admissibles indiquées pour les APPAREILS EM DE LA CATEGORIE AP sans réaliser l'essai d'inflammation.

L'extrapolation pour des tensions plus élevées n'est pas valable car la condition de combustion des gaz se modifie à des tensions plus élevées. La limite pour les inductances est introduite car les valeurs d'inductance élevées produisent généralement des tensions plus élevées.

Paragraphe G.5.4 – Ventilation externe avec surpression interne

Le volume d'air ou de gaz inerte qui s'échappe de l'APPAREIL EM par fuite est supposé limité de sorte que les conditions d'hygiène dans le local à usage médical ne sont pas perturbées de manière significative.

Pour les besoins de G.5.4 et de G.5.5, le terme “enveloppe” peut représenter l'ENVELOPPE telle que définie en 3.26 ou un compartiment ou boîtier distinct.

Paragraphe G.5.5 – ENVELOPPES avec aération limitée

Paragraphe G.5.5 a)

Cette exigence est estimée suffisante pour empêcher la combustion en UTILISATION NORMALE pendant une période de fonctionnement de plusieurs heures dans la mesure où les conditions moyennes en UTILISATION NORMALE sont moins strictes.

Paragraphe G.6.2 – Alimentation électrique

Cette exigence empêche l'introduction de tensions plus élevées que celles permises par G.6.3. Ces tensions peuvent exister sur le câblage de terre.

Paragraphe G.6.3 – Température et circuits à faible énergie

Les graphiques de la Figure G.4, la Figure G.5 et la Figure G.6 sont donnés pour aider la conception des circuits qui satisfont aux exigences relatives aux limites admissibles indiquées pour les APPAREILS EM DE LA CATEGORIE APG sans réaliser l'essai d'inflammation.

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Annexe B
(informative)

Ordre des essais

B.1 Généralités

Il convient que les essais soient effectués dans l'ordre donné ci-dessous, s'ils sont applicables, sauf stipulation contraire dans les normes particulières. Voir aussi 5.8.

Cependant, cela n'exclut pas la possibilité d'effectuer un essai dont un contrôle préliminaire indique qu'il pourrait causer une défaillance.

Les essais de DANGERS dus aux rayonnements de l'Article 10, de biocompatibilité de 11.7, d'APTITUDE A L'UTILISATION de 12.2, des ~~systèmes d'alarme~~ SYSTEMES D'ALARME de 12.3, des SEMP à l'Article 14 et de compatibilité électromagnétique à l'Article 17 peuvent être effectués indépendamment des autres essais dans l'ordre suivant.

Il convient que les essais spécifiés pour les SYSTEMES EM à l'Article 16 soient effectués dans le même ordre que les essais pour les APPAREILS EM.

B.2 PROCESSUS de GESTION DES RISQUES pour les APPAREILS et les SYSTEMES EM et PERFORMANCES ESSENTIELLES

Voir 4.2 et 4.3.

B.3 EXIGENCES générales

Voir 4.1, 4.5 à 4.10 (inclus) et 5.1 à 5.7 (inclus).

B.4 CLASSIFICATION des APPAREILS et les SYSTEMES EM

Voir Article 6.

B.5 DETERMINATION des PARTIES APPLIQUEES et des PARTIES ACCESSIBLES

Voir 5.9.

B.6 IDENTIFICATION des APPAREILS EM , marquage et documentation

Voir 7.2 à 7.8.2 (inclus), Annexe C

B.7 CONSOMMATION d'énergie (puissance absorbée)

Voir 4.11.

B.8 LIMITATION de la tension, du courant ou de l'énergie

Voir 8.4.

B.9 Séparation des parties

Voir 8.5.1 à 8.5.4 (inclus).

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B.10 LIGNES DE FUITE et DISTANCES DANS L'AIR

Voir 8.9.

B.11 DANGERS associés aux parties en mouvement

Voir 9.2 à l'exception de 9.2.2.4.1.

B.12 DANGERS associés aux surfaces, angles et arêtes

Voir 9.3.

B.13 Aptitude à l'entretien

Voir 15.2.

B.14 Précision des commandes et des appareils de mesure et protection contre les caractéristiques de sortie dangereuses

Voir 12.1 et 12.4.

B.15 DANGERS associés à l'instabilité

Voir 9.4.

B.16 Bruit, vibrations et énergie acoustique

Voir 9.6.

B.17 Coupure de l'alimentation du RESEAU D'ALIMENTATION vers les APPAREILS EM

Voir 11.8.

B.18 Mise à la terre de protection, mise à la terre fonctionnelle et égalisation des potentiels des APPAREILS EM

Voir 8.6.

B.19 Températures excessives dans les APPAREILS EM

Voir 11.1.

B.20 COURANTS DE FUITE et COURANTS AUXILIAIRES PATIENT et tension de tenue à la température de fonctionnement stabilisée

Voir 8.4.2, 8.7 et 8.8.3.

B.21 Pré-conditionnement humide

Voir 5.7.

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B.22 ~~Tension de tenue (CONDITION A FROID)~~ COURANTS DE FUITE et COURANTS AUXILIAIRES PATIENT et tension de tenue après pré-conditionnement humide à la température ambiante du laboratoire

Voir 8.4.2 et 8.7 et 8.8.3.

B.23 Protection contre la défibrillation

Voir 8.5.5.

B.24 DANGERS de projections d'objets

Voir 9.5.

B.25 Réservoirs et parties sous pression pneumatique et hydraulique

Voir 9.7.

B.26 DANGERS associés aux systèmes de support

Voir 9.8.

B.27 Résistance mécanique

Voir 15.3 et 9.2.2.4.1.

B.28 SITUATIONS DANGEREUSES et conditions de défaut

Voir Article 13.

B.29 TRANSFORMATEURS RESEAU des APPAREILS EM et transformateurs assurant la séparation selon 8.5

Voir 15.5.

B.30 Composants et ensembles des APPAREILS EM

Voir 15.4 et 8.10.

B.31 PARTIES RELIEES AU RESEAU, composants et montage

Voir 8.11.

B.32 Isolation autre que l'isolation des fils

Voir 8.8.4.

B.33 Prévention du feu et exigences de construction pour les ENVELOPPES à l'épreuve du feu des APPAREILS EM

Voir 11.2 et 11.3.

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B.34 Débordement, renversement, fuites, pénétration d'eau, nettoyage, désinfection, stérilisation et compatibilité avec des substances utilisées avec des APPAREILS EM

Voir 11.6.

B.35 APPAREIL EM DE LA CATEGORIE AP et de la CATEGORIE APG

Voir 11.4 et Annexe G.

B.36 VERIFICATION des marquages

Voir 7.2 à 7.8.2 (inclus), Annexe C et 7.1.

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Annexe C
(informative)

Guide pour le marquage et exigences d'étiquetage pour les APPAREILS EM et les SYSTEMES EM

C.1 Marquage à l'extérieur de l'APPAREIL EM, des SYSTEMES EM ou de leurs parties

Les exigences de marquage à l'extérieur des APPAREILS EM et de leurs parties sont données en 7.2. Des exigences complémentaires pour le marquage à l'extérieur des APPAREILS EM, des SYSTEMES EM et de leurs parties sont données dans les paragraphes dont la liste figure au Tableau C.1. Les symboles et les signes SECURITE utilisés pour le marquage à l'extérieur des APPAREILS EM sont donnés à l'Annexe D.

Tableau C.1 – Marquage à l'extérieur des APPAREILS EM, des SYSTEMES EM ou de leurs parties[22)]

Description du marquage	Paragraphe
APPAREIL EM DE CATEGORIE APG: marquage de	G.3.1
APPAREIL EM DE CATEGORIE AP: marquage de	G.3.2
CATEGORIES AP et APG: marquage des parties principales	G.3.3
APPAREIL EM DE CATEGORIE AP et APG: marquage des parties	G.3.5
Eléments de dépressurisation des systèmes sous pression: avertissement concernant	9.7.2
Organe de manœuvre du dispositif d'arrêt d'urgence: marquage de	9.2.4
Tension dangereuse: avertissement de	8.11.1 i)
Masse du PATIENT: si conçu pour moins de 135 kg: marquage de	9.8.3.1
Parties en mouvement: avertissement de	9.2.1
SOCLE DE PRISE DE COURANT MULTIPLE : marquage de	16.9.2.1 b)
Excès de balancement au cours du transport: avertissement concernant	9.4.2.2
Borne de CONDUCTEUR D'EGALISATION DES POTENTIELS: marquage de	8.6.7
Interdiction de pousser: de s'appuyer: de peser sur: avertissement d'	9.4.2.3 a)
Interdiction de s'asseoir ou de marcher dessus: avertissement	9.4.2.3 b)
Réservoir ou enceinte de stockage de liquide: marquage du DANGER de débordement	11.6.2
DISPOSITIF DE PROTECTION MECANIQUE destiné à fonctionner une seule fois: marquage de	9.8.4.3
Transformateurs de séparation: marquage de	16.9.2.1 d)
Surfaces où l'application d'une force donne lieu à un RISQUE de balancement excessif : marquage de	9.4.2.3
Conditions de transport: avertissement pour	9.4.2.2

22) Voir 7.2.1 pour les exigences minimales de marquage des APPAREILS EM et des parties interchangeables.

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C.2 Marquage à l'intérieur de l'APPAREIL EM, des SYSTEMES EM ou de leurs parties

Les exigences de marquage à l'intérieur des APPAREILS EM et de leurs parties sont données en 7.3. Des exigences complémentaires pour le marquage à l'intérieur des APPAREILS EM, des SYSTEMES EM et de leurs parties sont données dans les paragraphes dont la liste figure au Tableau C.2. Les symboles utilisés pour le marquage à l'intérieur des APPAREILS EM sont donnés à l'Annexe D.

Tableau C.2 – Marquage à l'intérieur des APPAREILS EM, des SYSTEMES EM ou de leurs parties

Description du marquage	Paragraphe
Energies dangereuses: marquage des condensateurs ou des parties connectées au circuit	8.4.4
Tension dangereuse: marquage des parties	8.11.1 i)
DISPOSITIFS DE RACCORDEMENT AU RESEAU: marquage des bornes autres que les blocs de jonction	8.11.4.1
Marquage des réservoirs sous pression et des tuyaux: marque de certification nationale	9.7.5
Transformateurs de séparation : marquage de	16.9.2.1 d)

C.3 Marquage des commandes et des instruments

Les exigences pour le marquage des commandes et des instruments sont données en 7.4 Des exigences complémentaires pour le marquage des commandes et des instruments sont données dans les paragraphes dont la liste figure au Tableau C.3.

Tableau C.3 – Marquage des commandes et des instruments

Description du marquage	Paragraphe
Commandes: marquage de l'échelle de	15.4.6.1 b)
Modification du réglage de température des THERMOSTATS: indication claire de	15.4.2.2 ~~a)~~

C.4 DOCUMENTS D'ACCOMPAGNEMENT, généralités

Les exigences pour les informations générales à inclure dans les DOCUMENTS d'ACCOMPAGNEMENT sont données en 7.9.1. Des exigences complémentaires pour les informations générales à inclure dans les DOCUMENTS D'ACCOMPAGNEMENT sont données dans les paragraphes dont la liste figure au Tableau C.4.

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Tableau C.4 – DOCUMENTS D'ACCOMPAGNEMENT, généralités

Description d'exigence	Articles
~~APPAREIL EM DE LA CATEGORIE AP et de la CATEGORIE APG et parties~~	~~G.3.4~~
~~Tension de défibrillation, tout temps de reprise nécessaire~~	~~8.5.1.1 b)~~
~~Fixation de structures au plancher, aux murs, au plafond, etc.~~	~~9.8.1~~
~~Instabilité à l'exclusion du transport, du placement et de la charge de portes, de tiroirs et tablettes~~	~~9.4.2.2 e)~~
~~Points de levée: indication de~~	~~9.4.4 a)~~
~~Masse du PATIENT, si les systèmes de support sont conçus pour moins de 135 kg~~	~~9.8.3.1~~
~~Masse du PATIENT, si les systèmes de support sont conçus pour plus de 135 kg~~	~~9.8.3.1~~
~~SYSTEMES EM : Exigences complémentaires~~	~~16.2~~
~~APPAREILS EM : placement de CHARGE DE FONCTIONNEMENT EN SECURITE~~	~~9.4.2.4 c)~~
~~Bruit: moyens de protection~~	~~9.6.2 b)~~
~~DISPOSITIF DE SECURITE destiné à fonctionner une seule fois: instruction pour appeler le PERSONNEL D'ENTRETIEN~~	~~9.8.4.3~~
APPAREILS EM ET PARTIES DE CATEGORIE AP ET CATEGORIE APG	G.3.4
APPAREILS EM DE CLASSE II AVEC ECRANS INTERNES ISOLES: EXPLICATION DES	8.6.9
TENSION DE DEFIBRILLATION, TOUT TEMPS DE REPRISE NECESSAIRE	8.5.5.1 b)
FIXATION DE STRUCTURES AU PLANCHER, AUX MURS, AU PLAFOND, ETC.	9.8.1
INSTABILITE A L'EXCLUSION DU TRANSPORT: PLACEMENT ET CHARGE DE PORTES, TIROIRS ET ETAGERES	9.4.2.2 e)
RESEAU INFORMATIQUE: INSTRUCTIONS DE CONNEXION DE L'APPAREIL EM	14.13
APPAREIL D'ISOLATION: EXIGENCES POUR	8.11.4.4
POINTS DE LEVEE: INDICATION DE	9.4.4 a)
MASSE DU PATIENT, SI LES SYSTEMES DE SUPPORT SONT CONÇUS POUR MOINS DE 135 KG	9.8.3.1
MASSE DU PATIENT, SI LES SYSTEMES DE SUPPORT SONT CONÇUS POUR PLUS DE 135 KG	9.8.3.1
DISPOSITIF DE PROTECTION MECANIQUE DESTINE A FONCTIONNER UNE SEULE FOIS: INSTRUCTION POUR APPELER LE PERSONNEL D'ENTRETIEN	9.8.4.3
APPAREILS EM: PLACEMENT DE CHARGE DE FONCTIONNEMENT EN SECURITE	9.4.2.4.3
SYSTEMES EM: EXIGENCES COMPLEMENTAIRES	16.2
BRUIT: MOYENS DE PROTECTION	9.6.2.1 b)
PASSAGE SUR UN OBSTACLE: INSTRUCTIONS	9.4.2.4.3
CONDITIONS DE FONCTIONNEMENT	5.4 a)

C.5 DOCUMENTS D'ACCOMPAGNEMENT, instructions d'utilisation

Les exigences pour les informations à inclure dans les instructions d'utilisation sont données en 7.9.2. Des exigences complémentaires pour les informations à inclure dans les instructions d'utilisation sont données dans les paragraphes dont la liste figure au Tableau C.5.

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Tableau C.5 – DOCUMENTS D'ACCOMPAGNEMENT, instructions d'utilisation

Description d'exigence	Paragraphe
PARTIES ACCESSIBLES : instruction de ne pas les toucher en même temps que le PATIENT	8.4.2 c)
PARTIES ACCESSIBLES : instructions pour que l'OPERATEUR ouvre les CAPOTS D'ACCES	8.4.2 c)
PARTIES APPLIQUEES (chaudes ou froides) : température et effets cliniques des	11.1.2.1
PARTIES APPLIQUEES qui ne sont pas destinées à fournir de la chaleur : température supérieure à 41 °C	11.1.2.2
PROCESSUS de nettoyage ou de désinfection : spécification de	11.6.6
Effet de multiples nettoyages/désinfections	11.6.6
Pédales de commande : destinées à être utilisées dans des zones où des liquides sont susceptibles de se trouver	15.4.3.3 b)
Masse des ACCESSOIRES	9.8.3.~~2~~1
SYSTEMES EM : Autres appareils destinés à fournir de la puissance à l'APPAREIL EM,	16.3
APPAREILS EM MOBILES : exigence prévoyant que plus d'une personne est nécessaire pour le déplacement	9.4.2.4.2 ~~a)~~
Parties en mouvement : avertissement de	9.2.1
Borne du CONDUCTEUR D'EGALISATION DES POTENTIELS : informations concernant la fonction et l'utilisation de	8.6.7
Réservoir ou enceinte de stockage de liquide : information sur le DANGER de débordement	11.6.2
Conditions de transport : avertissement pour	9.4.2.2

C.6 DOCUMENTS D'ACCOMPAGNEMENT, description technique

Les exigences pour les informations à inclure dans la description technique sont données en 7.9.3. Des exigences complémentaires pour les informations à inclure dans la description technique sont données dans les paragraphes dont la liste figure au Tableau C.6.

Tableau C.6 – DOCUMENTS D'ACCOMPAGNEMENT, description technique

Description d'exigence	Articles
~~APPAREILS EM DE CLASSE II avec écrans internes isolés: explication des~~	~~8.6.9~~
~~Moyens externes d'isolation: description de~~	~~8.11.1 b)~~
~~Dispositif de décharge non automatique pour les condensateurs internes: spécification de~~	~~8.4.4~~
~~Exigences réseau pour les SEMP destinés à être connectés à un réseau extérieur~~	~~14.13~~
Moyens externes d'isolation: description de	8.11.1 b)
Courants transitoires importants des SYSTEMES EM: communication de	16.3
Dispositif de décharge non automatique pour les condensateurs internes: spécification de	8.4.4

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Annexe D
(informative)

Symboles des marquages
(voir Article 7)

On utilise fréquemment sur les APPAREILS EM des symboles de préférence à des mots pour pallier les différences entre langues et pour permettre une compréhension plus facile des marquages ou indications, placés parfois dans un espace limité. Des symboles et des signes de sécurité nouveaux et améliorés ont été introduits depuis la publication de la deuxième édition de l'IEC 60601-1, ce qui nécessite des modifications dans la liste des symboles et signes de sécurité approuvés pour utilisation sur les APPAREILS EM.

La principale de ces modifications concerne la révision de l'usage du symbole 24 dans le Tableau D.1. Ce symbole était utilisé auparavant pour indiquer un avertissement ainsi qu'un marquage informatif (par exemple il indique le lieu de raccordement HAUTE TENSION). Un nouveau signe de sécurité (3) au Tableau D.2 a été ajouté pour indiquer “Avertissement : Tension Dangereuse.” Dans cette édition de la norme, les signes de sécurité du Tableau D.2 sont exigés là où un avertissement est désiré tandis que les symboles du Tableau D.1 sont utilisés lorsqu'il s'agit seulement d'informer.

Il en est de même de la révision de l'usage du symbole 10 du Tableau D.1, qui était utilisé auparavant pour indiquer “attention: consulter les DOCUMENTS D'ACCOMPAGNEMENT. Ce symbole est désormais utilisé pour indiquer un danger. Un nouveau symbole (11) a été ajouté au Tableau D.1 pour indiquer “suivre les instructions de fonctionnement”. De plus, un nouveau signe de sécurité (10) a été ajouté au Tableau D.2 pour marquer les APPAREILS EM lorsqu'un défaut de suivi des instructions de fonctionnement pourrait faire courir un RISQUE AU PATIENT ou à l'OPERATEUR.

Une utilisation cohérente de ces symboles et de ces signes de sécurité dans tous les domaines d'utilisation (par exemple médical, consommables et transport général) aidera les OPERATEURS d'APPAREILS EM à se familiariser avec leur signification. Au contraire, toute utilisation incohérente conduira à des confusions et des erreurs et compromettra la sécurité.

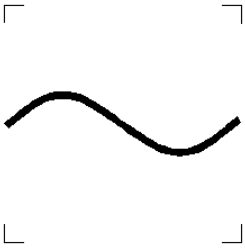
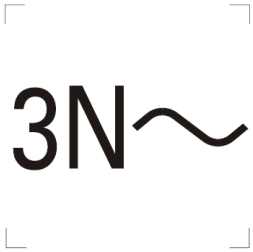
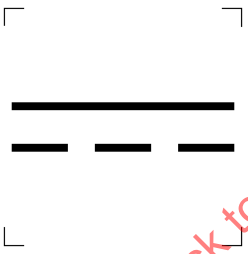
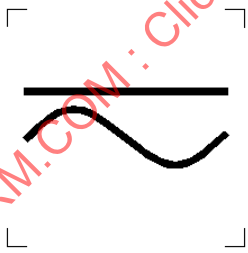
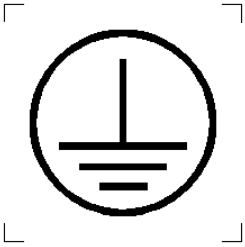
L'IEC 60878 [60] constitue un compendium utile des symboles graphiques et des signes de sécurité utilisés sur les appareils électriques en pratique médicale compilé à partir des normes ISO et IEC applicables. Voir aussi 7.5 et 7.6.

Pour les exigences en matière de symboles qui ne sont pas satisfaites par les symboles de l'IEC 60878, se référer en premier lieu aux symboles publiés par l'IEC ou l'ISO, tout en notant qu'il est admis, en cas de nécessité, de regrouper deux ou plus de deux symboles pour donner une signification particulière et que, pourvu que les caractéristiques essentielles de communication des symboles de base soient conservées, une certaine latitude est tolérée pour la conception graphique de ces symboles. Les couleurs des symboles ne sont pas spécifiées, à l'exception du fond des symboles pour AP et APG (voir Article G.3). Les couleurs utilisées pour les signes de sécurité sont spécifiées dans l'ISO 3864-1.

Dans les tableaux suivants, le symbole graphique et sa description sont donnés pour information.

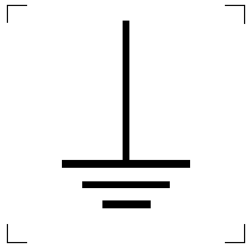
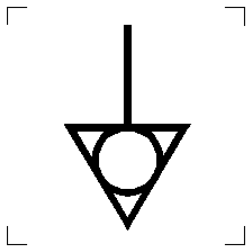
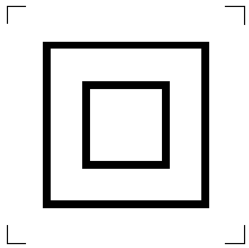
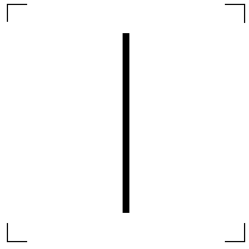
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Tableau D.1 – Symboles généraux

N°	Symbole	Référence	Titre
1		IEC 60417-5032	Courant alternatif
2		IEC 60417-5032-1	Courant alternatif triphasé
3		IEC 60417-5032-2	Courant alternatif triphasé avec neutre
4		IEC 60417-5031	Courant continu
5		IEC 60417-5033	Courant continu et courant alternatif
6		IEC 60417-5019	Terre de protection (masse)

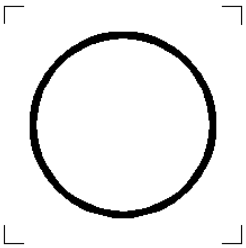
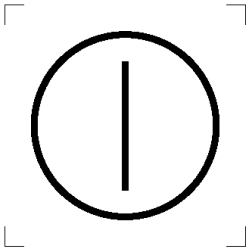
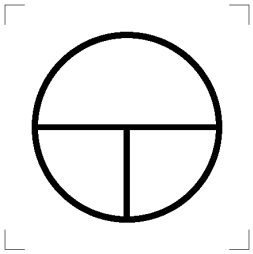
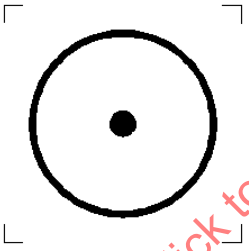
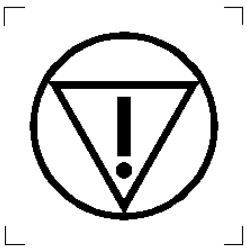
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Tableau D.1 *(suite)*

N°	Symbole	Référence	Titre
7		IEC 60417-5017	Terre (masse)
8		IEC 60417-5021	Equipotentialité
9		IEC 60417-5172	Appareils de la CLASSE II
10		ISO 7000-0434A	Avertissement En cas d'application comme signe de sécurité, les règles de l'ISO 3864-1 doivent être respectées. Voir signe de sécurité ISO 7010-W001 (Tableau D.2, signe de sécurité 2).
11		ISO 7000-1641	Instructions de fonctionnement
12		IEC 60417-5007	“MARCHE” (mise sous tension)

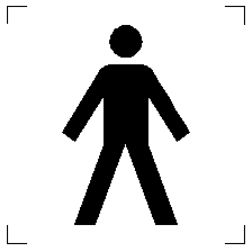
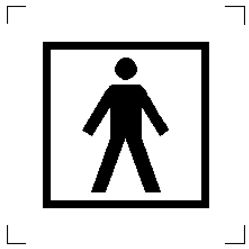
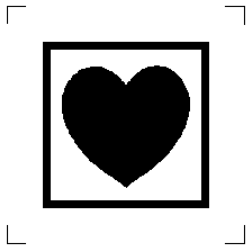
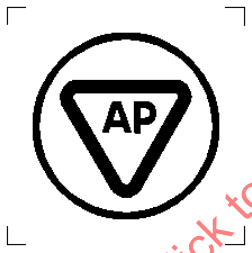
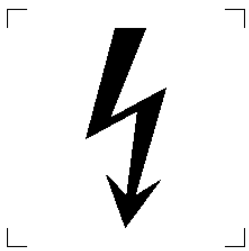
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Tableau D.1 *(suite)*

N°	Symbole	Référence	Titre
13		IEC 60417-5008	“ARRÊT” (mise hors tension)
14		IEC 60417-5010	“MARCHE” / “ARRÊT” (2 positions stables) NOTE Chaque position, "MARCHE" ou "ARRET", est une position stable.
15		IEC 60417-5011	“MARCHE” / “ARRÊT” (bouton poussoir) NOTE "ARRET" est une position stable, tandis que la position "MARCHE" ne reste que pendant la durée d'appui sur le bouton.
16		IEC 60417-5264	“Mise en service” d'une partie d'appareil
17		IEC 60417-5265	“ARRÊT” pour une partie de l'appareil
18		IEC 60417-5638	Arrêt d'urgence

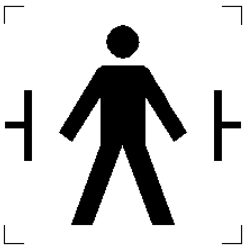
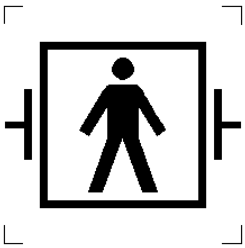
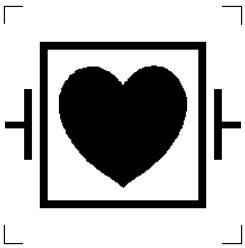
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Tableau D.1 *(suite)*

N°	Symbole	Référence	Titre
19		IEC 60417-5840	PARTIE APPLIQUEE DE TYPE B NOTE Le Paragraphe 7.2.10 exige que, pour faire une distinction claire avec le symbole 20, le symbole 19 ne soit pas appliqué d'une manière donnant l'impression qu'il est inscrit dans un carré.
20		IEC 60417-5333	PARTIE APPLIQUEE DE TYPE BF
21		IEC 60417-5335	PARTIE APPLIQUEE DE TYPE CF
22		IEC 60417-5331	Appareil de CATEGORIE AP
23		IEC 60417-5332	Appareil de CATEGORIE APG
24		IEC 60417-5036	Tension dangereuse

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Tableau D.1 *(suite)*

N°	Symbole	Référence	Titre
25		IEC 60417-5841	PARTIE APPLIQUEE DE TYPE B PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION
26		IEC 60417-5334	PARTIE APPLIQUEE DE TYPE BF PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION
27		IEC 60417-5336	PARTIE APPLIQUEE DE TYPE CF PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION
28		ISO 7000-1051	Ne pas réutiliser
29		IEC 60417-5009	Attente

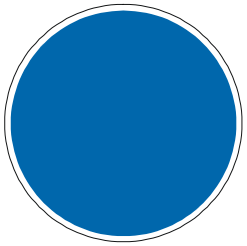
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Tableau D.2 – Signes de sécurité

1		ISO 3864-1, Figure 3	Modèle pour la construction d'un signal d'avertissement NOTE Couleur de fond : jaune Bande triangulaire : noire Symbole ou texte : noir
2		ISO 7010-W001	Signe de sécurité général
3		~~IEC 60878~~ ~~ISO 3864-B.3.6~~ [a] ISO 7010-W012	Avertissement ~~: tension dangereuse~~, électricité
4		ISO 7010-P001 et ISO 3864-1, Figure 1	Signe d'interdiction général et Modèle pour la construction d'un signe d'interdiction NOTE Couleur de fond : blanc Bande circulaire et barre oblique : rouge Symbole ou texte : noir
5		ISO 7010-P017	Interdiction de pousser
6		ISO 7010-P018	Interdiction de s'asseoir

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Tableau D.2 *(suite)*

7		ISO 7010-P019	Interdiction de monter dessus
8		ISO 3864-1 Figure 2	Modèle de construction d'un signe d'action obligatoire NOTE Couleur de fond : bleu Symbole ou texte : blanc
9		ISO 7010-M001	Signe d'action obligatoire général
10		ISO 7010-M002	Se référer au manuel/brochure d'instruction NOTE Sur LES APPAREILS EM "Suivre les instructions d'utilisation"

[a] La description de ce signe de sécurité d'utilisation courante est donnée à l'Annexe B de l'ISO 3864:1984. Lorsque les signes de sécurité ont été rassemblés dans l'ISO 7010, ce signe n'a pas été intégré à la nouvelle norme. L'ISO 3864:1984 a été annulée et remplacée par l'ISO 3864-1 et l'ISO 7010 en janvier 2003. Il est envisagé d'ajouter ce signe de sécurité à l'ISO 7010 dans le cadre d'un futur amendement.

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Tableau D.3 – Codes généraux

1	**N**	IEC 60445	Point de raccordement pour le conducteur neutre sur les APPAREILS INSTALLES DE FAÇON PERMANENTE
2	**IPN_1N_2**	IEC 60529	N_1 = 0 Non protégé 1 Protégé contre les corps étrangers solides de 50 mm ∅ et plus 2 Protégé contre les corps étrangers solides de 12,5 mm ∅ et plus 3 Protégé contre les corps étrangers solides de 2,5 mm ∅ et plus 4 Protégé contre les corps étrangers solides de 1,0 mm ∅ et plus 5 Protégé contre la poussière 6 Etanche à la poussière N_2 = 0 Non protégé 1 Protection contre les gouttes d'eau tombant verticalement 2 Protection contre les gouttes d'eau tombant verticalement lorsque L'ENVELOPPE est inclinée jusqu'à 15° 3 Protégé contre la pénétration d'eau sous forme de pluie 4 Protégé contre les projections d'eau 5 Protégé contre les projections à la lance 6 Protégé contre les projections puissantes à la lance 7 Protégé contre les effets d'immersion temporaire dans l'eau 8 Protégé contre les effets d'immersion prolongée dans l'eau NOTE Lorsqu'il n'est pas exigé de spécifier une caractéristique numérique, celle-ci est remplacée par la lettre “X” (“XX” si les deux chiffres sont omis).

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Annexe E
(informative)

Exemples de connexion du dispositif de mesure (DM) pour la mesure du COURANT DE FUITE PATIENT et du COURANT AUXILIAIRE PATIENT
(voir 8.7)

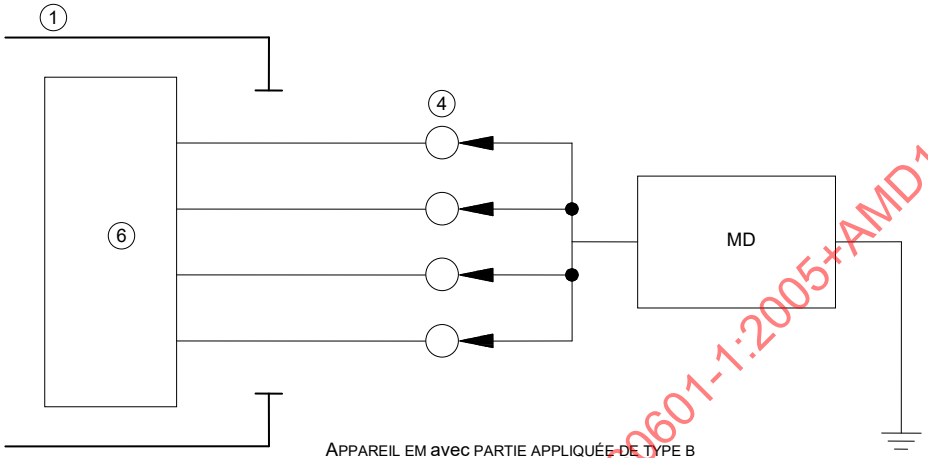


Figure E.1 – PARTIE APPLIQUEE DE TYPE B

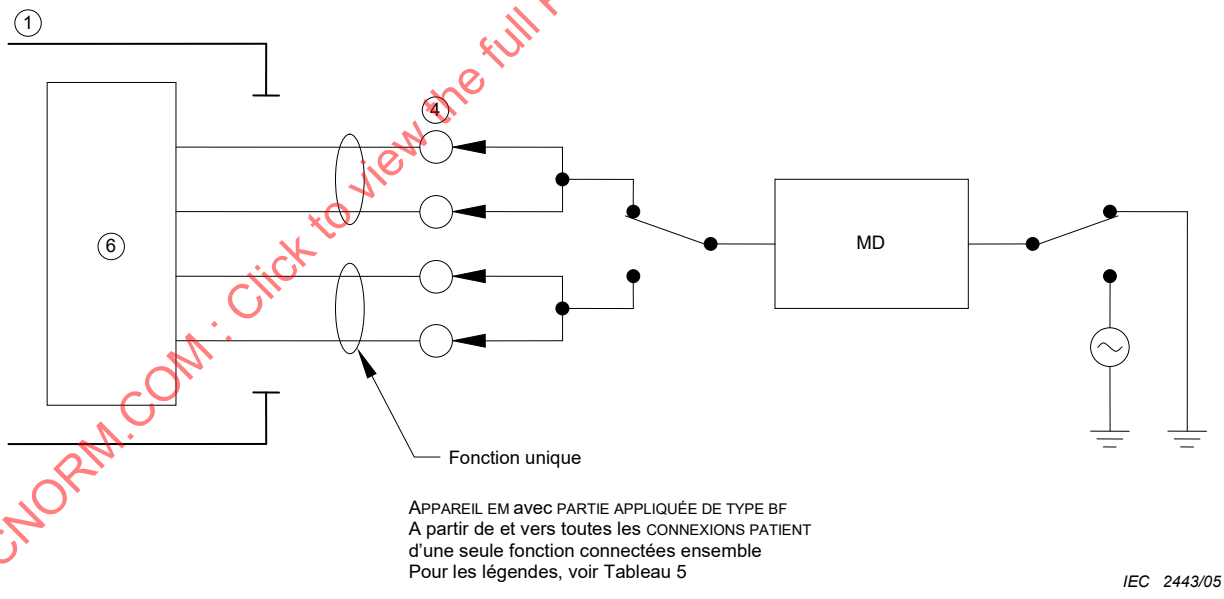


Figure E.2 – PARTIE APPLIQUEE DE TYPE BF

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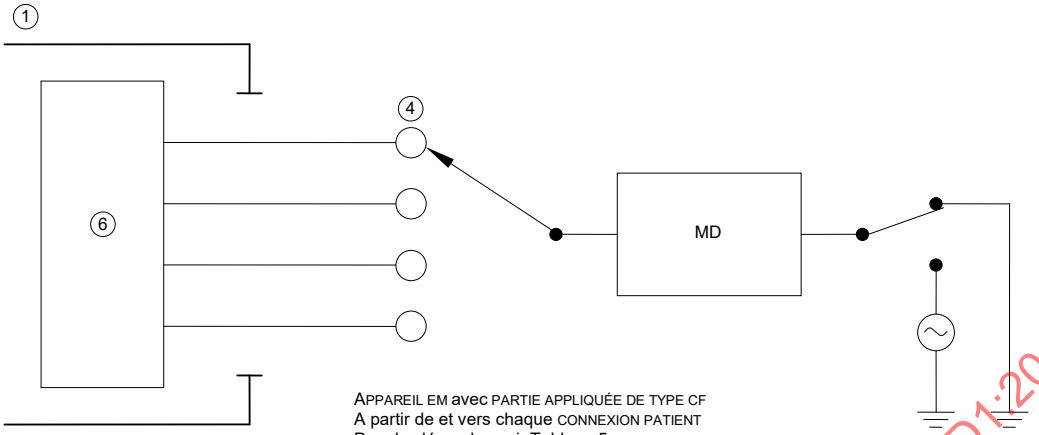


Figure E.3 – PARTIE APPLIQUEE DE TYPE CF

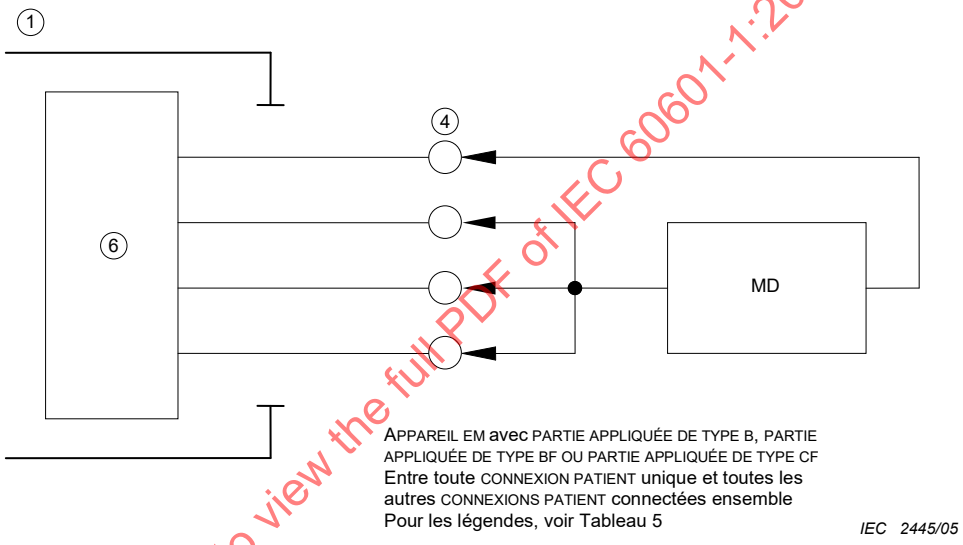


Figure E.4 – Courant auxiliaire patient

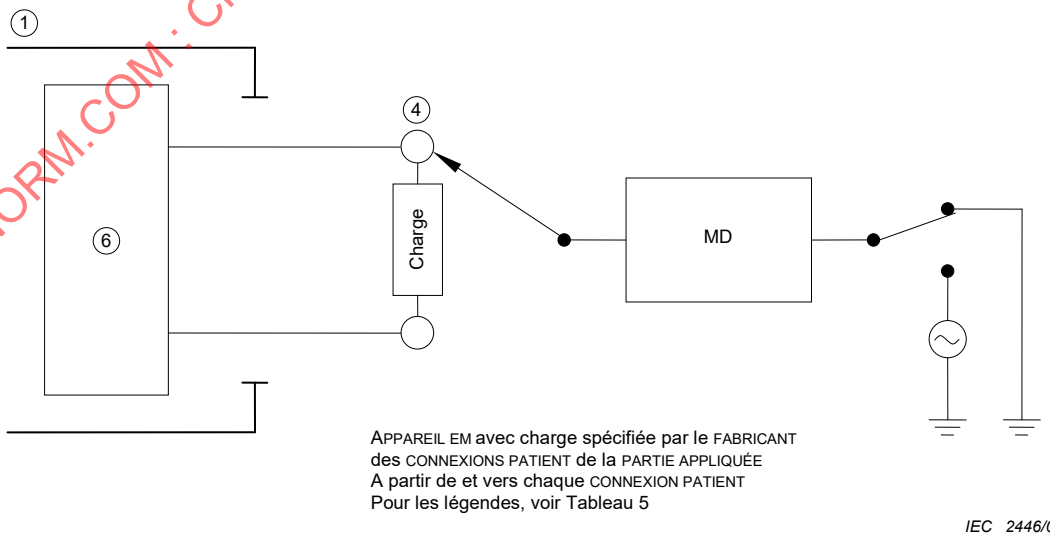
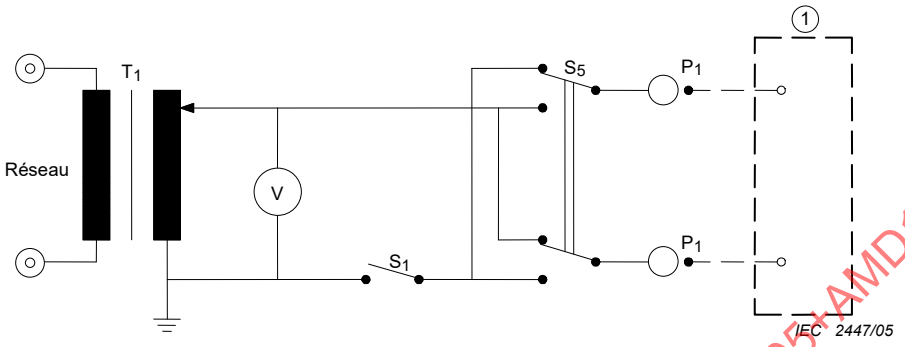


Figure E.5 – Charge des CONNEXIONS PATIENT si elles sont spécifiées par le FABRICANT

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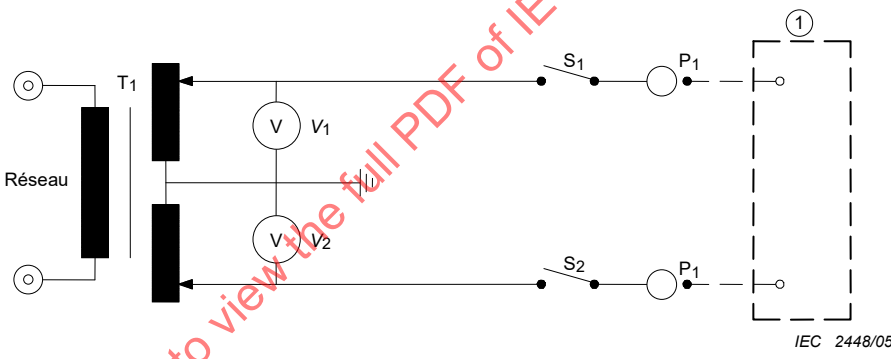
Annexe F
(informative)

Circuits d'alimentation de mesure adaptés



Pour les légendes, voir Tableau 5.

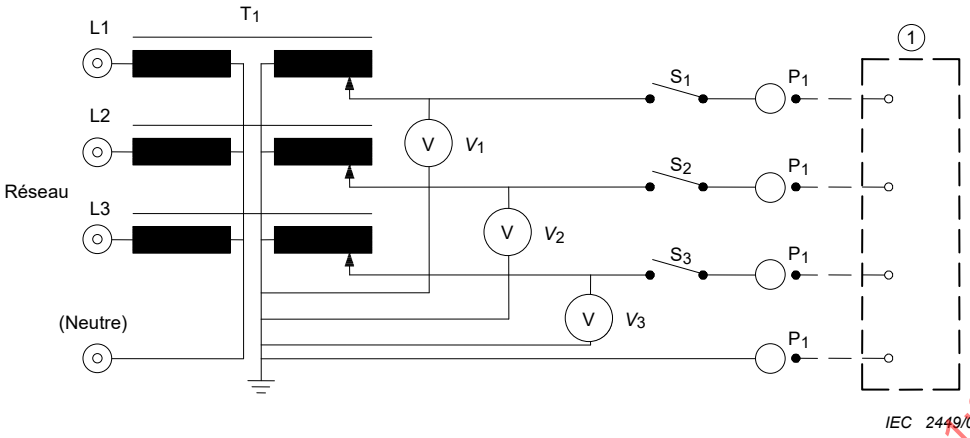
Figure F.1 – Circuit d'alimentation de mesure avec un côté du RESEAU D'ALIMENTATION approximativement au potentiel de terre
(voir 8.7.4.2)



Pour les légendes, voir Tableau 5.

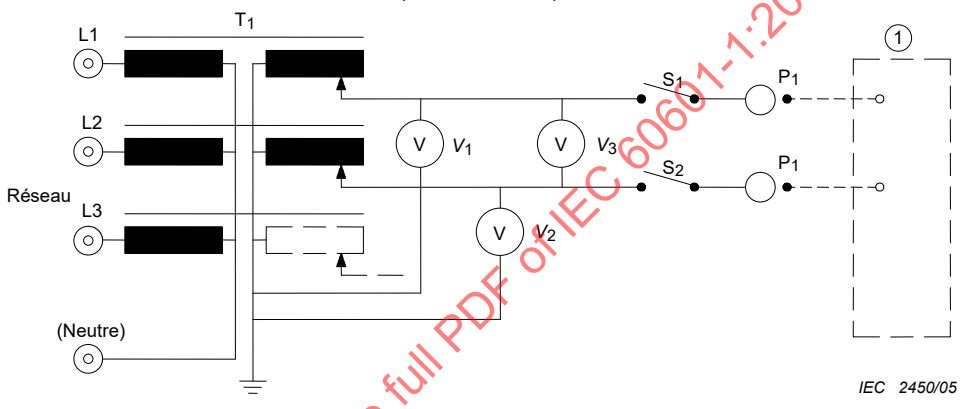
Figure F.2 – Circuit d'alimentation de mesure avec RESEAU D'ALIMENTATION approximativement symétrique au potentiel de terre
(voir 8.7.4.2)

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Pour les légendes, voir Tableau 5.

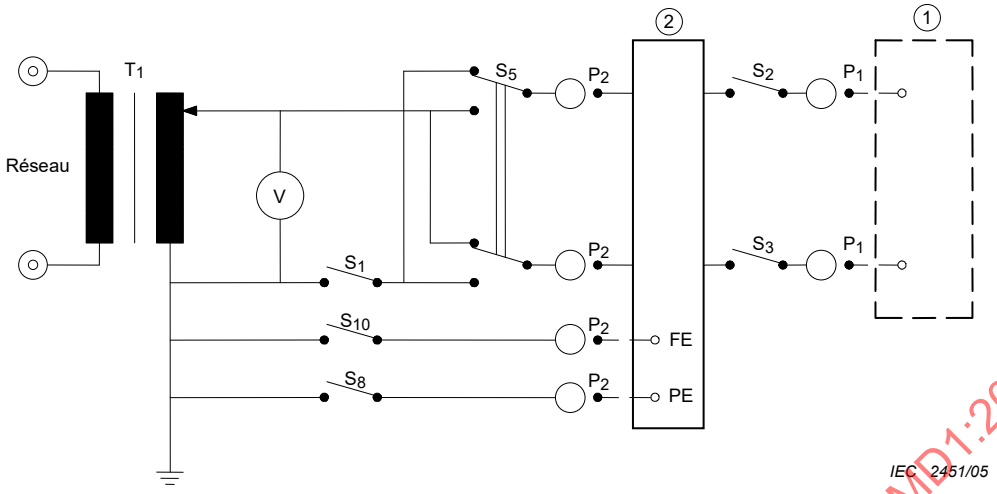
Figure F.3 – Circuit d'alimentation de mesure pour les APPAREILS EM polyphasés spécifiés pour connexion à un RESEAU D'ALIMENTATION polyphasé
(voir 8.7.4.2)



Pour les légendes, voir Tableau 5.

Figure F.4 – Circuit d'alimentation de mesure pour les APPAREILS EM monophasés spécifiés pour connexion à un RESEAU D'ALIMENTATION polyphasé
(voir 8.7.4.2)

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Pour les légendes, voir Tableau 5.

Figure F.5 – Circuit d'alimentation de mesure pour les APPAREILS EM ayant une unité d'alimentation séparée ou destiné à recevoir sa puissance d'un autre appareil du SYSTEME EM
(voir 8.7.4.2)

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Annexe G
(normative)

Protection contre les DANGERS d'inflammation des mélanges anesthésiques inflammables

NOTE Cette annexe remplace l'ancienne Section Six: "Protection contre les RISQUES d'ignition des mélanges anesthésiques inflammables" de la deuxième édition.

G.1 Introduction

G.1.1 Applicabilité

Lorsque les APPAREILS EM sont utilisés dans des zones dans lesquelles des anesthésiques inflammables ou des agents inflammables pour la désinfection ou le nettoyage de la peau sont utilisés, un RISQUE d'explosion peut exister si de tels anesthésiques ou agents sont mélangés à l'air ou à l'oxygène ou au protoxyde d'azote.

L'inflammation d'un tel mélange peut être causée par des étincelles ou par contact avec des parties ayant une température de surface élevée.

Les étincelles peuvent être produites lors de l'ouverture ou de la fermeture de circuits électriques commandée par des interrupteurs, des connecteurs, des fusibles ou des COUPE-CIRCUITS et des dispositifs similaires.

Dans les parties à HAUTE TENSION, les étincelles peuvent être causées par l'effet couronne. Des décharges statiques peuvent causer des étincelles.

La probabilité d'apparition d'une inflammation de tels mélanges anesthésiques dépend de leur concentration, de l'énergie d'inflammation minimale appropriée, de la présence de températures de surface élevées et de l'énergie des étincelles.

G.1.2 Appareils et composants industriels

Les exigences de construction de l'IEC 60079-0 ne sont généralement pas appropriées pour les APPAREILS EM pour plusieurs raisons:

a) elles conduisent à des constructions d'une taille, d'un poids ou d'une conception qui ne sont pas applicables pour des raisons médicales ou qui ne peuvent pas être stérilisées;

b) certaines constructions autorisent une explosion à l'intérieur d'une ENVELOPPE, mais en empêchent la propagation à l'extérieur. Une telle construction, qui pourrait être intrinsèquement sûre, serait inacceptable dans une salle d'opération dans laquelle la continuité de fonctionnement des APPAREILS EM est essentielle;

c) les exigences industrielles ont été conçues pour les agents inflammables mélangés à l'air. Elles ne peuvent pas être appliquées aux mélanges avec de l'oxygène ou du protoxyde d'azote utilisés en pratique médicale;

d) en pratique médicale, les mélanges anesthésiques inflammables apparaissent en quantités relativement faibles uniquement.

Cependant, certaines constructions décrites dans l'IEC 60079-0 sont acceptables pour des APPAREILS EM de CATEGORIE AP (voir G.5.1).

G.1.3 * Exigences pour les APPAREILS EM

Dans la présente annexe, la présence de mélanges anesthésiques inflammables est décrite:

– autant que nécessaire pour la construction des APPAREILS EM, à minima pour des conditions spécifiées d'évacuation et d'absorption;

– autant que nécessaire pour l'affectation des APPAREILS EM et la construction de l'installation électrique dans la série IEC 60364.

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Les recommandations, les limites et les essais de la présente annexe sont fondés sur les résultats de considérations statistiques obtenues à partir d'expériences réalisées avec les mélanges les plus facilement inflammables de vapeur d'éther avec l'air et avec l'oxygène, en utilisant l'appareillage d'essai décrit à l'Article G.7. Cela est justifié parce que les combinaisons avec l'éther ont les températures d'inflammation les plus faibles et les énergies d'inflammation les plus faibles des agents d'utilisation courante.

Lorsque les températures ou les paramètres de circuits des APPAREILS EM utilisés dans un MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'AIR dépassent les limites admissibles et que les étincelles ne peuvent pas être évitées, les parties et circuits concernés peuvent être enfermés dans des ENVELOPPES avec du gaz inerte sous pression ou de l'air propre ou dans des ENVELOPPES à ventilation réduite.

Les ENVELOPPES à ventilation réduite retardent la formation d'une concentration inflammable. Elles sont reconnues car on suppose qu'une période pendant laquelle un APPAREIL EM est utilisé dans un MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'AIR est suivie par une période de ventilation au cours de laquelle une telle concentration disparaît.

Pour les APPAREILS EM contenant ou utilisés dans un MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'OXYGENE OU DU PROTOXYDE D'AZOTE, les exigences, les limites et les essais sont beaucoup plus sévères.

Ces recommandations s'appliquent non seulement en CONDITION NORMALE mais, en outre, dans la CONDITION DE PREMIER DEFAUT, comme indiqué en 4.7. Seules deux exemptions de l'essai d'inflammation réel sont reconnues, il s'agit soit de l'absence d'étincelles avec une température limitée soit d'une température limitée avec des paramètres de circuit restreints.

G.2 Localisations et exigences fondamentales

G.2.1 Parties d' APPAREILS EM de CATEGORIE AP

Les parties d'un APPAREIL EM de CATEGORIE APG dans lesquelles un MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'AIR se produit doivent être de la CATEGORIE AP ou APG et doivent être conformes aux exigences des Articles G.3, G.4 et G.5.

G.2.2 MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'AIR

Lorsqu'il se produit un MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'AIR à la suite d'une fuite ou d'un dégagement de MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'OXYGENE OU DU PROTOXYDE D'AZOTE à partir d'une ENVELOPPE, on considère que par propagation il se forme un volume du mélange produit autour du point de fuite ou de dégagement à une distance comprise entre 5 cm et 25 cm de ce point.

G.2.3 MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'OXYGENE OU DU PROTOXYDE D'AZOTE

Un MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L' OXYGENE OU DU PROTOXYDE D'AZOTE peut être contenu dans une partie d'APPAREIL EM complètement ou partiellement fermée et dans les voies respiratoires du PATIENT. On considère qu'un tel mélange se propage jusqu'à une distance de 5 cm de la partie de l'ENVELOPPE où se produit la fuite ou le dégagement.

G.2.4 APPAREIL EM spécifié pour utilisation avec un MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'AIR

Un APPAREIL EM ou des parties de celui-ci, spécifié pour être utilisé avec un MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'AIR (dans une situation définie en G.2.2) doit être de la CATEGORIE AP ou APG et doit être conforme aux exigences des Articles G.4 et G.5.

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G.2.5 APPAREIL EM spécifié pour être utilisation avec un MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'OXYGENE OU DU PROTOXYDE D'AZOTE

Un APPAREIL EM, ou des parties de celui-ci, spécifié pour être utilisé avec un MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'OXYGENE OU DU PROTOXYDE D'AZOTE dans une situation définie en G.2.2) doit être de la CATEGORIE APG et doit être conforme aux exigences des Articles G.4 et G.6.

La conformité avec les exigences de ~~G.2.3~~ G.2.4 à G.2.5 ~~(inclus)~~ est vérifiée par examen et par les essais appropriés des Articles G.3, G.4 et G.5.

Ces essais doivent être réalisés après ceux applicables prévus en 11.6.6 et 11.6.7.

G.3 Marquage, DOCUMENTS D'ACCOMPAGNEMENT

G.3.1 Marquage de CATEGORIE APG

Les APPAREILS EM DE LA CATEGORIE APG doivent être marqués en un endroit bien visible par une bande de couleur verte d'au moins 2 cm de large portant les lettres "APG" (voir le symbole IEC 60417-5332 (~~DB:~~2002-10) (voir Tableau D.1, symbole 23)). Il convient que la longueur de la bande verte soit d'au moins 4 cm. Il convient que la taille du marquage soit aussi grande que possible pour ce cas particulier. Si ce marquage est impossible, une information équivalente doit être donnée dans les instructions d'utilisation.

La conformité est vérifiée par inspection et par application des essais et des critères de 7.1.2 et 7.1.3.

G.3.2 Marquage de CATEGORIE AP

Les APPAREILS EM de la CATEGORIE AP doivent être marqués à un endroit bien visible avec un macaron de couleur verte d'au moins 2 cm de diamètre portant les lettres "AP" (voir le symbole IEC 60417-5331 (~~DB:~~2002-10) (Tableau D.1, symbole 22)).

Il convient que la taille du marquage soit aussi grande que possible pour ce cas particulier. Si ce marquage est impossible, une information équivalente doit être donnée dans les instructions d'utilisation.

La conformité est vérifiée par inspection et par application des essais et des critères de 7.1.2 et 7.1.3.

G.3.3 Emplacement des marquages

Le marquage prévu en ~~G.3.2 et G.3.3~~ G.3.1 et G.3.2 doit figurer sur la partie principale de L'APPAREIL EM si cette partie est de CATEGORIE AP ou de CATEGORIE APG. Il n'est pas nécessaire de le répéter sur les parties amovibles qui ne peuvent être utilisées qu'associées avec L'APPAREIL EM marqué.

La conformité est vérifiée par inspection.

G.3.4 DOCUMENTS D'ACCOMPAGNEMENT

Les DOCUMENTS D'ACCOMPAGNEMENT doivent contenir une indication permettant à l'ORGANISME RESPONSABLE de distinguer les parties des APPAREILS EM (voir G.3.5) qui sont soit de la CATEGORIE AP soit de la CATEGORIE APG.

La conformité est vérifiée par inspection.

G.3.5 Marquage lorsque les parties de l'APPAREIL EM sont de CATEGORIE AP ou APG

Sur les APPAREILS EM dont seules certaines parties sont de la CATEGORIE AP ou de la CATEGORIE APG, le marquage doit indiquer clairement quelles sont les parties de la CATEGORIE AP ou de la CATEGORIE APG.

La conformité est vérifiée par inspection.

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G.4 Exigences communes aux APPAREILS EM de CATEGORIE AP et de CATEGORIE APG

G.4.1 Raccordements électriques

a) Les LIGNES DE FUITE et les DISTANCES DANS L'AIR entre les points de raccordement du CABLE D'ALIMENTATION doivent être conformes aux valeurs du Tableau 12, valeurs pour les MOYENS DE PROTECTION DU PATIENT.

b) Les raccordements, sauf ceux des circuits décrits en G.5.3 et G.6.3, doivent être protégés contre une déconnexion accidentelle en UTILISATION NORMALE ou doivent être conçus de manière que la connexion et/ou la déconnexion ne puisse se faire qu'à l'aide d'un OUTIL.

c) Les APPAREILS EM de la CATEGORIE AP et de la CATEGORIE APG ne doivent pas être équipés d'un CABLE D'ALIMENTATION–SOUPLE NON FIXE A DEMEURE à moins que le circuit ne soit conforme aux exigences de G.5.3 et G.6.3.

La conformité est vérifiée par inspection ou par mesurage.

G.4.2 Détails de construction

a) L'ouverture d'une ENVELOPPE assurant la protection contre la pénétration de gaz ou de vapeurs dans l'APPAREIL EM ou dans des parties de celui-ci ne doit être possible qu'à l'aide d'un OUTIL.

La conformité est vérifiée par inspection.

b) Pour réduire la formation d'arcs et d'étincelles due à la pénétration d'objets étrangers dans L'ENVELOPPE:

- les capots supérieurs des ENVELOPPES ne doivent pas avoir d'ouvertures; les ouvertures de passages pour commandes sont cependant permises si elles sont recouvertes par le bouton de commande;
- les dimensions des ouvertures dans les parois latérales ne doivent pas laisser pénétrer un objet solide cylindrique de plus de 4 mm de diamètre;
- les dimensions des ouvertures dans les fonds ne doivent pas laisser pénétrer un objet solide cylindrique de plus de 12 mm de diamètre.

La conformité est vérifiée au moyen d'une tige d'essai cylindrique de 4 mm de diamètre pour les parois latérales et de 12 mm de diamètre pour les fonds. La tige d'essai ne doit pas pénétrer dans l'ENVELOPPE lorsqu'elle est appliquée dans toutes les directions possibles, sans lui appliquer de force appréciable.

c) Lorsque l'isolation des conducteurs électriques équivalente à un MOYEN DE PROTECTION PATIENT peut entrer en contact avec une partie contenant un MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'OXYGENE OU DU PROTOXYDE D'AZOTE ou simplement des gaz inflammables ou de l'oxygène, un court-circuit de ces conducteurs ou un court-circuit entre un conducteur et une partie conductrice contenant le gaz ou le mélange ne doit pas provoquer la perte d'intégrité d'une telle partie ou entraîner une élévation de température inadmissible ~~ou tout autre DANGER~~ pour cette partie (voir G.6.3 a)) ou toute autre SITUATION DANGEREUSE.

La conformité est vérifiée par inspection. En cas de doute, il convient d'effectuer un essai de court-circuit (sans gaz explosif) et si possible, la température correspondante mesurée. L'essai de court-circuit n'a pas à être effectué si le produit de la tension en circuit ouvert en volts par le courant de court-circuit en ampères n'excède pas 10.

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G.4.3 Prévention des charges électrostatiques

a) Les charges électrostatiques doivent être évitées pour les APPAREILS EM DE LA CATEGORIE AP et de la CATEGORIE APG par une combinaison de mesures appropriées telles que:

- l'utilisation de matériaux antistatiques à résistance électrique limitée comme spécifié en G.4.3 b), et
- l'installation de cheminements électriques conducteurs entre l'APPAREIL EM ou ses parties et un sol conducteur ou le système de terre de protection ou le système d'égalisation des potentiels ou par l'intermédiaire des roues vers un sol antistatique du local à usage médical.

b) Les limites de la résistance électrique pour les tuyauteries d'anesthésie, les matelas et les coussins, les pneus de roulettes et les autres matériaux antistatiques doivent être conformes à l'ISO 2882.

La conformité aux limites des résistances admissibles données dans l'ISO 2882 est vérifiée par des mesures selon l' ISO 1853, l' ISO 2878 et l' ISO 23529.

G.4.4 Effet couronne

Les parties et les composants des APPAREILS EM fonctionnant à des tensions supérieures à 2 000 V en courant alternatif ou plus de 2 400 V en courant continu ne se trouvant pas dans des ENVELOPPES conformément à G.5.4 ou G.5.5 doivent être conçus de telle sorte qu'aucun effet couronne n'apparaisse.

La conformité est vérifiée par inspection ou mesurage.

G.5 Exigences et essais pour les APPAREILS EM de la CATEGORIE AP, leurs parties et leurs composants

G.5.1 Généralités

Les APPAREILS EM, leurs parties ou composants ne doivent pas enflammer les MELANGES ANESTHESIQUES INFLAMMABLES AVEC DE L'AIR en UTILISATION NORMALE et en CONDITION NORMALE.

Les APPAREILS EM, leurs parties ou composants conformes à l'un des Paragraphes G.5.2 à G.5.5 (inclus) sont considérés comme conformes aux exigences du présent paragraphe.

Les APPAREILS EM, leurs parties ou leurs composants conformes aux exigences de la IEC 60079-0 concernant les ENVELOPPES pressurisées (IEC 60079-2), les ENVELOPPES à remplissage pulvérulent (IEC 60079-5) ou les appareils immergés dans l'huile (IEC 60079-6) ainsi qu'aux exigences de la présente norme (à l'exclusion de celles de G.5.2 à G.5.5), sont considérés comme conformes aux exigences pour les APPAREILS EM DE CATEGORIE AP.

G.5.2 Limites de températures

Les APPAREILS EM, leurs parties ou leurs composants ne produisant ni étincelles ni températures de fonctionnement des surfaces en contact avec les mélanges gazeux en UTILISATION NORMALE et en CONDITION NORMALE excédant 150 °C dans le cas d'une réduction de la circulation verticale d'air par convection, ou excédant 200 °C dans le cas d'une circulation verticale d'air non réduite, si la mesure est effectuée à une température ambiante de 25 °C, sont considérés comme conformes aux exigences de G.5.1.

Les températures de fonctionnement sont mesurées pendant les essais décrits en 11.1.

G.5.3 * Circuits à faible énergie

Les APPAREILS EM, leurs parties ou leurs composants qui peuvent produire des étincelles en UTILISATION NORMALE et en CONDITION NORMALE (par exemple interrupteurs, relais, connexions

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par prise détachables sans l'aide d'un OUTIL, incluant les connexions à l'intérieur de l'APPAREIL EM qui ne sont pas suffisamment bloquées ou verrouillées et les balais des moteurs) doivent être conformes aux exigences relatives à la température de G.5.2. En outre la tension U_{max} et le courant I_{max}, qui peuvent se présenter dans les circuits, en tenant compte de la capacité C_{max} et de l'inductance L_{max} doivent être conformes aux exigences suivantes:

$U_{max} \leq U_{zR}$ pour un courant donné I_{zR}, voir Figure G.1,

$U_{max} \leq U_c$ pour une capacité donnée C_{max}, voir Figure G.2,

$I_{max} \leq I_{zR}$ pour une tension donnée U_{zR}, voir Figure G.1, et

$I_{max} \leq I_{zL}$ pour une inductance donnée L_{max} et pour $U_{max} \leq 24$ V, voir Figure G.3.

– Les graphiques des Figures G.1 à G.3 ont été obtenus avec l'appareillage d'essai ~~décrit à l'Article G.6~~ selon la Figure G.7 et avec les mélanges les plus facilement inflammables de vapeur d'éther et d'air (pourcentage d'éther en volume de 4,3 ± 0,2 %) pour une probabilité inflammation (sans facteur de sécurité) de 10^{-3}.

– L'extrapolation du graphique de la Figure G.1 est permise pour les combinaisons des courants avec les tensions correspondantes dans les limites $I_{zR} \cdot U_{zR} \leq 50$ W.

L'extrapolation pour des tensions supérieures à 42 V n'est pas valable.

– L'extrapolation du graphique de la Figure G.2 est permise pour les combinaisons des capacités avec les tensions correspondantes dans les limites de:

$$\frac{C}{2}U^2 \leq 1{,}2 \text{ mJ}$$

L'extrapolation pour des tensions supérieures à 242 V n'est pas valable.

Si la résistance R équivalente est inférieure à 8 000 Ω, U_{max} est déterminée en outre avec une résistance R réelle.

– L'extrapolation du graphique de la Figure G.3 est permise pour les combinaisons des courants avec les inductances correspondantes dans les limites de:

$$\frac{L}{2}I^2 \leq 0{,}3 \text{ mJ}$$

L'extrapolation pour des inductances supérieures à 900 mH n'est pas valable.

– La tension U_{max} est la tension d'alimentation la plus élevée apparaissant dans le circuit à l'essai, le contact d'amorçage étant ouvert, compte tenu des variations de la TENSION RESEAU exigées en 4.10.

– Le courant I_{max} est le courant le plus élevé parcourant le circuit à l'essai, le contact d'amorçage étant fermé, compte tenu des variations de la TENSION RESEAU exigées en 4.10.

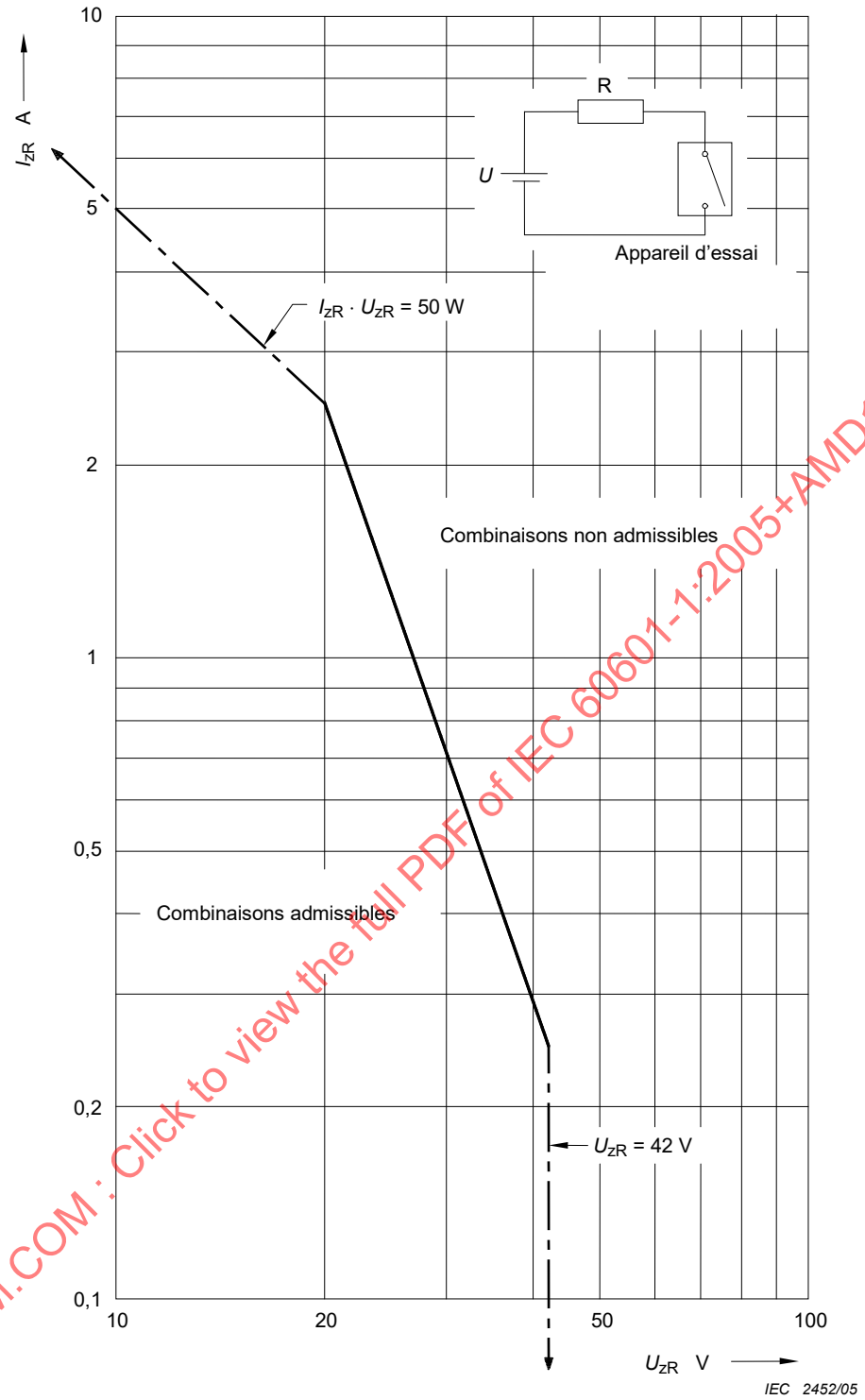
– La capacité C_{max} et l'inductance L_{max} sont les valeurs se présentant sur le composant à l'essai qui produit des étincelles dans l'APPAREIL EM.

– Si le circuit est alimenté en courant alternatif, la valeur de crête est prise en considération.

– Si le circuit est complexe, c'est-à-dire comporte plus d'une capacité, d'une inductance et d'une résistance, ou une combinaison de celles-ci, un circuit équivalent est calculé pour déterminer la capacité maximale équivalente, l'inductance maximale équivalente et de plus les équivalents de U_{max} et I_{max}, soit en valeurs de courant continu, soit en valeurs de crête pour l'alternatif.

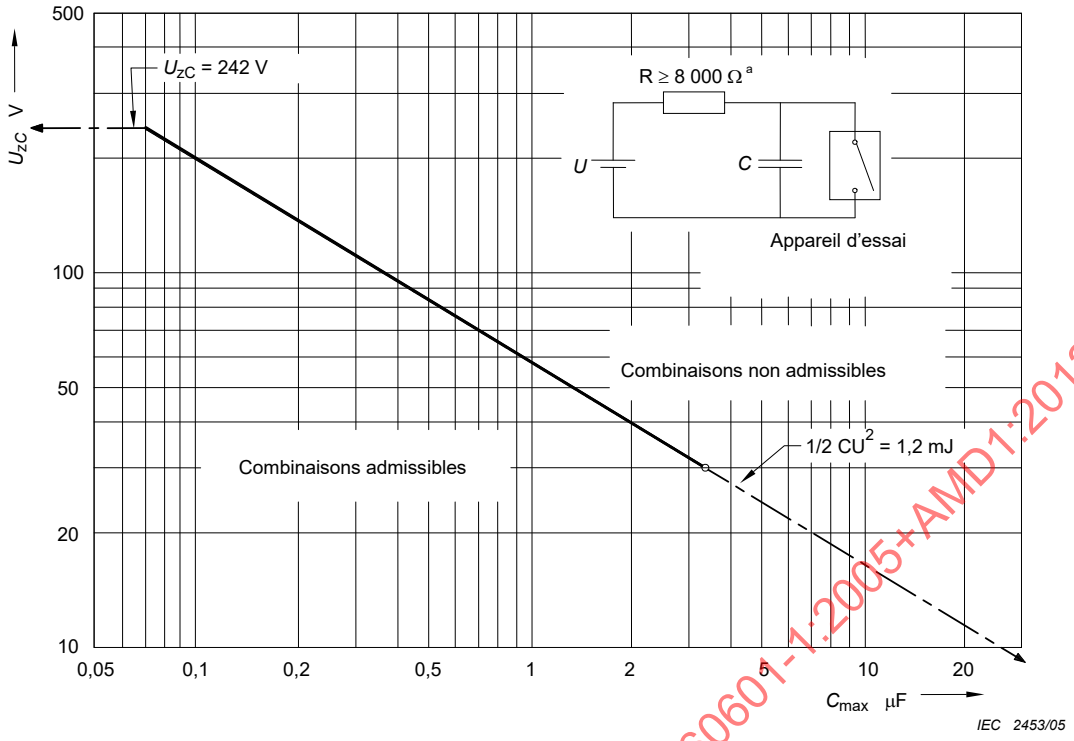
La conformité est vérifiée soit par mesurage des températures et par détermination de U_{max}, I_{max}, R, L_{max} et C_{max} en rapport avec les Figures G.1, G.2 et G.3 ou par examen des caractéristiques de conception.

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Figure G.1 – Courant maximal admissible I_{zR} en fonction de la tension maximale admissible U_{zR} mesuré dans un circuit purement résistif avec le mélange le plus facilement inflammable de vapeur d'éther et d'air



[a] 8 000 Ω ou la résistance réelle, si *R* est inférieure à 8 000 Ω

Figure G.2 – Tension maximale admissible U_{zC} en fonction de la capacité C_{max} mesurée dans un circuit capacitif avec le mélange le plus facilement inflammable de vapeur d'éther et d' air

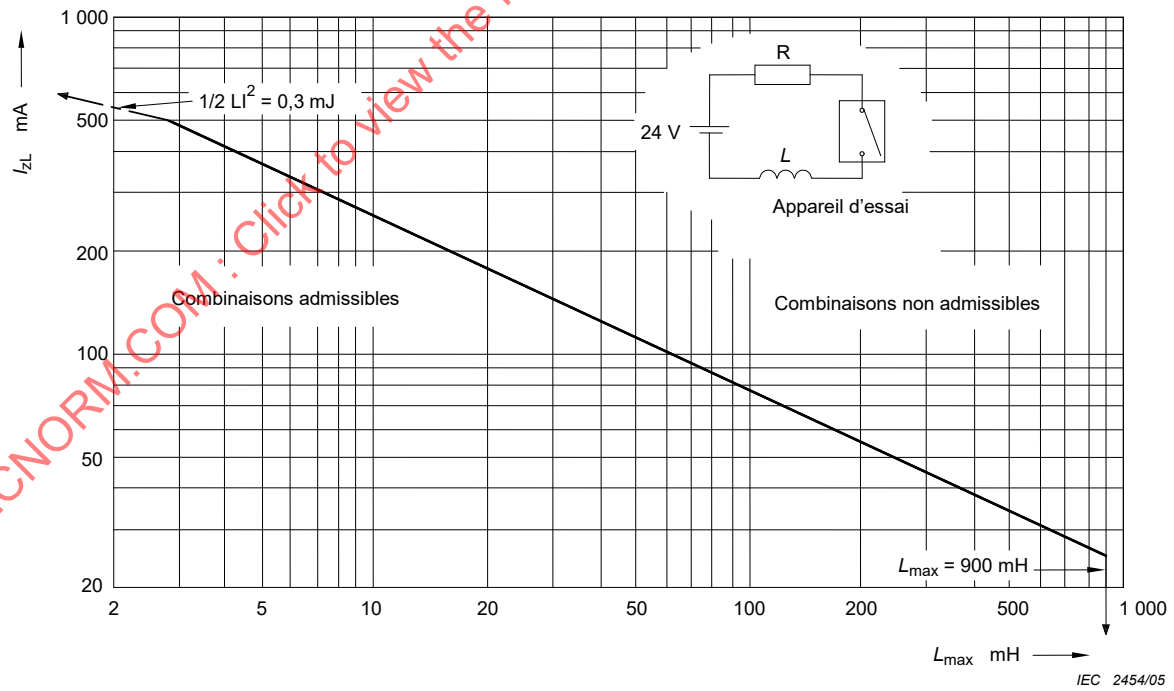


Figure G.3 – Courant maximal admissible I_{zL} en fonction de l'inductance L_{max} mesurée dans un circuit inductif avec le mélange le plus facilement inflammable de vapeur d'éther et d'air

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G.5.4 * Ventilation externe par surpression interne

Lorsqu'un APPAREIL EM, ses parties ou composants sont inclus dans une ENVELOPPE à ventilation externe assurée par une surpression interne, les exigences suivantes doivent s'appliquer.

a) Les MELANGES ANESTHESIQUES INFLAMMABLES AVEC DE L'AIR qui pourraient avoir pénétré à l'intérieur de l'ENVELOPPE d'un APPAREIL EM ou d'une partie d'APPAREIL EM doivent être évacués par ventilation, avant mise sous tension de l'APPAREIL EM ou de la partie de l'APPAREIL EM. On doit par la suite empêcher la pénétration de tels mélanges au cours du fonctionnement par le maintien dans l'APPAREIL EM ou dans la partie de l'APPAREIL EM d'une surpression obtenue avec de l'air ne contenant ni gaz ni vapeurs inflammables ou avec un gaz inerte physiologiquement acceptable (par exemple l'azote).

b) La surpression à l'intérieur de l'ENVELOPPE doit être d'au moins 75 Pa en CONDITION NORMALE. La surpression doit être maintenue là où se trouvent les sources d'inflammation, même si l'air ou le gaz inerte peut s'échapper à travers les ouvertures de L'ENVELOPPE qui sont nécessaires au fonctionnement normal de l'APPAREIL EM ou de ses parties.

   On ne doit pouvoir mettre l'APPAREIL EM sous tension qu'après établissement de la surpression minimale requise pendant un temps suffisant pour ventiler l'ENVELOPPE correspondante de telle sorte que le volume d'air ou de gaz inerte déplacé soit au moins cinq fois celui de l'ENVELOPPE. (Toutefois, les APPAREILS EM peuvent être mis sous tension à tout moment ou de manière répétée, si la surpression est assurée en permanence.)

c) Si la surpression tombe en dessous de 50 Pa au cours du fonctionnement, les sources d'inflammation doivent être mises hors tension automatiquement par un moyen qui doit être situé soit à un endroit où les exigences et les essais de l'Article G.4 ne s'appliquent pas soit à un endroit conforme aux exigences de l'Article G.5.

d) La température externe de l'ENVELOPPE dans laquelle la surpression interne est maintenue ne doit pas atteindre en CONDITION NORMALE et en UTILISATION NORMALE une température supérieure à 150 °C, mesurée à une température ambiante de 25 °C.

   La conformité aux exigences de G.5.4 a) à G.5.4 d) est vérifiée par mesurages des températures, des PRESSIONS et des débits et par examen du dispositif de contrôle de la PRESSION.

G.5.5 ENVELOPPES à respiration limitée

Lorsqu'un APPAREIL EM, ses parties ou composants sont placés à l'intérieur d'une ENVELOPPE à respiration limitée, les exigences suivantes doivent s'appliquer:

a) * Les ENVELOPPES à respiration limitée doivent être conçues de telle façon qu'il ne puisse pas se former de MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'AIR à l'intérieur de L'ENVELOPPE lorsque celle-ci est entourée d'un MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'AIR de haute concentration, pendant au moins 30 min mais sans différence de pression par rapport à l'intérieur de l'ENVELOPPE.

b) Si l'étanchéité exigée est obtenue par des joints ou par un scellement, le matériau utilisé à cet effet doit alors résister au vieillissement.

   La conformité est vérifiée par application de l'essai B-b de l'IEC 60068-2-2, Article 15, avec une température de 70 °C ± 2 °C et une durée de 96 h.

c) Si l'ENVELOPPE comprend des entrées pour câbles souples, leur étanchéité aux gaz doit être conservée lorsque les câbles subissent des contraintes de flexion ou de traction. Les

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câbles doivent être équipés de dispositifs appropriés d'arrêt de traction et de torsion limitant ces contraintes (voir 8.11.3.5).

La conformité aux exigences de G.5.5 a), G.5.5 b) et G.5.5 c) est vérifiée en effectuant les essais suivants:

A l'issue de l'essai de G.5.4 b), s'il est applicable, on crée une surpression interne de 400 Pa et on effectue 30 tractions de la valeur donnée au Tableau G.1 sur chaque câble souple, alternativement dans la direction axiale de l'entrée du câble et dans la direction perpendiculaire la moins favorable, chaque traction étant effectuée sans secousse pendant 1 s. A la fin de l'essai, la surpression n'est pas inférieure à 200 Pa.

Tableau G.1 – Etanchéité aux gaz des entrées de câbles

Masse (*m*) de l'APPAREIL EM kg	**Traction** N
$m \leq 1$	30
$1 < m \leq 4$	60
$m > 4$	100

Si l'ENVELOPPE de parties ou de composants d'APPAREIL EM est scellée ou étanche aux gaz et s'il n' y a pas de doute que l'ENVELOPPE est conforme aux exigences mentionnées ci-dessus, l'essai de l'ENVELOPPE est réduit à un simple examen.

La température de fonctionnement de la surface externe de l'ENVELOPPE ne doit pas dépasser 150 °C mesurée à une température ambiante de 25 °C. La température de fonctionnement stabilisée de l'ENVELOPPE doit également être mesurée.

G.6 Exigences et essais pour les APPAREILS EM de la CATEGORIE APG, leurs parties et leurs composants

G.6.1 Généralités

Les APPAREILS EM, leurs parties ou composants ne doivent pas enflammer les MELANGES ANESTHESIQUES INFLAMMABLES AVEC DE L'OXYGENE OU DU PROTOXYDE D'AZOTE. Cette exigence s'applique à la fois en UTILISATION NORMALE et pour toute CONDITION DE PREMIER DEFAUT éventuelle comme cela est décrit en 4.7.

Les APPAREILS EM, leurs parties ou composants qui ne sont pas conformes aux exigences de G.6.3 sont soumis à un essai de SERVICE CONTINU de 10 min dans un mélange éther/ oxygène (pourcentage d'éther en volume 12,2 % ± 0,4 %) après obtention des conditions thermiques stables, mais pas plus de 3 h après mise sous tension.

G.6.2 * Alimentation électrique

Les parties ou composants des APPAREILS EM de la CATEGORIE APG qui fonctionnent dans un MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'OXYGENE OU DU PROTOXYDE D'AZOTE doivent être alimentés par une source isolée de la terre par au moins une isolation égale à un MOYEN DE PROTECTION PATIENT et des parties électriques par une isolation égale à deux MOYENS DE PROTECTION PATIENT.

La vérification est effectuée par examen des schémas des circuits et par des mesurages.

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G.6.3 * Températures et circuits à faible énergie

Les APPAREILS EM et leurs parties ou composants sont considérés comme conformes aux exigences de G.6.1 sans subir les essais prévus au G.6.1 si, en USAGE NORMAL, en CONDITION NORMALE et en CONDITIONS DE PREMIER DEFAUT (voir 4.7):

a) il n'y a pas production d'étincelles et si aucun point n'atteint une température supérieure à 90 °C, ou

b) la limite de température de 90 °C n'est pas dépassée, l'APPAREIL EM ou ses parties contiennent des composants pouvant produire des étincelles en UTILISATION NORMALE, en CONDITION NORMALE et dans les CONDITIONS DE PREMIER DEFAUT applicables, mais la tension U_{max} et le courant I_{max} qui peuvent apparaître dans leurs circuits, compte tenu de la capacité C_{max} et de l'inductance L_{max}, sont conformes aux conditions suivantes:

   $U_{max} \leq$ ~~L~~U_{zR} avec une valeur donnée I_{zR}, voir Figure G.4, et

   $U_{max} \leq U_{zC}$ avec une valeur donnée C_{max}, voir Figure G.5, ainsi que

   $I_{max} \leq I_{zR}$ pour une tension donnée U_{zR}, voir Figure G.4, et

   $I_{max} \leq I_{zL}$ pour une inductance donnée L_{max} et pour $U_{max} \leq 24$ V, voir Figure G.6.

   – Les graphiques des Figures G.4 à G.6 ont été obtenus avec l'appareillage d'essai ~~décrit à l'Article F.8~~ selon la Figure G.7 avec le mélange le plus facilement inflammable de vapeur d'éther et d'oxygène (pourcentage d'éther en volume de ~~12,2 ± 0,4 %~~ 4,3 ± 0,2 %) pour une probabilité d'inflammation de 10^{-3}. Les valeurs maximales admissibles pour I_{zR} (Figure G.4), U_{zC} (Figure G.5) et I_{zL} (Figure G.6) comprennent un facteur de sécurité de 1,5.

   – L'extrapolation des courbes des Figures G.4, G.5 et G.6 est limitée aux zones indiquées.

   – La tension U_{max} est la tension sans charge la plus élevée apparaissant dans le circuit à l'essai, compte tenu des variations de la TENSION RESEAU comme exigé en 4.10.

   – Le courant I_{max} est le courant le plus élevé parcourant le circuit à l'essai, compte tenu des variations de la TENSION RESEAU comme exigé en 4.10.

   – La capacité C_{max} et l'inductance L_{max} sont les valeurs se présentant dans le circuit considéré.

   – Si la résistance R équivalente de la Figure G.5 est inférieure à 8 000 Ω, U_{max} est déterminé en outre avec une résistance R réelle.

   – Si le circuit est alimenté en courant alternatif, la valeur de crête est prise en considération.

   – Si le circuit est complexe, c'est-à-dire comporte plus d'une capacité, d'une inductance et d'une résistance, ou une combinaison de celles-ci, un circuit équivalent est calculé pour déterminer la capacité maximale équivalente, l'inductance maximale équivalente et de plus les équivalents de U_{max} et I_{max}, soit en valeurs de courant continu, soit en valeurs de crête pour le courant alternatif.

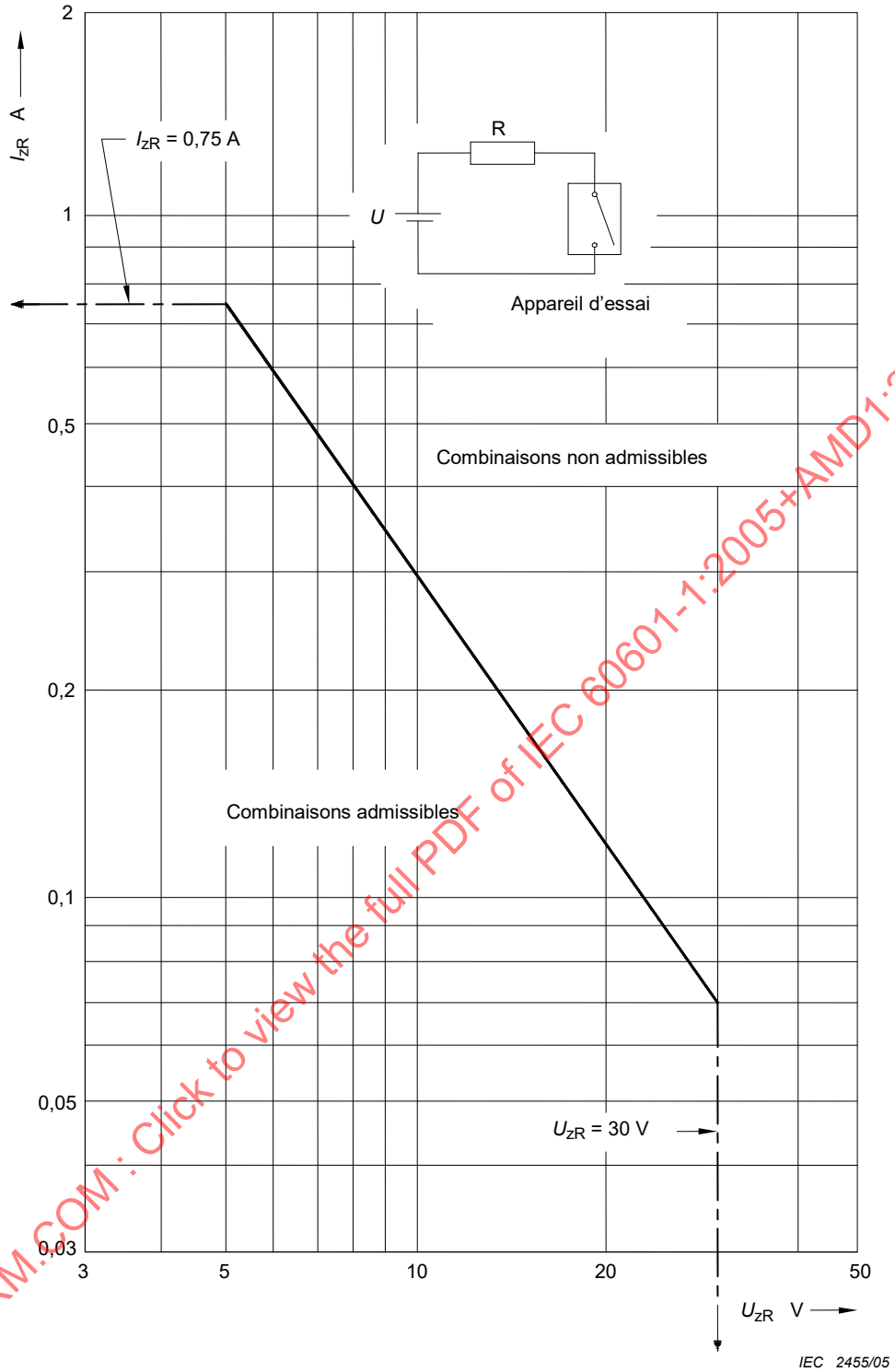
   – Si l'énergie produite dans une inductance ou une capacité dans un circuit est limitée par un limiteur de tension ou des limiteurs d'intensité interdisant de dépasser les limites indiquées par les Figures G.4, G.5 et G.6, deux composants indépendants doivent être appliqués de façon à ce que la limitation prescrite de tension ou d'intensité soit obtenue même en cas de premier défaut (court-circuit ou circuit ouvert) dans l'un de ces composants.

   Cette exigence ne s'applique pas aux transformateurs conçus et construits selon la présente norme ni aux résistances bobinées de limitation de courant munies d'une protection contre le déroulement du fil en cas de rupture.

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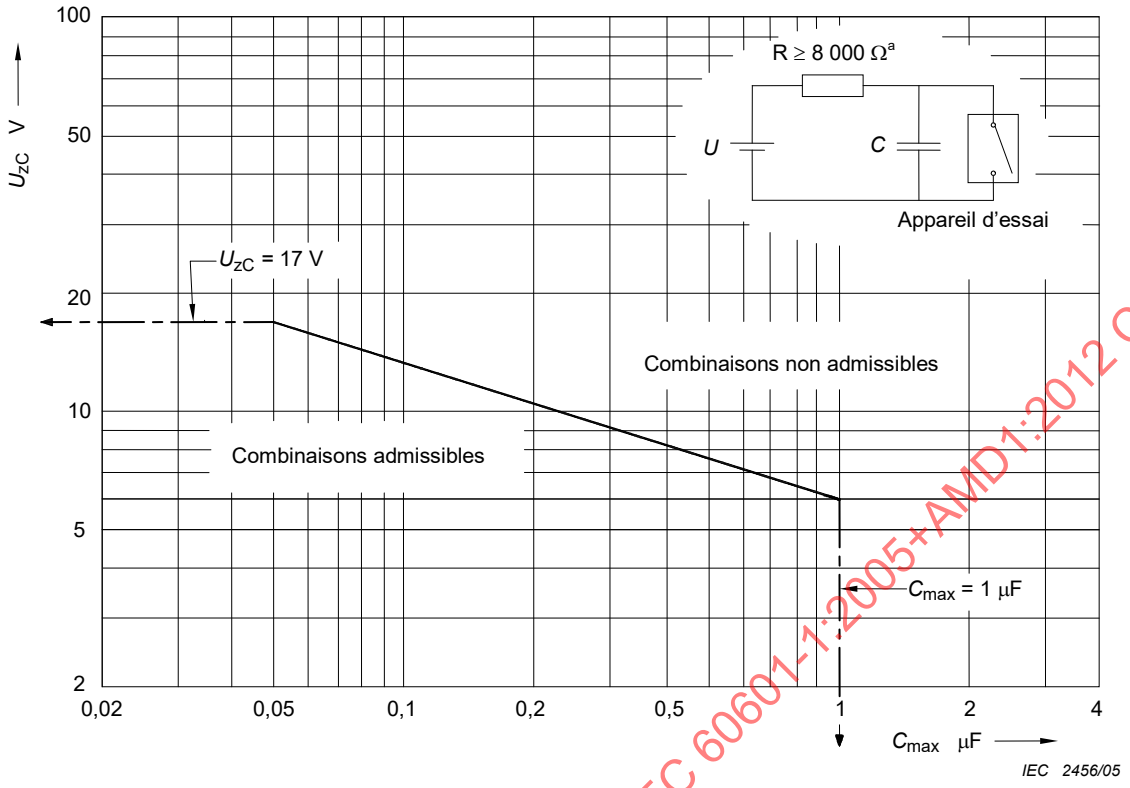
La conformité est vérifiée par examen, par mesurages des températures, par comparaison avec les caractéristiques de conception ou par mesurage de U_{max}, I_{max}, R, L_{max} et C_{max} et en utilisant les Figures G.4, G.5 et G.6.

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Figure G.4 – Courant maximal admissible I_{zR} en fonction de la tension maximale admissible U_{zR} mesuré dans un circuit purement résistif avec le mélange le plus facilement inflammable de vapeur d'éther et d'oxygène



[a] 8 000 Ω ou la résistance réelle, si *R* est inférieure à 8 000 Ω

Figure G.5 – Tension maximale admissible U_{ZC} en fonction de la capacité C_{max} mesurée dans un circuit capacitif avec le mélange le plus facilement inflammable de vapeur d'éther et d'oxygène

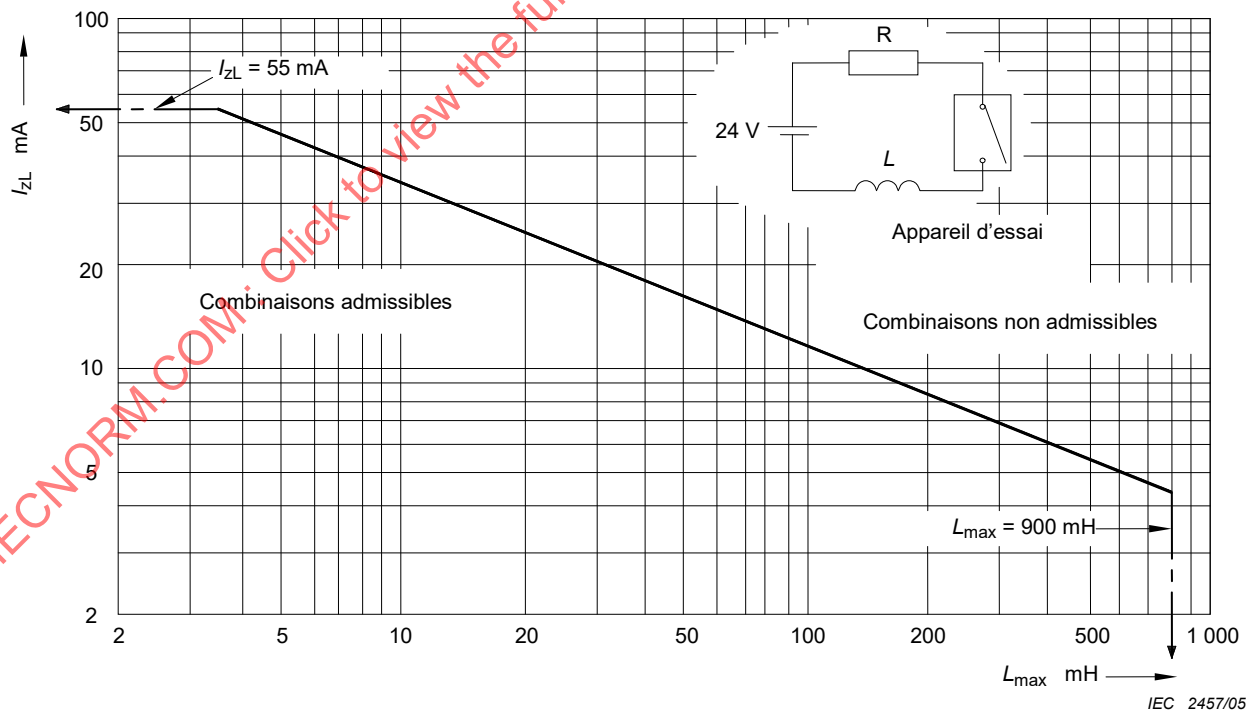


Figure G.6 – Courant maximal admissible I_{ZL} en fonction de l'inductance L_{max} mesurée dans un circuit inductif avec le mélange le plus facilement inflammable de vapeur d'éther et d'oxygène

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G.6.4 Eléments chauffants

Les APPAREILS EM, leurs parties et leurs composants qui chauffent un MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'OXYGENE OU DU PROTOXYDE D'AZOTE doivent être équipés d'un COUPE CIRCUIT THERMIQUE SANS REENCLENCHEMENT AUTOMATIQUE, comme protection supplémentaire contre la surchauffe.

La conformité est vérifiée par l'essai correspondant de 15.4.2.1.

La partie de l'élément chauffant parcourue par le courant ne doit pas être en contact direct avec le MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'OXYGENE OU DU PROTOXYDE D'AZOTE.

La conformité est vérifiée par examen.

G.7 Appareillage d'essai pour les mélanges inflammables

NOTE Anciennement Annexe F de la deuxième édition.

L'appareillage d'essai comprend une chambre d'inflammation d'un volume minimal de 250 cm³, qui contient l'atmosphère ou le mélange prescrit et un mécanisme de contact (voir Figure G.7) produisant des étincelles par ouverture et fermeture.

Le mécanisme de contact se compose d'un disque en cadmium avec deux cannelures et d'un second disque avec quatre fils de tungstène d'un diamètre de 0,2 mm qui glisse sur le premier disque. La longueur libre des fils de tungstène est de 11 mm. L'arbre auquel sont reliés les fils de tungstène tourne à une vitesse de 80 r/min. L'arbre relié au disque en cadmium tourne en sens inverse.

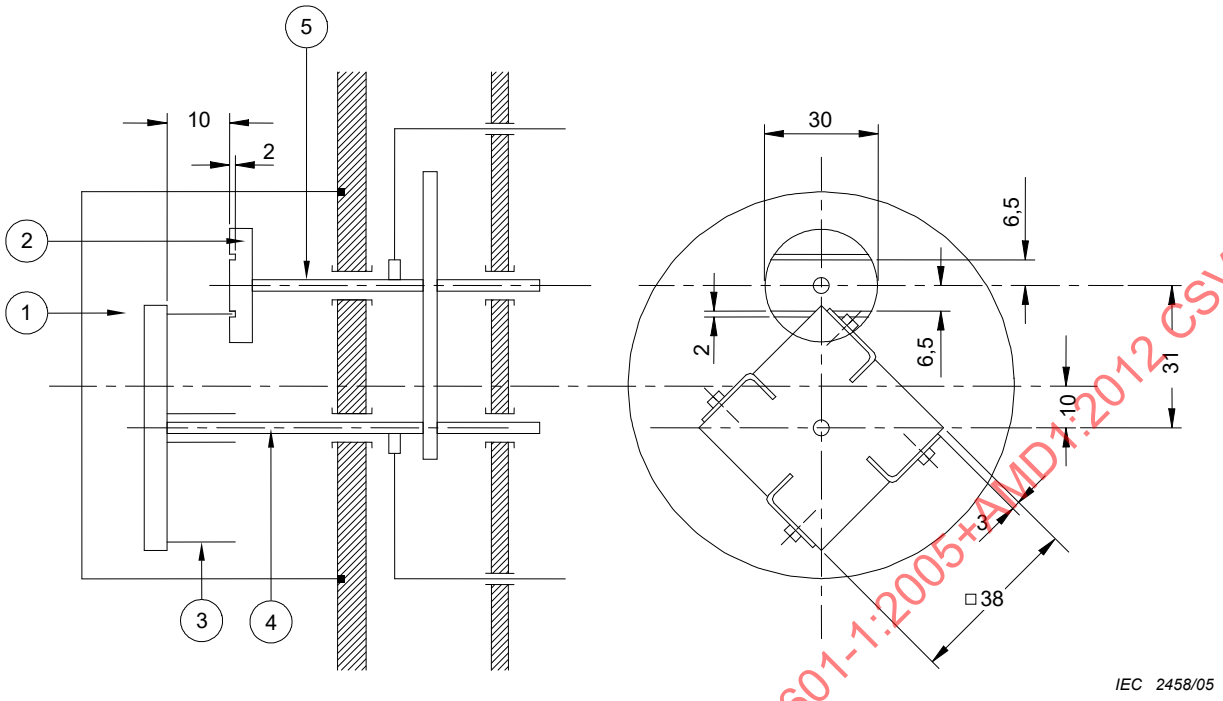
Le rapport des vitesses de rotation de l'arbre relié aux fils et de l'autre arbre est de 50:12.

Les deux arbres sont isolés l'un de l'autre ainsi que de la masse.

La chambre d'inflammation doit être capable de supporter une surpression interne de 1,5 MPa.

Par ce mécanisme de contact, le circuit à essayer est fermé ou ouvert et on vérifie si les étincelles enflamment l'atmosphère ou le mélange d'essai.

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Dimensions en millimètres

Légende

1 Chambre d'inflammation
2 Disque en cadmium
3 Fil de tungstène
4 Arbre du disque portant les fils
5 Arbre du disque à cannelures

Figure G.7 – Appareillage d'essai

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Annexe H
(informative)

Structure de SEMP, CYCLE DE DEVELOPPEMENT SEMP et documentation

H.1 Exemples de structures pour SEMP/SSEP

Un SEMP peut être un élément très simple d'un APPAREIL EM ou un SYSTEME EM complexe ou se situer entre les deux.

La Figure H.1 montre plusieurs exemples possibles de SEMP.

La Figure H.1 a) montre un système complexe. Le SEMP se décompose en plusieurs sous-systèmes principaux qui sont constitués à leur tour d'un certain nombre de sous-systèmes, constitués d'un SSEP.

La Figure H.1 b) montre une mise en œuvre plus simple. Dans ce cas, le niveau du sous-système principal intermédiaire manque et le SSEP est un sous-système du SEMP lui-même.

La Figure H.1 c) illustre la mise en œuvre la plus simple d'un SEMP. Dans ce cas, le SEMP et le SSEP sont les mêmes.

La structure du SEMP est extrêmement importante pour la mise en œuvre des exigences de sécurité. Il convient de documenter une architecture du SEMP qui en décrive la structure et la relation entre chaque SSEP et le SEMP dans son ensemble. Il convient que cette architecture indique:

– la division du SEMP en composants, en particulier ceux mis en œuvre dans chaque SSEP y compris les composants logiciels;
– les fonctions que doit réaliser chaque SSEP et ses composants (y compris le cas échéant les fonctions liées à la sécurité);
– les interfaces entre les composantes logicielles;
– les interfaces entre les composantes logicielles et les composantes externes au logiciel.

H.2 Modèle de CYCLE DE DEVELOPPEMENT DE SEMP

La conformité à l'article concernant les SEMP dans la présente norme (Article 14) exige qu'un CYCLE DE DEVELOPPEMENT DE SEMP soit spécifié puis suivi; elle n'exige pas qu'un CYCLE DE DEVELOPPEMENT DE SEMP particulier soit utilisé, mais elle exige que le CYCLE DE DEVELOPPEMENT présente certains attributs. Ces exigences peuvent être trouvées en 14.4.

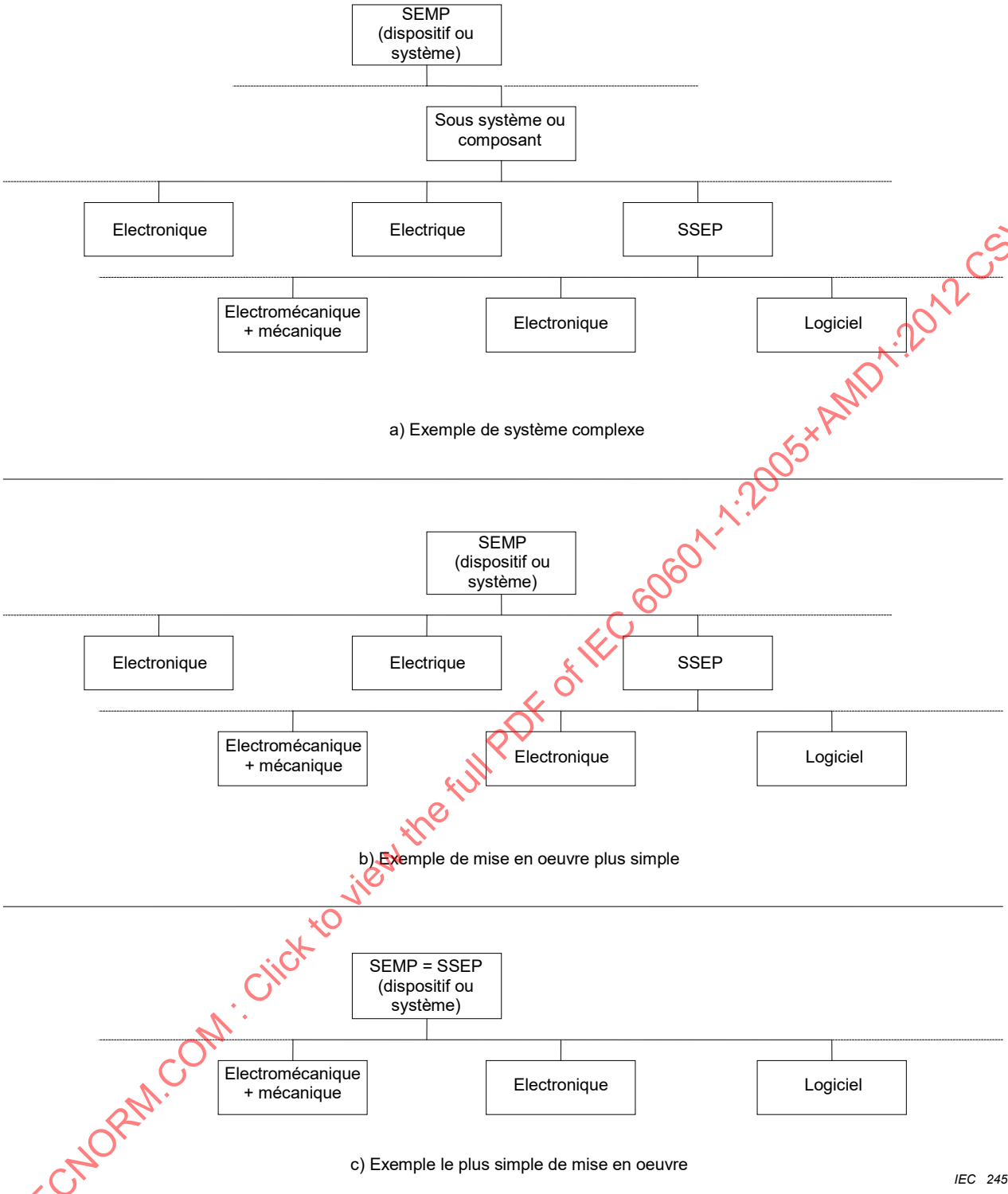
Le CYCLE DE DEVELOPPEMENT DE SEMP fait partie du cycle de vie global du produit.

La Figure H.2 présente le CYCLE DE DEVELOPPEMENT D'UN SEMP et montre les activités regroupées en deux PROCESSUS principaux. A gauche, elle donne le PROCESSUS de décomposition et à droite le PROCESSUS d'intégration.

La Figure H.2 illustre:

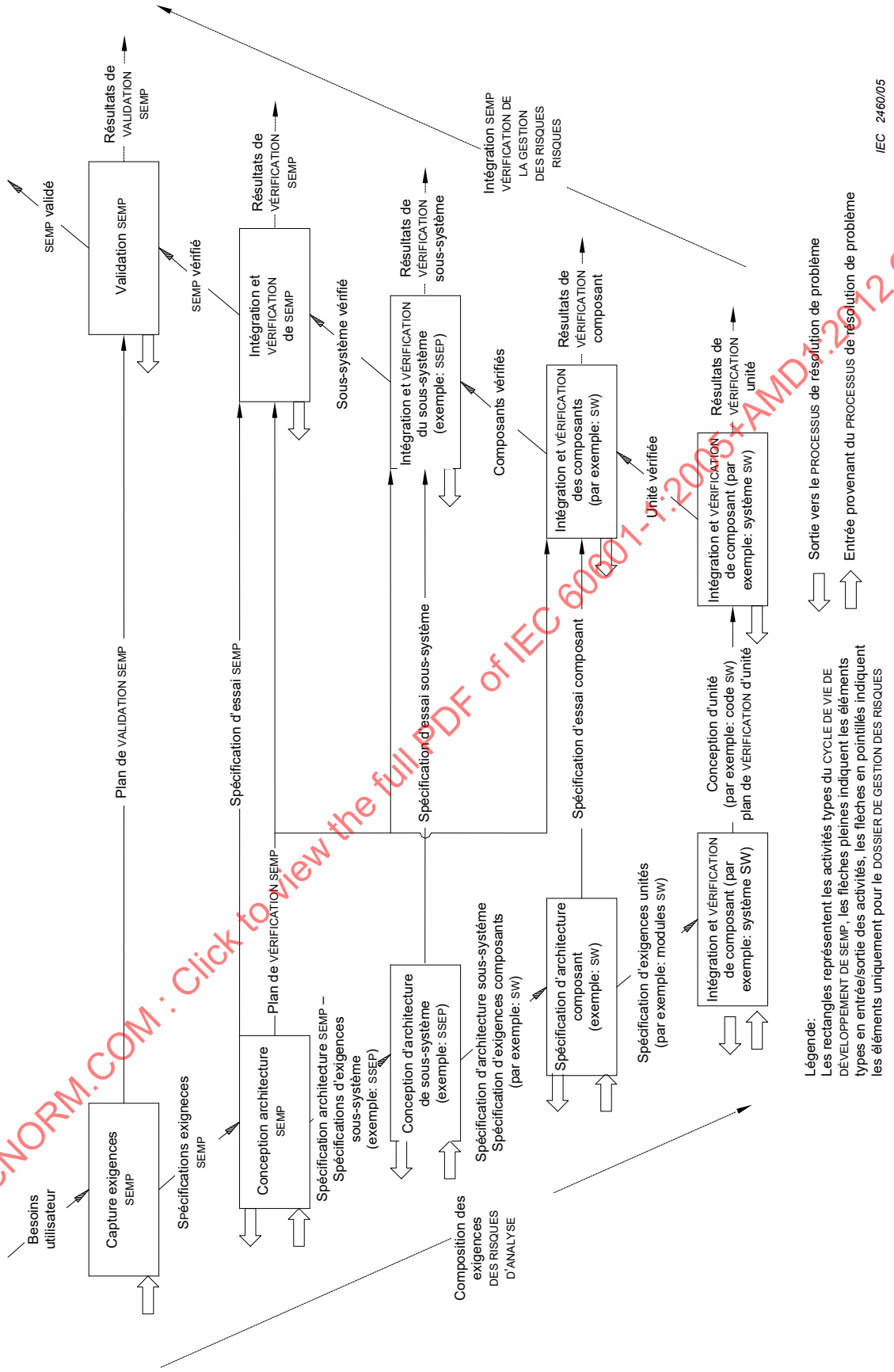
– les activités de conception par couches;
– pour chaque couche de conception, une couche correspondante d'intégration et de VERIFICATION;
– les parties vérifiées sont intégrées pour assembler la couche immédiatement supérieure;
– interactions du PROCESSUS de résolution des problèmes.

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Figure H.1 – Exemples de structures SEMP/ SSEP



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Figure H.2 – Modèle de CYCLE DE DEVELOPPEMENT DE SEMP

Les blocs fonctionnels de construction, l'architecture et la technologie sont décidés à partir de la conception qui résulte de la décomposition des exigences. Le PROCESSUS de décomposition est terminé lorsque l'information de conception permet aux composants du SEMP d'être fabriqués (parmi les exemples d'une telle information de conception, les schémas des circuits et la codification logicielle). Les composants de la décomposition sont intégrés les uns avec les autres. La VERIFICATION est effectuée lorsque les composants sont intégrés pour déterminer si l'exécution satisfait ou non aux exigences. A la fin d'un PROCESSUS d'intégration, une VALIDATION SEMP est effectuée pour déterminer si le SEMP fonctionne comme prévu ou non.

H.3 PROCESSUS logiciels

~~H.3.1 CYCLE DE DEVELOPPEMENT DE SEMP~~

~~Un CYCLE DE DEVELOPPEMENT DE SEMP, tel que celui illustré à la Figure H.3, se compose d'un certain nombre de PROCESSUS eux-mêmes composés d'activités. Chaque activité est menée pour atteindre des buts particuliers. Pour l'application de la GESTION DES RISQUES, la confiance dans les activités d'ingénierie sur lesquelles la GESTION DES RISQUES est fondée est nécessaire. En particulier, il s'agit d'une exigence pour le cycle de vie logiciel.~~

~~L'IEC 62304 [26] décrit les processus à inclure dans le cycle de vie de développement du logiciel pour le développement d'un logiciel sûr pour les appareils médicaux.~~

~~H.3.2 Spécification des exigences~~

~~Pour déterminer quelles fonctions créent ou contrôlent des RISQUES, il est nécessaire de complètement identifier les exigences des SEMP/SSER. Il est impossible de réaliser une EVALUATION DES RISQUES adéquate sans une spécification complète des exigences et une conception architecturale qui satisfait à cette spécification. Il convient que les exigences englobent, le cas échéant, le logiciel SEMP:~~

- ~~exigences fonctionnelles et de capacités, y compris de PERFORMANCES ESSENTIELLES, caractéristiques physiques et conditions d'environnement dans lequel le logiciel doit fonctionner;~~
- ~~interfaces extérieures au logiciel;~~
- ~~exigences de sécurité y compris les mesures de GESTION DES RISQUES pour les défaillances de matériel et les défauts potentiels de logiciel et spécifications liées aux méthodes de fonctionnement et de maintenance, aux influences environnementales et à la GESTION DES RISQUES;~~
- ~~signaux d'alarme, avertissements et messages OPERATEUR commandés par le logiciel;~~
- ~~exigences de sécurité, lorsque l'absence de sécurité compromettrait la sûreté;~~
- ~~les exigences d'ingénierie de facteurs humains liées à l'utilisation du SEMP, y compris celles liées au support des opérations manuelles, aux interactions homme-matériel, aux contraintes pesant sur le personnel et aux domaines exigeant une attention soutenue des personnes qui sont sensibles aux erreurs humaines et la formation;~~
- ~~définition des données et exigences de base de données;~~
- ~~exigences d'installation et d'acceptation pour le logiciel de SEMP;~~
- ~~documentation à développer;~~
- ~~exigences de fonctionnement et d'exécution;~~
- ~~exigences de maintenance.~~

~~Il convient que l'EVALUATION DES RISQUES soit utilisée pour déterminer dans quelle proportion la conception de l'architecture peut être utilisée pour réduire les RISQUES.~~

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H.3.3 Tierce partie et logiciels sur étagère

Pour avoir la capacité d'identifier les DANGERS connus ou prévisibles, il est également nécessaire de donner les caractéristiques de toute tierce partie ou de tout logiciel sur étagère utilisé dans le SEMP. Il convient que le développeur établisse des exigences logicielles pour tierce partie et logiciel sur étagère. Il convient que ces exigences comprennent les points suivants:

- titre et FABRICANT, niveau de la version, date de parution, référence de correction et désignation de mise à jour;
- le matériel et le logiciel du système nécessaires au fonctionnement correct (par exemple type et vitesse du processeur, type et taille de mémoire ainsi qu'exigences logicielles de système, de communication et d'affichage);
- interfaces avec la composante logicielle;
- fonctions de mesure de GESTION DES RISQUES et critiques pour la SECURITE dépendant de la composante logicielle.

H.3.4 Intégration

Il convient que le développeur établisse un plan d'intégration des composants de chaque SSEP et du SEMP. Il convient que ce plan inclue l'approche, les responsabilités et l'ordre suivi, et englobe toutes les composantes logicielles. Si le logiciel SSEP est construit en utilisant des méthodes d'intégration incrémentielle, il convient de réaliser des essais de régression suffisants pour s'assurer que la VERIFICATION antérieure est toujours adaptée. Il convient que les essais d'intégration incluent des cas d'essai qui exposent le comportement du logiciel non seulement en réponse au cas normal mais également en réponse aux conditions exceptionnelles, de contraintes et/ou du cas le plus défavorable.

H.3.5 Gestion de la configuration

Etant donné que l'ANALYSE DES RISQUES repose sur les exigences du logiciel, la gestion de la configuration et le contrôle des modifications sont nécessaires pour s'assurer que des fonctionnalités logicielles supplémentaires ne sont pas ajoutées au cours du développement sans être prises en compte dans le PROCESSUS de GESTION DES RISQUES. Il convient qu'un plan de gestion de la configuration soit établi et décrive:

- les éléments à contrôler;
- les activités de gestion de la configuration;
- les PROCEDURES et le programme pour conduire ces activités;
- les responsabilités pour conduire ces activités;
- les PROCEDURES pour contrôler la réception, l'installation et l'acceptation de chaque composante logicielle.

Il convient d'établir un programme pour l'identification unique des éléments de configuration logicielle et le contrôle des versions. Il convient que ce programme inclue la tierce partie et les composantes de logiciels sur étagère.

H.3.6 Contrôle de modification/de changement

Pour le contrôle des modifications/des changements, il convient de procéder comme suit:

- identification et enregistrement des demandes de changements;
- analyse et évaluation des changements;
- approbation ou refus de la demande;
- mise en œuvre, VERIFICATION et diffusion du logiciel modifié.

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~~Il convient de tenir un journal d'audit afin de pouvoir suivre toute modification, la raison de cette modification et l'autorisation de cette modification. Il convient que les ENREGISTREMENTS de cet historique des éléments contrôlés soient récupérables.~~

L'IEC 62304 décrit les processus à inclure dans le cycle de vie de développement du logiciel pour le développement d'un logiciel sûr pour les appareils médicaux.

H.4 Conception et mise en œuvre

Au cours de l'application du modèle du CYCLE DE DEVELOPPEMENT DU SEMP, la conception et la mise en œuvre englobent la sélection:

a) de l'environnement de conception, par exemple:
   - les méthodes de développement de logiciel;
   - les outils d'ingénierie logicielle assistée par ordinateur (computer aided software engineering – CASE);
   - le langage de programmation;
   - les plates-formes de développement matériel et logiciel;
   - les outils de simulation;
   - les normes de conception et de codage;

b) des composants électroniques;

c) du matériel redondant;

d) de l'interface homme-SEMP;

e) des sources d'énergie;

f) des conditions environnementales;

g) du logiciel tierce partie;

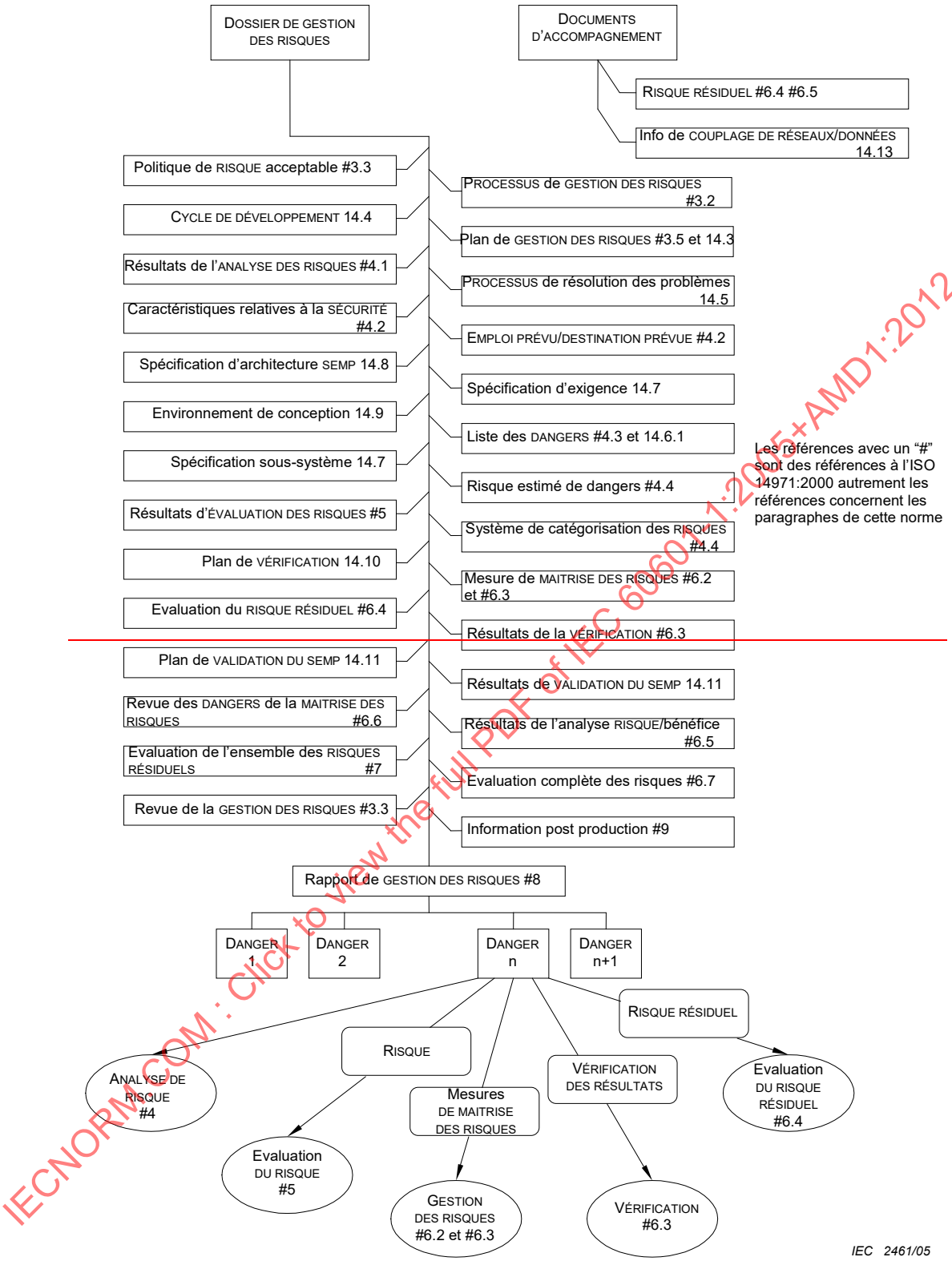
h) des options de réseaux.

Ces éléments de l'environnement de conception peuvent être caractérisés en général et spécifiquement en fonction leur utilisation dans le PROCESSUS de conception et de mise en œuvre.

H.5 Documentation

~~La Figure H.3 inclut toute la documentation exigée par l'Article 14 et l'ISO 14971:2000. Elle est destinée à représenter une structure exemple uniquement. Des références documentaires particulières peuvent être consolidées ou réparties sur plusieurs documents. Les numéros d'articles précédés de "#" sont des références aux numéros des articles dans l'ISO 14971:2000. Les autres numéros font référence aux paragraphes de la présente norme.~~
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Figure H.3 – ~~Exigences de documentation de SEMP de l'Article 14 et de l'ISO 14971:2000~~
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H.6 ~~COUPLAGE DE RESEAUX/DONNEES~~ SEMP destiné à être incorporé dans un RESEAU INFORMATIQUE

H.6.1 Généralités

Dans le contexte de la présente norme, les informations transmises ~~comme partie d'un COUPLAGE DE RESEAUX / DONNEES~~ par l'intermédiaire d'un RESEAU INFORMATIQUE sont celles que le FABRICANT a prévu comme pouvant être transmises (c'est-à-dire pas par des actions illégales ou illicites de personnes non autorisées).

~~Le COUPLAGE DE RESEAUX / DONNEES tel qu'il est utilisé dans la présente norme n'inclut pas les informations transférées par l'intermédiaire des interfaces UTILISATEUR. Le FABRICANT stipule les types d'informations possibles et leurs protocoles de transmission dans la description technique (voir 14.13).~~

H.6.2 Responsabilités d'intégration système

Les APPAREILS EM et les SYSTEMES EM sont quelquefois utilisés ensemble ~~pour créer~~ sur un ~~système~~ RESEAU INFORMATIQUE. Il est probable que cela deviendra de plus en plus fréquent avec l'utilisation croissante des ordinateurs pour analyser les données cliniques et pour contrôler les traitements.

~~Quelquefois, les APPAREILS EM auront été conçus par le FABRICANT pour travailler avec d'autres APPAREILS EM ; cependant, il se produira fréquemment le cas où des APPAREILS EM n'auront pas été conçus pour travailler ensemble. Quelqu'un doit avoir la responsabilité de s'assurer que tous les APPAREILS EM individuels travaillent ensemble de manière satisfaisante au sein d'un système intégré ; en d'autres termes, quelqu'un doit être responsable de la conception du système intégré.~~

Les APPAREILS EM seront quelquefois conçus par le FABRICANT pour fonctionner sur un RESEAU INFORMATIQUE avec d'autres APPAREILS EM. Il arrivera cependant souvent que les APPAREILS EM n'aient pas été conçus pour fonctionner avec tous les autres APPAREILS EM sur un RESEAU INFORMATIQUE. Il faut un responsable pour assurer que tous les APPAREILS EM séparés sur un réseau informatique fonctionnent ensemble correctement; en d'autres termes, il faut un responsable de la conception du RESEAU INFORMATIQUE.

Il est reconnu que l'intégrateur ~~système~~ du RESEAU INFORMATIQUE doit souvent ~~se conformer~~ satisfaire à des exigences réglementaires particulières.

Pour assurer sa fonction, l'intégrateur ~~système~~ du RESEAU INFORMATIQUE a besoin de connaître:

– de quelle manière il est prévu d'utiliser le ~~système~~ RESEAU INFORMATIQUE intégré;
– les performances exigées du ~~système~~ RESEAU INFORMATIQUE intégré;
– la configuration prévue du ~~système~~ RESEAU INFORMATIQUE;
– les contraintes de capacité d'extension ~~du système~~ du RESEAU INFORMATIQUE;
– les spécifications de tous les APPAREILS EM et des autres appareils à intégrer;
– les performances de chaque APPAREIL EM et des autres appareils; et
– le flux d'informations à l'intérieur et autour du ~~système~~ RESEAU INFORMATIQUE.

~~Ces informations ne seront pas à la disposition des FABRICANTS individuels et, pour cette raison, chaque FABRICANT individuel ne peut pas remplir le rôle d'intégrateur système. Dans tous les cas, l'intégrateur système doit être une personne ou un organisme unique qui a l'entière responsabilité, cette responsabilité entière ne peut pas être partagée entre différents FABRICANTS. La responsabilité d'un FABRICANT est limitée à la fourniture des informations demandées concernant son appareil (voir 14.13).~~

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Ces informations ne seront pas rendues disponibles aux FABRICANTS individuels et, pour cette raison, chaque FABRICANT individuel ne peut pas remplir le rôle d'intégrateur de RESEAU INFORMATIQUE. Dans tous les cas, l'intégrateur de RESEAU INFORMATIQUE doit être une seule personne ou un seul organisme en charge de la responsabilité générale. Cette responsabilité générale ne peut pas être partagée entre plusieurs FABRICANTS différents. La responsabilité d'un FABRICANT est limitée à la fourniture des informations demandées concernant ses appareils (voir 14.13).

Il est évident qu'un ORGANISME RESPONSABLE peut employer un FABRICANT pour l'intégration de son ~~système~~ RESEAU INFORMATIQUE. Dans ce cas, le ~~système~~ RESEAU INFORMATIQUE complet peut devenir un SYSTEME EM et il sera de la responsabilité du FABRICANT de fournir un système correctement intégré. Dans ce cas, le système pourrait être régulé séparément.

~~Il convient que l'intégrateur système soit compétent pour évaluer et traiter les DANGERS qui sont susceptibles d'apparaître à l'intégration d'un système et pour assurer que les RISQUES RESIDUELS du SEMP individuel sont contrôlés.~~

Il convient que l'intégrateur du RESEAU INFORMATIQUE dispose des compétences d'évaluation et de traitement des DANGERS susceptibles de se produire suite à l'intégration d'un RESEAU INFORMATIQUE et puisse assurer que les RISQUES RESIDUELS du SEMP individuel sont maintenus.

~~Normalement~~ Généralement, un intégrateur ~~système~~ de RESEAU INFORMATIQUE:

– planifie l'intégration de tout APPAREIL EM ou SYSTEME EM et des appareils non médicaux conformément aux instructions fournies par les différents FABRICANTS;
– assure la GESTION DES RISQUES sur le ~~système~~ RESEAU INFORMATIQUE intégré; et
– transmet toute instruction du FABRICANT à l'ORGANISME RESPONSABLE lorsque celle-ci est nécessaire pour le fonctionnement en toute sécurité du ~~système~~ RESEAU INFORMATIQUE intégré. Il convient que ces instructions contiennent des avertissements concernant les DANGERS de toute modification de la configuration.

H.7 ~~Considérations concernant la conception du COUPLAGE DE RESEAUX / DONNEES~~ Considérations de conception pour les RESEAUX INFORMATIQUES

H.7.1 ~~Introduction~~ Vue d'ensemble

Du point de vue d'un FABRICANT DE SEMP, tout type de ~~COUPLAGE DE RESEAUX / DONNEES~~ RESEAU INFORMATIQUE est une source de ~~causes~~ SITUATIONS DANGEREUSES supplémentaires ~~de DANGERS~~. En principe, il convient qu'un ~~COUPLAGE DE RESEAUX / DONNEES~~ RESEAU INFORMATIQUE quel qu'il soit qui est hors du contrôle du FABRICANT DE SEMP ne soit jamais présumé comme fiable à 100 %.

H.7.2 Causes ~~des DANGERS~~ de SITUATIONS DANGEREUSES associées aux ~~COUPLAGE DE RESEAUX / DONNEES~~ RESEAUX INFORMATIQUES

Dans ~~les systèmes COUPLES PAR RESEAUX / DONNEES, les causes probables de DANGERS~~ des RÉSEAUX INFORMATIQUES, les causes possibles de SITUATIONS DANGEREUSES sont les suivantes:

– perte de données;
– échange inapproprié de données;
– données corrompues;
– synchronisation inappropriée des données;
– réception inattendue de données;
– accès non autorisé aux données.

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~~En supplément à l'Annexe A de l'ISO 14971:2000 lors de l'identification des causes des DANGERS associés au COUPLAGE DE RESEAUX / DONNEES, il convient de tenir compte au moins des éléments suivants:~~

En complément à l'Annexe E de l'ISO 14971:2007, il convient d'envisager au moins les événements ou circonstances suivants comme pouvant entraîner des SITUATIONS DANGEREUSES associées aux RESEAUX INFORMATIQUES.

– entretien à distance (accès externe au réseau);
– système d'exploitation (compatibilité des systèmes d'exploitation);
– modification/mises à jours des logiciels (systèmes d'exploitation, applications, etc.);
– compatibilité d'interface (collisions de données, formats de données):
  • connexions (modification du matériel, connecteurs réseau);
  • cartes d'interface réseau (compatibilité);
  • protocoles réseau (DICOM, HL7, etc.);
– structure/synchronisation d'adresse de paquet;
– charges/largeur de bande normales de réseau;
– charge de crête de réseau;
– supports de données (longévité et caractère récupérable);
– sécurité (virus, vers, mises à jour ou mises à niveau de logiciels non autorisées);
– temps de réponse maximal acceptable;
– taux de défaillance acceptable du réseau;
– disponibilité du réseau (maintenance planifiée ou non);
– hétérogénéité dans les interfaces/formats donnant lieu à une perte de fidélité au cours du transfert d'informations;
– topologies hétérogènes de réseaux.

~~En supplément de l'Annexe D de l'ISO 14971:2000 lors de l'examen des causes potentielles de DANGERS indiquées ci-dessus, il convient de prendre en compte les questions suivantes:~~

En complément à l'Annexe C de l'ISO 14971:2007, il convient de tenir compte des questions suivantes pour identifier les caractéristiques pouvant avoir un impact sur la sécurité:

a) Mauvais usages raisonnablement prévisibles

   La connexion au réseau est-elle incohérente avec l'UTILISATION PREVUE de chaque SEMP constituant ?

b) Flux de données incorrectes vers ou provenant de chaque SEMP

   Quelle est l'utilisation des données transférées par le réseau et à quelle tâche sont-elles liées? Quelles sont les conséquences d'une panne du ~~COUPLAGE DE RESEAUX / DONNEES~~ RESEAU INFORMATIQUE?

c) Écart par rapport aux caractéristiques de fonctionnement spécifiées de tout SEMP

   Quelles sont les caractéristiques de fonctionnement du SEMP et à quel degré sont-elles affectées par le ~~COUPLAGE DE RESEAUX / DONNEES~~ RESEAU INFORMATIQUE?

d) Caractérisation incomplète des paramètres ~~de COUPLAGE DE RESEAUX / DONNEES~~ du RESEAU INFORMATIQUE

   La topologie du réseau, la configuration, les paramètres (par exemple ouvert ou fermé, la largeur de bande, le protocole de transmission) sont-ils complètement caractérisés? Existe-t-il des caractéristiques/concepts de panne et quels sont-ils?

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e) Utilisation/charge excessive du ~~COUPLAGE DE RESEAUX / DONNEES~~ RESEAU INFORMATIQUE par les nœuds réseau

Quel est le nombre planifié de nœuds réseau et leur degré d'utilisation prévu? Les ressources sont-elles suffisantes pour satisfaire les besoins à la fois du ~~COUPLAGE DE RESEAUX / DONNEES~~ RESEAU INFORMATIQUE lui-même et des dispositifs qui lui sont connectés?

f) Erreurs d'utilisation

Quelles aptitudes sont ~~demandées par~~ exigées de l'OPERATEUR pour le fonctionnement efficace du système?

g) Gestion de configuration inadéquate

Est-ce que les tâches d'entretien périodiques altèrent les caractéristiques du RESEAU INFORMATIQUE (par exemple après accès à distance, mises à jour ou mises à niveau)? L'ORGANISME RESPONSABLE assure-t-il que les modifications de chaque SEMP sont revues et approuvées?

h) Information mal placée

Les données arrivent-elles à un emplacement pratique et prévisible? Sont-elles accompagnées de données inappropriées pouvant apporter la confusion chez l'OPERATEUR ou faire de l'ombre aux données désirées? La source est-elle indiquée de manière adéquate à l'arrivée ?

H.7.3 ~~Classification réseau fondée sur la conséquence sur le PATIENT~~ Non utilisé

~~H.7.3.1 Conséquence sur le PATIENT~~

~~Pour faire la relation entre les causes de H.7.2 et les conséquences pour le PATIENT, il peut être utile de classer les COUPLAGES DE RESEAUX / DONNEES à la fois en fonction des conséquences et du temps de réaction, le temps de réaction étant le temps qui s'écoule entre une défaillance de COUPLAGE DE RESEAUX / DONNEES et le début du DOMMAGE affectant le PATIENT. Le Tableau H.1 contient un exemple de classification de COUPLAGE DE RESEAUX/ DONNEES fondé sur ces considérations.~~

~~H.7.3.2 COUPLAGE DE RESEAUX / DONNEES de classe C (données vitales PATIENT, durée critique)~~

~~Il s'agit du COUPLAGE DE RESEAUX / DONNEES pour toutes les applications/PROCESSUS pour lesquels le paramètre de temps est critique. Il n'est pas relié à un autre réseau parce qu'une liaison pourrait causer des RISQUES incontrôlables. Toutes les ressources sont uniquement disponibles pour les nœuds de ce réseau. La disponibilité doit être proche de 100 %. Les perturbations doivent être évitées et ne doivent durer que quelques minutes par an. La responsabilité est attribuée à un seul CONSTUCTEUR DE SEMP /fournisseur de système. Les nœuds de réseau sont conformes aux exigences établies par le FABRICANT/le fournisseur. Un exemple de cette classe est un réseau de surveillance du PATIENT.~~

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Tableau H.1 – ~~Classification de COUPLAGE DE RESEAUX / DONNEES~~ Non utilisé

~~Conséquence~~	~~Temps de réaction~~	~~Classe~~	~~Exemple(s)~~
~~Mort/blessure importante~~	~~Seconde(s)~~	~~C~~	~~Perfusion (boucle fermée) ; fausse commande d'un robot chirurgical~~
	~~Minute(s)~~	~~C~~	~~Transmission d'alarme supprimée~~
	~~Heure(s)~~	~~C/B~~	~~Données fausses de thérapie transmises à un appareil de ventilation~~
~~Blessure moyenne~~	~~Seconde(s)~~	~~C~~	~~Transmission erronée d'alarme, fausse commande d'un robot chirurgical~~
	~~Minute(s)~~	~~C/B~~	~~Transmission erronée d'alarme, fausse commande d'un robot chirurgical~~
	~~Heure(s)~~	~~C/B~~	~~Image dénaturée ; perte de rapport de thérapie~~
~~Blessure mineure~~	~~Seconde(s)~~	~~B~~	
	~~Minute(s)~~	~~B~~	~~Perte de radiographie~~
	~~Heure(s)~~	~~B/A~~	
~~Négligeable~~	~~Seconde(s)~~	~~A~~	
	~~Minute(s)~~	~~A~~	
	~~Heure(s)~~	~~A~~	

~~**H.7.3.3 COUPLAGE DE RESEAUX / DONNEES de classe B (données vitales PATIENT, durée non critique)**~~

~~Il s'agit du COUPLAGE DE RESEAUX / DONNEES pour des applications/des PROCESSUS pour lesquels le paramètre de temps n'est pas critique qui traitent les données thérapeutiques ou de diagnostic du PATIENT. Ce COUPLAGE DE RESEAUX / DONNEES peut être relié à un autre par une interface définie et contrôlable / sécurisée. La disponibilité doit être très élevée, et, compte tenu d'un manque d'alternatives, il convient que les perturbations ne durent que peu de temps.~~

- ~~La responsabilité est attribuée à l'ORGANISME RESPONSABLE ou à l'intégrateur de système. Lorsqu'il y a plusieurs SEMP, la gestion de priorité des données doit être définie.~~
- ~~Il convient que les nœuds de réseau respectent des critères choisis/un ensemble minimal de paramètres. Un réseau de radiologie peut servir d'exemple.~~

~~**H.7.3.4 COUPLAGE DE RESEAUX / DONNEES de classe A**~~

~~Il s'agit du COUPLAGE DE RESEAUX/ DONNEES pour toute application (y compris les données administratives PATIENT et les données démographiques), qui fonctionne sur des données PATIENT validées uniquement et qui ne sont pas attribuées aux réseaux de classe "C" ou "B". Il peut également être accepté que ces applications ne soient pas disponibles pendant une période assez longue parce qu'il existe des alternatives. On peut donner comme exemple un réseau d'administration générale d'un hôpital pour lequel~~

- ~~la responsabilité est attribuée à l'ORGANISME RESPONSABLE;~~
- ~~il existe de nombreux types de nœuds de réseaux.~~

H.7.4 Paramètres ~~de COUPLAGE DE RESEAUX / DONNEES~~ du RÉSEAU INFORMATIQUE

L'utilisation d'un ~~COUPLAGE DE RESEAUX / DONNEES pour l'échange~~ RESEAU INFORMATIQUE pour échanger des données soit entre des SEMP, soit entre un SEMP et ~~un~~ d'autres appareils ~~des Technologies de l'Information (TI) exige~~ de traitement de l'information, nécessite la connaissance ~~à la fois~~ de la structure du ~~COUPLAGE DE RESEAUX / DONNEES~~ RESEAU INFORMATIQUE et des PROCESSUS/fonctions exécutés à l'intérieur. Cela est important car il

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convient que les FABRICANTS de SEMP ou de ~~COUPLAGES DE RESEAUX / DONNEES~~ RESEAUX INFORMATIQUES choisissent la configuration de leurs produits de telle manière que:

– ceux-ci ~~soient conformes~~ satisfassent aux normes réseau reconnues au niveau international (Ethernet, Fast Ethernet, GigaBitEthernet, FDDI, etc.) et qu'ils utilisent la largeur de bande disponible de manière appropriée en fonction de l'UTILISATION PREVUE;

– ils atteignent les performances optimales pour leur application.

Il peut se produire un mélange de différentes configurations de ~~COUPLAGES DE RESEAUX / DONNEES~~ RESEAUX INFORMATIQUES et de réglages de paramètres qui ne sont pas toujours compatibles pour les différents nœuds de ~~COUPLAGES DE RESEAUX / DONNEES~~ RESEAUX INFORMATIQUES, bien ~~qu'ils soient conformes~~ qu'ils satisfassent à des normes internationales valables.

Pour éviter ou tout au moins minimiser les perturbations potentielles qui en résulteraient, une adéquation d'un ensemble minimal de paramètres de ~~COUPLAGES DE RESEAUX / DONNEES~~ RESEAU INFORMATIQUE pris dans les normes applicables est exigée.

~~Pour assurer une installation fiable des SEMP A COUPLAGE DE RESEAUX / DONNEES et réduire les RISQUES encourus par les PATIENTS, le FABRICANT DES SEMP, l'ORGANISME RESPONSABLE et l'intégrateur système doivent communiquer les uns aux autres tous les paramètres techniques utiles. Ce niveau de détail est nécessaire pour éviter des hypothèses inappropriées donnant lieu à un RISQUE inacceptable.~~

La Figure H.4 contient une liste de paramètres dont la spécification peut être exigée. Compte tenu de l'évolution rapide de la technologie dans le domaine des ~~COUPLAGES de RESEAUX / DONNEES~~ RESEAUX INFORMATIQUES, il convient de prendre ce tableau comme un point de départ. Il convient d'établir si le tableau doit être mis à jour et par quel responsable.

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Objets	Description		Valeur/commentaires
Application et Système d'exploitation :			
Système d'exploitation / Version :			
Protocoles réseau :			
Données détaillées pour application spécifique / protocole de transport (le cas échéant)			
HL7	Version HL 7		
	Formats des types de messages utilisés		
	Champs libres (qui sont utilisés)		
	Accès		
	Protocole HL7 (Couche basse TCP/IP)		
Classes de service DICOM	**A) Essai :**	Vérification	
	B) Transfert :	Stockage	
		Requête/Récupération	
	C) Documentation :	Gestion d'impression	
	D) Organisation :	Gestion de liste de modalité	
		Etape de procédure réalisée	
	E) Information :	Notification de contenu d'étude	
		Gestion patient	
		Engagement de stockage	
		Gestion de composants d'étude	
		Gestion des résultats	
	F) Stockage externe :	Stockage de media	
Objets DICOM	Exemple : IMAGE RADIOGRAPHIQUE PAR ORDINATEUR		
	Autres objets de modalité		
Nom d'hôte DICOM			
DICOM AET appelé			
DICOM AET appelant			
Accès DICOM appelé			
Accès DICOM appelant			
Paramètres détaillés concernant les couches basses de protocole			
Données réseau	**Connexion physique**		
	Paramètres de carte d'interface réseau		
Administration réseau			
Numéro de l'accès du commutateur connecté / concentrateur / Routeur			
Adresse IP			
Masque de sous réseau			
Nom d'hôte			
Domaine IT			
Répertoire actif / Serveur LDAP			
Passerelle par défaut (Accès par routeur)			
Commande à distance			
Surveillance à distance			
Connexion modem			
Adresse IP de service à distance			
Autres paramètres			

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Figure H.4 – Exemple de paramètres potentiels dont la spécification peut être exigée pour ~~le COUPLAGE DE RESEAUX/DONNEES~~ un RESEAU INFORMATIQUE

Annexe I
(informative)

Aspects des SYSTEMES EM

I.1 Combinaisons d'APPAREILS EM et d'APPAREILS non EM

I.1.1 Introduction

La présente annexe donne un résumé des situations pouvant survenir lorsque différentes combinaisons d'appareils sont utilisées dans des environnements médicaux différents. Afin que ce résumé reste dans des limites raisonnables, seulement deux appareils (A et B) sont utilisés par situation.

I.1.2 Localisation dans un environnement médical

Les localisations suivantes sont prévues (voir également Tableau I.1):

– l'ENVIRONNEMENT DU PATIENT faisant partie d'un local à usage médical;

– un local à usage médical, non compris l'ENVIRONNEMENT DU PATIENT;

– le local à usage non médical (une pièce non destinée au traitement médical, par exemple un bureau ou un local de stockage).

Une terre de protection peut être attribuée à chacune des trois localisations données ci-dessus.

NOTE Une différence de potentiels (*V*) peut exister entre les bornes de terre de protection de différentes localisations. En cas de connexion de terre de protection ouverte (condition de défaut) pour un appareil dans l'ENVIRONNEMENT DU PATIENT, cette différence de potentiel peut apparaître sur l'ENVELOPPE de l'appareil, ce qui ~~crée~~ entraine une ~~DANGER~~ SITUATION DANGEREUSE pour l'OPERATEUR ou pour le PATIENT si l'OPERATEUR touche en même temps l'APPAREIL EM et le PATIENT, ou pour le PATIENT si ~~l'appareil~~ la PARTIE APPLIQUEE est de TYPE B.

I.1.3 Principes de base

– Il convient que les PATIENTS soient reliés uniquement à des PARTIES APPLIQUEES d'APPAREIL qui sont en conformité avec la présente norme. Il convient que les autres appareils soient conformes aux normes IEC ou ISO qui leur sont spécifiques.

– En condition de défaut, le COURANT DE CONTACT est de 500 µA.

– Tous les appareils conformes à la norme de sécurité applicable à l'utilisation, non médicale, qui en est prévue au départ, appelée ici IEC XXXXX, et qui sont installés dans l'ENVIRONNEMENT DU PATIENT requièrent des mesures pour limiter le COURANT DE CONTACT, si ce dernier dépasse les valeurs spécifiées en 16.6.1.

I.1.4 Exemples de SYSTEMES EM

Deux appareils sont installés dans l'ENVIRONNEMENT DU PATIENT (voir situation n° 1 au Tableau I.1).

Il y a plusieurs possibilités, désignées par 1a à 1f:

1a : Les deux appareils A et B sont conformes à l'IEC 60601: Le Paragraphe 16.6 est satisfait.

1b : Les appareils A et B sont tous les deux conformes à l'IEC 60601-1 et ils sont alimentés par un SOCLE DE PRISES MULTIPLES: les COURANTS DE FUITE pourraient être trop élevés lorsque le conducteur de terre du SOCLE DE PRISES MULTIPLES est rompu.

1c : L'appareil A est conforme à l'IEC 60601 et l'appareil B est conforme à l'IEC XXXXX : seul le COURANT DE CONTACT de l'appareil B doit être limité, lorsqu'un seul CONDUCTEUR

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DE TERRE DE PROTECTION ou un conducteur équivalent de l'équipement est interrompu, si nécessaire, en ajoutant une terre de protection supplémentaire ou un transformateur de séparation à l'appareil B.

1d : Même chose qu'en 1c, avec les deux appareils alimentés par l'intermédiaires du SOCLE DE PRISES MULTIPLES, les COURANTS DE FUITE pourraient être trop élevés pour des raisons telles que celles indiquées en 1b et 1c.

1e : L'appareil A est alimenté par une alimentation spécifiée de l'appareil B, l'appareil A étant conforme à l'IEC 60601-1 et constituant une partie intégrée dans l'appareil B conforme à l'IEC XXXXX. L'appareil B requiert des mesures pour une alimentation spécifiée, comme décrit par le FABRICANT et doit répondre aux exigences de 16.3. Si nécessaire, appliquer une terre de protection supplémentaire ou un transformateur de séparation à l'appareil B.

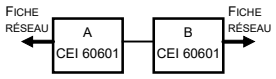
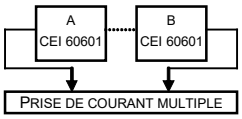
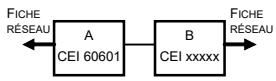
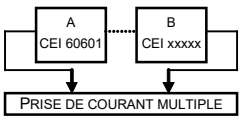
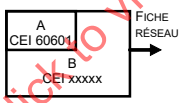
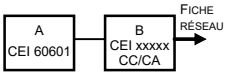
1f : Comme 1e, l'appareil A n'étant pas une partie intégré dans l'appareil B: voir 1e.

Les situations 2 et 3 peuvent être obtenues à partir de la situation 1 du Tableau I.1.

NOTE Les moyens pratiques de conformité indiqués au Tableau I.1 ne sont pas destinés à constituer une liste exhaustive.

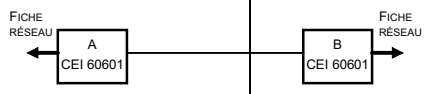
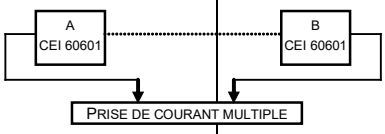
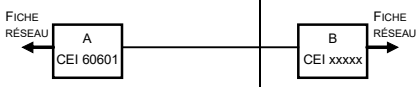
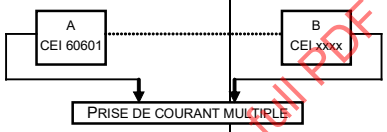
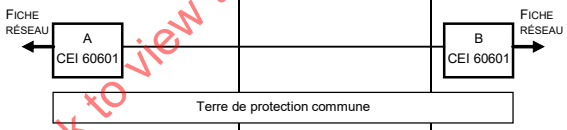
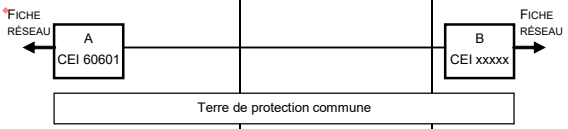
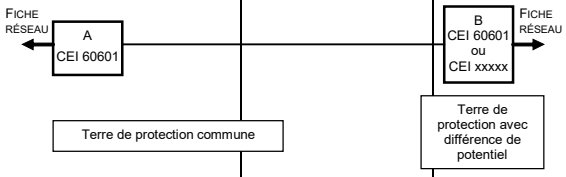
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Tableau I.1 – Exemples de SYSTEMES EM pour illustration

Situation n°		Local à usage médical		Local à usage non médical	Exemples de causes possibles de dépassement des limites de COURANT DE FUITE	Moyen pratique de conformité Appliquer 16.5 dans toutes les situations
		A l'intérieur de l'ENVIRONNEMENT PATIENT	A l'extérieur de l'ENVIRONNEMENT PATIENT			
1	**1a** A et B sont des APPAREILS EM				De multiples PARTIES APPLIQUEES du même type peuvent causer le dépassement des limites par le COURANT DE FUITE PATIENT total. [272] Voir Note 1.	– Vérifier le COURANT DE FUITE PATIENT total
	1b A et B sont des APPAREILS EM alimentés par un SOCLE DE PRISE DE COURANT MULTIPLE				Le conducteur de terre du SOCLE DE PRISE DE COURANT MULTIPLE est cassé. Voir aussi 1a.	– CONNEXION DE TERRE DE PROTECTION supplémentaire (pour A ou B) ou, – Transformateur de séparation
	1c A est un APPAREIL EM et B est un APPAREIL NON EM				En raison du COURANT DE CONTACT élevé de B	– CONNEXION DE TERRE DE PROTECTION supplémentaire (pour B) ou, – Transformateur de séparation (pour B)
	1d A est un APPAREIL EM et B un APPAREIL NON EM alimentés par un SOCLE DE PRISE S MULTIPLES				Le conducteur de terre du SOCLE DE PRISE DE COURANT MULTIPLE est cassé ou, En raison du COURANT DE CONTACT élevé de B	– CONNEXION DE TERRE DE PROTECTION supplémentaire (pour A ou B) ou, – Transformateur de séparation
	1e A est un APPAREIL EM alimenté par une alimentation spécifiée située dans B				En raison du COURANT DE CONTACT élevé de B	– CONNEXION DE TERRE DE PROTECTION supplémentaire (pour B) ou, – Transformateur de séparation (pour B)
	1f A est un APPAREIL EM alimenté par l'alimentation d'un APPAREIL NON EM dans B					

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Tableau I.1 *(suite)*

Situation n°		Local à usage médical		Local à usage médical	Exemples de causes possibles de dépassement des limites de COURANT DE FUITE	Moyen pratique de conformité Appliquer 0 dans toutes les situations
		A l'intérieur de l'ENVIRONNEMENT PATIENT	A l'extérieur de l'ENVIRONNEMENT PATIENT			
2	**2a** A et B sont des APPAREILS EM				Pas de causes de dépassement du COURANT DE FUITE	– Aucune autre mesure n'est nécessaire
	2b A et B sont des APPAREILS EM alimentés par un SOCLE DE PRISE DE COURANT MULTIPLE				Le conducteur de terre du SOCLE DE PRISE DE COURANT MULTIPLE est cassé	– CONNEXION DE TERRE DE PROTECTION supplémentaire (pour A ou B) ou, – Transformateur de séparation
	2c A est un APPAREIL EM B est un APPAREIL NON EM				En raison du COURANT DE CONTACT élevé de B Voir justification pour 16.5.	– Ne pas utiliser de boîtier de connecteur métallique ou, – DISPOSITIF DE SEPARATION
	2d A est un APPAREIL EM et B un APPAREIL NON EM alimentés par un SOCLE DE PRISE S MULTIPLES				Le conducteur de terre du SOCLE DE PRISE DE COURANT MULTIPLE est cassé	– CONNEXION DE TERRE DE PROTECTION supplémentaire (pour A ou B) ou, – Transformateur de séparation
3	**3a** A et B sont des APPAREILS EM				Pas de causes de dépassement du COURANT DE FUITE	– Aucune autre mesure n'est nécessaire
	3b A est un APPAREIL EM B est un APPAREIL NON EM				En raison du COURANT DE CONTACT élevé de B Voir justification pour 16.5.	– Ne pas utiliser de boîtier de conducteur métallique pour PARTIE ENTREE/SORTIE DE SIGNAL ou, – DISPOSITIF DE SEPARATION
	3c A est un APPAREIL EM et B un est ou non un appareil EM				*a)* Différence de potentiel entre LES CONNEXIONS DE TERRE DE PROTECTION de A et B b) En raison du COURANT DE CONTACT élevé de B Voir justification pour 16.5.	– CONNEXION DE TERRE DE PROTECTION supplémentaire (pour A) ou, – DISPOSITIF DE SEPARATION, ou – Ne pas utiliser de boîtier de connecteur métallique dans l'environnement du PATIENT

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Tableau I.1 *(suite)*

NOTE 1 Aucune cause de dépassement des limites du COURANT DE CONTACT ou du COURANT DE FUITE A LA TERRE.
NOTE 2 IEC 60601 : APPAREILS ELECTROMEDICAUX conformes à l'IEC 60601.
NOTE 3 IEC xxxxx : appareil non médical conforme aux normes de sécurité IEC applicables.
NOTE 4 Transformateur de séparation : voir 16.9.2.1.
NOTE 5 Si l'appareil "B" est à l'extérieur de l'ENVIRONNEMENT PATIENT et si l'appareil "A" est un appareil de la CLASSE II et possède des parties conductrices accessibles connectées à la CONNEXION DE TERRE DE PROTECTION de l'appareil "B", alors des mesures supplémentaires de sécurité pourraient être nécessaires, par exemple : terre de protection supplémentaire pour "B" ou transformateur de séparation ou DISPOSITIF DE SEPARATION.

I.2 Exemples d'application de socles de prises multiples (SPM)

La Figure I.1 montre un exemple de construction de SOCLE DE PRISES MULTIPLES. La Figure I.2 montre des exemples d'application de SOCLES DE PRISES MULTIPLES.

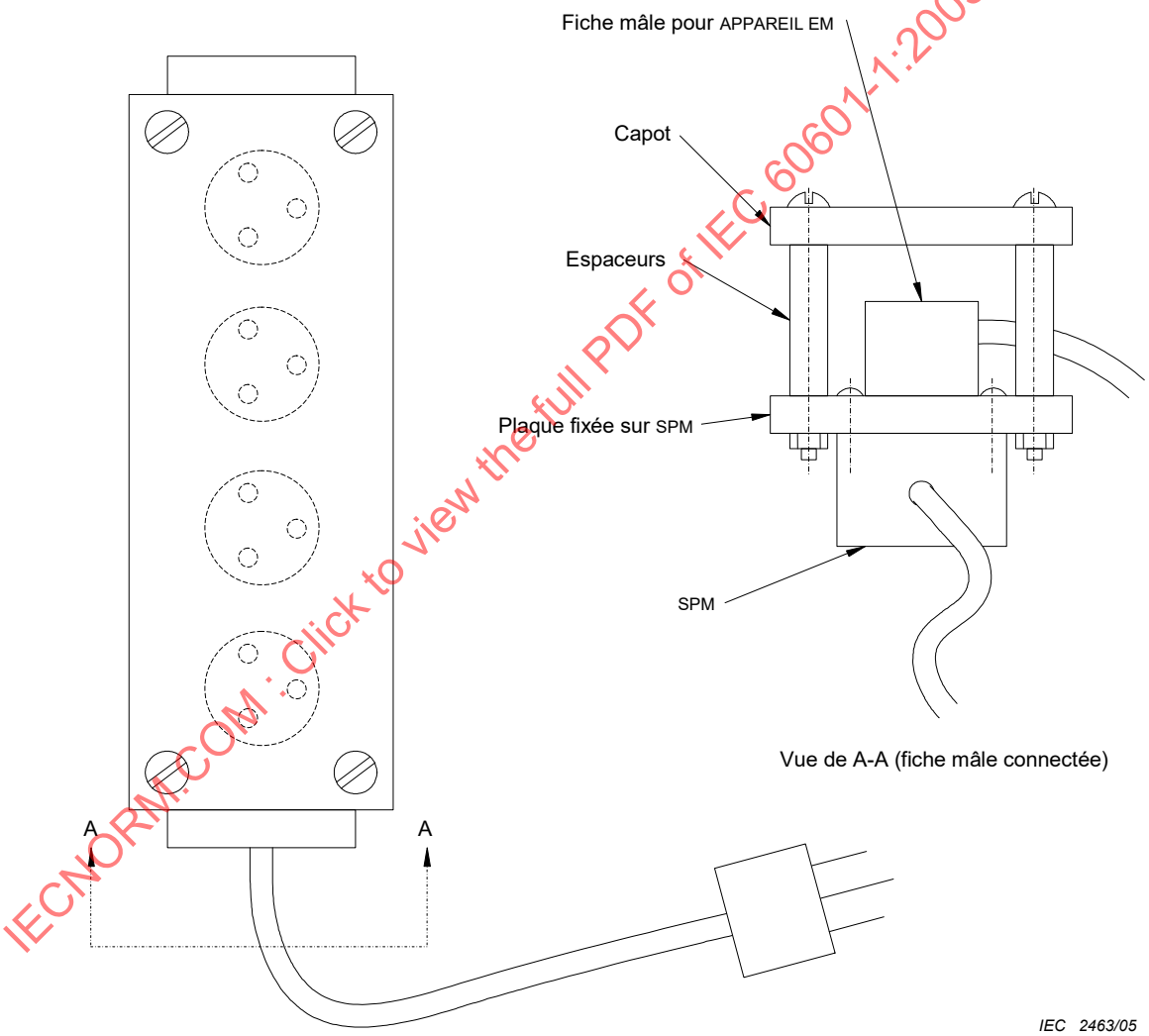


Figure I.1 – Exemple de construction de SOCLE DE PRISES MULTIPLES (SPM) (accessible uniquement à l'aide d'un outil)

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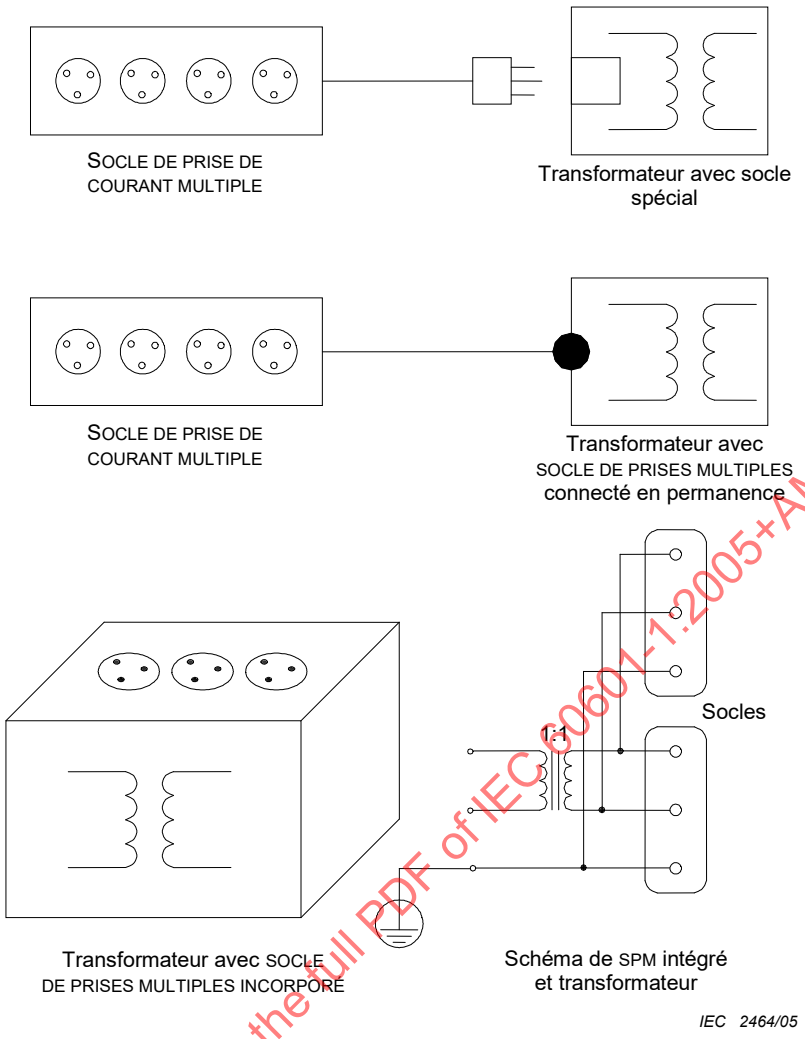


Figure I.2 – Exemples d'application de SOCLES DE PRISES MULTIPLES (SPM)

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Annexe J
(informative)

Etude des chemins d'isolation

(voir 8.5.1)

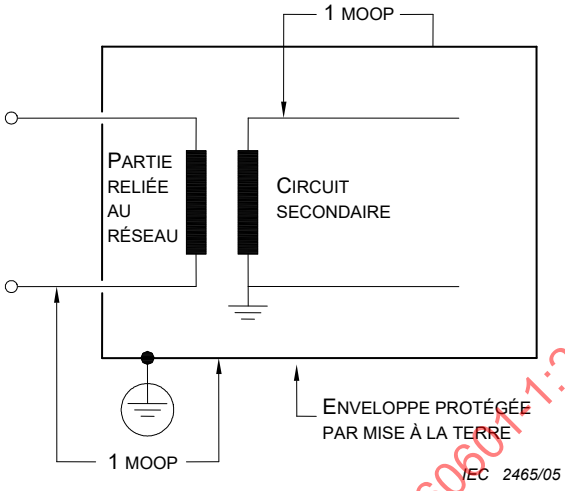


Figure J.1 – Isolation, exemple 1

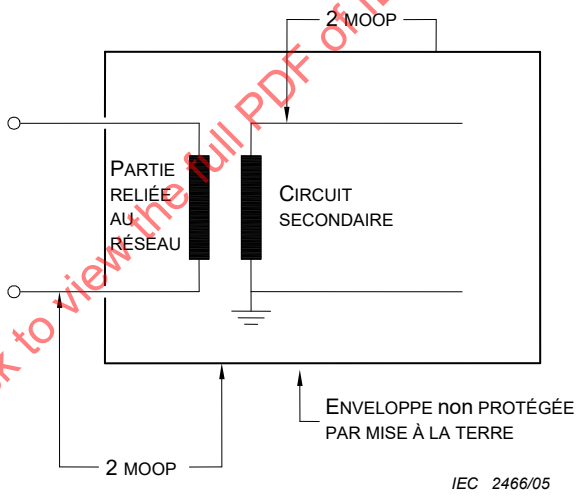


Figure J.2 – Isolation, exemple 2

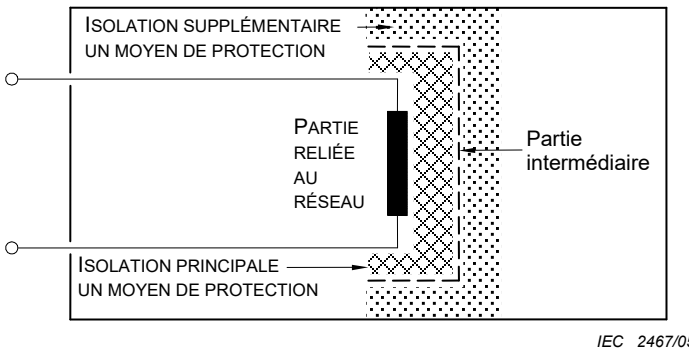


Figure J.3 – Isolation, exemple 3

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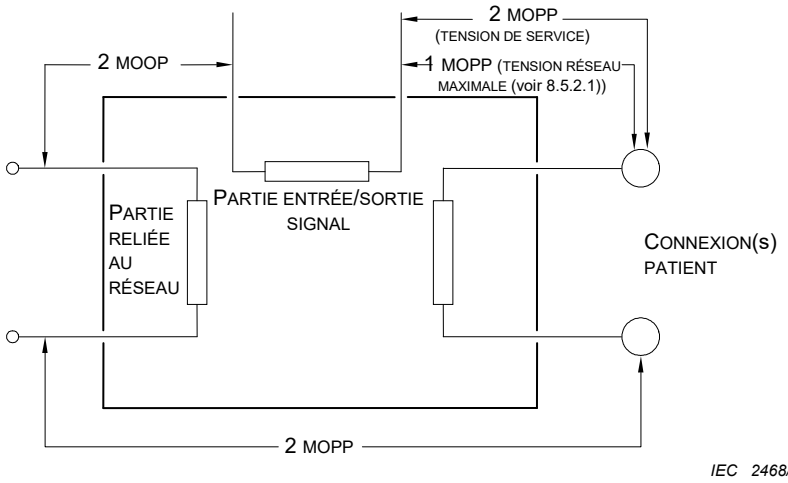


Figure J.4 – Isolation, exemple 4

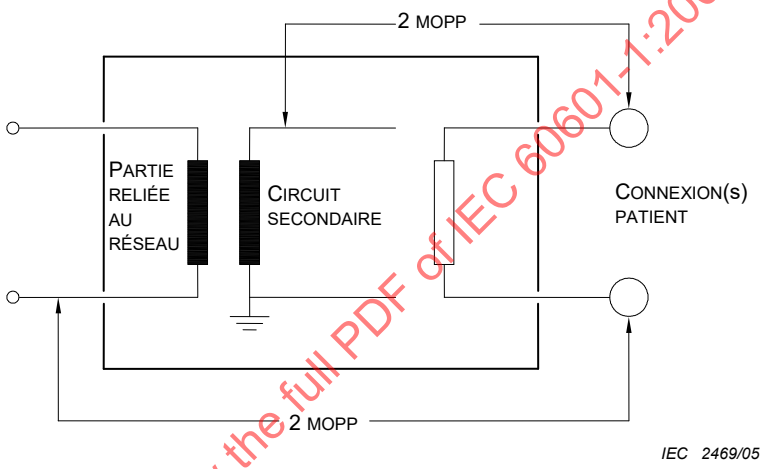


Figure J.5 – Isolation, exemple 5

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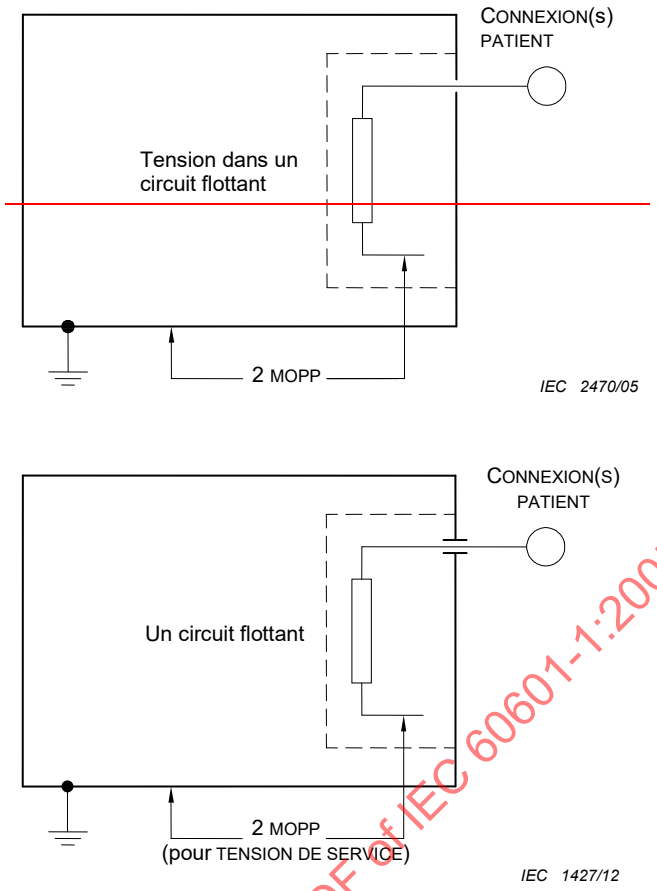
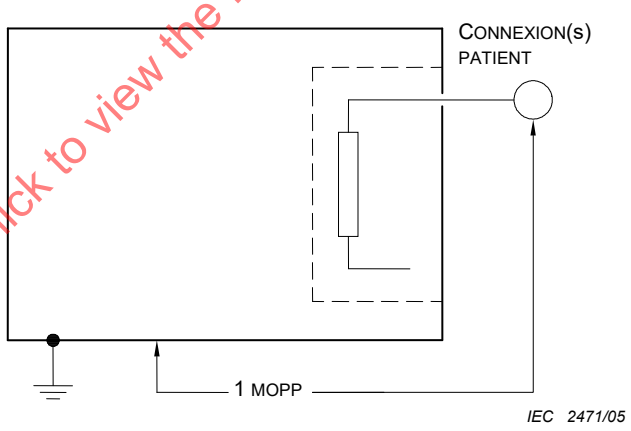


Figure J.6 – Isolation, exemple 6



NOTE La TENSION DE SERVICE est la TENSION RESEAU MAXIMALE.

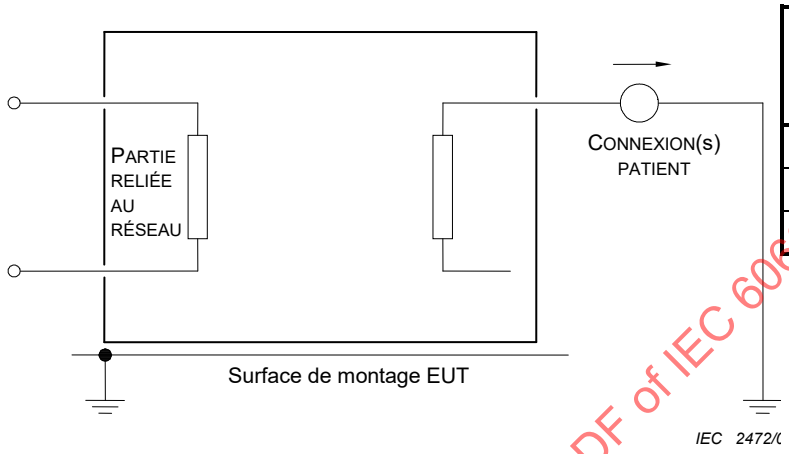
Figure J.7 – Isolation, exemple 7

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Annexe K
(informative)

Schémas simplifiés de COURANT DE FUITE PATIENT

La Figure K.2, la Figure K.4 et la Figure K.5 illustrent une condition d'essai particulière du Tableau 4, qui n'est pas une CONDITION NORMALE ni une CONDITION DE PREMIER DEFAUT.

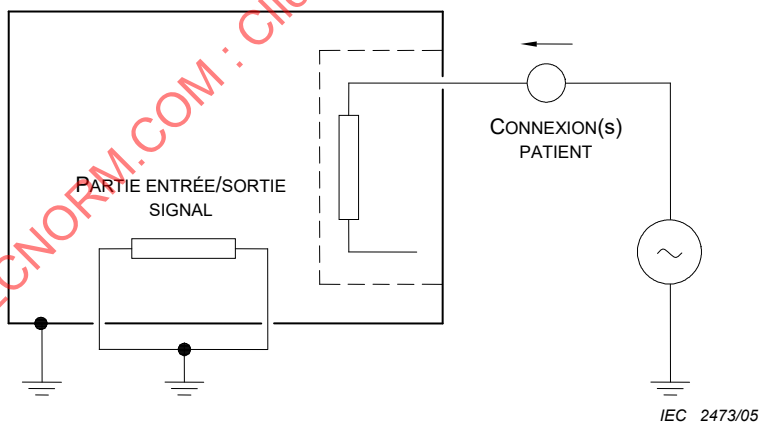


Courant en µA

TYPE DE PARTIE APPLIQUEE	CONDITION NORMALE	CONDITION DE PREMIER DEFAUT
CF	10	50
BF	100	500
B	100	500

Exemple de circuit d'alimentation de mesure de la Figure F.1

Figure K.1 – APPAREIL EM avec ENVELOPPE en matière isolante
(Figure 15 simplifiée)
(voir 8.7.4.7 a))



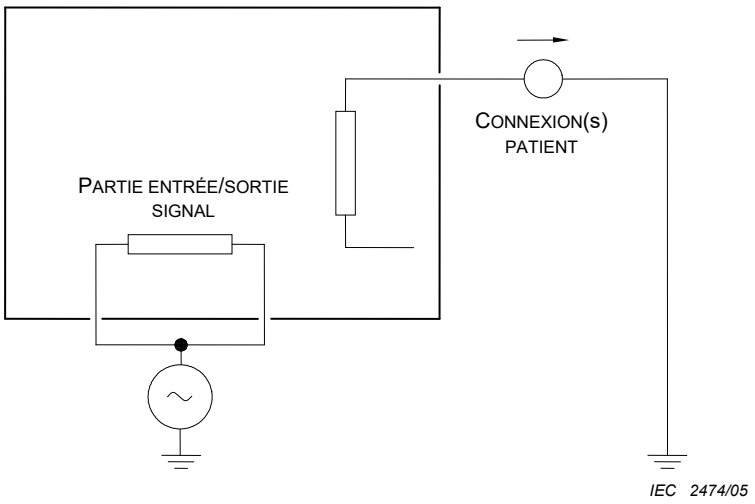
Courant en µA

TYPE DE PARTIE APPLIQUEE	Condition d'essai particulière
CF	50
BF	5 000
B	—

Exemple de circuit d'alimentation de mesure de la Figure F.1

Figure K.2 – APPAREIL EM avec PARTIE APPLIQUEE DE TYPE F
(Figure 16 simplifiée)
(voir 8.7.4.7 b))

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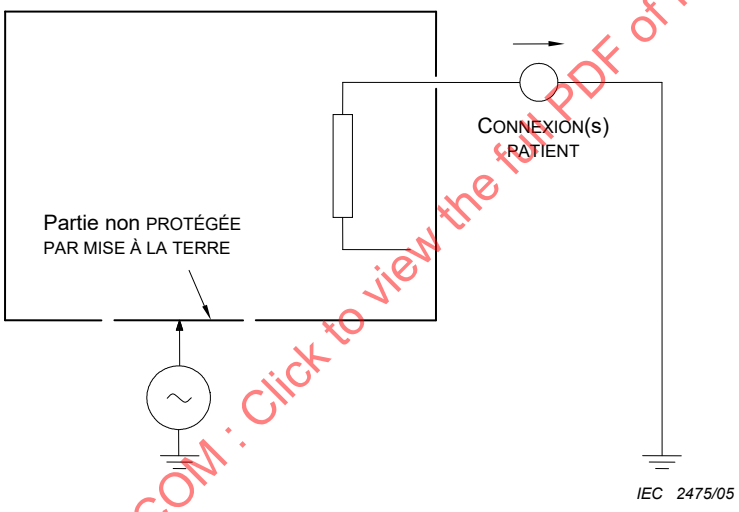


Courant en µA

TYPE DE PARTIE APPLIQUEE	CONDITION NORMALE	CONDITION DE PREMIER DEFAUT
CF	10	50
BF	100	500
B	100	500

Exemple de circuit d'alimentation de mesure de la Figure F.1

Figure K.3 – APPAREIL EM avec une PARTIE APPLIQUEE et une PARTIE E/S DE SIGNAL
(Figure 17 simplifiée)
(voir 8.7.4.7 c))



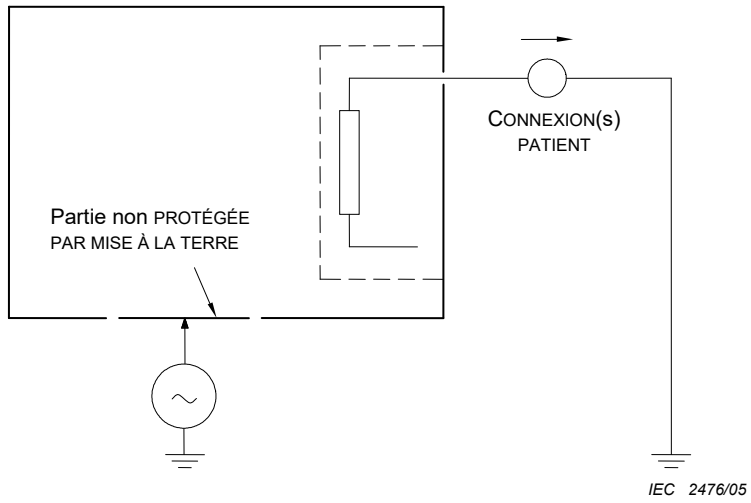
Courant en µA

TYPE DE PARTIE APPLIQUEE	Condition d'essai particulière
CF	—
BF	—
B	500

Exemple de circuit d'alimentation de mesure de la Figure F.1

Figure K.4 – APPAREIL EM avec une CONNEXION PATIENT d'une PARTIE APPLIQUEE DE TYPE B qui n'est pas PROTEGEE PAR MISE A LA TERRE
(Figure 18 simplifiée)
(voir 8.7.4.7 d))

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Courant en µA

TYPE DE PARTIE APPLIQUEE	Condition d'essai particulière
CF	—
BF	500
B	—

Exemple de circuit d'alimentation de mesure de la Figure F.1

Figure K.5 – APPAREIL EM avec une CONNEXION PATIENT d'une PARTIE APPLIQUEE DE TYPE BF qui n'est pas PROTEGEE PAR MISE A LA TERRE
(Figure 18 simplifiée)
(voir 8.7.4.7 d))

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Annexe L
(normative)

Fils de bobinage isolés pour utilisation sans isolation intercalée
(voir 8.8.2)

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L.1 Introduction

Cette annexe spécifie le fil de bobinage dont l'isolation peut être utilisée pour assurer l'ISOLATION PRINCIPALE, l'ISOLATION SUPPLEMENTAIRE, la DOUBLE ISOLATION ou l'ISOLATION RENFORCEE des composants enroulés sans isolation intercalée.

Cette annexe couvre les fils de bobinage ronds dont le diamètre est compris entre 0,05 mm et 5,00 mm.

L.2 Construction du fil

Si le fil est isolé par deux ou plus de deux couches de ruban enroulé en spirale, le chevauchement des couches doit être adapté pour assurer un chevauchement continu au cours de la construction du composant enroulé. Les couches d'isolation de fil enroulées en spirale doivent être suffisamment fixées pour maintenir la proportion du chevauchement.

L.3 ESSAI DE TYPE

Le fil doit subir avec succès les essais de L.3.1 à L.3.4 qui sont réalisés à une température comprise entre 15 °C et 35 °C et à une humidité relative comprise entre 45 % et 75 %, sauf spécification contraire.

L.3.1 Tension de tenue

Le spécimen est préparé conformément à 4.4.1 de l'IEC 60851-5:~~1996~~ 2008 (pour une paire torsadée). Le spécimen est ensuite soumis à l'essai de 8.8.3 pour le type et le nombre appropriés de MOPS. La tension d'essai est au moins le double de la tension appropriée au Tableau 6 et au Tableau 7 (voir 8.8.3), avec un minimum de:

– *3 000 V pour l'ISOLATION PRINCIPALE ou l'ISOLATION SUPPLEMENTAIRE; ou*

– *6 000 V pour l' ISOLATION RENFORCEE.*

L.3.2 Flexibilité et adhérence

Le spécimen est soumis à l'essai 8 de 5.1.1 de l'IEC 60851-3:~~1996~~ 2009, en utilisant les diamètres de mandrin du Tableau L.1. Le spécimen est ensuite examiné conformément à 5.11.4 de l'IEC 60851-3:~~1997~~ 2009, suivi de l'essai de 8.8.3, pour le type et le nombre appropriés de MOPS, sauf que la tension d'essai est appliquée entre le fil et le mandrin. La tension d'essai est au moins la tension appropriée indiquée au Tableau 6 et au Tableau 7 (voir 8.8.3), avec un minimum de:

– *1 500 V pour l'ISOLATION PRINCIPALE ou l'ISOLATION SUPPLEMENTAIRE; ou*

– *3 000 V pour l' ISOLATION RENFORCEE.*

Tableau L.1 – Diamètre du mandrin

Diamètre NOMINAL du conducteur mm	Diamètre du mandrin mm ± 0,2 mm
0,05 – 0,34	4,0
0,35 – 0,49	6,0
0,50 – 0,74	8,0
0,75 – 2,49	10,0
2,50 – 5,00	quatre fois le diamètre du conducteur [a)]
[a)] Conformément à l'IEC 60317-43 [9].	

La tension mécanique à appliquer au fil au cours de l'enroulement sur le mandrin est calculée à partir du diamètre du fil et est équivalente à 118 MPa ± 11,8 MPa (118 N/mm² ± 11,8 N/mm²).

L.3.3 Choc thermique

Le spécimen est soumis à l'essai 9 de l'IEC 60851-6:1996, suivi par l'essai de tension de tenue de 8.8.3 pour le type et le nombre appropriés de MOPs avec la particularité que la tension d'essai est appliquée entre le fil et le mandrin. La tension n'est pas inférieure à la tension appropriée du Tableau 6 et du Tableau 7 (voir 8.8.3), avec un minimum de:

– *1 500 V pour l'ISOLATION PRINCIPALE ou l'ISOLATION SUPPLEMENTAIRE; ou*

– *3 000 V pour l'ISOLATION RENFORCEE.*

La température du four est la température appropriée à la classe thermique de l'isolation du Tableau L.2.

Le diamètre du mandrin et la tension mécanique appliquée au fil au cours de l'enroulement sur le mandrin sont ceux donnés en L.3.2.

L'essai de tension de tenue est réalisé à température ambiante après retrait du four.

Tableau L.2 – Température du four

Classe thermique	A (105)	E (120)	B (130)	F (155)	H (180)
Température du four °C ± 5 °C	200	215	225	240	260

L.3.4 Maintien de la tension de tenue après pliage

Cinq spécimens sont préparés comme indiqué en L.3.2 ci-dessus et soumis aux essais comme suit : chaque spécimen est retiré du mandrin, placé dans un conteneur et positionné de façon à pouvoir être entouré par au moins 5 mm de grenaille. Les extrémités du conducteur dans le spécimen sont d'une longueur suffisante pour éviter tout contournement. La grenaille n'a pas un diamètre supérieur à 2 mm de diamètre et doit être formée de billes d'acier inoxydable, de nickel ou de fer plaqué au nickel. La grenaille est versée doucement dans le conteneur jusqu'à ce que le spécimen en essai soit recouvert par au moins 5 mm. La grenaille est nettoyée périodiquement avec un solvant adapté (par exemple, trichloroéthane 1,1,1).

NOTE La PROCEDURE d'essai ci-dessus est tirée de 4.6.1.c) de l'IEC 60851-5:1988 (deuxième édition y compris l'amendement 1), qui est maintenant annulée. Elle n'est pas incluse dans la ~~troisième~~ quatrième édition de la dite norme.

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La tension d'essai est au moins la tension d'essai appropriée du Tableau 6 et du Tableau 7 (voir 8.8.3) pour le type et le nombre appropriés de MOPs , avec un minimum de:

– *1 500 V pour l'ISOLATION PRINCIPALE ou l'ISOLATION SUPPLEMENTAIRE; ou*

– *3 000 V pour l'ISOLATION RENFORCEE.*

La tension d'essai est appliquée entre la grenaille et le conducteur.

Le diamètre du mandrin et la tension mécanique appliquée au fil au cours de l'enroulement sur le mandrin sont ceux donnés en L.3.2.

L.4 Essais en cours de fabrication

L.4.1 Généralités

Le fil est soumis à des essais de tension de tenue par son FABRICANT au cours de la fabrication comme spécifié en L.4.2 et L.4.3.

L.4.2 Essais de routine

La tension d'essai pour les ESSAIS DE ROUTINE est la tension appropriée définie dans le Tableau 6 et le Tableau 7 (voir 8.8.3) pour le type approprié et le nombre de MOPs avec un minimum de:

– *1 500 V en valeur efficace ou 2 100 V en valeur de crête pour l'ISOLATION PRINCIPALE ou l'ISOLATION SUPPLEMENTAIRE; ou*

– *3 000 V en valeur efficace ou 4 200 V en valeur de crête pour l'ISOLATION RENFORCEE.*

L.4.3 Essais d'échantillonnage

Les spécimens de paires torsadées sont soumis aux essais conformément à 4.4.1 de l'IEC 60851-5:~~1996~~ 2008. La tension de claquage minimale est le double de la tension appropriée définie dans le Tableau 6 et dans le Tableau 7 (voir 8.8.3) pour le type et le nombre appropriés de MOPs, avec un minimum de:

– *3 000 V en valeur efficace ou 4 200 V en valeur de crête pour l'ISOLATION PRINCIPALE ou l'ISOLATION SUPPLEMENTAIRE; ou*

– *6 000 V en valeur efficace ou 8 400 V en valeur de crête pour l'ISOLATION RENFORCEE.*

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Annexe M
(normative)

Réduction des degrés de pollution
(voir 8.9.1.8)

Le Tableau M.1 montre les mesures de protection supplémentaires qui peuvent être utilisées pour réduire le degré de pollution.

Tableau M.1 – Réduction du degré de pollution de l'environnement interne grâce à l'utilisation d'une protection supplémentaire

Protection supplémentaire	Du degré de pollution 2 de l'environnement extérieur à:	Du degré de pollution 3 de l'environnement extérieur à:
ENVELOPPE IPX4 selon l'IEC 60529	2	2
ENVELOPPE IPX5 ou IPX6 selon l'IEC 60529	2	2
ENVELOPPE IPX7 ou IPX8 selon l'IEC 60529	2 (voir note)	2 (voir note)
ENVELOPPE scellée hermétiquement	1	1
Chauffée en permanence	1	1
Encapsulée	1	1
Revêtue	1	2
NOTE La réduction peut descendre jusqu'au degré de pollution 1 si l'appareil est fabriqué avec une faible humidité interne et si les instructions du fabricant spécifient que, après l'ouverture de l'ENVELOPPE, l'ENVELOPPE est réassemblée dans un environnement à humidité contrôlée ou si un déshydratant est utilisé.		

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IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

INDEX

A

a froid • 611
  Définition • 438
A SOURCE ÉLECTRIQUE INTERNE • 498, 542
à source électrique interne • 470, 529, 541
  Définition • 442
ACCESSIBLE PART • 489, 513
accessoire • 444, 475
  Definition • 434
ACCESSOIRE
  Définition de PORTABLE • 447
  Définition de PORTATIF • 441
  Évacuation • 487
  Méthode de stérilisation • 477
  Nettoyages/désinfections multiples • 605
  Stérile • 477, 487
Accessoire • 434
ACCESSOIRE • 473
ACCESSOIRE
  NETTOYAGE • 486
ACCESSOIRE • 572
ACCESSOIRE • 579
ACCESSOIRE • 582
ACCESSOIRE • 584
ACCESSOIRE • 584
ACCESSOIRE • 584
ACCESSOIRE
  NETTOYAGE • 605
ACCESSOIRE
  NETTOYAGE • 605
ACCESSOIRE
  Stérilisation • 605
ACCESSOIRE
  Biocompatibilité • 605
ACCESSOIRES • 444, 465, 472, 477, 486, 487, 504, 579
ACCOMPANYING DOCUMENT • 478, 483
AIR CLEARANCE • 790
ALIMENTATION ELECTRIQUE INTERNE • 756
ALIMENTATION ELECTRIQUE INTERNE • 485
Alimentation isolée (IPS) • 638
Alimentations sans interruption (UPS) • 638
ANALYSE DE RISQUE • 460
ANALYSE DE RISQUE
  Shorting of gaps • 745
ANALYSE DE RISQUES
  COMPOSANT AVEC DES CARACTERISTIQUES A HAUTE FIABILITE • 674
ANALYSE DES RISQUES
  Identification des PERFORMANCES ESSENTIELLES • 458
  Révision de • 464
ANALYSE DES RISQUES • 669
analyse du risque • 449, 460
  Definition • 448
ANALYSE DU RISQUE
  SYSTÈME DE SUPPORT • 582
Année de construction • 472, 473
APPAREIL • 602
Appareil
  MOBILE • 724
  RÉSEAU INFORMATIQUE • 621
  TRANSPORTABLE définition • 451
APPAREIL • 473
Appareil • 811
Appareil électrique
  PARTIE RELIÉE AU RÉSEAU définition • 442
APPAREIL ELECTROMEDICAL
  Dépassement de course • 569
APPAREIL ELECTROMEDICAL • 440, 463, 464, 466, 470, 472, 474, 476, 477, 484, 485, 486, 488
  CLASSE II • 474
  condition normale et condition de premier deffaut • 460
  INSTRUCTIONS D'UTILISATION • 484
  INTERFERENCE RECIPROQUE • 484
  PORTATIF • 463
  SUPPORT DE FORMATION • 484
  UNITES SI • 480
APPAREIL ELECTROMEDICAL • 438
appareil electromedical • 461
APPAREIL ELECTROMEDICAL
  PROCEDURE DE DEMARRAGE • 486
APPAREIL ELECTROMEDICAL
  REMPLI D'HUILE • 488
APPAREIL ELECTROMEDICAL
  MODIFICATION • 488
APPAREIL ELECTROMEDICAL
  GALET DE GUIDAGE • 557
APPAREIL ELECTROMEDICAL
  PROJECTION D'OBJETS • 577
APPAREIL ELECTROMEDICAL
  PARTIES PNEUMATIQUES ET HYDRAULIQUES • 579
APPAREIL ELECTROMEDICAL
  PRESSION MAXIMALE D'ALIMENTATION • 579
APPAREIL ELECTROMEDICAL
  SOURCE D'ETINCELLE • 596
APPAREIL ELECTROMEDICAL
  CATEGORIE AP • 787
APPAREIL ELECTROMEDICAL
  CATEGORIE AP • 789
Appareil electromedical • 427, 428, 433, 434, 435, 438, 439, 443, 444, 446, 450, 459, 460, 465, 466, 467, 469, 470, 471, 472, 474, 475, 476, 478, 479, 481, 483, 484, 485, 486, 487, 488, 489, 490, 509, 529, 533, 534, 537, 541, 556, 557, 564, 565, 567, 572, 576, 577, 578, 579, 580, 581, 582, 584, 587, 588, 593, 603, 605, 607, 611, 627, 632, 637, 643, 787, 788, 789, 795
APPAREIL ELECTROMÉDICAL • 474, 478
APPAREIL ELECTROMEDICAL
  ARRET D'URGENCE • 568
APPAREIL ELECTROMÉDICAL
  ARRET D'URGENCE • 570
APPAREIL ELECTROMÉDICAL
  ARRET D'URGENCE • 570
APPAREIL ÉLECTROMEDICAL
  alimentés par le réseau • 485
  APPLICABILITÉ OU EXIGENCE • 427
  Parties en contact avec le patient • 459
appareil électromédical • 464
  Definition • 444
  securité equivalente • 459
appareil électromédical

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

remplacement de batterie • 628
APPAREIL ELECTROMEDICAL
Alimentation séparée • 473
Appareil de diagnostic in vitro • 427
Batterie • 628
Classification IP • 631
Composant • 456
Composants non fixés à demeure • 473
CONDITIONS DE PREMIER DEFAUT définition • 450
Contre-indication • 484
Coupure du RÉSEAU D'ALIMENTATION • 606
DUREE DE VIE PREVUE • 590
Émission de rayonnements • 487
Évacuation • 487
FIXE • 571
FIXE • 573
Fonction • 489
Groupement des commandes et des indicateurs • 621
Identification • 472
Identification des PERFORMANCES ESSENTIELLES • 458
Mesure de protection • 567, 568
Méthode de stérilisation • 477
MOBILE • 477, 575, 576, 603, 604, 624, 625, 680, 724
MOBILE *à moteur* • 575
MOBILE *manuel* • 575
Nettoyages/désinfections multiples • 605
Partie • 466, 471, 490, 568, 573, 622
Partie, nettoyages/désinfections multiples • 605
Partie, portative • 623, 624, 625, 628
Parties mobiles • 567
réseau d'alimentationEN COURANT CONTINU • 491
Séparation du RESEAU D'ALIMENTATION • 558
Stérile • 477, 487
Tension ASSIGNEE • 465
Transformateur • 635
TRANSPORTABLE • 603, 604, 742
APPAREIL EM • 627
appareil me • 447, 450, 452, 463, 477, 479, 482, 483, 490, 493, 494, 496, 499, 506, 508, 514, 528, 529, 530, 531, 537, 538, 555, 556, 557, 558, 559, 560, 561, 562, 563, 565, 593, 594, 595, 600, 603, 604, 605, 608, 610, 611, 613, 614, 615, 625, 626, 627, 628, 629, 630, 631, 641, 742, 787, 788, 789, 791, 792, 795, 796, 801
organisme responsable • 448
Partie • 450, 467, 470, 472, 475, 479
SYSTÈME ÉLECTROMEDICAL • 444
Voir Appareil électromédical • 444
APPAREIL ME
PARTIE • 485
APPAREIL ME
PARTIE • 486
APPAREIL ME
SOURCE ÉLECTRIQUE INTERNE • 498
APPAREIL ME
POLYPHASÉ • 498
APPAREIL ME
MONOPHASE • 528
APPAREIL ME
ALTITUDE ASSIGNEE • 539
APPAREIL ME
Partie • 556
APPAREIL ME
INSTALLE DE FAÇON PERMANENTE • 561
APPAREIL ME
PARTIE • 564
APPAREIL ME
PARTIE • 571
APPAREIL ME
PARTIE • 572
APPAREIL ME
PARTIE • 572
APPAREIL ME
PARTIE • 572
appareil me
Mobile • 574
APPAREIL ME
MOBILE, POWER-DRIVEN • 575
APPAREIL ME
MOBILE • 575
APPAREIL ME
MOBILE • 576
APPAREIL ME
PARTIE • 576
APPAREIL ME
PORTABLE • 577
APPAREIL ME
PORTABLE • 577
APPAREIL ME
PARTIE • 582
APPAREIL ME
PARTIE • 584
APPAREIL ME
PARTIE • 584
APPAREIL ME
TRANSPORTABLE • 601
APPAREIL ME
ENVELOPPE • 604
APPAREIL ME
nettoyage • 605
APPAREIL ME
nettoyage de partie • 605
APPAREIL ME
PARTIE • 608
APPAREIL ME
commandé automatiquement ou à distance • 611
APPAREIL ME
A COMMANDE THERMOSTATIQUE • 613
APPAREIL ME
Partie • 613
APPAREIL ME
PARTIE • 621
APPAREIL ME
PARTIE • 621
APPAREIL ME
ENVELOPPE • 623
APPAREIL ME
ENVELOPPE • 623
APPAREIL ME
PORTATIF • 623
APPAREIL ME
MOBILE • 624
APPAREIL ME
PARTIE MOBILE • 624
appareil me
voyant lumineux • 629
APPAREIL ME
portable • 631
APPAREIL ME
TRANSFORMATEUR • 634

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

APPAREIL ME
NON- • 641
APPAREIL ME
CATEGORIE APG • 788
APPAREIL ME
CATEGORIE APG • 791
APPAREIL ME
PARTIE • 791
APPAREIL ME
PARTIE • 791
APPAREIL ME
PARTIE • 791
~~APPAREIL ME~~
~~PARTIE~~ • 795
APPAREIL ME
PARTIE • 795
APPAREIL ME
PARTIE • 795
APPAREIL ME
PARTIE • 796
APPAREIL ME
CATEGORIE APG • 796
APPAREIL ME
PARTIE • 797
Appareil médical • 808
APPAREILS ELECTROMEDICAUX • 465
Partie • 466
APPAREILS ELECTROMEDICAUX
Partie • 489
APPAREILS ELECTROMEDICAUX
RAYONNEMENT EXCESSIF • 607
appareils electromedicaux
rayonnement excessif • 607
appareils électromedicaux
Composants • 460
SOURCE ELECTRIQUE INTERNE • 462
APPAREILS ELECTROMEDICAUX
INSTABILITE • 571
APPAREILS ELECTROMEDICAUX –EXAMEN • 555, 556, 563, 571, 577, 582, 583, 587, 588, 626
appareils me • 542
APPAREILS ME • 443, 463, 493
Condition d'application • 454
PART • 443
Partie • 438
processus de gestion du risque • 455
RESEAU • 463
appareils me
nettoyage de parties • 486
APPAREILS ME
Parties • 493
APPAREILS ME
A SOURCE ÉLECTRIQUE INTERNE • 498
APPAREILS ME
A SOURCE ELECTRIQUE INTERNE • 529
APPAREILS ME • 550
APPAREILS ME
CONDUCTEURS ET CONNECTEURS • 555
APPAREILS ME • 563
APPAREILS ME
PARTIE • 591
APPAREILS ME
PARTIE • 592
APPAREILS ME
Surface • 592
APPAREILS ME
PARTIE • 593
APPAREILS ME • 594
APPAREILS ME • 594
APPAREILS ME • 603
APPAREILS ME
nettoyage • 605
APPAREILS ME
NETTOYAGE DE PARTIES • 605
APPAREILS ME
BIOCOMPATIBILITE • 605
APPAREILS ME
biocompatibilité de partie • 605
APPAREILS ME
BIOCOMPATIBILITE • 605
APPAREILS ME
biocompatibilité de partie • 605
APPAREILS ME
BIOCOMPATIBILITE • 605
APPAREILS ME
biocompatibilité de partie • 605
APPAREILS ME
COUPURE DU RÉSEAU D'ALIMENTATION • 606
APPAREILS ME • 610
APPAREILS ME • 610
APPAREILS ME • 610
APPAREILS ME
à moteur • 611
APPAREILS ME
PORTATIF • 611
APPAREILS ME • 611
APPAREILS ME • 611
APPAREILS ME • 611
APPAREILS ME • 612
APPAREILS ME • 612
APPAREILS ME • 612
APPAREILS ME
Eléments chauffants • 612
APPAREILS ME • 613
APPAREILS ME • 613
APPAREILS ME • 613
APPAREILS ME • 613
APPAREILS ME • 613
APPAREILS ME • 614
APPAREILS ME • 614
APPAREILS ME • 615
APPAREILS ME • 615
APPAREILS ME
PORTATIF • 615
APPAREILS ME • 615
APPAREILS ME • 615
APPAREILS ME • 623
APPAREILS ME
PARTIE • 623
APPAREILS ME • 624
APPAREILS ME • 627
APPAREILS ME • 629
APPAREILS ME • 629
APPAREILS ME • 631
APPAREILS ME • 632
APPAREILS ME • 634
APPAREILS ME
NON- • 637
APPAREILS ME
NON- • 637
APPAREILS ME
NON- • 637
APPAREILS ME
Non- • 638
APPAREILS ME • 638
APPAREILS ME • 639
APPAREILS ME • 639
APPAREILS ME • 787

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

APPAREILS ME
CATÉGORIE APG • 789
APPAREILS ME
CATEGORIE AP • 790
APPAREILS ME
CATEGORIE APG • 790
APPAREILS ME • 791
Appareils médicaux • 747
application cardiaque directe • 452, 491
Definition • 439
APPLICATION CARDIAQUE DIRECTE • 452, 491
Applied part • 452, 489, 512, 513
Definition • 435
APPLIED PART
Multiple • 693
APPLIED PART
HAND-HELD • 754
APPRECIATION DU RISQUE • 599
APTITUDE À L'UTILISATION • 606, 682
aptitude a l'utilisation
Definition • 452
ASSIGNE
COURANT OU PUISSANCE DE SORTIE • 475
MARQUE • 475
plage de fréquences d'alimentation • 474
puissance absorbée • 463
TENSION • 463, 474
tension d'alimentation • 474
tension de sortie • 475
ASSIGNE
TENSION D'ALIMENTATION PHASE SUR NEUTRE • 498
assigné • 540
Definition • 448
Fréquence • 465
fréquence d'alimentation • 474
puissance absorbée • 463
tension • 463
ASSIGNE
tension • 493
ASSIGNE
Tension • 493
ASSIGNE
Tension • 494
ASSIGNÉ
TENSION ASSIGNEE • 498
ASSIGNE
Courant • 507
ASSIGNÉ
Fréquence • 509
ASSIGNE
ALTITUDE • 539
ASSIGNE
TENSION ASSIGNEE • 540
ASSIGNE
Caractéristique • 557
ASSIGNE
Température • 559
ASSIGNÉ
COURANT • 559
ASSIGNE
charge • 581
ASSIGNE
charge • 581
ASSIGNÉ
TENSION • 594
ASSIGNÉ
TENSION • 594
ASSIGNÉ
TENSION • 594
ASSIGNÉ
TENSION • 594
ASSIGNÉ
Périodes de marche et d'arrêt • 594
ASSIGNE
TENSION • 611
ASSIGNE
TENSION • 611
ASSIGNE
TENSION • 611
ASSIGNE
SERVICE NON CONTINU • 613
ASSIGNE
TENSION D'ALIMENTATION • 613
ASSIGNE
SERVICE NON CONTINU • 613
ASSIGNE
durée de fonctionnement • 613
ASSIGNE
TENSION D'ALIMENTATION • 613
ASSIGNE
TENSION • 614
ASSIGNE
TENSION • 615
ASSIGNÉ
TENSION • 632
ASSIGNÉ
FREQUENCE • 632
ASSIGNÉ
Courant • 634
assigné
tension • 634
ASSIGNE
FREQUENCE • 634
assigné
tension • 634
ASSIGNE
FREQUENCE • 634
ASSIGNÉ
Périodes marche et arrêt • 639
ASSIGNÉ
COMPOSANTS • 641
ASSIGNÉ
PUISSANCE DE SORTIE • 642
ASSIGNE
RESEAU D'ALIMENTATION • 465
Tension • 465
ASSIGNEE
TENSION • 614
avertissement • 679
Avertissement • 573, 811
AVERTISSEMENT • 471, 478, 484, 486, 488, 558, 572
Avertissement • 637
Avertissement • 637
Avertissement • 637

B

BIEN LISIBLE • 471, 472, 479
Biocompatibility • 754
BORNE DE PROTECTION DE MISE À LA TERRE • 642, 680
BORNE DE PROTECTION DE TERRE • 561, 641
BORNE DE TERRE DE PROTECTION • 447, 448, 478, 506, 507

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Definition • 448
BORNE DE TERRE FONCTIONNELLE • 438, 440, 477, 478, 504, 508
Définition • 440
BORNE DE TERRE FONCTIONNELLE • 508

C

câble d'alimentation
Definition • 447
CÂBLE D'ALIMENTATION
Raccordement de câble • 556
CABLE D'ALIMENTATION • 763
câble d'alimentation non fixé à demeure
Definition • 439
CABLE D'ALIMENTATION • 559
CABLE D'ALIMENTATION • 482, 506, 508, 528, 550, 558, 559, 560, 561, 562, 563, 572, 641
CABLE D'ALIMENTATION • 506
CABLE D'ALIMENTATION • 559
CABLE D'ALIMENTATION
Non- • 561
CABLE D'ALIMENTATION • 561
CÂBLE D'ALIMENTATION • 442, 482, 489
CÂBLE D'ALIMENTATION FIXÉ À DEMEURE
NON- • 489, 506
CÂBLE D'ALIMENTATION NON FIXÉ À DEMEURE • 528, 572, 790
CABLE SOUPLE D'ALIMENTATION NON FIXE A DEMEURE • 507
CÂBLE SOUPLE D'ALIMENTATION NON FIXÉ À DEMEURE • 700
capot d'accès
Définition • 433
CAPOT D'ACCES • 493
CAPOT D'ACCÈS • 492, 494, 556, 562
CAPOTS D'ACCES • 466
CAPOTS D'ACCÈS • 467
CAPOTS D'ACCÈS • 494
catégorie ap • 789
Definition • 438
CATEGORIE AP
CATEGORIE AP • 787
CATEGORIE AP • 788
CATEGORIE AP • 788
CATEGORIE AP • 789
CATEGORIE AP • 789
CATEGORIE AP • 789
CATEGORIE AP • 789
CATEGORIE AP • 790
CATEGORIE AP • 791
CATEGORIE AP • 791
catégorie apg • 789, 796
Definition • 438
CATEGORIE APG • 771
CATEGORIE APG • 788
CATEGORIE APG • 788
CATEGORIE APG • 789
CATÉGORIE APG • 789
CATEGORIE APG • 789
CATEGORIE APG • 789
CATEGORIE APG • 790
CATEGORIE APG • 791
charge de fonctionnement en sécurité • 451, 584, 585, 586, 588, 623, 624
Definition • 449
CHARGE DE FONCTIONNEMENT EN SÉCURITÉ
APPAREIL ÉLECTROMÉDICAL MOBILE • 680
CHARGE DE FONCTIONNEMENT EN SECURITE • 477, 569, 575, 576, 586
CHARGE DE FONCTIONNEMENT EN SECURITE • 771
charge totale
Definition • 451
CHARGE TOTALE • 450
CHARGE TOTALE • 582
CHARGE TOTALE • 586
CHARGE TOTALE • 583
circuit secondaire • 541, 542, 547
Definition • 449
SYSTÈME ÉLECTROMÉDICAL • 642
CLAIREMENT LISIBLE • 573
classe i
Definition • 438
CLASSE I • 707
CLASSE I • 448, 470, 484, 562, 639, 641, 642
classe ii
Definition • 438
CLASSE II • 707, 771
CLASSE II • 438, 470, 474, 508, 562
Classification IP • 470
Clearly legible
Definition • 438
compatibilité avec les substances utilisées avec L'APPAREIL ME • 605
composant aux caractéristique à haute fiabilité • 438
COMPOSANT AUX CARACTÉRISTIQUES À HAUTE FIABILITÉ • 460, 461, 462, 490, 618
COMPOSANT AVEC DES CARACTERISTIQUES A HAUTE FIABILITE • 674
COMPOSANTS AUX CARACTERISTIQUES A HAUTE FIABILITE • 609, 632
Condensateur Y1 • 495
CONDITION D'ALARME
Définition • 453
CONDITION D'ALARME • 454
CONDITION D'ALARME • 454
CONDITION D'ALARME • 671
condition de premier défaut • 460, 492, 493, 496, 507, 509, 510, 529, 595, 599, 600, 605, 608, 609, 610, 611, 612, 632, 788, 797, 826
Definition • 450
CONDITION DE PREMIER DEFAUT • 460
CONDITION DE PREMIER DEFAUT • 507
CONDITION DE PREMIER DEFAUT • 579
CONDITION DE PREMIER DEFAUT • 796
Condition de premier défaut • 438, 446, 450, 460, 489, 555, 579, 595, 611
condition normale • 492, 498, 509, 531, 599, 605, 609, 613, 636, 788, 795, 826
Definition • 445
CONDITION NORMALE • 460
CONDITION NORMALE • 489
CONDITION NORMALE • 495
CONDITION NORMALE • 496
CONDITION NORMALE • 509
CONDITION NORMALE • 510
CONDITION NORMALE • 579
CONDITION NORMALE • 595
CONDITION NORMALE • 639
CONDITION NORMALE • 791
CONDITION NORMALE • 791
CONDITION NORMALE • 797
CONDITION NORMALE • 797
CONDITION NORMALE • 491
Condition normale • 438, 446, 460, 479, 489
CONDITION NORMALE • 578

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

CONDITION NORMALE • 579
CONDITION NORMALE • 595
CONDITION NORMALE • 613
CONDITION NORMALE • 795
CONDITIONS DE PREMIER DEFAUT • 460, 608, 609, 762
CONDITIONS DE PREMIER DEFAUT • 456, 496, 510, 516, 518, 522, 567, 568, 592, 609, 675
CONDITIONS NORMALES • 496, 510, 592, 609
conducteur d'égalisation des potentiels
Definition • 447
CONDUCTEUR DE MISE A LA TERRE DE PROTECTION • 701
conducteur de terre de protection • 447, 448, 482, 490, 506, 507, 529, 560, 639, 642
Definition • 447
CONDUCTEUR DE TERRE FONCTIONNELLE • 701, 707
conducteur de terre fonctionnelle
Définition • 440
CONDUCTEUR DE TERRE FONCTIONNELLE
COURANT DE FUITE
Valeur • 510
CONDUCTEUR D'EGALISATION DES POTENTIELS • 508
CONDUCTEUR D'ÉGALISATION DES POTENTIELS • 482, 508
CONDUCTEURS DE TERRE DE PROTECTION • 482
CONDUCTOR DE TERRE FONCTIONNELLE • 438, 482
CONDUTEUR DE TERRE DE PROTECTION • 561, 562
connecteur • 442
Definition • 434
CONNECTEUR • 558
connecteur d'appareil • 435, 439, 486, 559
connexion de terre de protection • 482, 490, 495, 496, 506, 507, 508, 642, 743
Definition • 448
CONNEXION DE TERRE DE PROTECTION • 507
CONNEXION DE TERRE DE PROTECTION • 509
CONNEXION DE TERRE DE PROTECTION • 641
connexion fonctionnelle • 444
Définition • 440
CONNEXION FONCTIONNELLE • 638
CONNEXION PATIENT • 499
connexion patient • 491, 492, 497, 499
Definition • 446
connexion patient • 446
CONNEXION PATIENT • 498
CONNEXION PATIENT • 498
CONNEXION PATIENT • 503
CONNEXION PATIENT • 503
CONNEXION PATIENT • 503
CONNEXION PATIENT • 504
CONNEXION PATIENT • 530
CONNEXION PATIENT • 530
CONNEXION PATIENT • 530
CONNEXION PATIENT • 531
CONNEXION PATIENT • 531
CONNEXION PATIENT • 531
CONNEXION PATIENT • 531
CONNEXION PATIENT • 534
CONNEXION PATIENT
PARTIE APPLIQUEE DE TYPE CF • 704
CONNEXION PATIENT • 531
CONNEXION PATIENT • 435
connexions de terre de protection • 444, 507
CONNEXIONS FONCTIONNELLES • 639
CONNEXIONS PATIENT • 497
connexions patient • 440, 446, 451, 491
CONSTRUCTEUR • 441, 444, 445, 448, 463, 483, 487, 489, 506, 529, 550, 560, 584, 589, 590, 599, 603, 606, 607, 608, 619, 626
constructeur • 497
CONSTRUCTEUR
SYSTÈME ME • 636
CONSTRUCTEUR • 443, 444, 459, 486, 539, 564, 577, 582, 583, 584, 607
COORDINATION DE L'ISOLEMENT \
correctement installé
Definition • 447
COUPE CIRCUIT • 787
COUPE CIRCUIT THERMIQUE • 449, 627
COUPE CIRCUIT THERMIQUE
ENCLENCHEMENT MANUEL • 627
COUPE CIRCUIT THERMIQUE A REENCLENCHEMENT AUTOMATIQUE
NON- • 613
COUPE CIRCUIT THERMIQUE REENCLENCHEMENT AUTOMATIQUE
NON- • 801
COUPE CIRCUIT THERMIQUES • 612, 613
COUPE CIRCUIT THERMIQUES • 609
COUPE CIRCUIT THERMIQUES A REENCLENCHEMENT AUTOMATIQUE • 627
coupe-circuit thermique
Definition • 451
COUPE-CIRCUIT THERMIQUE • 626, 627
coupe-circuit thermique à réenclenchement automatique
Definition • 449
COUPE-CIRCUIT THERMIQUE A REENCLENCHEMENT AUTOMATIQUE
Sans • 626
COUPE-CIRCUIT THERMIQUES • 478, 595
couplage de réseau/données
Definition • 445
COUPLAGE DE RESEAUX / DE DONNEES • 485
COUPLAGE DE RESEAUX/DONNEES • 812
COUPLAGE DES RÉSEAUX/DONNÉES • 618
COURANT AUXILIAIRE PATIENT • 452, 491, 508, 509, 531
COURANT AUXILIAIRE PATIENT • 513
COURANT AUXILIAIRE PATIENT • 528
COURANT AUXILIAIRE PATIENT • 531
COURANT AUXILIAIRE PATIENT • 531
COURANT DE CONTACT • 681
courant de contact • 442, 492, 507, 509, 513, 529, 639
Definition • 451
COURANT DE CONTACT • 762
courant de fuite • 490, 492, 497, 507, 508, 510, 528, 609, 639
Définition • 442
COURANT DE FUITE • 509
COURANT DE FUITE
ESSAI • 605
COURANT DE FUITE
ESSAI • 605
COURANT DE FUITE • 638
COURANT DE FUITE
Mesure • 604
Valeur • 510
COURANT DE FUITE • 492
Courant de fuite • 442
COURANT DE FUITE • 681
COURANT DE FUITE • 707
courant de fuite à la terre • 442, 509, 513, 529
Definition • 439

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

COURANT DE FUITE A LA TERRE
TOTAL • 639
courant de fuite patient • 452, 491, 497, 507, 509, 513, 530, 531
Definition • 446
courant de fuite patient • 440, 442
COURANT DE FUITE PATIENT • 531
COURANT DE FUITE PATIENT • 639
COURANT DE FUITE PATIENT
Limite • 710
COURANT DE FUITE PATIENT
Mesure • 529
Total • 639
COURANT DE FUITE PATIENT • 527
COURANT DE FUITE PATIENT • 530
COURANT DE FUITE PATIENT • 681
COURANT DE FUITE PATIENT
Total • 704
CREEPAGE DISTANCE • 533, 790
cycle d'utilisation
Definition • 439
CYCLE DE DÉVELOPPEMENT DE SEMP • 616
cycle de vie de développement de semp • 617
Definition • 446
CYCLE DE VIE DE DÉVELOPPEMENT DE SEMP
DEFINITION • 616
CYCLE DE VIE DE DEVELOPPEMENT DE SEMP
DEFINITION • 616

D

danger • 444, 448, 450, 452, 478, 488, 568, 570, 571, 576, 577, 582, 617, 629, 636, 640, 655, 658, 790
Définition • 441
DANGER • 445
danger
système de support • 582
DANGER
Feu • 602
DANGER
Systèmes de support • 582
DANGER • 455, 457
DANGER • 617
DANGER • 668
DANGER • 678
DANGER • 811
DANGER MECANIQUE • 567
DANGERS • 427, 438
Date limite d'utilisation • 472, 473
Défauts
Simultanés indépendants • 464, 675
Défauts • 675
Degré de pollution 1 • 550
Degré de pollution 2 • 550
Degré de pollution 3 • 550
DEL • 735
Description technique
Identifiant unique • 489
Description technique • 463, 465, 467, 488
Description technique • 557
Description technique • 638
determination du risque
Definition • 449
disjoncteur • 562, 563, 609, 627
Definition • 445
DISJONCTEUR • 538
DISJONCTEUR RESEAU • 626, 627
DISJONCTEURS • 478
DISPOSITIF DE PROTECTION MECANIQUE
PAS EXIGE • 588
DISPOSITIF DE PROTECTION MÉCANIQUE • 460, 586, 587, 588
dispositif de protection mécanique
définition • 444
DISPOSITIF DE RACCORDEMENT • 442
Definition • 451
dispositif de raccordement au réseau • 561, 563, 641
Définition • 442
dispositif de séparation • 638, 639
Definition • 450
Dispositif médical • 456
Dispositif médical implantable actif • 427
DISPOSITIFS DE RACCORDEMENT AU RÉSEAU • 561, 562
DISTANCE DANS L'AIR
Transformateur • 636
DISTANCE DANS L'AIR • 548, 575, 585, 586, 622
DISTANCE DANS L'AI • 496
DISTANCE DANS L'AIR • 490, 492, 495, 496, 497, 498, 499, 537, 538, 539, 540, 542, 544, 546, 547, 548, 549, 550, 551, 557, 560, 561, 595, 734, 744
DISTANCE DANS L'AIR • 562
distances dans l'air • 444
distances dans l'air • 434, 538, 638, 641
DOCUMENT D'ACCOMPAGNEMENT
Conditions de service • 465
document d'accompagnement
Definition • 434
DOCUMENT D'ACCOMPAGNEMENT • 499
DOCUMENT D'ACCOMPAGNEMENT
Mécanisme de séparation du RESEAU D'ALIMENTATION • 557
DOCUMENT D'ACCOMPAGNEMENT • 483, 508
DOCUMENT D'ACCOMPAGNEMENT • 575
DOCUMENT D'ACCOMPAGNEMENT • 620
DOCUMENT D'ACCOMPAGNEMENT • 670
Document d'accompagnement • 681
DOCUMENT D'ACCOMPAGNEMENT • 443, 490, 572, 576, 578, 582, 584, 587, 637
Documentation de conception
Évaluation • 609
Inspection • 537, 588, 626, 627
DOCUMENTS D'ACCOMPAGNEMENT • 447, 462, 467, 472, 475, 477, 478, 483
DOCUMENTS D'ACCOMPAGNEMENT • 489, 491, 789
DOCUMENTS D'ACCOMPAGNEMENT
examen • 577
DOCUMENTS D'ACCOMPAGNEMENT
examen • 584
DOCUMENTS D'ACCOMPAGNEMENT
EXAMEN • 626
DOCUMENTS D'ACCOMPAGNEMENT
examen • 631
DOCUMENTS D'ACCOMPAGNEMENT • 637
DOMMAGE • 670
dommage • 448, 476, 568, 658
D&finition • 441
DOMMAGE • 575, 585, 586, 622, 668, 670, 698
DOSSIER D'INGENIERIE D'APTITUDE A L'UTILISATION
Définition • 454
dossier de gestion des risques • 592, 595, 596, 600, 606, 618, 619
Definition • 449, 459, 462

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dossier de gestion des risques
Definition • 492
dossier de gestion des risques
Definition • 537
DOSSIER DE GESTION DES RISQUES
DEFINITION • 556
dossier de gestion des risques
Definition • 556
dossier de gestion des risques
Definition • 563
dossier de gestion des risques
Definition • 567
dossier de gestion des risques
Definition • 571
dossier de gestion des risques
Definition • 577
dossier de gestion des risques
Definition • 579
DOSSIER DE GESTION DES RISQUES
DEFINITION • 582
dossier de gestion des risques
Definition • 583
dossier de gestion des risques
Definition • 584
DOSSIER DE GESTION DES RISQUES
DEFINITION • 587
DOSSIER DE GESTION DES RISQUES
Definition • 589
DOSSIER DE GESTION DES RISQUES
Definition • 590
DOSSIER DE GESTION DES RISQUES
Definition • 591
DOSSIER DE GESTION DES RISQUES
Definition • 593
DOSSIER DE GESTION DES RISQUES
Definition • 599
dossier de gestion des risques
Definition • 603
dossier de gestion des risques
Definition • 605
DOSSIER DE GESTION DES RISQUES
Examen • 607
DOSSIER DE GESTION DES RISQUES
Examen • 607
DOSSIER DE GESTION DES RISQUES
Examen • 610
DOSSIER DE GESTION DES RISQUES
Examen • 623
DOSSIER DE GESTION DES RISQUES
Examen • 624
DOSSIER DE GESTION DES RISQUES
Examen • 625
DOSSIER DE GESTION DES RISQUES
Examen • 626
DOSSIER DE GESTION DES RISQUES
Examen • 627
DOSSIER DE GESTION DES RISQUES
Examen • 628
DOSSIER DE GESTION DES RISQUES
Examen • 631
DOSSIER DE GESTION DES RISQUES
Examen • 643
DOSSIER DE GESTION DES RISQUES
Contenu • 742
Inspection • 459, 571, 578, 626, 627, 641
Nettoyage/désinfection • 605
Renversement • 604
Sécurité équivalente • 672
Temperature limits • 593
DOSSIER DE GESTION DES RISQUES • 457, 458
DOSSIER DE GESTION DES RISQUES • 459
DOSSIER DE GESTION DES RISQUES • 563
DOSSIER DE GESTION DES RISQUES • 568
DOSSIER DE GESTION DES RISQUES • 586
DOSSIER DE GESTION DES RISQUES • 592
DOSSIER DE GESTION DES RISQUES • 592
DOSSIER DE GESTION DES RISQUES • 593
DOSSIER DE GESTION DES RISQUES • 593
DOSSIER DE GESTION DES RISQUES • 607
double isolation • 460, 490, 498
Definition • 439
DOUBLE ISOLATION
Transformateur • 636
DOUBLE ISOLATION • 438, 439, 509
DURÉE DE SERVICE ATTENDUE • 438, 440, 450, 459, 460, 461, 472, 483, 506, 537, 582
DURÉE DE VIE PRÉVUE
Évacuation • 487
DUREE DE VIE PREVUE • 590
DURÉE DE VIE PRÉVUE • 605
DURÉE DE VIE PRÉVUE • 671
DUTY CYCLE • 736

E

EARTH LEAKAGE CURRENT • 512
Éclairage ambiant • 471
EMPLOI PRÉVU / LA DESTINATION PRÉVUE • 434
EN CONDITION DE PREMIER DEFAUT • 509
en partie appliquée du type f
Definition • 440
Enclosure • 623, 624
Definition • 439
enregistrement
Definition • 448
enregistrements • 449
entrée/sortie de signal • 489, 499, 530
Definition • 450
ENTREES/SORTIES DE SIGNAL • 485, 530, 534
ENVELOPPE • 451, 470, 472, 492, 497, 529, 530, 558, 623, 641, 788
ENVELOPPE • 442
ENVELOPPE
FEU • 600
ENVELOPPE
FEU • 601
ENVELOPPE
FEU • 609
ENVELOPPE • 795
ENVELOPPE • 796
ENVELOPPE • 796
ENVELOPPE
Classification IP • 631
IPX0 • 466
Non conductrice • 527
Séparée • 490
Supérieur à IPX0 • 466
ENVELOPPE • 433
ENVELOPPE • 492
ENVELOPPE • 493
ENVELOPPE • 494
ENVELOPPE • 498
ENVELOPPE • 499
ENVELOPPE • 529
ENVELOPPE • 529
ENVELOPPE • 529
ENVELOPPE • 529
ENVELOPPE • 529

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ENVELOPPE • 529
ENVELOPPE • 529
ENVELOPPE • 529
ENVELOPPE • 529
ENVELOPPE • 529
ENVELOPPE • 530
ENVELOPPE • 534
ENVELOPPE
ESSAI A LA BILLE • 537
ENVELOPPE • 551
ENVELOPPE • 551
ENVELOPPE • 565
ENVELOPPE • 595
ENVELOPPE • 599
ENVELOPPE • 599
ENVELOPPE • 600
ENVELOPPE • 601
ENVELOPPE • 601
ENVELOPPE • 601
ENVELOPPE • 602
ENVELOPPE • 602
ENVELOPPE • 608
ENVELOPPE • 609
ENVELOPPE • 610
ENVELOPPE • 623
ENVELOPPE • 623
ENVELOPPE
MOULE • 625
ENVELOPPE • 625
ENVELOPPE • 625
ENVELOPPE
Classification IP • 648
ENVELOPPE
Classification IP • 743
ENVELOPPE • 788
ENVELOPPE • 790
ENVELOPPE • 790
ENVELOPPE • 790
ENVELOPPE • 791
ENVELOPPE • 795
ENVELOPPE • 795
ENVELOPPE • 795
ENVELOPPE • 795
ENVELOPPES • 604, 790
ENVIRONNEMENT DU PATIENT • 639
ENVIRONNEMENT DU PATIENT • 637, 638
ENVIRONNEMENT DU PATIENT • 639
ENVIRONNEMENT DU PATIENT • 640
Environnement du patient
Definition • 446
environnement riche en oxygène • 470, 595, 598, 599, 600
Definition • 445
ENVIRONNEMENT RICHE EN OXYGÈNET • 597
ENVIRONNEMENT RICHES EN OXYGÈNE • 600
ENVIRONNEMENTS RICHES EN OXYGENE • 470, 612
ESSAI A LA BILLE • 537
essai de type
Définition • 452
ESSAI DE TYPE • 464
Essai fonctionnel
Caractéristiques de pression des parties des APPAREILS EM • 580
PERFORMANCES ESSENTIELLES • 459
Régulateur de pression • 581
Vitesse de mouvement • 568, 586
ESSENTIAL PERFORMANCE • 428, 668
EVALUATION DES RISQUES • 452, 461, 490, 498, 604, 606, 607, 608, 631, 642
ÉVALUATION DES RISQUES • 457
évaluation du risque
Definition • 449
EVALUATION DU RISQUE • 449
exempt de premier défaut • 460, 610, 611
Definition • 450

F

FABRICANT
DURÉE DE VIE PRÉVUE • 440
PERFORMANCES ESSENTIELLES • 439
FABRICANT • 470
FABRICANT • 485
FABRICANT • 606
FABRICANT • 606
FABRICANT • 608
FABRICANT • 608
FABRICANT • 627
FABRICANT • 629
FABRICANT • 648
FABRICANT • 667
FABRICANT • 693
FABRICANT • 698
FABRICANT • 736
FABRICANT • 745
FABRICANT
Composants non fixés à demeure • 473
Identification des PERFORMANCES ESSENTIELLES • 458
Intégration dans un système • 810
Marquage du nom ou de la marque et de l'adresse • 472, 473, 484
Mauvais usage raisonnablement prévisible • 667
Mesure ou méthode d'essai alternative • 459, 671
Nom ou marque • 473
PERFORMANCES ESSENTIELLES • 657, 669, 670
SEMP • 620, 811
SYSTÈME EM • 638
FABRICANT • 442, 456, 457, 458
FABRICANT • 488
FABRICANT • 507
FABRICANT • 580
FABRICANT • 581
FABRICANT • 605
FABRICANT • 606
FABRICANT • 606
FABRICANT • 607
FABRICANT • 616
FABRICANT • 617
FABRICANT • 621
FABRICANT • 654
FABRICANT • 681
FABRICANT • 682
FABRICANT • 723
FABRICANT • 724
FABRICANT • 724
FABRICANT • 724
FABRICANT • 724
FABRICANT • 724
FABRICANT • 730
FABRICANT • 730
FABRICANT • 742
FABRICANT • 742
FACTEUR DE SÉCURITÉ • 586
facteur de sécurité de traction • 460
Definition • 450

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

FACTEUR DE SECURITE EN TRACTION • 583
FACTEUR DE TRACTION DE SÉCURITÉ • 583
FACTEURS DE SECURITE • 460
fiche réseau • 490, 506, 507, 508, 558, 560, 641, 642
  Definition • 442
FICHE RESEAU • 507, 558
FIXE
  Definition • 450
  RÉSEAU • 440
Fixe
  Definition • 440
FIXE
  BORNES • 562
FIXE
  CABLAGE • 562
FIXE
  PROTECTION • 565
FIXÉ
  APPAREIL EM • 571, 573
FIXÉ
  APPAREIL ME • 471
FIXÉ
  APPAREIL ME • 529
FIXE
  APPAREIL ME • 601
Fonction • 531, 626, 771
Fonction • 693
Fonction • 704
Fonction • 710
FONCTION PRINCIPALE DE SERVICE
  Définition • 454

G

gestion des risques • 460, 610
  Definition • 449
  PROCESSUS • 449
GESTION DES RISQUES
  Activités • 617
GESTION DES RISQUES
  Application • 652, 654, 667
  CYCLE DE DÉVELOPPEMENT DE SEMP • 616
  Documentation requise par la présente Norme • 457
  Intégration dans un système • 811
  Plan • 456, 457
  PROCESSUS • 455, 456, 459, 593, 607, 616, 667, 671
GESTION DES RISQUES • 458
GESTION DES RISQUES • 616
GESTION DU RISQUE • 435, 605, 607, 608, 629
GESTION DU RISQUE • 603
GRAVITE • 658
GRAVITE • 670

H

HAND-HELD
  APPLIED PART • 754
haute tension
  Définition • 441
  Partie • 477
HAUTE TENSION
  Partie, Marquage de • 773
HAZARD • 458
HAZARD • 668
HAZARD • 669
HAZARDOUS SITUATION • 668
HAZARDOUS SITUATION • 668
HAZARDOUS SITUATION • 669

I

Identifiant de lot
  ACCESSOIRE • 473
  APPAREIL EM • 472
RISQUE • 568
Incendie • 745
Incendie • 689
INGÉNIERIE • 667
INGÉNIERIE D'APTITUDE À L'UTILISATION
  PROCESSUS • 621, 681
INGÉNIERIE D'APTITUDE À L'UTILISATION • 606
ingénierie d'aptitude a l'utilisation
  Definition • 453
INSTALLE CORRECTEMENT • 476, 564
installé de façon permanente • 528, 562
  Definition • 446
INSTALLE DE FAÇON PERMANENTE
  APPAREIL ME • 561
INSTALLE DE MANIERE PERMANENTE • 472, 474, 478, 479, 489, 506
INSTALLE EN PERMANENCE
  Non • 510, 558
INSTALLÉS DE MANIÈRE PERMANENTE • 490
Instructions d'installation • 638
Instructions d'utilisation
  Identifiant unique • 488
Instructions d'utilisation • 484
INSTRUCTIONS D'UTILISATION • 485
Instructions d'utilisation • 592
Instructions d'utilisation • 682
instructions d'utilisation • 679
Instructions d'utilisation • 445, 463, 465, 466, 467, 476, 481, 483, 488, 492, 493, 508, 533, 572, 574
INTENDED USE • 668
ISOLATION DE BASE • 533
ISOLATION DOUBLE • 691
isolation principale • 450, 532, 637, 642, 762
  Definition • 435, 438
ISOLATION PRINCIPALE • 658
ISOLATION PRINCIPALE • 438, 439, 532
ISOLATION PRINCIPALE • 829
ISOLATION PRINCIPALE • 829
ISOLATION PRINCIPALE • 830
ISOLATION PRINCIPALE • 831
ISOLATION PRINCIPALE • 831
ISOLATION PRINCIPALE • 831
ISOLATION RENFORCEE • 691
isolation renforcée • 532, 537
  Definition • 448
ISOLATION RENFORCEE • 460
ISOLATION RENFORCEE • 575, 585, 586, 622
ISOLATION RENFORCÉE • 438, 460, 533
ISOLATION RENFORCÉE • 829
ISOLATION RENFORCÉE • 830
Isolation renforcée • 831
ISOLATION RENFORCÉE • 831
ISOLATION RENFORCÉE • 831
isolation supplémentaire • 532, 537
  Definition • 450
Isolation supplémentaire • 439, 532, 533, 829, 830, 831

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

K

KERMA DANS L'AIR
Définition • 453

L

L'UTILISATION NORMALE • 444
LE CONDUCTEUR DE TERRE DE PROTECTION • 451, 641
LEAKAGE CURRENT • 668, 693, 817, 818
L'ENVIRONNEMENT DU PATIENT • 636
ligne de fuite • 490, 495, 496, 498, 499, 537, 538, 539, 542, 544, 548, 549, 550, 551, 557, 561, 595, 638, 734, 744
Définition • 439
LIGNE DE FUITE • 562
LIGNE DE FUITE
Transformateur • 636
Transformateur moulé • 636
LIGNE DE FUITE • 548, 575, 585, 586, 622
LIGNE DE FUITE • 756
lignes de fuite • 444, 492, 497, 538, 550, 560, 641
Logiciel • 616, 617, 619, 682, 747, 808
L'ORGANISME RESPONSABLE • 487, 489, 492, 637, 638, 640
l'UTILISATION PREVUE • 699

M

maîtrise du risque • 617
Definition • 449
MAITRISE DU RISQUE
Mesure • 617
MAITRISE DU RISQUE
Mesure • 618
MAÎTRISE DU RISQUE
Mesure • 618
MAITRISE DU RISQUE
Mesures • 618
MAITRISE DU RISQUE
Analyse • 670
Compatibilité avec les substances • 605
Mesure • 456, 616, 670, 671, 672, 724
Mesure ou méthode d'essai alternative • 459
Mesures • 458
RISQUE RESIDUEL • 448
MAÎTRISE DU RISQUE • 456
Marking • 669
Marquage
Débordement • 603
Mauvais usage raisonnablement prévisible • 569, 667, 724
MAXIMUM MAINS VOLTAGE • 513
MEDICAL ELECTRICAL EQUIPMENT • 466, 631
INTENDED USE • 668
Part • 466
MEDICAL ELECTRICAL EQUIPMENT
FIXED • 601
MEDICAL ELECTRICAL EQUIPMENT
STATIONARY • 601
MEDICAL ELECTRICAL EQUIPMENT
PART • 789
MEDICAL ELECTRICAL SYSTEM • 463, 600, 603
INTENDED USE • 668
MEDICAL ELECTRICAL SYSTEM
CLEANING • 605
mélange anesthésique inflammable avec de l'air
Définition • 440
MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'AIR • 788
MÉLANGE ANESTHÉSIQUE INFLAMMABLE AVEC DE L'AIR • 438
MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'OXYGENE OU DU PROTOXYDE D'AZOTE • 788
MÉLANGE ANESTHÉSIQUE INFLAMMABLE AVEC DE L'OXYGÈNE OU DU PROTOXYDE D'AZOTE • 438, 790, 796, 801
mélange anesthésique inflammable avec oxygène ou protoxyde d'azote
Définition • 440
MELANGES ANESTHESIQUES INFLAMMABLES AVEC DE L'AIR • 795
MESURES DU COURANT DE FUITE • 640
MOBILE
APPAREIL ELECTROMEDICAL • 477, 680
APPAREIL EM • 575, 576, 603, 604, 625, 724
Mobile • 452
Definition • 444
MOBILE
APPAREILS ME • 574
Mobile
appareil • 574
MOBILE
APPAREIL ME • 575
MOBILE
APPAREIL ME • 575
MOBILE • 575
MOBILE • 575
MOBILE
APPAREIL ME • 576
MOBILE • 576
MOBILE • 576
MOBILE
APPAREIL ME • 624
MOBILE
APPAREIL A TRACTION MOTEUR • 625
MOBILE
APPAREILS ME • 631
MOBILE • 724
MOBILE • 724
MOOP
VOIR MOYEN DE PROTECTION DE L'OPERATEUR • 443
MOP
VOIR MOYEN DE PROTECTION • 443
MOPP
VOIR MOYEN DE PROTECTION DU PATIENT • 443
MOYEN DE PROTECTION • 442, 443, 449, 450, 461, 490, 494, 495, 498, 532, 537, 538, 540, 548, 556, 557, 562, 595
MOYEN DE PROTECTION
Tension d'essai pour l'isolation solide • 535
MOYEN DE PROTECTION
Écrans internes et câblage interne • 508, 701
Transformateurs formant • 635
Moyen de protection • 439, 495, 496
MOYEN DE PROTECTION • 532
MOYEN DE PROTECTION • 538
MOYEN DE PROTECTION • 559
MOYEN DE PROTECTION • 561
MOYEN DE PROTECTION • 562
MOYEN DE PROTECTION • 562
MOYEN DE PROTECTION • 612
MOYEN DE PROTECTION • 670

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

MOYEN DE PROTECTION
Tension d'essai pour • 713
MOYEN DE PROTECTION • 829
MOYEN DE PROTECTION • 830
MOYEN DE PROTECTION • 831
MOYEN DE PROTECTION • 831
moyen de protection de l'opérateur
Definition • 443
MOYEN DE PROTECTION DE L'OPÉRATEUR
LIGNE DE FUITE minimale • 548
Revêtements, etc. conformes à la CEI 60950-1 • 494
MOYEN DE PROTECTION DE L'OPERATEUR • 550
MOYEN DE PROTECTION DE L'OPERATEUR • 629
MOYEN DE PROTECTION DE L'OPERATEUR • 756
MOYEN DE PROTECTION DE L'OPERATEUR • 757
MOYEN DE PROTECTION DE L'OPERATEUR • 758
MOYEN DE PROTECTION DE L'OPERATEUR • 495, 496, 506, 538, 542, 545, 547, 548
MOYEN DE PROTECTION DE L'OPÉRATEUR
Tension d'essai pour • 536
MOYEN DE PROTECTION DE L'OPERATEUR • 542
MOYEN DE PROTECTION DE L'OPÉRATEUR
Tension d'essai pour l'isolation solide • 535
moyen de protection du patient • 496
Definition • 443
MOYEN DE PROTECTION DU PATIENT • 495
MOYEN DE PROTECTION DU PATIENT • 497
MOYEN DE PROTECTION DU PATIENT • 497
MOYEN DE PROTECTION DU PATIENT • 544
MOYEN DE PROTECTION DU PATIENT
Condensateurs • 495
MOYEN DE PROTECTION DU PATIENT
Tension d'essai pour l'isolation solide • 535
MOYEN DE PROTECTION DU PATIENT • 550
MOYEN DE PROTECTION DU PATIENT • 636
MOYEN DE PROTECTION DU PATIENT • 758
MOYEN DE PROTECTION OPERATEUR • 532, 638
MOYEN DE PROTECTION PATIENT • 790, 796
MOYEN DE PROTECTION PATIENT • 497
PARTIE APPLIQUEE DE TYPE F • 693
MOYEN DE PROTECTION PATIENT • 600
MOYENS DE PROTECTION • 448
MOYENS DE PROTECTION DE L'OPÉRATEUR • 496
MOYENS DE PROTECTION DE L'OPERATEUR
CEI 60950-1 • 539
MOYENS DE PROTECTION DU PATIENT • 506
MOYENS DE PROTECTION DU PATIENT • 539
MOYENS DE PROTECTION OPERATEUR • 638
MULTIPLE SOCKET-OUTLET • 817

N

NOMINAL • 474, 546
DEFINITION • 445
Fréquence • 463
tension • 463
tension d'alimentation • 474
NOMINAL
section des conducteurs • 559
NOMINAL
section des conducteurs • 559
NOMINAL
section • 562
NORMAL CONDITION • 489, 512, 743
Numéro de série
ACCESSOIRE • 473
APPAREIL EM • 472

O

OBJECTIVE EVIDENCE • 669
Operateur • 434, 486, 487, 492, 584, 689
OPERATEUR
RISQUE pour • 773
OPÉRATEUR • 445, 448, 451, 476, 483, 484, 485
Definition • 445
OPERATEUR
APPAREIL ÉLECTROMÉDICAL MOBILE • 680
Langue comprise par • 481
Mécanisme de séparation du RESEAU D'ALIMENTATION • 557
Parties mobiles • 568
Rayonnements à micro-ondes parasites • 590
OPÉRATEUR • 446, 471
OPÉRATEUR • 484
OPÉRATEUR • 492
OPÉRATEUR • 508
OPÉRATEUR • 529
OPERATEUR • 565
OPÉRATEUR • 570
OPERATEUR • 578
OPERATEUR • 579
OPERATEUR • 584
OPERATEUR • 584
OPERATEUR • 584
OPERATEUR • 584
OPERATEUR • 585
OPERATEUR • 585
OPERATEUR • 585
OPERATEUR • 587
OPÉRATEUR • 588
OPERATEUR • 599
OPÉRATEUR • 607
OPERATEUR • 607
OPERATEUR • 611
OPÉRATEUR • 621
OPERATEUR • 629
OPERATEUR • 629
OPÉRATEUR • 638
OPERATEUR • 638
OPERATEUR • 657
OPÉRATEUR • 670
OPÉRATEUR • 670
OPÉRATEUR • 682
OPÉRATEUR • 698
OPERATEUR • 813
OPERATOR • 679
organisme responsable • 434, 443, 448, 450, 483, 484, 493, 636
Definition • 448
INSTRUCTIONS D'UTILISATION • 484
ORGANISME RESPONSABLE
Mécanisme de séparation du RESEAU D'ALIMENTATION • 557
ORGANISME RESPONSABLE • 620
ORGANISME RESPONSABLE • 621
ORGANISME RESPONSABLE • 682
ORGANISME RESPONSABLE • 811
ORGANISME RESPONSABLE • 811
ORGANISME RESPONSABLE • 813
OUTIL • 440, 446, 466, 467, 477, 478, 492, 493, 494, 506, 508, 556, 561, 565, 581, 595, 626, 630, 638, 641, 642, 790, 792
Definition • 451
OUTIL • 491, 590, 640
OUTIL • 434, 472

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

OUTIL • 493
OUTIL • 493
OUTIL • 587
OUTIL • 641

P

PARTIE APPLIQUEE • 530
partie accessible • 492, 494, 496, 530
Definition • 434
PARTIE ACCESSIBLE • 490
partie accessible • 492
PARTIE ACCESSIBLE
METALLIQUE • 497
PARTIE ACCESSIBLE
MÉTALLIQUE • 497
PARTIE ACCESSIBLE
MÉTALLIQUE • 497
PARTIE ACCESSIBLE • 530
PARTIE ACCESSIBLE
Métallique • 556
PARTIE ACCESSIBLE • 559
PARTIE ACCESSIBLE
MOBILE • 611
PARTIE ACCESSIBLE
Écrans internes et câblage interne • 508, 701
PARTIE ACCESSIBLE • 496
PARTIE ACCESSIBLE • 467, 470, 476, 489
PARTIE ACCESSIBLE • 609
PARTIE ACCESSIBLE • 655
PARTIE APPLIQUE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION • 499
PARTIE APPLIQUEE • 513
PARTIE APPLIQUÉE • 499
PARTIE APPLIQUEE • 450, 452, 470, 475, 491, 494, 496, 497, 498
partie appliquée • 440, 446
partie appliquée • 491
partie appliquée
multiple • 497
PARTIE APPLIQUEE • 499
PARTIE APPLIQUÉE • 503
PARTIE APPLIQUÉE • 503
PARTIE APPLIQUEE • 504
PARTIE APPLIQUÉE • 528
~~PARTIE APPLIQUÉE~~ • 528
PARTIE APPLIQUEE • 530
PARTIE APPLIQUEE • 530
PARTIE APPLIQUEE • 530
PARTIE APPLIQUEE • 530
PARTIE APPLIQUEE • 530
PARTIE APPLIQUEE • 531
PARTIE APPLIQUEE • 531
PARTIE APPLIQUEE • 531
PARTIE APPLIQUEE • 531
PARTIE APPLIQUÉE • 592
PARTIE APPLIQUÉE • 592
PARTIE APPLIQUÉE • 592
PARTIE APPLIQUEE • 592
PARTIE APPLIQUEE • 593
PARTIE APPLIQUEE • 605
PARTIE APPLIQUÉE • 608
PARTIE APPLIQUÉE • 608
PARTIE APPLIQUÉE • 609
PARTIE APPLIQUÉE
MOBILE • 611
PARTIE APPLIQUÉE • 640
PARTIE APPLIQUEE
Froid • 593
Non destinée à fournir de la chaleur • 592
Température • 593
PARTIE APPLIQUÉE • 459, 496, 499
PARTIE APPLIQUÉE • 434, 439
PARTIE APPLIQUÉE • 654
PARTIE APPLIQUÉE • 698
PARTIE APPLIQUEE • 698
PARTIE APPLIQUÉÉ • 467, 475, 485, 489
PARTIE APPLIQUEE DE TYPE • 704
partie appliquée de type b • 491, 497, 530
partie appliquée de type b • 452
PARTIE APPLIQUEE DE TYPE B
Total ***COURANT DE FUITE PATIENT*** • 704
PARTIE APPLIQUÉE DE TYPE B
Classification • 459
PARTIE APPLIQUEE DE TYPE B • 531
partie appliquée de type bf • 491, 530, 531
Definition • 452
PARTIE APPLIQUÉE DE TYPE BF • 452
partie appliquée de type bf • 497
PARTIE APPLIQUÉE DE TYPE BF
Classification • 459
PARTIE APPLIQUEE DE TYPE BF • 470
PARTIE APPLIQUEE DE TYPE BF • 475
PARTIE APPLIQUEE DE TYPE BF • 531
PARTIE APPLIQUÉE DE TYPE CF
Classification • 459
partie appliquée de type cf
Definition • 452
PARTIE APPLIQUEE DE TYPE CF • 470
PARTIE APPLIQUEE DE TYPE CF • 475
partie appliquée de type cf • 491
PARTIE APPLIQUÉE DE TYPE CF • 491
partie appliquée de type cf • 497
PARTIE APPLIQUEE DE TYPE CF • 531
Partie appliquée de type cf • 531
PARTIE APPLIQUÉE DE TYPE F • 446, 452, 497
Partie appliquée de type f • 497
partie appliquée du type b
Definition • 452
PARTIE APPLIQUEE DU TYPE F • 498, 530
partie appliquée isolée du type f (flottante) •
Voir en partie appliquée du type f
PARTIE APPLIQUÉE PROTÉGÉE CONTRE LES CHOCS DE DÉFIBRILLATION • 499
partie appliquée protégée contre les chocs de défibrillation • 499
Definition • 439
PARTIE APPLIQUEE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION • 498
PARTIE APPLIQUEE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION • 503
PARTIE APPLIQUEE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION • 542
PARTIE APPLIQUEE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION • 475
PARTIE APPLIQUÉEDE TYPE BF • 672
PARTIE APPLIQUÉEDE TYPE CF • 672
PARTIE RELIEE AU RESEAU • 535
partie reliée au réseau • 449, 465, 509, 534, 537, 538, 540, 541, 543, 545, 546, 548, 556, 562, 563
Définition • 442
PARTIE RESEAU • 684

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parties accessibles • 491
PARTIES APPLIQUEES • 467
PARTIES APPLIQUEES DE TYPE B • 710
PARTIES APPLIQUEES DE TYPE B • 452, 470, 475
PARTIES APPLIQUEES DE TYPE BF • 452
PARTIES APPLIQUÉES DU TYPE BF • 440
PARTIES APPLIQUÉES DU TYPE CF • 440
parties appliquées du type f • 440
PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION • 697
PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION • 699
PATIENT
Agissant comme OPÉRATEUR • 681
Besoins particuliers • 568
Câble • 497, 626, 640, 641, 651, 654
Conducteur • 626, 641, 651, 654
Contact • 459, 568, 652, 672
LE PATIENT est un OPÉRATEUR prévu • 484
MASSE • 771
PARTIE APPLIQUEE dépasse 41 °C • 592
RISQUE pour • 657
Sensibilité à *l'énergie acoustique et aux vibrations* • 578
Support • 574
Patient • 435, 439, 440, 443, 446, 448, 451, 459
Definition • 446
PATIENT
Cable • 476
PATIENT • 476
PATIENT • 479
PATIENT • 485
PATIENT • 485
PATIENT • 486
PATIENT • 486
PATIENT • 491
PATIENT • 491
PATIENT • 492
PATIENT • 497
PATIENT • 497
PATIENT • 498
PATIENT • 499
PATIENT
Conducteur • 499
PATIENT • 529
PATIENT • 530
PATIENT • 530
PATIENT • 531
PATIENT • 531
PATIENT • 564
PATIENT • 565
Patient • 568
Patient
besoins particuliers • 568
PATIENT • 571
PATIENT • 571
PATIENT • 578
PATIENT • 578
PATIENT • 579
PATIENT • 584
PATIENT • 584
PATIENT
humain adulte • 584
PATIENT • 584
PATIENT • 584
PATIENT • 584
PATIENT • 584
PATIENT • 584
PATIENT • 585
PATIENT • 585
PATIENT • 585
PATIENT • 585
PATIENT • 586
PATIENT • 588
PATIENT • 592
PATIENT • 592
PATIENT • 599
PATIENT • 599
PATIENT • 607
PATIENT • 607
PATIENT • 607
PATIENT • 621
PATIENT • 638
PATIENT • 655
PATIENT • 657
PATIENT • 670
PATIENT
tension imprévue sur • 693
PATIENT
Nombre de PARTIES APPLIQUEES • 704
PATIENT
RISQUE pour • 773
PATIENT • 788
Patient auxiliary current • 512
Definition • 446
PATIENT CONNECTION • 512
PATIENT CONNECTION
F-TYPE APPLIED PART • 513
PATIENT CONNECTION
F-TYPE APPLIED PART • 693
PATIENT CONNECTION
Single • 710
PATIENT LEAKAGE CURRENT • 512, 513
PATIENT LEAKAGE CURRENT
Total • 512
PATIENT LEAKAGE CURRENT
Total • 512
PATIENT LEAKAGE CURRENT
Total • 513
PATIENT LEAKAGE CURRENT
Value • 513
PEMS DEVELOPMENT LIFE-CYCLE • 617
performance essentielle • 618, 674
Definition • 439
PERFORMANCE ESSENTIELLE VERIFICATION • 618
Performance essentielle • 427, 428, 434, 619
PERFORMANCES ESSENTIELLES • 657
PERFORMANCES ESSENTIELLES • 655
PERFORMANCES ESSENTIELLES
Communication de • 488
PERFORMANCES ESSENTIELLES • 458, 459
PERFORMANCES ESSENTIELLES • 575
PERFORMANCES ESSENTIELLES • 585
PERFORMANCES ESSENTIELLES • 585
PERFORMANCES ESSENTIELLES • 586
PERFORMANCES ESSENTIELLES • 616
PERFORMANCES ESSENTIELLES • 617
PERFORMANCES ESSENTIELLES • 622
PERFORMANCES ESSENTIELLES • 627
PERFORMANCES ESSENTIELLES • 667
PERFORMANCES ESSENTIELLES • 733
PERFORMANCES ESSENTIELLES • 733
PERSONNEL D'ENTRETIEN
Mécanisme de séparation du RESEAU D'ALIMENTATION • 557

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Rayonnements à micro-ondes parasites • 590
PERSONNEL D'ENTRETIEN • 484
PERSONNEL D'ENTRETIEN • 771
personnel de service • 451, 465, 473, 477, 478, 487, 489, 587, 680
Definition • 450
PERSONNEL DE SERVICE • 489
PERSONNEL D'ENTRETIEN • 561
PORTABLE
APPAREIL EM • 624
Portable • 452
Definition • 447
Portable
appareil me • 577
Portable
appareil me • 577
portatif
APPAREIL ME • 463
Définition • 441
PORTATIF
APPAREILS ME • 611
PORTATIF
APPAREILS ME • 615
PORTATIF
APPAREIL ME • 623
PORTATIF
APPAREIL ME • 624
PORTATIF
dispositif de commande • 630
PORTATIF
dispositif • 631
PORTATIF
APPAREIL EM • 623, 624
PORTATIF • 454
PORTÉ • 499
PORTÉ SUR LE CORPS
Définition • 454
POWER SUPPLY CORD • 790
pression d'essai hydraulique
Définition • 441
PRESSION D'ESSAI HYDRAULIQUE • 580
pression maximale admissible de fonctionnement • 580, 581
Definition • 443
preuve tangible
Definition • 445
PREUVE TANGIBLE • 453
PREUVE TANGIBLE • 457
PREUVES TANGIBLES • 448
prise réseau • 434, 559, 560
Définition • 442
PRISE RÉSEAU • 560
Procedure • 509, 533, 549
Definition • 447
PROCEDURE
Start-up • 486
PROCEDURE
arrêt • 486
PROCEDURE
Essai • 604
PROCEDURE • 504, 513, 529, 590
PROCEDURE • 604
PROCEDURE • 605
PROCEDURE • 605
PROCEDURE • 605
PROCEDURE • 616
PROCEDURE • 617
PROCEDURE • 619
PROCÉDURE • 638
PROCÉDURES • 449
PROCESS • 452, 610
RISK MANAGEMENT • 668
PROCESSUS • 441, 449
DEFINITION • 447
PROCESSUS • 461
PROCESSUS • 603
PROCESSUS
Conception • 667
CYCLE DE DÉVELOPPEMENT DE SEMP • 616
Développement de logiciel • 616
GESTION DES RISQUES • 456, 459, 593, 607, 616, 667, 671
INGÉNIERIE D'APTITUDE À L'UTILISATION • 606, 621, 667
MAÎTRISE DU RISQUE • 449
Procédure • 447
PROCESSUS • 441
PROCESSUS • 435
PROCESSUS • 446
PROCESSUS • 449
Processus • 449
PROCESSUS • 452
PROCESSUS • 456
PROCESSUS • 461
PROCESSUS • 498
PROCESSUS • 507
PROCESSUS • 582
PROCESSUS • 585
PROCESSUS • 599
PROCESSUS • 605
PROCESSUS • 606
PROCESSUS • 607
PROCESSUS • 607
PROCESSUS • 608
PROCESSUS • 608
PROCESSUS • 617
PROCESSUS • 631
PROCESSUS • 642
PROCESSUS
fabrication • 744
PROCESSUS DE GESTION DES RISQUES
PROCESSUS • 461
PROCESSUS DE GESTION DES RISQUES
PROCESSUS • 617
protection
Définition • 441
PROTECTIVELY EARTHED
Non- • 513
protégé contre les chocs de défibrillation • 497
PROTEGÉ PAR MISE À LA TERRE • 451, 497, 506
protégé par mise à la terre • 529, 530
Definition • 448
PROTÉGÉ PAR MISE À LA TERRE
NON- • 559
PROTEGE PAR MISE A LA TERRE • 507
PROTEGE PAR MISE A LA TERRE • 529
PROTEGE PAR MISE A LA TERRE • 529
PROTÉGÉE PAR MISE À LA TERRE • 504, 506
PROTEGEE PAR MISE A LA TERRE • 507
PROTEGEE PAR MISE A LA TERRE
NON- • 530
PROTEGEE PAR MISE A LA TERRE • 529, 530
PROTEGEES PAR MISE A LA TERRE • 499
PROTEGEES PAR MISE A LA TERRE • 508
RÉSEAU D'ALIMENTATION • 474

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

R

RECORD • 754
REFERENCE DE MODELE OU DE TYPE
Composants non fixés à demeure • 473
REFERENCE DE MODELE OU DE TYPE • 472
Référence de modèle ou de type • 473
REFERENCE DE MODELE OU DE TYPE • 473
REFERENCE DE MODELE OU DE TYPE • 484
RÉFÉRENCE DE MODÈLE OU DE TYPE • 678
référence du modèle ou du type
Definition • 444
REGISTRE • 616
RESEAU • 488, 713
RESEAU • 462, 463, 474, 490, 498
RESEAU
Isolation du • 684
RESEAU • 465, 470
RÉSEAU D'ALIMENTATION • 442, 443, 444, 446, 447, 474, 541
Definition • 450
RESEAU D'ALIMENTATION
CARACTERISTIQUES assignées • 465
Interrupteur • 558
Séparation de • 558
RÉSEAU D'ALIMENTATION • 442, 458
RESEAU D'ALIMENTATION • 527
RÉSEAU D'ALIMENTATION • 655
RÉSEAU D'ALIMENTATION • 670
RÉSEAU D'ALIMENTATION • 490, 491, 507, 528, 538, 540, 541, 545, 546, 557, 558, 572, 606, 635, 638, 640
INTERRUPTEUR • 558
RESEAU D'ALIMENTATION
INTERRUPTEUR • 557
RESEAU D'ALIMENTATION
INTERRUPTEUR • 558
RESEAU D'ALIMENTATION • 563
RÉSEAU INFORMATIQUE
Configuration • 621
Connexion d'unités supplémentaires • 621
Déconnexion d'unités • 621
Définition • 454
Intégrateur système • 811
Mise à jour d'appareil • 621
Mise à niveau d'appareil • 621
Paramètres • 814
SITUATION DANGEREUSE possible • 811
RÉSEAU INFORMATIQUE • 617
RÉSEAU INFORMATIQUE • 620
RÉSEAU INFORMATIQUE • 620
RÉSEAU INFORMATIQUE • 621
RÉSEAU INFORMATIQUE • 621
RÉSEAU INFORMATIQUE • 754
RÉSEAU INFORMATIQUE • 810
RESEAU INFORMATIQUE • 810
RESEAU INFORMATIQUE • 810
RESEAU INFORMATIQUE • 811
RESEAU INFORMATIQUE • 811
RESIDUAL RISK • 669
Unacceptable • 669
RESISTANCE A LA TRACTION • 450
Definition • 451
SITUATION DANGEREUSE • 620
RISK
Unacceptable • 668
RISK • 669
RISK • 669
RISK
Acceptable • 669
RISK
Acceptability of • 669
RISK CONTROL • 669
RISK CONTROL
Measure • 679
RISK EVALUATION • 669
RISK MANAGEMENT • 452
RISK MANAGEMENT
PLAN • 616
RISK MANAGEMENT FILE
Inspection • 669
RISQUE • 448, 449, 450, 497
acceptable • 460
choc électrique • 443
choc électrique sur des personnes autres que le patient • 443
choc électrique sur le PATIENT • 443
défaillance du composant • 460
Definition • 448
inacceptable • 461, 479, 485
RÉDUCTION • 460
remplacement de batteries au lithium ou de piles à combustible • 478
RISQUE
inacceptable • 485
RISQUE
inacceptable • 537
RISQUE
inacceptable • 555
RISQUE
parties en mouvement • 564
RISQUE
parties en mouvement • 564
RISQUE
inacceptable • 565
RISQUE
inacceptable • 568
RISQUE
inacceptable • 568
RISQUE
acceptable • 570
RISQUE
inacceptable • 571
RISQUE
inacceptable • 571
RISQUE
acceptable • 571
RISQUE
inacceptable • 571
RISQUE
inacceptable • 575
RISQUE
inacceptable • 577
RISQUE
projection d'objets • 577
RISQUE
inacceptable • 577
RISQUE
inacceptable • 579
RISQUE
inacceptable • 579
RISQUE
inacceptable • 579
RISQUE
inacceptable • 579
RISQUE
inacceptable • 579
RISQUE

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

inacceptable • 580
RISQUE
inacceptable • 582
RISQUE
inacceptable • 582
RISQUE
inacceptable • 583
RISQUE
inacceptable • 585
RISQUE
inacceptable • 585
RISQUE
inacceptable • 585
RISQUE
inacceptable • 586
RISQUE
inacceptable • 595
risque
compatibilité avec des substances • 605
risque
sortie incorrecte • 607
risque
délivrance incorrecte d'énergie ou de substances • 607
risque
Energie acoustique à des fins de diagnostic ou de thérapie • 608
RISQUE • 610
RISQUE
résolution de problèmes • 617
RISQUE
acceptable • 618
RISQUE
inacceptable • 621
RISQUE
inacceptable • 622
RISQUE
inacceptable • 623
RISQUE
inacceptable • 623
RISQUE
inacceptable • 623
RISQUE
inacceptable • 624
RISQUE
inacceptable • 624
RISQUE
inacceptable • 625
RISQUE
inacceptable • 625
RISQUE
inacceptable • 626
RISQUE
inacceptable • 627
RISQUE
inacceptable • 628
RISQUE
inacceptable • 630
RISQUE
inacceptable • 631
RISQUE
inacceptable • 631
RISQUE
inacceptable • 631
RISQUE
inacceptable • 636
RISQUE
compatibilité électromagnétique • 642
RISQUE
Acceptable • 456, 457, 668, 724
Basculement • 573
Critères d'acceptabilité • 457
Critères d'acceptation • 449
d'accumulation et d'inflammation • 628
Déconnexion accidentelle • 508, 509
Évaluation • 457
Faible APTITUDE À L'UTILISATION • 606
Groupement des commandes et des indicateurs • 621
Inacceptable • 439, 456, 568, 593, 603, 604, 605, 616, 623, 624, 640, 657, 658
Incendie • 745
Non identifié précédemment • 621
Nouveau • 621
PERFORMANCES ESSENTIELLES • 670
pour le PATIENT • 657
RISQUE • 458
RISQUE • 481
RISQUE • 481
RISQUE
interférence réciproque • 484
RISQUE • 579
RISQUE • 584
RISQUE • 592
RISQUE
DE FEU • 599
RISQUE
inflammation • 600
Risque
Dépassement intentionnel des limites de sécurité • 606
RISQUE • 608
RISQUE • 623
RISQUE • 624
RISQUE • 625
RISQUE • 629
RISQUE
Acceptable • 658
RISQUE
Brûlure • 689
RISQUE
Mise à la terre du PATIENT • 693
RISQUE
CONNEXIONS PATIENT multiples • 710
RISQUE
inacceptable • 724
RISQUE
inacceptable • 745
RISQUE
Acceptable • 754
RISQUE
pour le PATIENT ou l'OPERATEUR • 773
RISQUE INACCEPTABLE • 605
risque résiduel
Definition • 448
RISQUE RESIDUEL
acceptabilité • 572
RISQUE RESIDUEL
Acceptabilité de • 698
RISQUE RESIDUEL
Critères d'acceptabilité • 457
Évaluation • 457
Intégrateur système • 811
Mesure ou méthode d'essai alternative • 672
PERFORMANCES ESSENTIELLES • 670
Sécurité équivalente • 672
RISQUE RÉSIDUEL • 455, 456
RISQUE RÉSIDUEL • 670

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

S

SECONDARY CIRCUIT • 535, 713
SECURISE EN PREMIER DEFAUT • 567, 568, 756, 757
SECURITE DE BASE • 655
SECURITE DE BASE • 674
sécurité de base • 427, 428, 434, 619
SÉCURITÉ DE BASE • 439, 458, 575, 585, 586, 616, 617, 620, 622, 657, 667, 676, 733
Sélection accidentelle de valeurs excessives des caractéristiques de sortie • 607
SEMP
Voir SYSTEME ELECTROMEDICAL PROGRAMMABLE • 447
service continu • 476, 594, 639, 796
Definition • 439
NON- • 470, 476
service continu
Non- • 594
SERVICE CONTINU • 470
Service CONTINU
Non- • 639
SERVICE PERSONNEL • 684
SEVERITE • 448
Definition • 450
SIGNAL D'ALARME
Définition • 454
SIGNAL D'ALARME • 454
SIGNAL D'ALARME • 458
SIGNAL D'ALARME • 578
SIGNAL D'ALARME • 657
SIGNAL D'ALARME • 670
SIGNAL INPUT/OUTPUT PART • 512
SIGNE DE SECURITE • 471, 476, 477
Signe de sécurité • 573
SINGLE FAULT CONDITION • 489, 513, 668, 743
situation dangereuse • 460, 490, 514, 548, 555, 556, 563, 608, 628, 629, 630, 632, 640, 658, 668
Définition • 441
SITUATION DANGEREUSE • 628
SITUATION DANGEREUSE
Pénétration d'eau et de corps solides • 743
SITUATION DANGEREUSE
Conditions ou défauts • 456
COUPE-CIRCUIT THERMIQUES et DISJONCTEURS • 626, 627
Débordement • 603
Détachement des conducteurs et des connecteurs • 556
Mécanisme de séparation du RESEAU D'ALIMENTATION • 557
RESEAU INFORMATIQUE comme source • 811
THERMOSTAT • 626
SITUATION DANGEREUSE • 491
SITUATION DANGEREUSE • 670
SITUATION DANGEREUSE • 812
SITUATION DANGEREUSES • 679, 694
SOCLE À PRISES MULTIPLES • 638, 639, 641
socle de connecteur • 434, 478, 506, 507, 528, 550, 572
SOCLE DE CONNECTEUR • 563
SOCLE DE PRISE DE COURANT MULTIPLE • 444, 475, 484, 558, 639
Definition • 445
SOCLE DE PRISES MULTIPES • 642
SOCLE DE PRISES MULTIPLES • 642, 818
SOCLE DE PRISES MULTIPLES • 707, 763
SOCLE FIXE DE PRISE DE COURANT RÉSEAU • 440
SOCLE MOBILE À PRISES MULTIPLES • 637
SOCLES MOBILES À PRISES MULTIPLES • 637, 639
SOURCE ELECTRIQUE INTERNE • 465, 628
source électrique interne • 442, 462
Définition • 442
SOURCE ELECTRIQUE INTERNE • 449
SOURCE ELECTRIQUE INTERNE • 629
SOURCE ELECTRIQUE INTERNE D'UN APPAREIL • 628
sous-système électronique programmable
Definition • 447
SOUS-SYSTEME ELECTRONIQUE PROGRAMMABLE (SSEP) • 618
SOUS-SYSTÈME ÉLECTRONIQUE PROGRAMMABLE (SSEP) • 616, 617
SOUS-SYSTÈME ÉLECTRONIQUES PROGRAMMABLES (SSEP) • 618
SOUS-SYSTEMES ELECTRONIQUES PROGRAMMABLES (SSEP) • 447
SSEP
Voir SOUS-SYSTEME ELECTRONIQUE PROGRAMMABLE • 447
stabilité thermique • 594, 611, 614, 615, 633, 634, 639
Definition • 451
STATIONARY
ME EQUIPMENT • 471
STATIONARY
ME EQUIPMENT • 601
SUPPLY MAINS • 463, 485
Symbole • 452, 472, 474, 475, 476, 477, 478, 479, 481, 484, 486, 494, 508, 558
SYSTÈME D'ALARME
Définition • 454
SYSTÈME D'ALARME • 454
SYSTÈME D'ALARME • 606
SYSTÈME D'ALARME • 657
SYSTÈME D'ALARME • 670
SYSTÈME D'ALARME • 670
SYSTEME D'ALARME • 671
Système de distribution de gaz médical • 427
SYSTEME ELECTROMEDICAL
ENVIRONNEMENT DU PATIENT • 446
Parties en contact avec le patient • 459
sécurité equivalente • 459
SYSTÈME ELECTROMEDICAL
APPLICABILITE OU EXIGENCE • 427
système électromédical
Definition • 444
SYSTÈME ÉLECTROMÉDICAL
Alimenté par une UPS ou une IPS • 638
Composant • 456
COURANT DE FUITE • 510
Identification des PERFORMANCES ESSENTIELLES • 458
Nettoyages/désinfections multiples • 605
SYSTÈME ÉLECTROMÉDICAL • 640
SYSTEME ELECTROMEDICAL PROGRAMMABLE • 618
Système électromédical programmable définition) • 447
SYSTEME ELECTROMEDICAL PROGRAMMABLE (SEMP) • 446, 473
SYSTEME ELECTROMEDICAL PROGRAMMABLE (SEMP) • 618
SYSTÈME EM
Forts courants transitoires • 638
SYSTEME ME • 637, 638

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

système me • 427, 434, 435, 443, 447, 450, 452, 459, 463, 470, 484, 485, 490, 491, 508, 509, 565, 604, 636, 637, 638, 639, 640, 642, 643
organisme responsable • 448
SYSTEME ME
RISQUE D'INCENDIE • 595
SYSTEME ME • 636
SYSTEME ME • 636
SYSTÈME ME • 637
SYSTEME ME
Partie • 639
SYSTÈME ME • 640
SYSTÈMES ÉLECTROMÉDICAUX PROGRAMMABLES (SEMP) • 617, 618, 619
SYSTÈMES ÉLECTROMÉDICAUX PROGRAMMABLES (SEMP)
SYSTÈMES ÉLECTROMÉDICAUX PROGRAMMABLES (SEMP) • 615, 616, 617
SYSTÈMES ÉLECTROMÉDICAUX PROGRAMMABLES (SEMP) • 621
SYSTEMES ELECTROMEDICAUX PROGRAMMABLES (SEMP) • 754
systèmes me • 463, 636
Condition d'application • 454
processus de gestion du risque • 455
RESEAU • 463
SYSTEMES ME
NETTOYAGE • 605
SYSTEMES ME
BIOCOMPATIBILITE • 605
SYSTEMES ME
BIOCOMPATIBILITE • 605
SYSTEMES ME
BIOCOMPATIBILITE • 605

T

TAUX D'UTILISATION • 476
TAUX D'UTILISATION • 594
température ambiante • 736
Température ambiante • 593
TENSION DE SERVICE • 446, 496, 497, 498
tension de service
Definition • 453
TENSION DE SERVICE • 499
TENSION DE SERVICE • 534
TENSION DE SERVICE • 539
TENSION DE SERVICE • 545
TENSION DE SERVICE • 547
TENSION DE SERVICE • 635
TENSION DE SERVICE • 639
TENSION DE SERVICE • 691
TENSION DE SERVICE • 691
TENSION DE SERVICE • 691
TENSION DE SERVICE • 691
TENSION DE SERVICE • 713
TENSION DE SERVICE • 548
tension de service de crete • 535, 536
TENSION DE SERVICE DE CRÊTE • 539, 540, 546
TENSION DE SERVICE DE CRETE+ • 542
TENSION MAXIMALE RÉSEAU • 498
TENSION RESEAU • 513
tension réseau • 498, 540, 639, 792, 797
Definition • 443
NOMINAL • 445
TENSION RÉSEAU
ASSIGNÉ • 509
TENSION RESEAU
NOMINAL • 540
TENSION RESEAU
ASSIGNE • 540
tension réseau maximale • 489, 497, 498, 530
Definition • 443
TENSION TRANSITOIRE RESEAU • 540, 541, 545
TENU A LA MAIN
Dispositif de commande • 556
Partie • 556
TENU A LA MAIN
Dispositif de commande • 556
THERMOSTAT
Défaillance • 626
Thermostat • 610, 613
Definition • 451
THERMOSTAT • 627
TOUCH CURRENT • 512
transformateur d'alimentation réseau
Définition • 442
TRANSPORTABLE
APPAREIL EM • 603, 604, 742
TRANSPORTABLE
Appareil • 444, 447
APPAREIL ME • 471
Definition • 451
TRANSPORTABLE
APPAREIL ME • 601
TYPE CF APPLIED PART • 513
TYPE TEST • 533, 829

U

UN COUPE CIRCUIT THERMIQUE A REENCLENCHEMENT AUTOMATIQUE
NON- • 613
USAGE NORMAL • 585, 797
Usage prévu
Définition • 441
DURÉE DE VIE PRÉVUE • 671
Identification des PERFORMANCES ESSENTIELLES • 458
PERFORMANCES ESSENTIELLES • 657
USAGE PRÉVU • 484
USAGE PREVU • 588
USAGE PRÉVU • 655
USAGE PREVU • 724
USAGE PRÉVU • 725
USAGE PREVU • 812
USAGE PREVU • 815
UTILISATION IMPROPRE PREVISIBLE • 454, 461, 564, 565, 595, 618
UTILISATION IMPROPRE PRÉVISIBLE • 438
utilisation normale • 451, 454, 464, 476, 479, 492, 494, 498, 508, 557, 559, 572, 578, 593, 594, 600, 604, 605, 623, 624, 626, 629, 631, 632, 633, 639, 658, 736, 744
Definition • 445
UTILISATION NORMALE • 438
UTILISATION NORMALE • 492
UTILISATION NORMALE • 530
UTILISATION NORMALE • 532
UTILISATION NORMALE APPAREIL PORTABLE • 577
utilisation normale • 615
UTILISATION NORMALE • 623
UTILISATION NORMALE • 629
UTILISATION NORMALE • 629
UTILISATION NORMALE • 630
UTILISATION NORMALE • 630

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

UTILISATION NORMALE • 790
UTILISATION NORMALE • 791
UTILISATION NORMALE • 791
UTILISATION NORMALE • 795
UTILISATION NORMALE • 796
UTILISATION NORMALE • 797
UTILISATION NORMALE
USAGE PRÉVU définition • 442
Utilisation normale • 435, 441
Utilisation normale • 446
UTILISATION NORMALE • 449
UTILISATION NORMALE • 451
UTILISATION NORMALE • 453
UTILISATION NORMALE • 467
UTILISATION NORMALE • 471
UTILISATION NORMALE • 471
UTILISATION NORMALE • 472
UTILISATION NORMALE • 479
UTILISATION NORMALE • 479
UTILISATION NORMALE • 485
UTILISATION NORMALE • 486
UTILISATION NORMALE • 491
UTILISATION NORMALE • 531
UTILISATION NORMALE • 533
UTILISATION NORMALE • 565
UTILISATION NORMALE • 569
UTILISATION NORMALE • 571
UTILISATION NORMALE • 572
UTILISATION NORMALE • 572
UTILISATION NORMALE • 572
UTILISATION NORMALE • 573
UTILISATION NORMALE • 575
UTILISATION NORMALE • 576
UTILISATION NORMALE • 584
UTILISATION NORMALE • 585
UTILISATION NORMALE • 585
UTILISATION NORMALE • 593
UTILISATION NORMALE • 593
UTILISATION NORMALE • 593
UTILISATION NORMALE • 604
UTILISATION NORMALE • 641
UTILISATION NORMALE • 652
UTILISATION NORMALE • 654
UTILISATION NORMALE • 724
UTILISATION NORMALE • 742

V

validation de semp
Definition • 446
VALIDATION DU SEMP • 446
VALIDATION DU SEMP
Méthodes • 619
VALIDATION SEMP • 619
VALIDATION SEMP
Plan • 619
VALIDATION SEMP • 619
VALIDATION SEMP
Plan • 619
VALIDATION SEMP • 619
VALIDATION SEMP • 619
VALIDATION SEMP
équipe • 619
VERIFICATION
résultats • 619
SEMP • 618, 619
Verification
Definition • 453
VERIFICATION
Methods • 616
VERIFICATION
Tools • 754
VÉRIFICATION
étapes • 619
VERIFICATION
Critères de couverture • 619
outils • 619
Plan • 619
Stratégies • 619

Z

zone de piégeage • 565
Definition • 452

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

INDEX DES ABREVIATIONS ET ACRONYMES

Abréviation	Terme
a.c.	Courant alternatif
AMSO	Auxiliary mains socket-outlet (Socle de prise réseau auxiliaire)
AP	Anaesthetic-proof (Résistant aux anesthésiques)
APG	Anaesthetic-proof category G (gas) (Résistant aux anesthésiques, catégorie G)
ASI	Alimentations sans interruption
CASE	Computer aided software engineering (Ingénierie logicielle assistée par ordinateur)
CAT	Computer assisted tomography (Tomographie assistée par ordinateur)
CIPR	Commission internationale pour la protection radiologique
CRT	Tube cathodique
CTP	Coefficient de température positif
d.c.	Courant continu
DEL	Diode électroluminescente
DICOM	Digital imaging and communication in medicine (Imagerie et communication numérique en médecine)
EM	ELECTROMEDICAL, voir 3.63 et 3.64
EUT	Equipment under test (appareil en essai)
FDDI	Fibre distributed data interface
FMEA	Failure Modes and Effects Analysis (Analyse de modes de défaillance et de leurs effets)
FV	Classification d'inflammabilité selon l'IEC 60695-11-10
HL7	Health level 7 (Santé niveau 7)
IBP	Cathéter pour la mesure de la pression artérielle
IP	International protection (Protection internationale) en relation avec les exigences de protection de l'IEC 60529 ou Internet protocol (Protocole Internet) en relation avec COUPLAGE DE RESEAUX / DONNEES
IPS	Alimentation isolée
IRC	Indice de résistance au cheminement
LDAP	Light weight directory access protocol
LEA	Limite d'émission accessible
MAR	Minimum angle resolvable
MD	Measuring device (Dispositif de mesure (voir 8.7.4.4))
MOOP	MEANS OF OPERATOR PROTECTION, (Moyen de protection opérateur – voir 3.58)
MOP	MEANS OF PROTECTION, (Moyen de protection – voir 3.60)
MOPP	MEANS OF PATIENT PROTECTION, (Moyen de protection patient – voir 3.59)
MPSO	Multiple portable socket-outlet (Socle multiple portable)
MSO	MULTIPLE SOCKET-OUTLET, (socle à prises multiples – voir 3.67)
OTS	Off the shelf (sur étagère)
PTFE	Polytétrafluoroéthylène
PVC	Polychlorure de vinyle
PVC	Chlorure de polyvinyle (Polyvinyl chloride)
RFID	Identification par radiofréquence
r.m.s.	Root mean square (valeur efficace)
SAR	Taux d'absorption spécifique

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SEMP	SYSTEME ELECTROMEDICAL PROGRAMMABLE, voir 3.90
SI	Système international
SIP/SOP	SIGNAL INPUT/OUTPUT PART (PARTIE ENTREE/SORTIE DE SIGNAL), voir 3.115.
SSEP	SOUS-SYSTEME ELECTROMEDICAL PROGRAMMABLE, voir 3.91
TBT	Très basse tension
TBTS	Très basse tension de sécurité
TCP	Transport connection protocol
TENS	Transcutaneous electronic nerve stimulator (neurostimulateur électrique transcutané)
TFE	Tétrafluoroéthylène
TI	Technologie de l'information
VDU	Unité d'affichage vidéo
VEI	Vocabulaire Electrotechnique International

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Medical electrical equipment –
Part 1: General requirements for basic safety and essential performance

Appareils électromédicaux –
Partie 1: Exigences générales pour la sécurité de base et les performances essentielles



IEC 60601-1:2005-07+AMD1:2012-08 CSV(en-fr)

Publication IEC 60601-1 (Third edition – 2005) I-SH 01

MEDICAL ELECTRICAL EQUIPMENT – Part 1: General requirements for basic safety and essential performance

INTERPRETATION SHEET 1

This interpretation sheet has been prepared by SC 62A: Common aspects of electrical equipment used in medical practice

The text of this interpretation sheet is based on the following documents:

ISH	Report on voting
62A/599/ISH	62A/613/RVD

Full information on the voting for the approval of this interpretation sheet can be found in the report on voting indicated in the above table.

Subclause 1.1

This subclause is clarified by the following:

IEC 60601-1 does not apply to medical gas pipeline systems covered by ISO 7396-1, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum.*

NOTE Subclause 6.3 of ISO 7396-1 applies the requirement of IEC 60601-1-8 to certain monitoring and alarm signals.

This clarification will remain valid until a new version of IEC 60601-1 is published.

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Publication IEC 60601-1 (Third edition – 2005) I-SH 02

MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

INTERPRETATION SHEET 2

This interpretation sheet has been prepared by subcomittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this interpretation sheet is based on the following documents:

ISH	Report on voting
62A/634/ISH	62A/640/RVD

Full information on the voting for the approval of this interpretation sheet can be found in the report on voting indicated in the above table.

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Subclause 11.3

This subclause is clarified by the following:

As stated in the rationale for this subclause, fire ENCLOSURES are intended to be used only where there is a significant likelihood of fire due to the presence of a source of ignition (as described in the subclause) *and* a *significant* source of fuel. Most materials used in the construction of ME EQUIPMENT are not considered to be such a source of fuel unless they are in the presence of an OXYGEN RICH ENVIRONMENT. MANUFACTURERS should determine, through analyses documented in the RISK MANAGEMENT FILE, whether the ME EQUIPMENT contains combustible materials (fuel) in sufficient quantities to support combustion in conjunction with ignition sources (capable of releasing greater than 900 J).

Subclause 13.1.2

This subclause is clarified by the following:

As stated in subclause 4.7, it is the MANUFACTURER'S RISK ANALYSIS that determines which components are subject to failure testing based on the associated RISK. Where the associated RISK of fire exceeds the MANUFACTURER'S criteria for RISK acceptability, the MANUFACTURER'S simulation analysis (such as FMEAs) should be accepted in lieu of physical testing. As also stated in 4.7, component reliability and ratings are to be considered in such failure simulation analyses. Common electronic components that have a history of use without causing equipment fires should not be considered a likely source of ignition.

Where the subclause identifies "emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities;" as a hazardous situation, this refers to emissions from *the ENCLOSURE* not from components themselves. Where it identifies "exceeding the allowable values for 'other components and materials' identified in Table 22 times 1,5 minus 12,5 °C", this applies only where doing so would result in an unacceptable RISK (as identified in the MANUFACTURER'S RISK ANALYSIS according to 4.7). Typically, this would be cases where

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ESSENTIAL PERFORMANCE would not be maintained or where greater than 900 J of energy would be released in the presence of flammable materials that could sustain combustion.

The first exemption to fault analysis or testing identified in subclause 13.1.2 ("The construction or the supply circuit limits the power dissipation in SINGLE FAULT CONDITION to less than 15 W or the energy dissipation to less than 900 J.") is intended to apply where the component design itself ("The construction") or fusing (or other current limiting devices) in the supply circuit ("or the supply circuit") assure the energy released during failures will not exceed the limits. For most common signal level components rated for operation below 5 Watts, the energy released by short-circuiting of outputs will not exceed the 900 J limit.

This clarification will remain valid until a new version of IEC 60601-1 is published.

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SC 62A/Publication IEC 60601-1:2005, including Amendment 1:2012, Third edition/I-SH 03

MEDICAL ELECTRICAL EQUIPMENT –
Part 1: General requirements for basic safety and essential performance

INTERPRETATION SHEET 3

This interpretation sheet has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this interpretation sheet is based on the following documents:

ISH	Report on voting
62A/858/ISH	62A/875/RVD

Full information on the voting for the approval of this interpretation sheet can be found in the report on voting indicated in the above table.

Subclause 13.1.2 fourth dash (Emissions, deformation of ENCLOSURE or exceeding maximum temperature)

This subclause states the following:

The following HAZARDOUS SITUATIONS shall not occur:

– ....

– temperatures of ME EQUIPMENT parts that are not APPLIED PARTS but are likely to be touched, exceeding the allowable values in Table 23 when measured and adjusted as described in 11.1.3;

This is clarified by the following:

The above requirement is regarded as fulfilled in accordance with Subclause 4.5 for temperatures at the surfaces of the enclosure, if the following conditions are fulfilled:

– The maximum allowed temperature on OPERATOR accessible surfaces in SINGLE FAULT CONDITION is 105 °C; and

– the instructions for use contain a warning that, under some SINGLE FAULT CONDITIONS, the temperature of: (*indicate the surface of concern*) could get hot and there is a possible RISK of a burn if touched, and

– if the RISK ANALYSIS demonstrates a need for a warning symbol on the ENCLOSURE, safety sign ISO 7010-W018 () shall be used on or adjacent to the hot spot on the ENCLOSURE; and

– the RISK ASSESSMENT demonstrates that the temperature attained in the SINGLE FAULT CONDITION is acceptable, and

– the RISK ASSESSMENT demonstrates that applying the alternative RISK CONTROL measures in this Interpretation Sheet results in a RESIDUAL RISK that is comparable to the RESIDUAL RISK resulting from applying the requirement of the standard.

NOTE 1 This Interpretation Sheet is intended to be used with both Edition 3.0 and Edition 3.1 of IEC 60601-1.

NOTE 2 An example of an analysis that demonstrates an adequately low probability of occurrence of HARM is shown below.

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Example RISK ASSESSMENT:

The sum failure rate for parts that could increase the surface temperature of parts of the enclosure of XYZ device touchable only by the OPERATOR to values above those of Table 23 calculates to be 60 FIT (1 FIT = 1E-9/h) according to the standard MIL-HDBK-217F where FIT stands for "failure in time". In case of such failures, the device would emit an odour and would no longer function properly. It is estimated, that only in one of 3 cases the device would not be switched off immediately and the hot surface would be resulting in a burn.

The resulting overall probability of such HARM where adequate warning is provided in the instructions for use in combination with warning sign ISO 7010 W018 would be: probability = 1/3 * 60 FIT = 2 E-8/h =approx. 0,0002 per year.

In this example, the WXW Company's RISK acceptance criteria require that a HARM of that severity must have a probability of less than 0,0003 per year for the associated RISK to be considered acceptable. Based on that RISK acceptance criterion, the RISK associated with overtemperature of the ENCLOSURE caused by single faults in the circuitry is acceptable.

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IEC 60601-1

Edition 3.0 2005-12
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MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

INTERPRETATION SHEET 1

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This interpretation sheet has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this interpretation sheet is based on the following documents:

DISH	Report on voting
62A/1403/DISH	62A/1414/RVDISH

Full information on the voting for the approval of this interpretation sheet can be found in the report on voting indicated in the above table.

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Interpretation of Subclauses 4.3 of IEC 60601-1:2005/AMD1:2012 and 4.7 of IEC 60601-1:2005

This interpretation sheet is intended to clarify the requirements which are needed to maintain ESSENTIAL PERFORMANCE in SINGLE FAULT CONDITION.

Subclause 4.3 * ESSENTIAL PERFORMANCE

The requirements in this subclause of IEC 60601-1:2005/AMD1:2012 are clarified by the following.

aa) IEC 60601-1:2005/AMD1:2012 requires that both the NORMAL CONDITION and the SINGLE FAULT CONDITIONS are to be considered in the identification of ESSENTIAL PERFORMANCE, because:

IEC 60601-1:2005-12/AMD1:2012-07/ISH1:2021-03(en)

ICS 11.040.01

1) ESSENTIAL PERFORMANCE is defined in terms of the performance of a clinical function (see 3.27);

NOTE 1 ESSENTIAL PERFORMANCE can have multiple aspects.

2) in particular, SINGLE FAULT CONDITIONS can cause or contribute to the loss or degradation of such a clinical function that results in unacceptable RISK; and

3) according to IEC 60601-1:2005, 4.7, ME EQUIPMENT is required to remain SINGLE FAULT SAFE or the RISK remains acceptable and this also applies to ESSENTIAL PERFORMANCE.

bb) The subclause requires the MANUFACTURER to:

NOTE 2 Many particular standards specify performance limits, RISK CONTROL measures and VERIFICATION methods for some aspects of ESSENTIAL PERFORMANCE.

1) identify performance of clinical functions, other than that related to BASIC SAFETY, that is necessary to achieve the INTENDED USE or that could affect safety;

2) specify performance limits between fully functional and total loss of the identified performance in both

   i) NORMAL CONDITION, and

   ii) SINGLE FAULT CONDITION;

   NOTE 3 The specified performance limits can be different in NORMAL CONDITION and SINGLE FAULT CONDITION.

3) evaluate the RISK from loss or degradation of the identified performance beyond the specified limits;

   i) Where the resulting RISK is unacceptable, the identified performance is ESSENTIAL PERFORMANCE.

4) implement RISK CONTROL measures to reduce these RISKS to an acceptable level for both

   i) NORMAL CONDITION, and

   ii) SINGLE FAULT CONDITION;

5) assess and determine which RISK CONTROL measures need VERIFICATION of effectiveness; and

6) specify methods for the VERIFICATION of the effectiveness of the RISK CONTROL measures.

cc) The requirements of IEC 60601-1:2005/AMD1:2012 4.3 as clarified in items 4.3 bb) 1) to 4.3 bb) 6) above include documentation of the relevant results in the RISK MANAGEMENT FILE. The documentation is intended to serve as OBJECTIVE EVIDENCE that the required activities have been performed.

dd) The compliance statement refers to “inspection of the RISK MANAGEMENT FILE”. Inspection means the careful examination or scrutiny of the contents of the RISK MANAGEMENT FILE. Only confirming the existence of a RISK MANAGEMENT FILE is insufficient. Inspection can include functional tests as clarified in IEC 60601-1:2005/AMD1:2012/ISH1 items 4.3 bb) 5) and 4.3 bb) 6). This is similar to the other uses of “inspection” throughout this standard.

Subclause 4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT

The requirements in this subclause of IEC 60601-1:2005 are clarified by the following.

aa) IEC 60601-1:2005 requires that ME EQUIPMENT remains SINGLE FAULT SAFE or the RISK remains acceptable according to 4.2 during the EXPECTED SERVICE LIFE and this also applies to ESSENTIAL PERFORMANCE.

bb) SINGLE FAULT CONDITION (as defined in 3.116) describes the condition where “a single means for reducing a RISK is defective or a single abnormal condition is present”. Either condition anticipates the failure or fault of one component [other than those indicated in 4.7 a), e.g. a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS].

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Component failure or fault can relate to:

1) a single part (e.g. resistor, capacitor, wire, mechanical part),

2) a subassembly (e.g. battery block, power supply unit, line filter, PESS), or

3) a device with a specified function (e.g. protective unit, control unit, monitoring unit).

Any SINGLE FAULT CONDITION that could result in a HAZARDOUS SITUATION, including those mentioned in 13.1, needs to be simulated, physically or theoretically. Care needs to be taken to adequately determine the worst case situation when analysing failure or fault of subassemblies and functional units.

cc) It can be necessary to investigate the consequences of a second independent fault or failure. This is relevant when the initial fault or failure remains undetected during NORMAL USE for the EXPECTED SERVICE LIFE or when the fault or failure is so likely that it is considered to be a NORMAL CONDITION. See 4.7 b) and 5.1 and their rationales in Annex A.

dd) The RISK ASSESSMENT is used to determine which SINGLE FAULT CONDITIONS are to be tested in agreement with 4.3, 4.7 and 5.1. This includes consideration of a second independent fault or failure following an initial SINGLE FAULT CONDITION that remains undetected during NORMAL USE for the EXPECTED SERVICE LIFE. This also applies to the VERIFICATION of the effectiveness of the RISK CONTROL measures needed to maintain ESSENTIAL PERFORMANCE [see IEC 60601-1/AMD1:2012/ISH1 4.3 bb) 5) and 4.3 bb) 6)].

ee) The requirements of 4.7 include documentation of the relevant tests in the RISK MANAGEMENT FILE. The documentation is intended to serve as OBJECTIVE EVIDENCE that the required activities have been performed.

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CONTENTS

FOREWORD 10
INTRODUCTION 13
INTRODUCTION TO THE AMENDMENT 15
1 Scope, object and related standards 16
1.1 * Scope 16
1.2 Object 16
1.3 * Collateral standards 16
1.4 * Particular standards 17
2 * Normative references 17
3 * Terminology and definitions 20
4 General requirements 40
4.1 * Conditions for application to ME EQUIPMENT or ME SYSTEMS 40
4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS 41
4.3 * ESSENTIAL PERFORMANCE 43
4.4 * EXPECTED SERVICE LIFE 44
4.5 * Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS 44
4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT 44
4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT 44
4.8 * Components of ME EQUIPMENT 45
4.9 * Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT 46
4.10 * Power supply 46
4.11 Power input 47
5 * General requirements for testing ME EQUIPMENT 48
5.1 * TYPE TESTS 48
5.2 * Number of samples 48
5.3 Ambient temperature, humidity, atmospheric pressure 48
5.4 Other conditions 48
5.5 Supply voltages, type of current, nature of supply, frequency 48
5.6 Repairs and modifications 49
5.7 * Humidity preconditioning treatment 49
5.8 Sequence of tests 50
5.9 * Determination of APPLIED PARTS and ACCESSIBLE PARTS 50
6 * Classification of ME EQUIPMENT and ME SYSTEMS 52
6.1 General 52
6.2 * Protection against electric shock 52
6.3 * Protection against harmful ingress of water or particulate matter 53
6.4 Method(s) of sterilization 53
6.5 Suitability for use in an OXYGEN RICH ENVIRONMENT 53
6.6 * Mode of operation 53
7 ME EQUIPMENT identification, marking and documents 53
7.1 General 53
7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.1) 54
7.3 Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.2) 59

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

7.4 Marking of controls and instruments (see also Table C.3) 60
7.5 Safety signs 62
7.6 Symbols 62
7.7 Colours of the insulation of conductors 63
7.8 * Indicator lights and controls 63
7.9 ACCOMPANYING DOCUMENTS 64
8 * Protection against electrical HAZARDS from ME EQUIPMENT 70
8.1 Fundamental rule of protection against electric shock 70
8.2 Requirements related to power sources 71
8.3 Classification of APPLIED PARTS 71
8.4 Limitation of voltage, current or energy 72
8.5 Separation of parts 74
8.6 * Protective earthing, functional earthing and potential equalization of ME EQUIPMENT 82
8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS 85
8.8 Insulation 101
8.9 * CREEPAGE DISTANCES and AIR CLEARANCES 107
8.10 Components and wiring 122
8.11 MAINS PARTS, components and layout 124
9 * Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS 129
9.1 MECHANICAL HAZARDS of ME EQUIPMENT 129
9.2 * MECHANICAL HAZARDS associated with moving parts 130
9.3 * MECHANICAL HAZARD associated with surfaces, corners and edges 136
9.4 * Instability HAZARDS 136
9.5 * Expelled parts HAZARD 141
9.6 Acoustic energy (including infra- and ultrasound) and vibration 141
9.7 * Pressure vessels and parts subject to pneumatic and hydraulic pressure 142
9.8 * MECHANICAL HAZARDS associated with support systems 145
10 * Protection against unwanted and excessive radiation HAZARDS 151
10.1 X-Radiation 151
10.2 Alpha, beta, gamma, neutron and other particle radiation 152
10.3 Microwave radiation 152
10.4 * Lasers 152
10.5 Other visible electromagnetic radiation 153
10.6 Infrared radiation 153
10.7 Ultraviolet radiation 153
11 Protection against excessive temperatures and other HAZARDS 153
11.1 * Excessive temperatures in ME EQUIPMENT 153
11.2 * Fire prevention 157
11.3 * Constructional requirements for fire ENCLOSURES of ME EQUIPMENT 162
11.4 * ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics 164
11.5 * ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents 165
11.6 Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT 165
11.7 Biocompatibility of ME EQUIPMENT and ME SYSTEMS 167
11.8 * Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT 167

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

12 * Accuracy of controls and instruments and protection against hazardous outputs 167
12.1 Accuracy of controls and instruments 167
12.2 USABILITY of ME EQUIPMENT 167
12.3 ALARM SYSTEMS 167
12.4 Protection against hazardous output 167
13 * HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT 169
13.1 Specific HAZARDOUS SITUATIONS 169
13.2 SINGLE FAULT CONDITIONS 170
14 * PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 175
14.1 * General 175
14.2 * Documentation 176
14.3 * RISK MANAGEMENT plan 176
14.4 * PEMS DEVELOPMENT LIFE-CYCLE 176
14.5 * Problem resolution 176
14.6 RISK MANAGEMENT PROCESS 176
14.7 * Requirement specification 177
14.8 * Architecture 177
14.9 * Design and implementation 178
14.10 * VERIFICATION 178
14.11 * PEMS VALIDATION 178
14.12 * Modification 179
14.13 * PEMS intended to be incorporated into an IT-NETWORK 179
15 Construction of ME EQUIPMENT 180
15.1 * Arrangements of controls and indicators of ME EQUIPMENT 180
15.2 * Serviceability 180
15.3 Mechanical strength 180
15.4 ME EQUIPMENT components and general assembly 184
15.5 * MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5 189
16 * ME SYSTEMS 193
16.1 * General requirements for the ME SYSTEMS 193
16.2 * ACCOMPANYING DOCUMENTS of an ME SYSTEM 193
16.3 * Power supply 194
16.4 ENCLOSURES 195
16.5 * SEPARATION DEVICES 195
16.6 * LEAKAGE CURRENTS 195
16.7 * Protection against MECHANICAL HAZARDS 196
16.8 Interruption of the power supply to parts of an ME SYSTEM 197
16.9 ME SYSTEM connections and wiring 197
17 * Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 199
Annex A (informative) General guidance and rationale 200
Annex B (informative) Sequence of testing 307
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS 311
Annex D (informative) Symbols on marking (see Clause 7) 314
Annex E (informative) Examples of the connection of the measuring device (MD) for measurement of the PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT (see 8.7) 323

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Annex F (informative) Suitable measuring supply circuits 325
Annex G (normative) Protection against HAZARDS of ignition of flammable anaesthetic mixtures 328
Annex H (informative) Pems structure, PEMS DEVELOPMENT LIFE-CYCLE and documentation 343
Annex I (informative) ME SYSTEMS aspects 351
Annex J (informative) Survey of insulation paths 357
Annex K (informative) Simplified PATIENT LEAKAGE CURRENT diagrams 360
Annex L (normative) Insulated winding wires for use without interleaved insulation 363
Annex M (normative) Reduction of pollution degrees 366
Bibliography 367
INDEX OF ABBREVIATIONS AND ACRONYMS 371
INDEX 373

Figure 1 – Detachable mains connection 22
Figure 2 – Example of the defined terminals and conductors 23
Figure 3 – Example of a CLASS I ME EQUIPMENT 24
Figure 4 – Example of a metal-enclosed CLASS II ME EQUIPMENT 24
Figure 5 – Schematic flow chart for component qualification 46
Figure 6 – Standard test finger 51
Figure 7 – Test hook 52
Figure 8 – Test pin 73
Figure 9 – Application of test voltage to bridged PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS 79
Figure 10 – Application of test voltage to individual PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS 80
Figure 11 – Application of test voltage to test the delivered defibrillation energy 82
Figure 12 – Example of a measuring device and its frequency characteristics 86
Figure 13 – Measuring circuit for EARTH LEAKAGE CURRENT of CLASS I ME EQUIPMENT, with or without APPLIED PART 89
Figure 14 – Measuring circuit for TOUCH CURRENT 90
Figure 15 – Measuring circuit for PATIENT LEAKAGE CURRENT from the PATIENT CONNECTION to earth 91
Figure 16 – Measuring circuit for PATIENT LEAKAGE current via the PATIENT CONNECTION(s) of an F-TYPE APPLIED PART to earth caused by an external voltage on the PATIENT CONNECTION(s) 92
Figure 17 – Measuring circuit for PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(s) to earth caused by an external voltage on a SIGNAL INPUT/OUTPUT PART 93
Figure 18 – Measuring circuit for PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(s) to earth caused by an external voltage on a metal ACCESSIBLE PART that is not PROTECTIVELY EARTHED 94
Figure 19 – Measuring circuit for PATIENT AUXILIARY CURRENT 95
Figure 20 – Measuring circuit for total PATIENT LEAKAGE CURRENT with all PATIENT CONNECTIONS of all APPLIED PARTS of the same type (TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS) connected together 96
Figure 21 – Ball-pressure test apparatus 107
Figure 22 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 1 119

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Figure 23 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 2 119
Figure 24 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 3 119
Figure 25 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 4 119
Figure 26 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 5 120
Figure 27 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 6 120
Figure 28 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 7 120
Figure 29 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 8 121
Figure 30 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 9 121
Figure 31 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 10 122
Figure 32 – Ratio between hydraulic test pressure and maximum permissible working pressure 144
Figure 33 – Body upper-carriage module 150
Figure 34 – Spark ignition test apparatus 159
Figure 35 – Maximum allowable current I as a function of the maximum allowable voltage U measured in a purely resistive circuit in an OXYGEN RICH ENVIRONMENT 160
Figure 36 – Maximum allowable voltage U as a function of the capacitance C measured in a capacitive circuit used in an OXYGEN RICH ENVIRONMENT 160
Figure 37 – Maximum allowable current I as a function of the inductance L measured in an inductive circuit in an OXYGEN RICH ENVIRONMENT 161
Figure 38 – Baffle 164
Figure 39 – Area of the bottom of an ENCLOSURE as specified in 11.3 b) 1) 164
Figure A.1 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in an ECG monitor 205
Figure A.2 – Example of the insulation of an F-TYPE APPLIED PART with the insulation incorporated in the ME EQUIPMENT 206
Figure A.3 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a PATIENT monitor with invasive pressure monitoring facility 206
Figure A.4 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a multifunction PATIENT monitor with invasive pressure monitoring facilities 207
Figure A.5 – Identification of APPLIED PARTS and PATIENT CONNECTIONS in an X-ray me system 208
Figure A.6 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a transcutaneous electronic nerve stimulator (TENS) intended to be worn on the patient's belt and connected to electrodes applied to the PATIENT'S upper arm 209
Figure A.7 – Identification of ME EQUIPMENT or ME SYSTEM, APPLIED PARTS and PATIENT CONNECTIONS in a personal computer with an ECG module 210
Figure A.8 – Pictorial representation of the relationship of HAZARD, sequence of events, HAZARDOUS SITUATION and HARM 213
Figure A.9 – Example of PATIENT ENVIRONMENT 218
Figure A.10 – Floating circuit 236
Figure A.11 – Interruption of a power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES 238
Figure A.12 – Identification of MEANS OF PATIENT PROTECTION and MEANS OF OPERATOR PROTECTION 241
Figure A.13 – Allowable protective earth impedance where the fault current is limited 248
Figure A.14 – Probability of ventricular fibrillation 254
Figure A.15 – Example of a measuring circuit for the PATIENT LEAKAGE CURRENT from a PATIENT CONNECTION to earth for ME EQUIPMENT with multiple PATIENT CONNECTIONS 259

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Figure A.16 – Instability test conditions 270
Figure A.17 – Example of determining TENSILE SAFETY FACTOR using Table 21 277
Figure A.18 – Example of determining design and test loads 277
Figure A.19 – Example of human body mass distribution 278
Figure A.20 – Relationship of the terms used to describe equipment, ACCESSORIES or equipment parts 215
Figure A.21 – Example of ME EQUIPMENT having two different functions on one common APPLIED PART circuit 246
Figure A.22 – Maximum allowable temperature for surfaces and APPLIED PARTS at higher altitudes 282
Figure A.23 – Example of the needed MEANS OF OPERATOR PROTECTION between the terminals of an INTERNAL ELECTRICAL POWER SOURCE and a subsequent protective device 299
Figure E.1 – TYPE B APPLIED PART 323
Figure E.2 – TYPE BF APPLIED PART 323
Figure E.3 – TYPE CF APPLIED PART 324
Figure E.4 – PATIENT AUXILIARY CURRENT 324
Figure E.5 – Loading of the PATIENT CONNECTIONS if specified by the MANUFACTURER 324
Figure F.1 – Measuring supply circuit with one side of the SUPPLY MAINS at approximately earth potential 325
Figure F.2 – Measuring supply circuit with SUPPLY MAINS approximately symmetrical to earth potential 325
Figure F.3 – Measuring supply circuit for polyphase me equipment specified for connection to a polyphase supply mains 326
Figure F.4 – Measuring supply circuit for single-phase me equipment specified for connection to a polyphase supply mains 326
Figure F.5 – Measuring supply circuit for me equipment having a separate power supply unit or intended to receive its power from another equipment in an me system 327
Figure G.1– Maximum allowable current IZR as a function of the maximum allowable voltage UZR measured in a purely resistive circuit with the most flammable mixture of ether vapour with air 334
Figure G.2 – Maximum allowable voltage UZC as a function of the capacitance Cmax measured in a capacitive circuit with the most flammable mixture of ether vapour with air 335
Figure G.3 – Maximum allowable current IZL as a function of the inductance Lmax measured in an inductive circuit with the most flammable mixture of ether vapour with air 335
Figure G.4 – Maximum allowable current IZR as a function of the maximum allowable voltage UZR measured in a purely resistive circuit with the most flammable mixture of ether vapour with oxygen 339
Figure G.5 – Maximum allowable voltage UZC as a function of the capacitance Cmax measured in a capacitive circuit with the most flammable mixture of ether vapour with oxygen 340
Figure G.6 – Maximum allowable current IZL as a function of the inductance Lmax measured in an inductive circuit with the most flammable mixture of ether vapour with oxygen 340
Figure G.7 – Test apparatus 342
Figure H.1 – Examples of PEMS/ PESS structures 344
Figure H.2 – A PEMS DEVELOPMENT LIFE-CYCLE model 345
IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Figure H.3 – Not used 346
Figure H.4 – Example of potential parameters required to be specified for an IT-NETWORK 350
Figure I.1 – Example of the construction of a MULTIPLE SOCKET-OUTLET (MSO) 355
Figure I.2 – Examples of application of MULTIPLE SOCKET-OUTLETS (MSO) 356
Figure J.1 – Insulation example 1 357
Figure J.2 – Insulation example 2 357
Figure J.3 – Insulation example 3 357
Figure J.4 – Insulation example 4 358
Figure J.5 – Insulation example 5 358
Figure J.6 – Insulation example 6 359
Figure J.7 – Insulation example 7 359
Figure K.1 – ME EQUIPMENT with an ENCLOSURE made of insulating material 360
Figure K.2 – ME EQUIPMENT with an F-TYPE APPLIED PART 360
Figure K.3 – ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART 361
Figure K.4 – Me equipment with a PATIENT CONNECTION of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED 361
Figure K.5 – Me equipment with a PATIENT CONNECTION of a TYPE BF APPLIED PART that is not PROTECTIVELY EARTHED 362

Table 1 – Units outside the SI units system that may be used on ME EQUIPMENT 61
Table 2 – Colours of indicator lights and their meaning for ME EQUIPMENT 64
Table 3 – * Allowable values of PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL CONDITION and SINGLE FAULT CONDITION 87
Table 4 – * Allowable values of PATIENT LEAKAGE CURRENTS under the special test conditions identified in 8.7.4.7 88
Table 5 – Legends of symbols for Figure 9 to Figure 11, Figure 13 to Figure 20, Figure A.15, Annexes E and F 97
Table 6 – Test voltages for solid insulation forming a MEANS OF PROTECTION 104
Table 7 – Test voltages for MEANS OF OPERATOR PROTECTION 105
Table 8 – Multiplication factors for AIR CLEARANCES for altitudes up to 5 000 m 108
Table 9 – Material group classification 108
Table 10 – MAINS TRANSIENT VOLTAGE 110
Table 11 – Not used 111
Table 12 – Minimum CREEPAGE DISTANCES and AIR CLEARANCES providing MEANS OF PATIENT PROTECTION 112
Table 13 – Minimum AIR CLEARANCES providing MEANS OF OPERATOR PROTECTION from the MAINS PART 113
Table 14 – Additional AIR CLEARANCES for insulation in MAINS PARTS with PEAK WORKING VOLTAGES exceeding the peak value of the NOMINAL MAINS VOLTAGE [a] 114
Table 15 – Minimum AIR CLEARANCES for MEANS OF OPERATOR PROTECTION in SECONDARY CIRCUITS 115
Table 16 – Minimum CREEPAGE DISTANCES providing MEANS OF OPERATOR PROTECTION [a] 116
Table 17 – NOMINAL cross-sectional area of conductors of a POWER SUPPLY CORD 125
Table 18 – Testing of cord anchorages 126
Table 19 – MECHANICAL HAZARDS covered by this clause 130

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Table 20 – Acceptable gaps [a] 132
Table 21 – Determination of TENSILE SAFETY FACTOR 146
Table 22 – Allowable maximum temperatures of parts 154
Table 23 – Allowable maximum temperatures for ME EQUIPMENT parts that are likely to be touched 154
Table 24 – Allowable maximum temperatures for skin contact with ME EQUIPMENT APPLIED PARTS 155
Table 25 – Acceptable perforation of the bottom of an ENCLOSURE 163
Table 26 – * Temperature limits of motor windings 172
Table 27 – Maximum motor winding steady-state temperature 174
Table 28 – Mechanical strength test applicability 181
Table 29 – Drop height 182
Table 30 – Test torques for rotating controls 188
Table 31 – Maximum allowable temperatures of transformer windings under overload and short-circuit conditions at 25 °C (± 5 °C) ambient temperature 190
Table 32 – Test current for transformers 191
Table 33 – Test conditions for overtravel end stop test 135
Table A.1 – Values of AIR CLEARANCE and CREEPAGE DISTANCE derived from Table 7 of IEC 61010-1:2001 and Table 12 262
Table A.2 – CREEPAGE DISTANCES to avoid failure due to tracking from IEC 60664-1 263
Table A.3 – Instability test conditions 270
Table A.4 – Allowable time exposure for level of acceleration 272
Table A.5 – Guidance on surface temperatures for ME EQUIPMENT that creates low temperatures (cools) for therapeutic purposes or as part of its operation 282
Table C.1– Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts 311
Table C.2 – Marking on the inside of ME EQUIPMENT, ME SYSTEMS or their parts 312
Table C.3 – Marking of controls and instruments 312
Table C.4 – ACCOMPANYING DOCUMENTS, general 312
Table C.5 – ACCOMPANYING DOCUMENTS, instructions for use 313
Table D.1 – General symbols 315
Table D.2 – Safety signs 320
Table D.3 – General codes 322
Table G.1 – Gas-tightness of cord inlets 337
Table H.1 – Not used 349
Table I.1 – Some examples of ME SYSTEMS for illustration 353
Table L.1– Mandrel diameter 364
Table L.2 – Oven temperature 364
Table M.1 – Reduction of the pollution degree of internal environment through the use of additional protection 366

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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DISCLAIMER
This Consolidated version is not an official IEC Standard and has been prepared for user convenience. Only the current versions of the standard and its amendment(s) are to be considered the official documents.

This Consolidated version of IEC 60601-1 bears the edition number 3.1. It consists of the third edition (2005-12) [documents 62A/505A/FDIS and 62A/512/RVD] and its amendment 1 (2012-07) [documents 62A/805/FDIS and 62A/820/RVD]. The technical content is identical to the base edition and its amendment.

This Consolidated version includes the contents of the corrigenda 1 (2006-12) and 2 (2007-12), the contents of the corrigendum to Amendment 1 (2014-07), as well as the interpretation sheets 1 (2008-04), 2 (2009-01), 3 (2013-05) and the Interpretation Sheet 1 to Amendment 1 (2021-03).

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This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted is available in this publication.

International Standard IEC 60601-1 has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 1988, its Amendment 1 (1991) and Amendment 2 (1995), the second edition of IEC 60601-1-1 published in 2000 and the first edition of IEC 60601-1-4 published in 1996 and its Amendment 1 (1999). This edition constitutes a technical revision. This edition has been significantly restructured. Requirements in the electrical section have been further aligned with those for information technology equipment covered by IEC 60950-1 and a requirement for including a RISK MANAGEMENT PROCESS has been added. For an expanded description of this revision, see Annex A.3.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard the following print types are used:

- Requirements and definitions: in roman type.
- *Test specifications: in italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS USED THROUGHOUT THIS STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 3 AND ALSO GIVEN IN THE INDEX: IN SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex G of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

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The committee has decided that the contents of the base publication and its amendment will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The "colour inside" logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.

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INTRODUCTION

In 1976, IEC subcommittee 62A published the first edition of IEC/TR 60513, *Basic aspects of the safety philosophy for electrical equipment used in medical practice*. The first edition of IEC/TR 60513 provided the basis for developing:

– the first edition of IEC 60601-1 (the parent safety standard for MEDICAL ELECTRICAL EQUIPMENT);

– the IEC 60601-1-xx series of collateral standards for MEDICAL ELECTRICAL EQUIPMENT;

– the IEC 60601-2-xx series of particular standards for particular types of MEDICAL ELECTRICAL EQUIPMENT; and

– the IEC 60601-3-xx series of performance standards for particular types of MEDICAL ELECTRICAL EQUIPMENT.

Aware of the need and the urgency for a standard covering electrical equipment used in medical practice, the majority of National Committees voted in 1977 in favour of the first edition of IEC 60601-1, based on a draft that at the time represented a first approach to the problem. The extent of the scope, the complexity of the equipment concerned, and the specific nature of some of the protective measures and the corresponding tests for verifying them, required years of effort in order to prepare this first standard, which can now be said to have served as a universal reference since its publication.

However, the frequent application of the first edition revealed room for improvement. These improvements were all the more desirable in view of the considerable success that this standard has enjoyed since its publication.

The careful work of revision subsequently undertaken and continued over a number of years resulted in the publication of the second edition in 1988. This edition incorporated all the improvements that could be reasonably expected up to that time. Further developments remained under constant study. The second edition was amended in 1991 and then again in 1995.

The original IEC approach was to prepare separate BASIC SAFETY and performance standards for MEDICAL ELECTRICAL EQUIPMENT. This was a natural extension of the historical approach taken at the national and international level with other electrical equipment standards (e.g. those for domestic equipment), where BASIC SAFETY is regulated through mandatory standards but other performance specifications are regulated by market pressure. In this context, it has been said that, “The ability of an electric kettle to boil water is not critical to its safe use!”

It is now recognized that this is not the situation with many items of MEDICAL ELECTRICAL EQUIPMENT, and RESPONSIBLE ORGANIZATIONS have to depend on standards to ensure ESSENTIAL PERFORMANCE as well as BASIC SAFETY. Such areas include the accuracy with which the equipment controls the delivery of energy or therapeutic substances to the PATIENT, or processes and displays physiological data that will affect PATIENT management.

This recognition means that separating BASIC SAFETY and performance is somewhat inappropriate in addressing the HAZARDS that result from inadequate design of MEDICAL ELECTRICAL EQUIPMENT. Many particular standards in the IEC 60601-2-xx series address a range of ESSENTIAL PERFORMANCE requirements that cannot be directly evaluated by the RESPONSIBLE ORGANIZATION without applying such standards. (However, the current IEC 60601 series includes fewer requirements for ESSENTIAL PERFORMANCE than for BASIC SAFETY).

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In anticipation of a third edition of IEC 60601-1, IEC subcommittee 62A prepared a second edition of IEC/TR 60513 [12][1)] in 1994. It was intended that the second edition of IEC/TR 60513 would provide guidance for developing this edition of IEC 60601-1, and for the further development of the IEC 60601-1-xx and IEC 60601-2-xx series.

In order to achieve consistency in international standards, address present expectations in the health care community and align with developments in IEC 60601-2-xx, the second edition of IEC/TR 60513 includes two major new principles:

– the first change is that the concept of "SAFETY" has been broadened from the BASIC SAFETY considerations in the first and second editions of IEC 60601-1 to include ESSENTIAL PERFORMANCE matters, (e.g. the accuracy of physiological monitoring equipment). Application of this principle leads to the change of the title of this publication from "Medical electrical equipment, Part 1: General requirements for safety" in the second edition, to "Medical electrical equipment, Part 1: General requirements for basic safety and essential performance";

– the second change is that, in specifying minimum safety requirements, provision is made for assessing the adequacy of the design PROCESS when this is the only practical method of assessing the safety of certain technologies such as programmable electronic systems. Application of this principle is one of the factors leading to introduction of a general requirement to carry out a RISK MANAGEMENT PROCESS. In parallel with the development of the third edition of IEC 60601-1, a joint project with ISO/TC 210 resulted in the publication of a general standard for RISK MANAGEMENT of medical devices. Compliance with this edition of IEC 60601-1 requires that the MANUFACTURER have in place a RISK MANAGEMENT PROCESS complying with parts of ISO 14971 (see 4.2).

This standard contains requirements concerning BASIC SAFETY and ESSENTIAL PERFORMANCE that are generally applicable to MEDICAL ELECTRICAL EQUIPMENT. For certain types of MEDICAL ELECTRICAL EQUIPMENT, these requirements are either supplemented or modified by the special requirements of a collateral or particular standard. Where particular standards exist, this standard should not be used alone.

Amendment 1 to this standard is intended to address:

– issues identified by National Committees and other interested parties since the publication of IEC 60601-1:2005;

– the way in which RISK MANAGEMENT has been introduced into IEC 60601-1:2005; and

– the way the concept of ESSENTIAL PERFORMANCE is used in IEC 60601-1:2005.

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1) Figures in square brackets refer to the Bibliography.

INTRODUCTION TO THE AMENDMENT

The third edition of IEC 60601-1 was published in 2005. At the time of publication, there were 94 National Committee comments on the 2nd CDV and the FDIS that were deferred to a future amendment/revision. Each of their deferred comments was captured in an Issue Sheet by the SC 62A secretariat. By the time of the Auckland meeting in April 2008, the Subcommittees had developed two Interpretation Sheets and the SC 62A secretariat has received an additional 15 issues from National Committees and other interested parties.

At the Auckland meeting, IEC/TC 62 approved a project to develop the 1st amendment to IEC 60601-1:2005 based on the issues outstanding at the time. The TC approved developing the 1st amendment with a view to addressing outstanding issues, including but not limited to:

– those listed in 62A/593/DC and 62A/602/INF;
– the way in which risk management has been introduced into IEC 60601-1:2005; and
– the way the concept of essential performance is used in IEC 60601-1:2005.

Since the Auckland meeting, the secretariat has received 73 additional issues from National Committees or other interested parties for a total of 182 Issues Sheets. This amendment is intended to address those issues.

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MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

1 Scope, object and related standards

1.1 * Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1.

NOTE 1 See also 4.2.

The IEC 60601 series does not apply to:

– in vitro diagnostic equipment that does not fall within the definition of ME EQUIPMENT, which is covered by the IEC 61010 series [61];

– implantable parts of active implantable medical devices covered by the ISO 14708 series [69]; or

– medical gas pipeline systems covered by ISO 7396-1 [68].

NOTE 2 ISO 7396-1 applies the requirement of IEC 60601-1-8 to certain monitoring and ALARM SIGNALS.

1.2 Object

The object of this standard is to specify general requirements and to serve as the basis for particular standards.

1.3 * Collateral standards

In the IEC 60601 series, collateral standards specify general requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE applicable to:

– a subgroup of ME EQUIPMENT (e.g. radiological equipment);

– a specific characteristic of all ME EQUIPMENT not fully addressed in this standard.

Applicable collateral standards become normative at the date of their publication and shall apply together with this standard.

NOTE 1 When evaluating compliance with IEC 60601-1, it is permissible to independently assess compliance with the collateral standards.

NOTE 2 When declaring compliance with IEC 60601-1, the declarer should specifically list the collateral standards that have been applied. This allows the reader of the declaration to understand which collateral standards were part of the evaluation.

NOTE 3 Collateral standards in the IEC 60601 family are numbered IEC 60601-1-xx. The IEC maintains a catalogue of valid International Standards. Users of this standard should consult this catalogue at "http://webstore.iec.ch" to determine which collateral standards have been published.

If a collateral standard applies to ME EQUIPMENT for which a particular standard exists, then the particular standard takes priority over the collateral standard.

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1.4 * Particular standards

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in this standard as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

NOTE Particular standards in the IEC 60601 family that are developed by IEC committees are numbered IEC 60601-2-xx. In addition, particular standards developed by joint projects between ISO and IEC can be numbered either IEC 80601-2-xx or ISO 80601-2-xx depending on which committee administered the project. IEC and ISO maintain catalogues of valid International Standards. Users of this standard should consult these catalogues at "http://webstore.iec.ch" and "http://www.iso.org/iso/store.htm" to determine which particular standards have been published.

A requirement of a particular standard takes priority over this standard.

2 * Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ATTENTION: Additional collateral standards of the IEC 60601 series, which are issued subsequent to publication of this standard, become normative at the date of their publication and shall be considered as being included among the normative references below. See 1.3.

NOTE Informative references are listed in the Bibliography on page 396.

IEC 60065:2001, *Audio, video and similar electronic apparatus – Safety requirements* [2)]
Amendment 1:2005
Amendment 2:2010

IEC 60068-2-2:2007, *Environmental testing – Part 2-2: Tests – Test B: Dry heat*

IEC 60079-0, *Electrical apparatus for explosive gas atmospheres – Part 0: General requirements*

IEC 60079-2, *Electrical apparatus for explosive gas atmospheres – Part 2: Pressurized enclosures "p"*

IEC 60079-5, *Electrical apparatus for explosive gas atmospheres – Part 5: Powder filling "q"*

IEC 60079-6, *Electrical apparatus for explosive gas atmospheres – Part 6: Oil-immersion "o"*

IEC 60083, *Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC*

IEC 60085, *Electrical insulation – Thermal classification*

IEC 60086-4, *Primary batteries – Part 4: Safety of lithium batteries*

IEC 60112, *Method for the determination of the proof and the comparative tracking indices of solid insulating materials*

IEC 60127-1, *Miniature fuses – Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links*

IEC 60227-1:2007, *Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V – Part 1: General requirements*

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2) There exists a consolidated edition 7.2 including IEC 60065:2001 and its Amendment 1 (2005) and Amendment 2 (2010).

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IEC 60245-1:2003, *Rubber insulated cables – Rated voltages up to and including 450/750 V – Part 1: General requirements*[3]
Amendment 1:2007

IEC 60252-1, *AC motor capacitors – Part 1: General – Performance, testing and rating – Safety requirements – Guide for installation and operation*

IEC 60320-1, *Appliance couplers for household and similar general purposes – Part 1: General requirements*

IEC 60335-1:2010, *Household and similar electrical appliances – Safety – Part 1: General requirements*

IEC 60364-4-41, *Electrical installations of buildings – Part 4-41: Protection for safety – Protection against electric shock*

IEC 60384-14:2005, *Fixed capacitors for use in electronic equipment – Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains*

IEC 60417, *Graphical symbols for use on equipment.* Available from: <http://www.graphical-symbols.info/equipment>

IEC 60445, *Basic and safety principles for man-machine interface, marking and identification – Identification of equipment terminals and of terminations of certain designated conductors, including general rules for an alphanumeric system*

IEC 60447, *Basic and safety principles for man-machine interface, marking and identification – Actuating principles*

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)* [4)]
Amendment 1 (1999)

IEC 60601-1-2, *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-3, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance. Collateral standard: Radiation protection in diagnostic X-ray equipment*

IEC 60601-1-6, *Medical electrical equipment – Part 1-6: General requirements for safety – Collateral standard: Usability*

IEC 60601-1-8, *Medical electrical equipment – Part 1-8: General requirements for safety –- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

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3) There exists a consolidated edition 4.1 including IEC 60245-1:2003 and its Amendment 1 (2007).

4) There exists a consolidated version 2.1, including IEC 60529:1989 and its Amendment 1 (1999).

IEC 60664-1:2007, *Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests*

IEC 60695-11-10, *Fire hazard testing – Part 11-10: Test flames – 50 W horizontal and vertical flame test methods*

IEC 60730-1:2010, *Automatic electrical controls for household and similar use – Part 1: General requirements*

IEC 60825-1:2007, *Safety of laser products – Part 1: Equipment classification and requirements*

IEC 60851-3: 2009, *Winding wires – Test methods – Part 3: Mechanical properties*

IEC 60851-5: 2008, *Winding wires – Test methods – Part 5: Electrical properties*

IEC 60851-6:1996, *Winding wires – Test methods – Part 6: Thermal properties*
Amendment 1 (1997)

IEC 60884-1, *Plugs and socket-outlets for household and similar purposes - Part 1: General requirements*

IEC 60950-1:2001, *Information technology equipment – Safety – Part 1: General requirements*

IEC 61058-1:2000, *Switches for appliances – Part 1: General requirements* [5)]
Amendment 1:2001
Amendment 2:2007

IEC 61558-2-1, *Safety transformers, power supply units and similar – Part 2: Particular requirements for separating transformers for general use*

IEC 61672-1, *Electroacoustics – Sound level meters – Part 1: Specifications*

IEC 61672-2, *Electroacoustics – Sound level meters – Part 2: Pattern evaluation tests*

IEC 61965, *Mechanical safety of cathode ray tubes*

IEC 62133, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications*

IEC 62304:2006, *Medical device software – Software lifecycle processes*

ISO 780, *Packaging – Pictorial marking for handling of goods*

ISO 1853, *Conducting and dissipative rubbers, vulcanized or thermoplastic – Measurement of resistivity*

ISO 2878, *Rubber, vulcanized – Antistatic and conductive products – Determination of electrical resistance*

ISO 2882 [6)], *Rubber, vulcanized – Antistatic and conductive products for hospital use – Electrical resistance limits*

ISO 3746, *Acoustics – Determination of sound power levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane*

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5) There exists a consolidated edition 3.2, including IEC 61058-1:2000 and its Amendment 1 (2001) and Amendment 2 (2007)

6) ISO 2882 was withdrawn on 1 February 2005 and no replacement standard has been identified.

ISO 3864-1:2002, *Graphical symbols – Safety colours and safety signs – Part 1: Design principles for safety signs in workplaces and public areas*

ISO 5349-1, *Mechanical vibration – Measurement and evaluation of human exposure to hand-transmitted vibration – Part 1: General requirements*

ISO 7000-DB:2004 [7)], *Graphical symbols for use on equipment – Collection of symbols*

ISO 7010:2011, *Graphical symbols – Safety colours and safety signs – Registered safety signs*

ISO 9614-1, *Acoustics – Determination of sound power levels of noise sources using sound intensity – Measurement at discrete points*

ISO 10993 (all parts), *Biological evaluation of medical devices*

ISO 11135-1:2007, *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1:2006, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 13857:2008, *Safety of machinery – Safety distances to prevent hazard zones being reached by the upper and lower limbs*

ISO 14971:2007, *Medical devices – Application of risk management to medical devices*

ISO 15223-1:2012, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*

ISO 17665-1:2006, *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 23529, *Rubber – General procedures for preparing and conditioning test pieces for physical test methods*

ISO 80000-1:2009, *Quantities and units – Part 1: General*

3 * Terminology and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE 1 Where the terms “voltage” and “current” are used in this document, they mean the r.m.s. values of an alternating, direct or composite voltage or current unless stated otherwise.

NOTE 2 The term “electrical equipment” is used to mean ME EQUIPMENT (see 3.63) or other electrical equipment. This standard also uses the term “equipment” to mean ME EQUIPMENT or other electrical or non-electrical equipment in the context of an ME SYSTEM (see 3.64).

NOTE 3 When the term "safety" is used in this document in roman or italic type, it does not mean "safety" as defined in ISO 14971, but rather is used to mean "the state of being protected from or guarded against hurt or injury; freedom from danger”.

NOTE 4 An index is found beginning on page 402.

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7) "DB" refers to the joint ISO-IEC on-line database.

3.1
ACCESS COVER
part of an ENCLOSURE or GUARD providing the possibility of access to electrical equipment parts for the purpose of adjustment, inspection, replacement or repair

3.2
ACCESSIBLE PART
part of electrical equipment other than an APPLIED PART that can be touched by means of the standard test finger

NOTE See also 5.9.2.1.

3.3
ACCESSORY
additional part for use with equipment in order to:

– achieve the INTENDED USE,

– adapt it to some special use,

– facilitate its use,

– enhance its performance, or

– enable its functions to be integrated with those of other equipment

[IEC 60788:2004, rm-83-06 modified]

3.4
ACCOMPANYING DOCUMENT
document accompanying ME EQUIPMENT, an ME SYSTEM, equipment or an ACCESSORY and containing information for the RESPONSIBLE ORGANIZATION or OPERATOR, particularly regarding BASIC SAFETY and ESSENTIAL PERFORMANCE

3.5
AIR CLEARANCE
shortest path in air between two conductive parts

NOTE Adapted from IEC 60664-1:2007, definition 3.2.

3.6
APPLIANCE COUPLER
means enabling the connection of a flexible cord to electrical equipment without the use of a TOOL, consisting of two parts: a MAINS CONNECTOR and an APPLIANCE INLET

NOTE See Figure 1.

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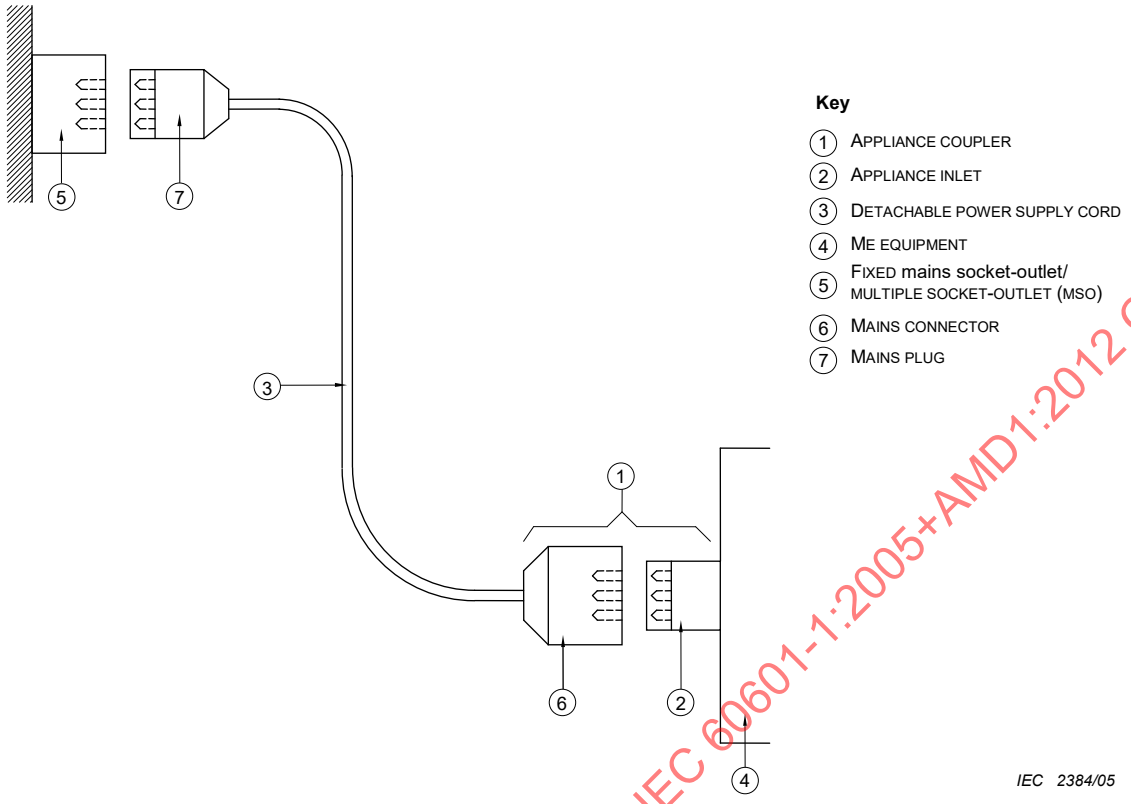


Figure 1 – Detachable mains connection
(see definitions)

3.7
APPLIANCE INLET
part of an APPLIANCE COUPLER either integrated in or FIXED to electrical equipment

NOTE See Figure 1 and Figure 2.

3.8
*** APPLIED PART**
part of ME EQUIPMENT that in NORMAL USE necessarily comes into physical contact with the PATIENT for ME EQUIPMENT or an ME SYSTEM to perform its function

NOTE 1 See Figure 3, Figure 4 and Figure A.1 to Figure A.7 (inclusive).

NOTE 2 See also 4.6 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be treated as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

NOTE 3 See also 3.78 for the definition of the associated term PATIENT CONNECTION.

3.9
*** BASIC INSULATION**
insulation providing basic protection against electric shock

[IEV 826-12-14, modified]

NOTE BASIC INSULATION provides one MEANS OF PROTECTION.

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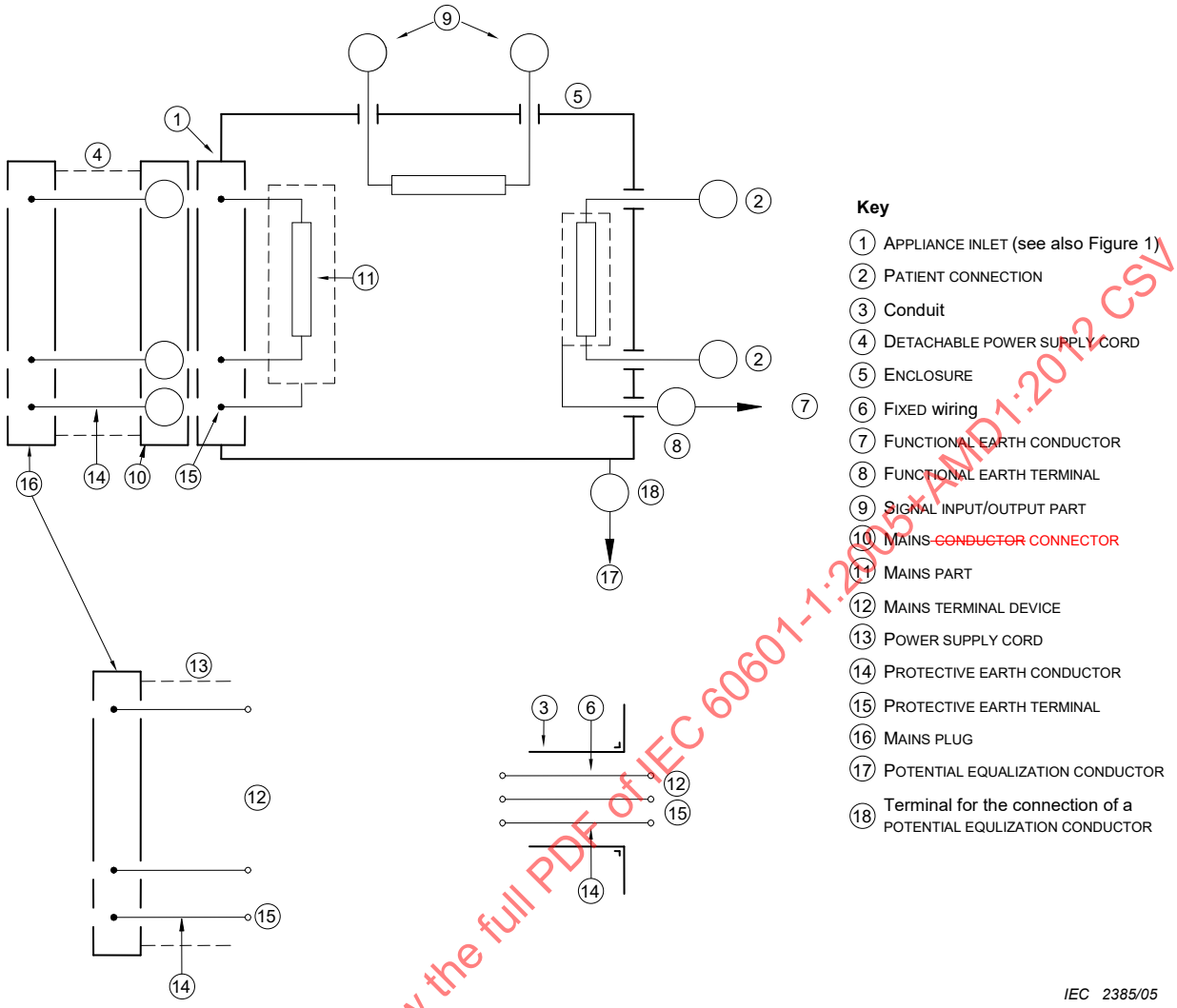
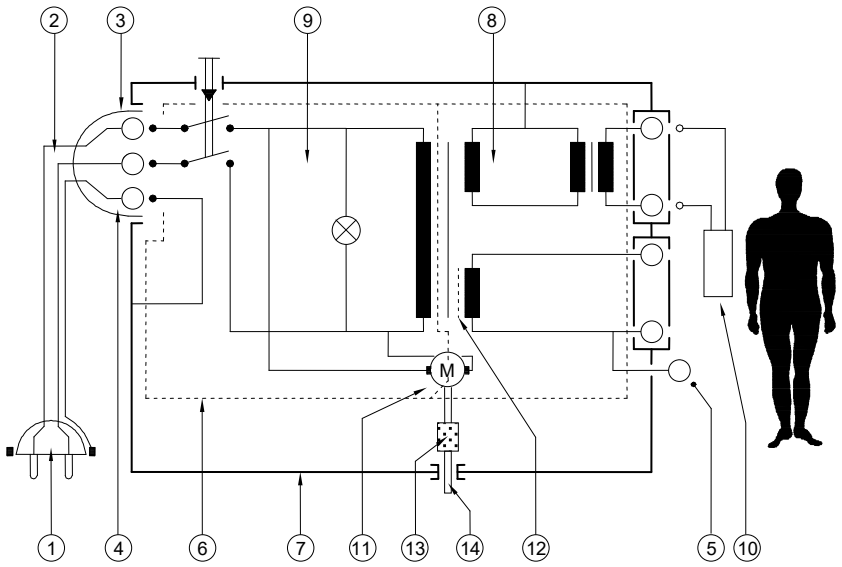


Figure 2 – Example of the defined terminals and conductors
(see definitions)

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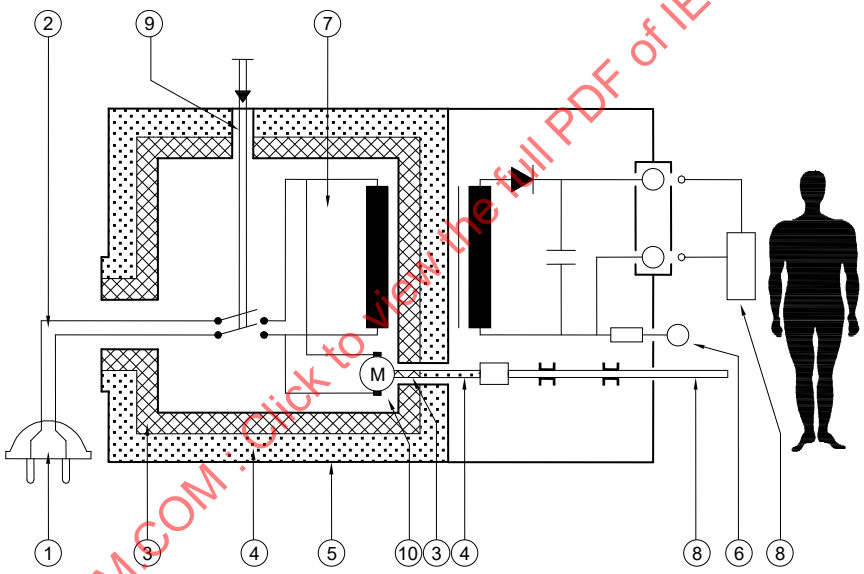


Key

1 MAINS PLUG with protective earth contact
2 DETACHABLE POWER SUPPLY CORD
3 APPLIANCE COUPLER
4 Protective earth contact and pin
5 FUNCTIONAL EARTH TERMINAL
6 BASIC INSULATION
7 ENCLOSURE
8 SECONDARY CIRCUIT
9 MAINS PART
10 APPLIED PART
11 Motor
12 PROTECTIVELY EARTHED screen
13 SUPPLEMENTARY INSULATION
14 Shaft that is an ACCESSIBLE PART

IEC 2386/05

Figure 3 – Example of a CLASS I ME EQUIPMENT
(see definitions)



Key

1 MAINS PLUG
2 POWER SUPPLY CORD
3 BASIC INSULATION
4 SUPPLEMENTARY INSULATION
5 ENCLOSURE
6 FUNCTIONAL EARTH TERMINAL
7 MAINS PART
8 APPLIED PART
9 REINFORCED INSULATION
10 Motor

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Figure 4 – Example of a metal-enclosed CLASS II ME EQUIPMENT
(see definitions)

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3.10
*** BASIC SAFETY**
freedom from unacceptable RISK directly caused by physical HAZARDS when ME EQUIPMENT is used under NORMAL CONDITION and SINGLE FAULT CONDITION

3.11
CATEGORY AP
rating for ME EQUIPMENT or an ME EQUIPMENT part complying with specified requirements on construction, marking and documentation in order to avoid sources of ignition in a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR

3.12
CATEGORY APG
rating for ME EQUIPMENT or an ME EQUIPMENT part complying with specified requirements on construction, marking and documentation in order to avoid sources of ignition in a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE

3.13
CLASS I
term referring to electrical equipment in which protection against electric shock does not rely on BASIC INSULATION only, but which includes an additional safety precaution in that means are provided for ACCESSIBLE PARTS of metal or internal parts of metal to be PROTECTIVELY EARTHED

NOTE See Figure 3.

3.14
CLASS II
term referring to electrical equipment in which protection against electric shock does not rely on BASIC INSULATION only, but in which additional safety precautions such as DOUBLE INSULATION or REINFORCED INSULATION are provided, there being no provision for protective earthing or reliance upon installation conditions

NOTE 1 See Figure 4.

NOTE 2 CLASS II equipment can be provided with a FUNCTIONAL EARTH TERMINAL or a FUNCTIONAL EARTH CONDUCTOR. See also 8.6.8 and 8.6.9.

3.15
*** CLEARLY LEGIBLE**
capable of being read by a person with normal vision

NOTE See the test in 7.1.2.

3.16
COLD CONDITION
condition obtained if electrical equipment is de-energized for a sufficiently long time to attain the ambient temperature

3.17
*** COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS**
component where one or more characteristics ensure that its function is fault-free in relation to the safety requirements of this standard during the EXPECTED SERVICE LIFE of the ME EQUIPMENT in NORMAL USE and reasonably foreseeable misuse

3.18
*** CONTINUOUS OPERATION**
operation in NORMAL USE for an unlimited period of time without the specified limits of temperature being exceeded

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3.19
CREEPAGE DISTANCE
shortest distance along the surface of the insulating material between two conductive parts

[IEV 151-15-50, modified]

3.20
*** DEFIBRILLATION-PROOF APPLIED PART**
APPLIED PART that is protected against the effects of a discharge of a cardiac defibrillator to the PATIENT

3.21
*** DETACHABLE POWER SUPPLY CORD**
flexible cord intended to be connected to electrical equipment by means of a suitable APPLIANCE COUPLER for mains supply purposes

NOTE See Figure 1, Figure 2 and Figure 3.

3.22
*** DIRECT CARDIAC APPLICATION**
use of APPLIED PART that can come in direct contact with the PATIENT'S heart

3.23
*** DOUBLE INSULATION**
insulation comprising both BASIC INSULATION and SUPPLEMENTARY INSULATION

[IEV 195-06-08]

NOTE DOUBLE INSULATION provides two MEANS OF PROTECTION.

3.24
*** DUTY CYCLE**
maximum activation (on) time followed by minimum deactivation (off) time necessary for the safe operation of the ME EQUIPMENT

3.25
EARTH LEAKAGE CURRENT
current flowing from the MAINS PART through or across the insulation into the PROTECTIVE EARTH CONDUCTOR or a functional earthed connection according to 8.6.9

3.26
*** ENCLOSURE**
exterior surface of electrical equipment or parts thereof

NOTE For the purpose of testing to this standard, metal foil, with specified dimensions, applied in contact with parts of the exterior surface made of material with low conductivity or made of insulating material is considered a part of the ENCLOSURE (see Figure 2, Figure 3 and Figure 4).

3.27
*** ESSENTIAL PERFORMANCE**
performance of a clinical function, other than that related to BASIC SAFETY, where loss or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable RISK

NOTE ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or degradation would result in an unacceptable RISK.

3.28
EXPECTED SERVICE LIFE
time period specified by the MANUFACTURER during which the ME EQUIPMENT or ME SYSTEM is expected to remain safe for use (i.e. maintain BASIC SAFETY and ESSENTIAL PERFORMANCE)

NOTE Maintenance can be necessary during the EXPECTED SERVICE LIFE.

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3.29
F-TYPE ISOLATED (FLOATING) APPLIED PART (herein F-TYPE APPLIED PART)
APPLIED PART in which the PATIENT CONNECTIONS are isolated from other parts of the ME EQUIPMENT to such a degree that no current higher than the allowable PATIENT LEAKAGE CURRENT flows if an unintended voltage originating from an external source is connected to the PATIENT, and thereby applied between the PATIENT CONNECTION and earth

NOTE F-TYPE APPLIED PARTS are either TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.

3.30
FIXED
term meaning fastened or otherwise secured at a specific location either permanently or so that it can only be detached by means of a TOOL

EXAMPLE 1 Permanently affixed by welding, etc.

EXAMPLE 2 Affixed by means of fasteners (screws, nuts, etc.) making removal/opening impossible without using a TOOL.

NOTE See the taxonomy in the rationale for definition 3.63.

3.31
FLAMMABLE ANAESTHETIC MIXTURE WITH AIR
mixture of a flammable anaesthetic vapour with air in such a concentration that ignition can occur under specified conditions

3.32
FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE
mixture of a flammable anaesthetic vapour with oxygen or with nitrous oxide in such a concentration that ignition can occur under specified conditions

3.33
*** FUNCTIONAL CONNECTION**
connection, electrical or otherwise, including those intended to transfer signals, data, power or substances

NOTE Connection to a FIXED SUPPLY MAINS socket-outlet, whether single or multiple, is not considered to result in a FUNCTIONAL CONNECTION.

3.34
FUNCTIONAL EARTH CONDUCTOR
conductor to be connected to a FUNCTIONAL EARTH TERMINAL

NOTE See Figure 2.

3.35
*** FUNCTIONAL EARTH TERMINAL**
terminal, directly connected to a circuit or to a screening part, that is intended to be earthed for functional purposes

NOTE See Figure 2, Figure 3 and Figure 4.

3.36
GUARD
part of equipment specifically used to provide protection by means of a physical barrier

NOTE Depending on its construction, a GUARD can be called a casing, cover, screen, door, enclosing guard, etc. A GUARD can act:

– alone; it is then only effective when it is in place;

– in conjunction with an interlocking device with or without guard locking; in this case, protection is ensured whatever the position of the GUARD.

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3.37
HAND-HELD
term referring to equipment that, once installed and placed into service, is intended to be supported by the hand

NOTE 1 Equipment can refer to ACCESSORIES or equipment parts.

NOTE 2 See the taxonomy in the rationale for definition 3.63.

3.38
*** HARM**
physical injury or damage to the health of people or animals, or damage to property or the environment

[ISO 14971:2007, definition 2.2, modified]

3.39
HAZARD
potential source of HARM

[ISO 14971:2007, definition 2.3]

3.40
*** HAZARDOUS SITUATION**
circumstance in which people, property, or the environment are exposed to one or more HAZARD(S)

[ISO 14971:2007, definition 2.4]

3.41
HIGH VOLTAGE
voltage over 1 000 V a.c. or over 1 500 V d.c. or over 1 500 V peak value

3.42
HYDRAULIC TEST PRESSURE
pressure applied to test a vessel or part of it

NOTE See 9.7.5.

3.43
INSULATION CO-ORDINATION
mutual correlation of insulation characteristics of electrical equipment taking into account the expected micro-environment and other influencing stresses

NOTE This includes insulation types, CREEPAGE DISTANCES, AIR CLEARANCES, distance through insulation, coatings, encapsulation, environmental aspects, etc.

3.44
INTENDED USE
INTENDED PURPOSE
use for which a product, PROCESS or service is intended according to the specifications, instructions and information provided by the MANUFACTURER

[ISO 14971:2007, definition 2.5]

NOTE INTENDED USE should not be confused with NORMAL USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, transport, etc. as well.

3.45
INTERNAL ELECTRICAL POWER SOURCE
electrical power source for operating equipment that is a part of the equipment and which produces electrical current from some other form of energy

EXAMPLE Chemical, mechanical, solar, or nuclear

NOTE An INTERNAL ELECTRICAL POWER SOURCE can be inside the principal part of equipment, attached to the outside, or contained in a separate ENCLOSURE.

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3.46
INTERNALLY POWERED
term referring to electrical equipment that is able to operate from an INTERNAL ELECTRICAL POWER SOURCE

3.47
LEAKAGE CURRENT
current that is not functional

NOTE The following LEAKAGE CURRENTS are defined: EARTH LEAKAGE CURRENT, TOUCH CURRENT and PATIENT LEAKAGE CURRENT.

3.48
MAINS CONNECTOR
part of an APPLIANCE COUPLER integral with or intended to be attached to a flexible cord that is intended to be connected to the SUPPLY MAINS

NOTE A MAINS CONNECTOR is intended to be inserted into the APPLIANCE INLET of electrical equipment (see Figure 1 and Figure 2).

3.49
*** MAINS PART**
part of electrical equipment forming a circuit that is intended to be connected to the SUPPLY MAINS

NOTE 1 The MAINS PART includes all conductive parts that are not separated from the SUPPLY MAINS by at least one MEANS OF PROTECTION.

NOTE 2 For the purpose of this definition, the PROTECTIVE EARTH CONDUCTOR is not regarded as a part of the MAINS PART (see Figure 2 and Figure 3).

3.50
*** MAINS PLUG**
part, integral with or intended to be attached to a POWER SUPPLY CORD of electrical equipment, to be inserted into a mains socket-outlet

NOTE 1 See Figure 1.

NOTE 2 See also IEC 60083 and IEC 60309-1 [8].

3.51
MAINS SUPPLY TRANSFORMER
static piece of equipment with two or more windings which, by electro-magnetic induction, transforms an alternating voltage and current from a SUPPLY MAINS into a voltage and current usually of different values at the same frequency

3.52
MAINS TERMINAL DEVICE
TERMINAL DEVICE by which the electrical connection to the SUPPLY MAINS is made

NOTE See Figure 2.

3.53
MAINS TRANSIENT VOLTAGE
highest peak voltage expected at the power input to the electrical equipment, arising from external transients on the SUPPLY MAINS

3.54
MAINS VOLTAGE
voltage of a SUPPLY MAINS between two line conductors of a polyphase system or voltage between the line conductor and the neutral conductor of a single-phase system

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3.55
MANUFACTURER
natural or legal person with responsibility for the design, manufacture, packaging, or labelling of ME EQUIPMENT, assembling an ME SYSTEM, or adapting ME EQUIPMENT or an ME SYSTEM, regardless of whether these operations are performed by that person or on that person's behalf by a third party

NOTE 1 ISO 13485 [30] defines "labelling" as written, printed or graphic matter

– affixed to a medical device or any of its containers or wrappers, or

– accompanying a medical device,

related to identification, technical description, and use of the medical device, but excluding shipping documents. In this standard, that material is described as markings and ACCOMPANYING DOCUMENTS.

NOTE 2 "Adapting" includes making substantial modifications to ME EQUIPMENT or an ME SYSTEM already in use.

NOTE 3 In some jurisdictions, the RESPONSIBLE ORGANIZATION can be considered a MANUFACTURER when involved in the activities described.

NOTE 4 Adapted from ISO 14971:2007, definition 2.8.

3.56
*** MAXIMUM MAINS VOLTAGE**
voltage used for test purposes related to the voltage of the SUPPLY MAINS and connected to certain ME EQUIPMENT parts

NOTE The value for MAXIMUM MAINS VOLTAGE is determined according to 8.5.3.

3.57
*** MAXIMUM PERMISSIBLE WORKING PRESSURE**
maximum pressure permitted on a component according to a declaration of the manufacturer of such component

3.58
*** MEANS OF OPERATOR PROTECTION**
MOOP
MEANS OF PROTECTION for reducing the RISK due to electric shock to persons other than the PATIENT

3.59
*** MEANS OF PATIENT PROTECTION**
MOPP
MEANS OF PROTECTION for reducing the RISK due to electric shock to the PATIENT

3.60
*** MEANS OF PROTECTION**
MOP
means for reducing the RISK due to electric shock in accordance with the requirements of this standard

NOTE MEANS OF PROTECTION include insulation, AIR CLEARANCES, CREEPAGE DISTANCES, impedances, and PROTECTIVE EARTH CONNECTIONS.

3.61
MECHANICAL HAZARD
HAZARD connected with or produced by physical force

3.62
MECHANICAL PROTECTIVE DEVICE
device that eliminates or reduces mechanical RISK to an acceptable level and which operates in the case of SINGLE FAULT CONDITION

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3.63
*** MEDICAL ELECTRICAL EQUIPMENT**
ME EQUIPMENT
electrical equipment having an APPLIED PART or transferring energy to or from the PATIENT or detecting such energy transfer to or from the PATIENT and which is:

a) provided with not more than one connection to a particular SUPPLY MAINS; and

b) intended by its MANUFACTURER to be used:

1) in the diagnosis, treatment, or monitoring of a PATIENT; or

2) for compensation or alleviation of disease, injury or disability

NOTE 1 ME EQUIPMENT includes those ACCESSORIES as defined by the MANUFACTURER that are necessary to enable the NORMAL USE of the ME EQUIPMENT.

NOTE 2 Not all electrical equipment used in medical practice falls within this definition (e.g. some in vitro diagnostic equipment).

NOTE 3 The implantable parts of active implantable medical devices can fall within this definition, but they are excluded from the scope of this standard by appropriate wording in Clause 1.

NOTE 4 This standard uses the term "electrical equipment" to mean ME EQUIPMENT or other electrical equipment.

NOTE 5 See also 4.10.1, 8.2.1 and 16.3.

3.64
*** MEDICAL ELECTRICAL SYSTEM**
ME SYSTEM
combination, as specified by its MANUFACTURER, of items of equipment, at least one of which is ME EQUIPMENT to be inter-connected by FUNCTIONAL CONNECTION or by use of a MULTIPLE SOCKET-OUTLET

NOTE Equipment, when mentioned in this standard, should be taken to include ME EQUIPMENT.

3.65
MOBILE
term referring to TRANSPORTABLE equipment that, once installed and placed into service, is intended to be moved from one location to another while supported by its own wheels or equivalent means

NOTE See the taxonomy in the rationale for definition 3.63.

3.66
*** MODEL OR TYPE REFERENCE**
combination of figures, letters or both used to identify a particular model of equipment or ACCESSORY

3.67
*** MULTIPLE SOCKET-OUTLET**
MSO
one or more socket-outlets intended to be connected to, or integral with, flexible cables, cords or ME EQUIPMENT providing SUPPLY MAINS or equivalent voltage

NOTE A MULTIPLE SOCKET-OUTLET can be a separate item or an integral part of equipment.

3.68
*** NETWORK/DATA COUPLING**
any means to transmit or receive information to or from other equipment in accordance with the MANUFACTURER'S specifications

3.69
NOMINAL (value)
value quoted for reference purposes that is subject to agreed tolerances

EXAMPLE NOMINAL MAINS VOLTAGE or NOMINAL diameter of a screw

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3.70
NORMAL CONDITION
condition in which all means provided for protection against HAZARDS are intact

3.71
NORMAL USE
operation, including routine inspection and adjustments by any OPERATOR, and stand-by, according to the instructions for use

NOTE NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, transport, etc. as well.

3.72
OBJECTIVE EVIDENCE
data supporting the existence or verity of something

NOTE Objective evidence can be obtained through observation, measurement, testing or other means.

[ISO 14971:2007, definition 2.10]

3.73
*** OPERATOR**
person handling equipment

NOTE See also 3.101.

3.74
OVER-CURRENT RELEASE
protective device that causes a circuit to open, with or without time-delay, when the current in the device exceeds a predetermined value

[IEV 441-16-33, modified]

3.75
*** OXYGEN RICH ENVIRONMENT**
environment in which the concentration of oxygen is:

a) greater than 25 % for ambient pressures up to 110 kPa; or

b) the partial pressure of oxygen is greater than 27,5 kPa at ambient pressures exceeding 110 kPa

3.76
PATIENT
living being (person or animal) undergoing a medical, surgical or dental procedure

NOTE A PATIENT can be an OPERATOR.

3.77
*** PATIENT AUXILIARY CURRENT**
current flowing in the PATIENT in NORMAL USE between any PATIENT CONNECTION and all other PATIENT CONNECTIONS and not intended to produce a physiological effect

3.78
*** PATIENT CONNECTION**
individual point on the APPLIED PART through which current can flow between the PATIENT and the ME EQUIPMENT in NORMAL CONDITION or SINGLE FAULT CONDITION

3.79
*** PATIENT ENVIRONMENT**
any volume in which intentional or unintentional contact can occur between a PATIENT and parts of the ME EQUIPMENT or ME SYSTEM or between a PATIENT and other persons touching parts of the ME EQUIPMENT or ME SYSTEM

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3.80
PATIENT LEAKAGE CURRENT
current:

– flowing from the PATIENT CONNECTIONS via the PATIENT to earth; or

– originating from the unintended appearance of a voltage from an external source on the PATIENT and flowing from the PATIENT via the PATIENT CONNECTIONS of an F-TYPE APPLIED PART to earth

3.81
*** PEAK WORKING VOLTAGE**
highest peak or d.c. value of a WORKING VOLTAGE, including repetitive peak impulses generated in the electrical equipment, but not including external transients

[IEC 60950-1:2005, definition 1.2.9.8, modified]

3.82
PEMS DEVELOPMENT LIFE-CYCLE
necessary activities occurring during a period of time that starts at the concept phase of a project and finishes when the PEMS VALIDATION is complete

NOTE See also 3.90.

3.83
PEMS VALIDATION
PROCESS of evaluating a PEMS or a component of a PEMS during or at the end of the development PROCESS, to determine whether it satisfies the requirements for its INTENDED USE

NOTE See also 3.90.

3.84
PERMANENTLY INSTALLED
term meaning electrically connected to the SUPPLY MAINS by means of a permanent connection that can only be detached by the use of a TOOL

3.85
PORTABLE
term referring to TRANSPORTABLE equipment that, once installed and placed into service, is intended to be moved from one location to another while being carried by one or more persons

NOTE 1 Equipment can refer to ACCESSORIES or equipment parts.

NOTE 2 See the taxonomy in the rationale for definition 3.63.

3.86
POTENTIAL EQUALIZATION CONDUCTOR
conductor other than a PROTECTIVE EARTH CONDUCTOR or a neutral conductor, providing a direct connection between electrical equipment and the potential equalization busbar of the electrical installation

NOTE See Figure 2.

3.87
POWER SUPPLY CORD
flexible cord, FIXED to or assembled with electrical equipment for connection to SUPPLY MAINS

NOTE See Figure 1 to Figure 4 (inclusive).

3.88
PROCEDURE
specified way to carry out an activity or a PROCESS

[ISO 14971:2007, definition 2.12]

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3.89
PROCESS
set of interrelated or interacting activities which transforms inputs into outputs

[ISO 14971:2007, definition .13]

3.90
PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM
PEMS
ME EQUIPMENT or an ME SYSTEM containing one or more PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS)

3.91
PROGRAMMABLE ELECTRONIC SUBSYSTEM
PESS
system based on one or more central processing units, including their software and interfaces

3.92
PROPERLY INSTALLED
installed in accordance with the ACCOMPANYING DOCUMENTS

3.93
PROTECTIVE EARTH CONDUCTOR
conductor to be connected between the PROTECTIVE EARTH TERMINAL and an external protective earthing system

NOTE See Figure 2.

3.94
PROTECTIVE EARTH CONNECTION
connection to the PROTECTIVE EARTH TERMINAL provided for protective purposes and complying with the requirements of this standard

3.95
PROTECTIVE EARTH TERMINAL
terminal connected to conductive parts of CLASS I equipment for safety purposes. This terminal is intended to be connected to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR

NOTE See Figure 2.

3.96
PROTECTIVELY EARTHED
connected to the PROTECTIVE EARTH TERMINAL for protective purposes by means complying with the requirements of this standard

3.97
RATED (value)
term referring to a value assigned by the MANUFACTURER for a specified operating condition

3.98
RECORD
document stating results achieved or providing evidence of activities performed

[ISO 14971:2007, definition 2.14]

3.99
*** REINFORCED INSULATION**
single insulation system that provides two MEANS OF PROTECTION

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3.100
RESIDUAL RISK
RISK remaining after RISK CONTROL measures have been taken

[ISO 14971:2007, definition 2.15]

3.101
RESPONSIBLE ORGANIZATION
entity accountable for the use and maintenance of an ME EQUIPMENT or an ME SYSTEM

NOTE 1 The accountable entity can be, for example, a hospital, an individual clinician or a layperson. In home use applications, the PATIENT, OPERATOR and RESPONSIBLE ORGANIZATION can be one and the same person.

NOTE 2 Education and training is included in "use."

3.102
RISK
combination of the probability of occurrence of HARM and the SEVERITY of that HARM

[ISO 14971:2007, definition 2.16]

3.103
RISK ANALYSIS
systematic use of available information to identify HAZARDS and to estimate the RISK

[ISO 14971:2007, definition 2.17]

3.104
RISK ASSESSMENT
overall PROCESS comprising a RISK ANALYSIS and a RISK EVALUATION

[ISO 14971:2007, definition 2.18]

3.105
RISK CONTROL
PROCESS in which decisions are made and measures implemented by which RISKS are reduced to, or maintained within, specified levels

[ISO 14971:2007, definition 2.19]

3.106
RISK EVALUATION
PROCESS of comparing the estimated RISK against given RISK criteria to determine the acceptability of the RISK

[ISO 14971:2007, definition 2.21]

3.107
RISK MANAGEMENT
systematic application of management policies, PROCEDURES and practices to the tasks of analyzing, evaluating and controlling RISK

[ISO 14971:2007, definition 2.22]

NOTE For the purposes of this standard, RISK MANAGEMENT does not include planning for or monitoring of production and post-production information; whereas this is required for compliance with ISO 14971 (see 4.2.2).

3.108
RISK MANAGEMENT FILE
set of RECORDS and other documents that are produced by RISK MANAGEMENT

[ISO 14971:2007, definition 2.23]

NOTE All safety related information including MANUFACTURER'S calculations, test results, etc. is considered to be part of the RISK MANAGEMENT FILE. See also 4.2.

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3.109
SAFE WORKING LOAD
maximum external mechanical load (mass) on equipment or an equipment part that is permitted in NORMAL USE

3.110
*** SECONDARY CIRCUIT**
circuit which is separated from the MAINS PART by at least one MEANS OF PROTECTION and derives its power from a transformer, converter or equivalent isolation device, or from an INTERNAL ELECTRICAL POWER SOURCE

NOTE See also 8.9.1.12.

3.111
SELF-RESETTING THERMAL CUT-OUT
THERMAL CUT-OUT that automatically restores the current after the relevant part of electrical equipment has cooled

3.112
*** SEPARATION DEVICE**
component or arrangement of components with input parts and output parts that, for safety reasons, prevents a transfer of unwanted voltage or current between parts of an ME SYSTEM

3.113
SERVICE PERSONNEL
individuals or entity accountable to the RESPONSIBLE ORGANIZATION that install, assemble, maintain or repair ME EQUIPMENT, ME SYSTEMS or equipment

3.114
SEVERITY
measure of the possible consequences of a HAZARD

[ISO 14971:2007, definition 2.25]

3.115
*** SIGNAL INPUT/OUTPUT PART**
SIP/SOP
part of ME EQUIPMENT, not being an APPLIED PART, intended to deliver or receive signals to or from other electrical equipment, for example, for display, recording or data processing

NOTE See Figure 2.

3.116
SINGLE FAULT CONDITION
condition of ME EQUIPMENT in which a single means for reducing a RISK is defective or a single abnormal condition is present

NOTE See 4.7 and 13.2.

3.117
SINGLE FAULT SAFE
characteristic of ME EQUIPMENT or its parts whereby it remains free of unacceptable RISK during its EXPECTED SERVICE LIFE under SINGLE FAULT CONDITIONS

NOTE See 4.7.

3.118
STATIONARY
term referring to equipment that, once installed and placed into service, is not intended to be moved from one place to another

NOTE See the taxonomy in the rationale for definition 3.63.

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3.119
SUPPLEMENTARY INSULATION
independent insulation applied in addition to BASIC INSULATION in order to provide protection against electric shock in the event of a failure of BASIC INSULATION

[IEV 826-12-15, modified]

NOTE SUPPLEMENTARY INSULATION provides one MEANS OF PROTECTION.

3.120
* **SUPPLY MAINS**
source of electrical energy not forming part of ME EQUIPMENT or ME SYSTEM

NOTE This also includes battery systems and converter systems in ambulances and the like.

3.121
TENSILE SAFETY FACTOR
ratio between TENSILE STRENGTH and the stress corresponding to the TOTAL LOAD

3.122
TENSILE STRENGTH
maximum tensile stress a test piece will withstand before rupturing

3.123
TERMINAL DEVICE
part of electrical equipment by which electrical connection is made

NOTE A TERMINAL DEVICE can contain several individual contacts.

3.124
THERMAL CUT-OUT
device that, during an abnormal condition, limits the temperature of electrical equipment or of part of it, by automatically opening the circuit or by reducing the current, and that is so constructed that its setting cannot be altered except by qualified SERVICE PERSONNEL

3.125
THERMAL STABILITY
condition under which the temperature of an object does not increase by more than 2 °C over a period of 1 h

3.126
THERMOSTAT
temperature sensing control that is intended to keep a temperature within a specific range or above/below a preset value

3.127
TOOL
extra-corporeal object that can be used to secure or release fasteners or to make adjustments

NOTE Coins and keys are considered TOOLS within the context of this standard.

3.128
TOTAL LOAD
maximum total loading of a part including the maximum SAFE WORKING LOAD, where applicable, and the static and dynamic forces occurring in NORMAL USE

NOTE 1 Examples of dynamic forces include forces caused by acceleration or deceleration of masses.

NOTE 2 Where a load is divided over several parallel supporting parts and the distribution over these parts is not determined unequivocally, the least favourable possibility is to be considered.

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3.129
TOUCH CURRENT
LEAKAGE CURRENT flowing from the ENCLOSURE or from parts thereof, excluding PATIENT CONNECTIONS, accessible to any OPERATOR or PATIENT in NORMAL USE, through an external path other than the PROTECTIVE EARTH CONDUCTOR, to earth or to another part of the ENCLOSURE

NOTE The meaning of this term is the same as that of "enclosure leakage current" in the first and second editions of this standard. The term has been changed to align with IEC 60950-1 and to reflect the fact that the measurement now applies also to parts that are normally PROTECTIVELY EARTHED.

3.130
TRANSPORTABLE
term referring to equipment that, once installed and placed into service, is intended to be moved from one place to another whether or not connected to a supply and without an appreciable restriction of range

EXAMPLE MOBILE equipment, PORTABLE equipment. and BODY-WORN equipment

NOTE See the taxonomy in the rationale for definition 3.63.

3.131
TRAPPING ZONE
accessible location on or within the ME EQUIPMENT, ME SYSTEM or in the equipment environment where a human body or a part of the human body is exposed to a trapping, crushing, shearing, impact, cutting, entanglement, drawing in, stabbing or abrasion HAZARD

3.132
*** TYPE B APPLIED PART**
APPLIED PART complying with the specified requirements of this standard to provide protection against electric shock, particularly regarding allowable PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT

NOTE 1 A TYPE B APPLIED PART is marked with symbol IEC 60417-5840 (2002-10) (see Table D.1, symbol 19) or, when applicable, with symbol IEC 60417-5841 (2002-10) (see Table D.1, symbol 25). See also 3.20.

NOTE 2 TYPE B APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

NOTE 3 See also 4.6 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be considered as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

3.133
*** TYPE BF APPLIED PART**
F-TYPE APPLIED PART complying with the specified requirements of this standard to provide a higher degree of protection against electric shock than that provided by TYPE B APPLIED PARTS

NOTE 1 A TYPE BF APPLIED PART is marked with symbol IEC 60417-5333 (2002-10) (see Table D.1, symbol 20) or, when applicable, with symbol 60417-5334 (2002-10) (see Table D.1, symbol 26). See also 3.20.

NOTE 2 TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

NOTE 3 See also 4.6 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be considered as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

3.134
*** TYPE CF APPLIED PART**
F-TYPE APPLIED PART complying with the specified requirements of this standard to provide a higher degree of protection against electric shock than that provided by TYPE BF APPLIED PARTS

NOTE 1 A TYPE CF APPLIED PART is marked with symbol IEC 60417-5335 (2002-10) (see Table D.1, symbol 21) or, when applicable, with symbol 60417-5336 (2002-10) (see Table D.1, symbol 27). See also 3.20.

NOTE 2 See also 4.6 regarding the treatment of parts that do not fall within the definition of APPLIED PARTS but need to be considered as APPLIED PARTS as a result of applying the RISK MANAGEMENT PROCESS.

NOTE 3 See the rationale for the definition of DIRECT CARDIAC APPLICATION (3.22) concerning the applied parts that need to be TYPE CF APPLIED PARTS.

3.135
TYPE TEST
test on a representative sample of the equipment with the objective of determining if the equipment, as designed and manufactured, can meet the requirements of this standard

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3.136
USABILITY
characteristic of the OPERATOR interface that establishes effectiveness, efficiency, ease of OPERATOR learning and OPERATOR satisfaction

[IEC 62366:2007, definition 3.17, modified]

3.137
USABILITY ENGINEERING
application of knowledge about human behaviour, abilities, limitations, and other characteristics to the design of tools, devices, systems, tasks, jobs, and environments to achieve adequate USABILITY

[IEC 62366:2007, definition 3.18]

3.138
VERIFICATION
confirmation, through the provision of OBJECTIVE EVIDENCE that specified requirements have been fulfilled

NOTE 1 The term "verified" is used to designate the corresponding status.

NOTE 2 Confirmation can comprise activities such as:

– performing alternative calculations;

– comparing a new design specification with a similar proven design specification;

– undertaking tests and demonstrations;

– reviewing documents prior to issue.

[ISO 14971:2007, definition 2.28]

3.139
*** WORKING VOLTAGE**
highest voltage to which the insulation or the component under consideration is, or can be, subjected when the electrical equipment is operating under conditions of NORMAL USE

[IEC 60950-1:2005, definition 1.2.9.6]

3.140
AIR KERMA
K
quotient of dE_{tr} by dm, where dE_{tr} is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of air, thus

$$K = \frac{dE_{tr}}{dm}$$

Unit: J kg^{-1}

The special name for the unit of AIR KERMA is gray (Gy) (ICRU 60)

[IEC 60601-1-3:2008, definition 3.4]

3.141
ALARM CONDITION
state of the ALARM SYSTEM when it has determined that a potential or actual HAZARDOUS SITUATION exists for which OPERATOR awareness or response is required

NOTE 1 An ALARM CONDITION can be invalid, i.e. a false positive ALARM CONDITION.

NOTE 2 An ALARM CONDITION can be missed, i.e. a false negative ALARM CONDITION.

[IEC 60601-1-8:2006 / Amendment 1 (2012), definition 3.1]

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3.142
ALARM SIGNAL
type of signal generated by the ALARM SYSTEM to indicate the presence (or occurrence) of an ALARM CONDITION

[IEC 60601-1-8:2006, definition 3.9]

3.143
ALARM SYSTEM
parts of ME EQUIPMENT or a ME SYSTEM that detect ALARM CONDITIONS and, as appropriate, generate ALARM SIGNALS

[IEC 60601-1-8:2006, definition 3.11]

3.144
BODY-WORN
term referring to TRANSPORTABLE equipment whose INTENDED USE includes operation while being worn by a PATIENT or attached to a PATIENT'S clothing

NOTE 1 TRANSPORTABLE equipment can be both BODY-WORN and HAND-HELD.

[IEC 60601-1-11:2010, definition 3.1]

NOTE 2 See the taxonomy in the rationale for definition 3.63.

3.145
IT-NETWORK
INFORMATION TECHNOLOGY NETWORK
a system or systems composed of communicating nodes and transmission links to provide physically linked or wireless transmission between two or more specified communication nodes

[IEC 80001-1:2010, definition 2.12]

3.146
PRIMARY OPERATING FUNCTION
function that involves OPERATOR interaction that is frequently used or related to the safety of the ME EQUIPMENT

[IEC 62366:2007, definition 3.14, modified]

3.147
USABILITY ENGINEERING FILE
set of RECORDS and other documents that are produced by the USABILITY ENGINEERING PROCESS

[IEC 62366:2007, definition 3.19]

4 General requirements

4.1 * Conditions for application to ME EQUIPMENT or ME SYSTEMS

Unless otherwise specified, the requirements of this standard shall apply in NORMAL USE and reasonably foreseeable misuse.

When applying this standard to ME EQUIPMENT or ME SYSTEMS intended for the compensation or alleviation of disease, injury or disability, the definitions and requirements that use the term PATIENT shall be considered as applying to the person for whom the ME EQUIPMENT or ME SYSTEM is intended.

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4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

4.2.1 Introduction to RISK MANAGEMENT

Subclause 4.2 specifies the RISK MANAGEMENT PROCESS that is required for compliance with this standard. This RISK MANAGEMENT PROCESS is intended to serve the following purposes:

a) To identify whether the normative requirements specified in Clauses 5 to 17 of this standard, together with the requirements of applicable collateral and particular standards, address all the HAZARDS associated with the particular ME EQUIPMENT or ME SYSTEM under consideration.

b) To identify the way in which some particular tests specified in this standard should be applied to a particular ME EQUIPMENT or ME SYSTEM.

c) To identify whether particular HAZARDS or HAZARDOUS SITUATIONS for which this standard does not provide specific acceptance criteria result in any RISKS for a particular ME EQUIPMENT or ME SYSTEM, and, if so, to establish acceptable RISK levels and evaluate the RESIDUAL RISKS.

d) To evaluate the acceptability of alternative RISK CONTROL strategies by comparing RESIDUAL RISK with that achieved by applying the full requirements of this standard.

Although the RISK MANAGEMENT PROCESS specified in this standard is required to comply with the relevant requirements of ISO 14971, it is not as extensive as and does not include all of the elements required for compliance with ISO 14971. For example, the RISK MANAGEMENT PROCESS required for compliance with this standard does not include the production and post-production monitoring required in ISO 14971. Furthermore, verification of compliance with the RISK MANAGEMENT requirements of this standard can be accomplished by examination of the RECORDS and other documentation required by this standard and assessment of the processes cited in this standard and does not require auditing of the RISK MANAGEMENT PROCESS.

4.2.2 General requirement for RISK MANAGEMENT

A RISK MANAGEMENT PROCESS complying with ISO 14971 shall be performed. For compliance with this standard, all elements of the ISO 14971:2007 RISK MANAGEMENT PROCESS shall be applied except:

– the planning for and execution of production and post-production monitoring (subclause 3.1, fourth dash, subclause 3.4, item f), and Clause 9 of ISO 14971:2007), and

– periodic reviews of the suitability of the RISK MANAGEMENT PROCESS (subclause 3.2, fourth dash, of ISO 14971:2007).

When applying any of the requirements of ISO 14971:

– the term “medical device” shall assume the same meaning as ME EQUIPMENT or ME SYSTEM; and

– the term “fault conditions” referred to in ISO 14971 shall include, but shall not be limited to, SINGLE FAULT CONDITIONS identified in this standard.

NOTE 1 This standard specifies requirements that are generally applicable to RISKS associated with the ME EQUIPMENT or ME SYSTEMS. Those requirements are intended to facilitate the RISK MANAGEMENT PROCESS. The RISK MANAGEMENT PROCESS is aimed at identifying not only those HAZARDS addressed by this standard, but all HAZARDS, their associated RISKS and RISK CONTROL measures.

NOTE 2 Conditions or faults that can give rise to HAZARDOUS SITUATIONS are identified in the clauses of this standard. In these cases, it will often be necessary to carry out a RISK MANAGEMENT PROCESS to determine what the actual HAZARDOUS SITUATIONS are and the tests that need to be done to show that the identified HAZARDOUS SITUATIONS do not arise in the specified circumstances.

NOTE 3 It is recognized that the MANUFACTURER might not be able to follow all the PROCESSES identified in this standard for each constituent component of the ME EQUIPMENT or ME SYSTEM, such as proprietary components, subsystems of non-medical origin, and legacy devices. In this case, the MANUFACTURER would need to take special account of the need for additional RISK CONTROL measures.

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NOTE 4 Where requirements of this standard refer to freedom from unacceptable RISK, acceptability or unacceptability of this RISK is determined by the MANUFACTURER in accordance with the MANUFACTURER'S policy for determining acceptable RISK.

NOTE 5 Not all the RISKS associated with the ME EQUIPMENT or ME SYSTEM are subject to specific requirements of this standard (see 1.1).

Compliance is checked by:

– *inspection of the MANUFACTURER'S policy for determining criteria for RISK acceptability;*

– *inspection of the RISK MANAGEMENT plan for the particular ME EQUIPMENT or ME SYSTEM under consideration; and*

– *confirming the MANUFACTURER has prepared a RISK MANAGEMENT FILE containing the RISK MANAGEMENT RECORDS and other documentation required by this standard for the particular ME EQUIPMENT or ME SYSTEM under consideration.*

NOTE 6 It is helpful to keep an index containing references or pointers to the RISK MANAGEMENT RECORDS and other documentation required by this standard.

4.2.3 Evaluating RISK

4.2.3.1 HAZARDS identified in the IEC 60601-series

The requirements of this standard shall be applied in the following way when evaluating RISK:

a) Where this standard or its collateral or particular standards specify requirements addressing particular HAZARDS or HAZARDOUS SITUATIONS, together with specific acceptance criteria, compliance with these requirements is presumed to establish that the RESIDUAL RISKS have been reduced to acceptable levels unless there is OBJECTIVE EVIDENCE to the contrary.

EXAMPLE 1 Subclause 8.5.1.2, MEANS OF PATIENT PROTECTION (MOPP)

EXAMPLE 2 Subclause 9.4.2.1, Instability in transport position

Compliance is checked by satisfying the relevant requirements of this standard and its collateral and particular standards.

b) Where this standard or its collateral or particular standards specify requirements addressing particular HAZARDS or HAZARDOUS SITUATIONS but do not provide specific acceptance criteria, the MANUFACTURER shall provide the acceptance criteria defined in the RISK MANAGEMENT plan. These acceptance criteria shall ensure that the RESIDUAL RISK is acceptable according to the criteria for RISK acceptability recorded in the RISK MANAGEMENT plan.

EXAMPLE 3 Subclause 9.8.3.3, Dynamic forces due to loading from persons

EXAMPLE 4 Subclause 11.6.3, Spillage on ME EQUIPMENT and ME SYSTEMS

Compliance is checked by confirming that the RECORDS in the RISK MANAGEMENT FILE demonstrate that, after applying the specific requirements of this standard, the acceptance criteria determined by the MANUFACTURER are satisfied. Only the relevant parts of the RISK MANAGEMENT FILE need to be reviewed, e.g. the *MANUFACTURER'S calculations or test results, or the determination of RISK acceptability.*

c) Where this standard or its collateral or particular standards identify particular HAZARDS or HAZARDOUS SITUATIONS that have to be investigated without providing specific technical requirements:

– the MANUFACTURER shall determine whether such HAZARDS or HAZARDOUS SITUATIONS exist for the particular ME EQUIPMENT or ME SYSTEM, and

– where such HAZARDS or HAZARDOUS SITUATIONS exist for the particular ME EQUIPMENT or ME SYSTEM, the MANUFACTURER shall evaluate and (if necessary) control these RISKS following the RISK MANAGEMENT PROCESS specified in 4.2.2.

EXAMPLE 5 Subclause 10.2, Alpha, beta, gamma, neutron and other particle radiation

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Compliance is checked by confirming that the RECORDS in the RISK MANAGEMENT FILE demonstrate that the RESIDUAL RISK is acceptable using the criteria for RISK acceptability recorded in the RISK MANAGEMENT plan, i.e. no unacceptable RISK remains. Only the relevant parts of the RISK MANAGEMENT FILE need to be reviewed, e.g. the MANUFACTURER'S calculations or test results, or the determination of RISK acceptability.

NOTE When ME EQUIPMENT or an ME SYSTEM has been designed in such way that for a certain type of HAZARDS no HAZARDOUS SITUATION exists, no further RISK ASSESSMENT for that HAZARD is necessary. This can be verified by tests or inspections.

4.2.3.2 HAZARDS not identified in the IEC 60601 series

For HAZARDS or HAZARDOUS SITUATIONS that are identified for the particular ME EQUIPMENT or ME SYSTEM but are not specifically addressed in this standard or its collateral or particular standards, the MANUFACTURER shall address those HAZARDS in the RISK MANAGEMENT PROCESS as specified in 4.2.2.

EXAMPLE ME EQUIPMENT or an ME SYSTEM for which there are particular RISKS but no particular standard.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

4.3 * ESSENTIAL PERFORMANCE

During RISK ANALYSIS, the MANUFACTURER shall identify the performance of the clinical function(s) of the ME EQUIPMENT or ME SYSTEM, other than that related to BASIC SAFETY, that is necessary to achieve its INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM.

The MANUFACTURER shall then specify performance limits between fully functional and total loss of the identified performance in both NORMAL CONDITION and SINGLE FAULT CONDITION.

The MANUFACTURER shall then evaluate the RISK from the loss or degradation of the identified performance beyond the limits specified by the MANUFACTURER. If the resulting RISK is unacceptable, then the identified performance constitutes an ESSENTIAL PERFORMANCE of the ME EQUIPMENT or ME SYSTEM.

The MANUFACTURER shall implement RISK CONTROL measures to reduce the RISK from the loss or degradation of the identified performance to an acceptable level.

NOTE 1 The performance of the RISK CONTROL measure might well become an aspect of the ESSENTIAL PERFORMANCE of the ME EQUIPMENT or ME SYSTEM. For example, the generation of the ALARM SIGNAL to indicate the interruption of the SUPPLY MAINS could be “essential” if an interruption of the SUPPLY MAINS could result in an unacceptable RISK if it went unattended.

The MANUFACTURER shall specify the methods used to verify the effectiveness of the RISK CONTROL measures. This shall include any assessment made to determine whether verification is needed.

NOTE 2 Following the principles of RISK MANAGEMENT, the MANUFACTURER is required to verify the effectiveness of each RISK CONTROL measure. This can involve demonstrating that the RISK CONTROL measure will operate in the presence of the conditions that result in the loss or degradation of the identified performance.

EXAMPLE 1 If ESSENTIAL PERFORMANCE is lost because of an interruption of the SUPPLY MAINS, an ALARM SYSTEM intended to notify the OPERATOR that the SUPPLY MAINS has been interrupted would need to have a backup power source so that the generation of the ALARM SIGNAL would not depend on the SUPPLY MAINS.

EXAMPLE 2 If the failure of a component results in the loss of ESSENTIAL PERFORMANCE, the design of the ME EQUIPMENT or ME SYSTEM would need to be such that the component failure does not compromise the effectiveness of any RISK CONTROL measures put in place to mitigate the RISK from the loss of the ESSENTIAL PERFORMANCE.

NOTE 3 Each collateral standard or particular standard in the IEC 60601 or the IEC/ISO 80601 series can list potential ESSENTIAL PERFORMANCES to guide the MANUFACTURER to identify particular ESSENTIAL PERFORMANCE in accordance with 4.3.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

Where this standard requires that ESSENTIAL PERFORMANCE is to be maintained following a particular test, compliance is checked by inspection and, if necessary, by functional test(s)

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that demonstrate the MANUFACTURER'S specified limits are maintained or the ME EQUIPMENT or ME SYSTEM transitions to a safe state as defined by the MANUFACTURER.

4.4 * EXPECTED SERVICE LIFE

The MANUFACTURER shall state the EXPECTED SERVICE LIFE of the ME EQUIPMENT or ME SYSTEM in the RISK MANAGEMENT FILE.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

4.5 * Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS

Where this standard specifies a particular RISK CONTROL measure or test method, an alternative RISK CONTROL measure or test method is acceptable, provided that the MANUFACTURER can demonstrate through scientific data or clinical opinion or comparative studies that the RESIDUAL RISK that results from applying the alternative RISK CONTROL measure or test method remains acceptable and is comparable to the RESIDUAL RISK that results from applying the requirements of this standard.

Comparative studies in this context mean studies comparing the effect of the alternative RISK CONTROL measure or test method with the RISK CONTROL measure or test method specified in this standard.

NOTE Alternative RISK CONTROL measures can allow for exceeding limits specified in this standard or in its collateral or particular standards if additional measures for compensation are provided.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

The RISK MANAGEMENT PROCESS shall include an assessment of whether parts that can come into contact with the PATIENT but fall outside of the definition of APPLIED PARTS need to be subject to the requirements for APPLIED PARTS. For the parts concerned, the requirements for TYPE B APPLIED PART shall be applied unless the assessment identifies a need for the requirements for a TYPE BF APPLIED PART or TYPE CF APPLIED PART to apply.

If the RISK MANAGEMENT PROCESS determines that such parts are subject to the requirements for APPLIED PARTS, then all the relevant requirements and tests of this standard and of relevant collateral and particular standards shall apply, except that 7.2.10 does not apply to such parts.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

4.7 * SINGLE FAULT CONDITION for ME EQUIPMENT

ME EQUIPMENT shall be so designed and manufactured that it remains SINGLE FAULT SAFE, or the RISK remains acceptable as determined through application of 4.2.

NOTE 1 The NORMAL CONDITIONS identified in 8.1 a) are taken into consideration during evaluation of compliance with any requirement of this standard that they might affect.

ME EQUIPMENT is considered SINGLE FAULT SAFE if:

a) it employs a single means for reducing a RISK that has a negligible probability of failure (e.g. REINFORCED INSULATION, suspended masses without MECHANICAL PROTECTIVE DEVICES employing a TENSILE SAFETY FACTOR of 8X, COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS), or

b) a SINGLE FAULT CONDITION occurs, but:

- the initial fault will be detected during the EXPECTED SERVICE LIFE of the ME EQUIPMENT and before a second means for reducing a RISK fails (e.g. suspended masses with MECHANICAL PROTECTIVE DEVICES); or

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– the probability that the second means of reducing the RISK will fail during the EXPECTED SERVICE LIFE of the ME EQUIPMENT is negligible.

Where a SINGLE FAULT CONDITION causes another SINGLE FAULT CONDITION, the two failures are considered as one SINGLE FAULT CONDITION.

During any test under SINGLE FAULT CONDITION, only one fault at a time shall be applied.

NOTE 2 Faults are generally divided into 3 probability categories:

a) so remote that they can be ignored. The RISKS arising from these faults are considered acceptable;

b) probable enough that they need to be considered, but improbable enough that they need only be considered one at a time (single fault). Faults of this category include all those identified as SINGLE FAULT CONDITIONS in this standard, and any other faults identified in applying ISO 14971 that meet the SINGLE FAULT CONDITION criteria;

c) so likely, so unpredictable or undetectable that they are considered to be a NORMAL CONDITION and need to be considered individually and collectively.

The results of the RISK ANALYSIS shall be used to determine which failures shall be tested. The failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those mentioned in 13.1, shall be simulated, physically or theoretically. The evaluation of whether a component is subject to failure simulation shall take into account the RISK associated with the failure of the component during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. This evaluation shall be accomplished by applying the principles of RISK MANAGEMENT. The evaluation shall take into account issues such as reliability, TENSILE SAFETY FACTORS and rating of components. Additionally, during the simulation of SINGLE FAULT CONDITIONS, component failures that are highly probable or undetectable shall be simulated.

NOTE 3 See also Note 2 in 4.2.

This requirement and relevant tests shall not be applied to failures of DOUBLE or REINFORCED INSULATION or COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS.

Compliance is determined by applying the specific requirements and tests associated with the SINGLE FAULT CONDITIONS identified in 13.2, and tests for the failures identified from evaluation of the results of the RISK ANALYSIS. Compliance is confirmed if the introduction of any of the SINGLE FAULT CONDITIONS described in 13.2, one at a time, does not lead directly to the HAZARDOUS SITUATIONS described in 13.1, or any other outcome that results in an unacceptable RISK.

4.8 * Components of ME EQUIPMENT

All components, including wiring, the failure of which could result in a HAZARDOUS SITUATION shall be used in accordance with their specified ratings unless a specific exception is made in this standard or through the RISK MANAGEMENT PROCESS. The reliability of components that are used as MEANS OF PROTECTION shall be assessed for the conditions of use in the ME EQUIPMENT. They shall comply with one of the following (see also 4.5):

a) the applicable safety requirements of a relevant IEC or ISO standard;

NOTE 1 For the components, it is not necessary to carry out identical or equivalent tests already performed to check compliance with the component standard.

b) where there is no relevant IEC or ISO standard, the requirements of this standard have to be applied.

NOTE 2 If there are neither requirements in this standard nor in an IEC or ISO standard, any other applicable source (e.g. standards for other types of devices, national standards) could be used to demonstrate compliance with the RISK MANAGEMENT PROCESS.

See Figure 5 for a schematic flow chart for a) and b).

Compliance is checked by inspection and, where necessary, by test. The tests of this standard for motors (see 13.2.8 and 13.2.13.3) and transformers (see 15.5.3) are considered to be comprehensive and together with the evaluation of the motor or transformer insulation system according to Table 22 represent all testing required by this standard. ME SYSTEM components that provide isolation from non-ME EQUIPMENT are evaluated to Clause 16.

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4.9 * Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS in ME EQUIPMENT

A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS shall be used when a fault in a particular component can generate an unacceptable RISK. COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS shall be selected and evaluated consistent with their conditions of use and reasonably foreseeable misuse during the EXPECTED SERVICE LIFE of the ME EQUIPMENT.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and the selection criteria for the COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS.

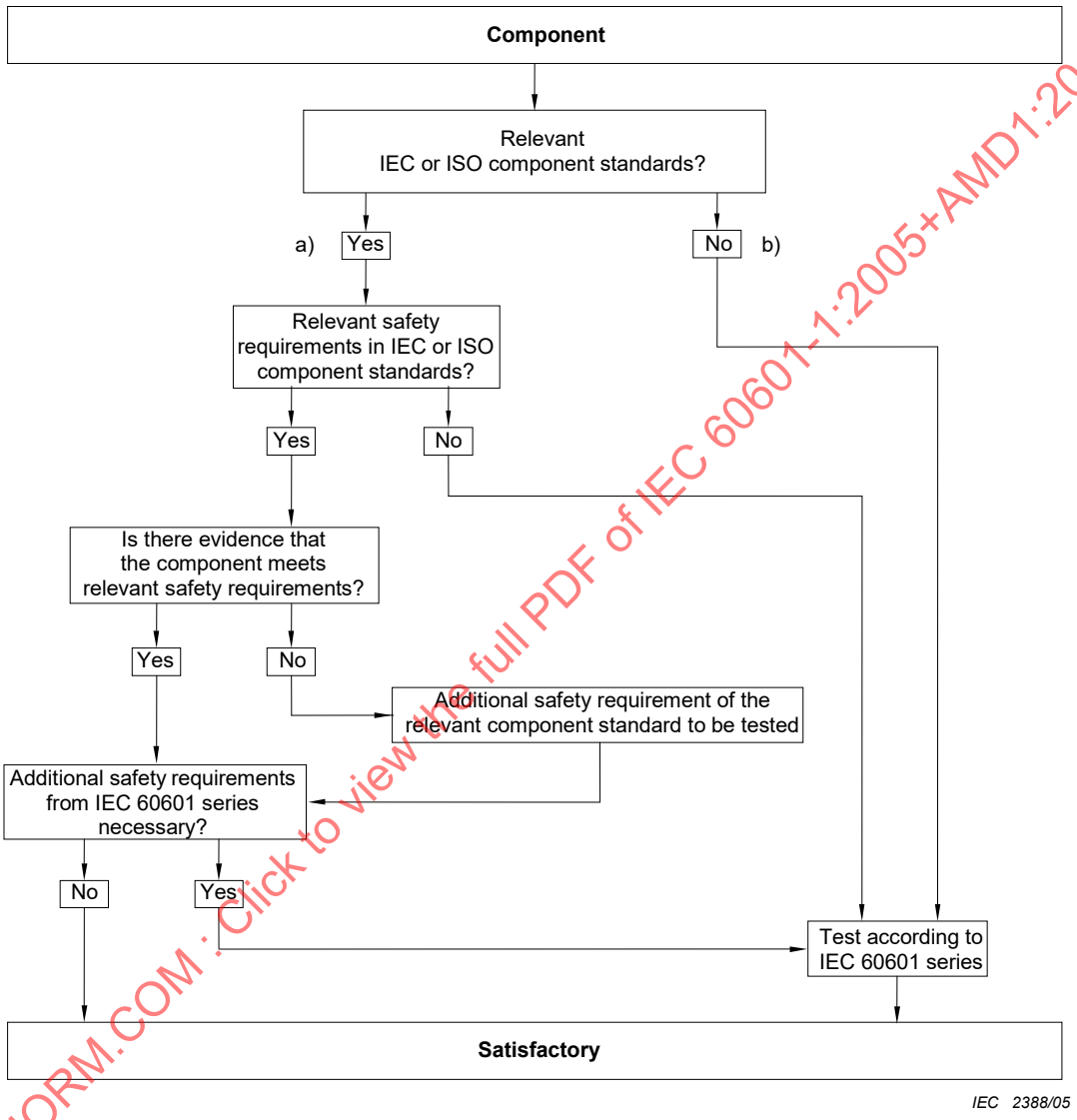


Figure 5 – Schematic flow chart for component qualification
(see 4.8)

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4.10 * Power supply

4.10.1 Source of power for ME EQUIPMENT

ME EQUIPMENT shall be suitable for connection to a SUPPLY MAINS, be specified for connection to a separate power supply or be powered by an INTERNAL ELECTRICAL POWER SOURCE. Alternatively, a combination of these sources may be used.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

4.10.2 SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

For ME EQUIPMENT intended to be connected to SUPPLY MAINS, the following RATED voltages shall not be exceeded:

– 250 V for HAND-HELD ME EQUIPMENT;

– 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA; or

– 500 V for all other ME EQUIPMENT and ME SYSTEMS.

SUPPLY MAINS in this standard shall be assumed to have the following characteristics:

– overvoltage category II for mains transients unless a higher category is specified by the MANUFACTURER;

– no voltage in excess of 110 % or lower than 90 % of the NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth (see 7.9.3.1);

NOTE 1 IEC 60601-1-2 contains requirements and tests for voltage dips, short interruptions and voltage variations on the SUPPLY MAINS. See also 1.3.

– voltages that are practically sinusoidal and forming a practically symmetrical supply system in case of polyphase supply;

– a frequency of ≤ 1 kHz;

– a frequency deviation of ≤ 1 Hz from the NOMINAL frequency up to 100 Hz and ≤ 1 % from the NOMINAL frequency from 100 Hz to 1 kHz;

– the protective measures as described in IEC 60364-4-41;

NOTE 2 If ME EQUIPMENT or an ME SYSTEM is intended to be operated from a SUPPLY MAINS with characteristics different from the SUPPLY MAINS described in this subclause, additional safety measures could be necessary.

– a d.c. voltage (as measured by a moving coil meter or equivalent method) having a peak-to-peak ripple not exceeding 10 % of the average value.

Where peak-to-peak ripple exceeds 10 % of the average value, the peak voltage has to be applied.

4.11 Power input

The steady-state measured input of the ME EQUIPMENT or ME SYSTEM at RATED voltage and at operating settings indicated in the instructions for use shall not exceed the marked rating by more than 10 % (see 7.2.7).

Compliance is checked by inspection and by the following tests.

– *The ME EQUIPMENT or ME SYSTEM is operated as specified in the instructions for use until the input has reached a stable value. Input is measured and compared with markings and the contents of the technical description.*

– *ME EQUIPMENT or an ME SYSTEM marked with one or more RATED voltage ranges is tested at both upper and lower limits of the range, unless each marking of RATED input is related to the mean value of the relevant voltage range, in which case the test is performed at a voltage equal to the mean value of that range.*

– *The steady state current is measured with a true r.m.s. reading instrument.*

Power input, if expressed in volt-amperes, is either measured with a volt-ampere meter or determined as the product of the steady state current (measured as described above) and the supply voltage.

NOTE 1 Technical details of a true r.m.s. meter can be found in IEC 62354 [66].

NOTE 2 Supplier information can be used to supplement the above measurement as a power input specification.

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5 * General requirements for testing ME EQUIPMENT

5.1 * TYPE TESTS

The tests described in this standard are TYPE TESTS. The tests to be performed are determined taking into consideration the requirements of Clause 4, in particular 4.2.

A test need not be performed if analysis shows that the condition being tested has been adequately evaluated by other tests or methods.

The combination of simultaneous independent faults that could result in a HAZARDOUS SITUATION shall be documented in the RISK MANAGEMENT FILE (see also 4.7). When testing is necessary to demonstrate that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained under such simultaneous independent faults, the related testing may be limited to worst case situations.

NOTE 1 The test results might necessitate a revision of the RISK ANALYSIS.

NOTE 2 When considering use of tests described in this standard as routine tests, see Annex K of IEC/TR 62354 (production line tests) or see IEC 62353 (recurrent tests).

5.2 * Number of samples

TYPE TESTS are performed on a representative sample of the item being tested.

NOTE Multiple samples can be utilized simultaneously if the validity of the results is not significantly affected.

5.3 Ambient temperature, humidity, atmospheric pressure

a) After the ME EQUIPMENT to be tested has been set up for NORMAL USE (according to 5.7), tests are performed within the range of environmental conditions indicated in the technical description (see 7.9.3.1).

b) ME EQUIPMENT is shielded from other influences (for example, draughts), that might affect the validity of the tests.

c) In cases where ambient temperatures cannot be maintained, the test conditions are to be consequently modified and results adjusted accordingly.

5.4 Other conditions

a) Unless otherwise specified in this standard, ME EQUIPMENT is to be tested under the least favourable working conditions. The working conditions are specified in the ACCOMPANYING DOCUMENTS. The least favourable working conditions shall be documented for every test where they apply.

b) ME EQUIPMENT having operating values that can be adjusted or controlled by anyone other than SERVICE PERSONNEL shall be adjusted as part of the tests to values least favourable for the relevant test, but in accordance with the instructions for use.

c) If the test results are influenced by the inlet pressure and flow or chemical composition of a cooling liquid, the test is performed within the limits for these characteristics as prescribed in the technical description.

d) Where cooling water is required, potable water is used.

5.5 Supply voltages, type of current, nature of supply, frequency

a) Where test results are influenced by deviations of the characteristics of the SUPPLY MAINS from their RATED values, the effect of such deviations is taken into account.

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The values used during testing are according to 4.10.2 or according to that marked on the ME EQUIPMENT (see 7.2.6), whichever is least favourable.

NOTE 1 For the RATED value(s) given on the ME EQUIPMENT, deviations of the SUPPLY MAINS as provided in 4.10.2 are only to be tested if the deviations have a negative impact on BASIC SAFETY or ESSENTIAL PERFORMANCE.

b) ME EQUIPMENT having a MAINS PART intended for connection to a.c. SUPPLY MAINS is only tested with a.c. at RATED frequency ME EQUIPMENT marked with a RATED frequency range is tested at the least favourable frequency within that range.

c) ME EQUIPMENT designed for more than one RATED voltage, for both a.c. and d.c., or for both external power and an INTERNAL ELECTRICAL POWER SOURCE, is tested in conditions (described in 5.4) related to the least favourable voltage and nature of supply, for example, number of phases (except for single-phase supply) and type of current. It could be necessary to perform some tests more than once in order to establish which supply configuration is least favourable.

d) ME EQUIPMENT having a MAINS PART intended for connection to d.c. SUPPLY MAINS is only tested with d.c. When performing the tests, the possible influence of polarity on the operation of the ME EQUIPMENT is taken into consideration, according to the instructions for use. See also 8.2.2.

e) ME EQUIPMENT for which alternative ACCESSORIES or components specified in the ACCOMPANYING DOCUMENTS (see 7.9.2.14 and 7.9.3.2) are available is tested with those ACCESSORIES or components that give the least favourable conditions.

f) If the instructions for use specify that ME EQUIPMENT is intended to receive its power from a separate power supply, it is connected to such a power supply. See also 7.2.5 and 8.2.1.

NOTE 2 What was referred to in the first and second editions of this standard as a “specified power supply” is now considered either as another part of the same ME EQUIPMENT or as another equipment in an ME SYSTEM.

5.6 Repairs and modifications

In the event of the necessity for repairs or modifications after a failure or a probability of future failure during the sequence of tests, the testing laboratory and the supplier of the ME EQUIPMENT for the test can agree, either upon the presentation of a new sample on which all tests influencing the result are performed again or, preferably, upon making all the necessary repairs or modifications after which only relevant tests are repeated.

5.7 * Humidity preconditioning treatment

Prior to the tests of 8.7.4 and 8.8.3, all ME EQUIPMENT or its parts shall be subjected to a humidity preconditioning treatment.

ME EQUIPMENT or its parts shall be set up complete (or where necessary partially). Covers used during transport and storage are detached.

This treatment is applied only to those ME EQUIPMENT parts which are influenced by the climatic conditions that are simulated by the test.

Parts that can be detached without the use of a TOOL are detached but are treated simultaneously with the major part.

ACCESS COVERS that can be opened or detached without the use of a TOOL are opened and detached.

The humidity preconditioning treatment is performed in a humidity cabinet containing air with a relative humidity of 93 % ± 3 % where the ME EQUIPMENT or its parts under test are located. The humidity conditions at other locations in the chamber may vary by ± 6 %. The temperature of the air in the cabinet, at all places where ME EQUIPMENT or its parts can be

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located, shall be maintained within 2 °C of any convenient value *T* in the range of + 20 °C to +30 °C. Before being placed in the humidity cabinet, ME EQUIPMENT or its parts are be brought to a temperature between *T* and *T* + 4 °C, and kept at this temperature for at least 4 h before the humidity treatment starts.

KEEP ME EQUIPMENT and its parts, where the ENCLOSURE is classified as IPX0, in the humidity cabinet for 48 h.

Keep ME EQUIPMENT and its parts, where the ENCLOSURE is designed to provide higher ingress protection against liquids, in the humidity cabinet for 168 h.

After the treatment, the ME EQUIPMENT is reassembled, if necessary.

5.8 Sequence of tests

Unless stated otherwise, the tests in this standard are sequenced in such a way that the results of any test do not influence the results of a subsequent test.

NOTE It is recommended that all tests be performed in the sequence given in Annex B.

5.9 * Determination of APPLIED PARTS and ACCESSIBLE PARTS

5.9.1 APPLIED PARTS

APPLIED PARTS are identified by inspection and by reference to the ACCOMPANYING DOCUMENTS See also 4.6.

5.9.2 ACCESSIBLE PARTS

5.9.2.1 * Test finger

Parts of ME EQUIPMENT that are to be regarded as ACCESSIBLE PARTS are identified by inspection and where necessary by test. In case of doubt, accessibility is determined by a test with the standard test finger shown in Figure 6, applied in a bent or straight position:

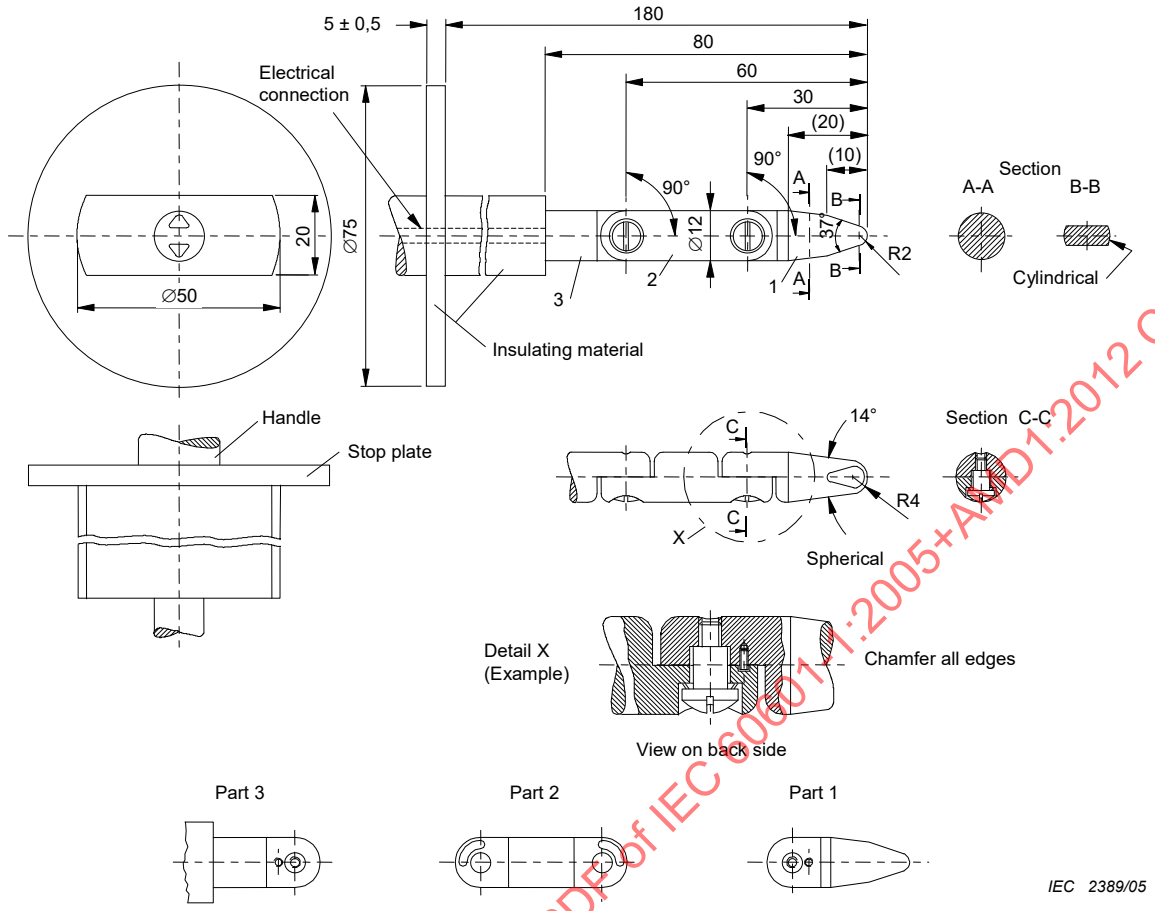
– for all positions of ME EQUIPMENT when operated as in NORMAL USE,

– even after opening of ACCESS COVERS and removal of parts, including lamps, fuses and fuseholders, without the use of a TOOL or according to the instructions for use.

The standard test finger is applied without appreciable force in every possible position, except that ME EQUIPMENT intended to be used on the floor and having a mass in any operational condition exceeding 45 kg is not tilted. ME EQUIPMENT which, according to the technical description, is intended for mounting into a cabinet, is tested in its final mounting position.

Openings preventing the entry of the standard test finger of Figure 6 are mechanically tested by means of a straight unjointed test finger of the same dimensions, which is applied with a force of 30 N. If this finger enters, the test with the standard test finger of Figure 6 is repeated, the finger being pushed through the opening if necessary.

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Linear dimensions in millimetres

Tolerances on dimensions without specific tolerances:

– 14° and 37° angles: ± 15′

– on radii: ± 0,1 mm

– on linear dimensions:

  ≤ 15 mm: $^{0}_{0,1}$ mm

  > 15 mm ≤ 25 mm: ± 0,1 mm

  > 25 mm: ± 0,3 mm

Material of finger: heat-treated steel, for example.

Both joints of this finger can be bent through an angle of 90 $^{+10°}_{0°}$ but in one and the same direction only.

NOTE 1 Using the pin and groove solution is only one of the possible approaches in order to limit the bending angle to 90°. For this reason, dimensions and tolerances of these details are not given in the drawing. The actual design must insure a 90° bending angle with a 0° to + 10° tolerance.

NOTE 2 Dimensions in parentheses are for information only.

NOTE 3 The test finger is taken from IEC 60950-1, Figure 2A. That test finger is based on IEC 61032[8)], Figure 2, test probe B. In some cases, the tolerances are different.

Figure 6 – Standard test finger
(see 5.9.2.1)

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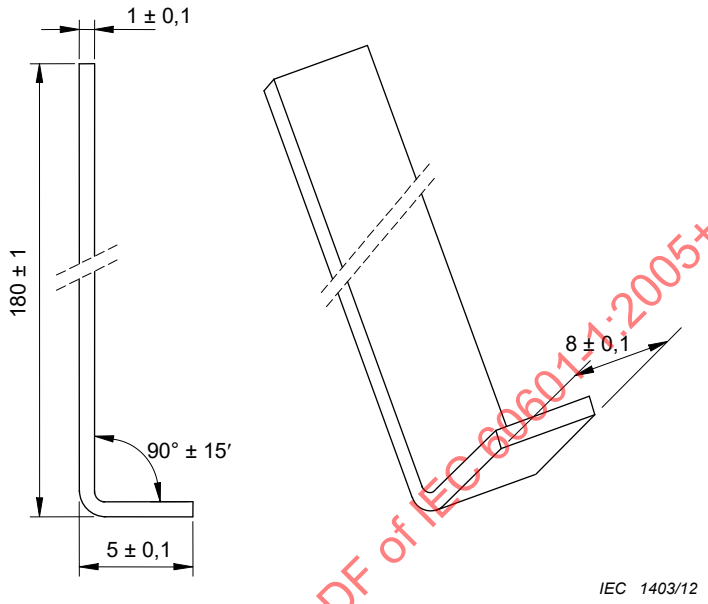
8) IEC 61032:1997, *Protection of persons and equipment by enclosures - Probes for verification*

5.9.2.2 Test hook

ME EQUIPMENT openings are mechanically tested by means of the test hook (see Figure 7), if the hook can be inserted.

The test hook is inserted in all openings in question and is subsequently pulled with a force of 20 N for 10 s and in a direction substantially perpendicular to the surface in which the relevant opening is present. Any additional parts that have become accessible are identified by using the standard test finger of Figure 6 and by inspection.

Dimensions in millimetres



Material: steel

Figure 7 – Test hook
(see 5.9.2.2)

5.9.2.3 Actuating mechanisms

Conductive parts of actuating mechanisms of electrical controls that are accessible after the removal of handles, knobs, levers and the like are regarded as ACCESSIBLE PARTS. Conductive parts of actuating mechanisms are not considered ACCESSIBLE PARTS if removal of handles, knobs, etc. requires the use of a TOOL.

Compliance is checked by tests according to 5.9.2.1 and 15.4.6.1.

6 * Classification of ME EQUIPMENT and ME SYSTEMS

6.1 General

For purposes of this standard, ME EQUIPMENT, or parts thereof, including APPLIED PARTS, shall be classified as follows.

6.2 * Protection against electric shock

ME EQUIPMENT energized from an external electrical power source shall be classified as CLASS I ME EQUIPMENT or CLASS II ME EQUIPMENT (see 7.2.6). Other ME EQUIPMENT shall be classified as INTERNALLY POWERED ME EQUIPMENT.

INTERNALLY POWERED ME EQUIPMENT having a means of connection to a SUPPLY MAINS shall comply with the requirements for CLASS I ME EQUIPMENT or CLASS II ME EQUIPMENT while so connected, and with the requirements for INTERNALLY POWERED ME EQUIPMENT while not so connected.

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APPLIED PARTS shall be classified as TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS (see 7.2.10 and 8.3). APPLIED PARTS may be classified as DEFIBRILLATION-PROOF APPLIED PARTS (see 8.5.5).

6.3 * Protection against harmful ingress of water or particulate matter

ENCLOSURES shall be classified according to the degree of protection against harmful ingress of water and particulate matter as detailed in IEC 60529 (see 7.2.9 and 11.6.5).

NOTE 1 This classification is IPN_1N_2, where:

– N_1 is an integer indicating degree of protection against particulate matter or the letter "X".

– N_2 is an integer indicating the degree of protection against ingress of water or the letter "X".

NOTE 2 See also Table D.3.

6.4 Method(s) of sterilization

ME EQUIPMENT or its parts intended to be sterilized shall be classified according to the method(s) of sterilization as indicated in the instructions for use (see 7.9.2.12 and 11.6.7).

EXAMPLE 1 By ethylene oxide gas

EXAMPLE 2 By irradiation such as gamma ray

EXAMPLE 3 By moist heat such as by autoclave

EXAMPLE 4 By other methods validated and described by the MANUFACTURER

6.5 Suitability for use in an OXYGEN RICH ENVIRONMENT

ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT shall be classified for such use (see 11.2.2).

6.6 * Mode of operation

ME EQUIPMENT shall be classified for either CONTINUOUS OPERATION or non-CONTINUOUS OPERATION (see 7.2.11).

7 ME EQUIPMENT identification, marking and documents

NOTE Annex C contains a guide to assist the reader in locating the marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS contained in other clauses of this standard.

7.1 General

7.1.1 * USABILITY of the identification, marking and documents

See 12.2.

7.1.2 * Legibility of markings

The markings required by 7.2, 7.3, 7.4, 7.5 and 7.6 shall be CLEARLY LEGIBLE under the following conditions:

– for warning statements, instructive statements, safety signs and drawings on the outside of ME EQUIPMENT: from the intended position of the person performing the related function;

– for FIXED ME EQUIPMENT: when the ME EQUIPMENT is mounted in its position of NORMAL USE;

– for TRANSPORTABLE ME EQUIPMENT and for STATIONARY ME EQUIPMENT that is not FIXED ME EQUIPMENT: in NORMAL USE or after dislodging the ME EQUIPMENT from a wall against which it has been positioned, or after turning the ME EQUIPMENT from its position of NORMAL USE and, in the case of dismountable rack units, after their removal from the rack;

– for markings on the inside of ME EQUIPMENT or ME EQUIPMENT parts: when viewed from the intended position of the person performing the related function.

Compliance for clear legibility is checked by the following test:

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The ME EQUIPMENT or its part is positioned so that the viewpoint is the intended position of the OPERATOR. If the intended position of the OPERATOR is not specified and the position is not obvious, the viewpoint is at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m. The ambient illumination is the least favourable level in the range of 100 lx to 1 500 lx.

The observer has a visual acuity, corrected if necessary, of:

– *0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20); and*

– *is able to read N6 of the Jaeger test card*;

in normal room lighting conditions (approximately 500 lx).

The observer correctly reads the marking from the viewpoint.

7.1.3 * Durability of markings

The markings required by 7.2, 7.3, 7.4, 7.5 and 7.6 shall be removable only with a TOOL or by appreciable force and shall be sufficiently durable to remain CLEARLY LEGIBLE during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. In considering the durability of the markings, the effect of NORMAL USE shall be taken into account.

Compliance is checked by inspection and the following tests:

a) *After all the tests of this standard have been performed (see the recommended sequence of tests in Annex B):*

   – *markings are tested to the requirements of 7.1.2; and*

   – *adhesive labels are not to have worked loose or become curled at the edges.*

b) *For markings required by 7.2, 7.4, 7.5 and 7.6, an additional test for durability is to be performed. Markings are rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ethanol 96 % and then for 15 s with a cloth rag soaked with isopropyl alcohol.*

7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.1)

7.2.1 Minimum requirements for marking on ME EQUIPMENT and on interchangeable parts

If the size of the ME EQUIPMENT, an ME EQUIPMENT part or an ACCESSORY, or the nature of its ENCLOSURE, does not allow affixation of all markings specified in 7.2.2 to 7.2.20 (inclusive), then at least the markings as indicated in 7.2.2, 7.2.5, 7.2.6 (not for PERMANENTLY INSTALLED ME EQUIPMENT), 7.2.10 and 7.2.13 (if applicable) shall be affixed and the remaining markings shall be recorded in full in the ACCOMPANYING DOCUMENTS. Where no marking of the ME EQUIPMENT is practicable, these markings may be affixed to the individual packaging.

Any material, component, ACCESSORY or ME EQUIPMENT that is intended for a single use or its packaging shall be marked "Single Use Only", “Do Not Reuse” or with symbol ISO 7000-1051 (2004-01) (see Table D.1, symbol 28).

NOTE See also 7.9.2.12.

7.2.2 * Identification

ME EQUIPMENT shall be marked with:

– the name or trademark and contact information of the MANUFACTURER;

– a MODEL OR TYPE REFERENCE;

– a serial number or lot or batch identifier; and

– the date of manufacture or use by date, if applicable.

NOTE See ISO 15223-1 for symbols for MANUFACTURER, serial number, lot or batch, year of manufacture and use by date.

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The serial number, lot or batch identifier, and the date of manufacture may be provided in a human readable code or through automatic identification technology such as barcodes or RFID.

Detachable components of the ME EQUIPMENT shall be marked with:

– the name or trademark of the MANUFACTURER; and

– a MODEL OR TYPE REFERENCE;

unless misidentification does not result in an unacceptable RISK.

Software that forms part of a PEMS shall be identified with a unique identifier, such as revision level or date of release/issue. The identification shall be available to designated persons, e.g. SERVICE PERSONNEL. The identification need not be on the outside of the ME EQUIPMENT.

7.2.3 * Consult ACCOMPANYING DOCUMENTS

When appropriate, symbol ISO 7000-1641 (2004-01) (see Table D.1, symbol 11) may be used to advise the OPERATOR to consult the ACCOMPANYING DOCUMENTS. When consulting the ACCOMPANYING DOCUMENTS is a mandatory action, safety sign ISO 7010-M002 (see Table D.2, safety sign 10) shall be used instead of symbol ISO 7000-1641.

7.2.4 * ACCESSORIES

ACCESSORIES shall be marked with:

– the name or trade-mark and contact information of their MANUFACTURER

– a MODEL OR TYPE REFERENCE;

– a serial number or lot or batch identifier; and

– the date of manufacture or use by date, if applicable.

NOTE See ISO 15223-1 for symbols for MANUFACTURER, serial number, lot or batch, year of manufacture and use by date.

The serial number, lot or batch identifier, and the date of manufacture may be provided in a human readable code or through automatic identification technology such as barcodes or RFID.

Where no marking of the ACCESSORIES is practicable, these markings may be affixed to the individual packaging.

7.2.5 ME EQUIPMENT intended to receive power from other equipment

If ME EQUIPMENT is intended to receive its power from other electrical equipment in an ME SYSTEM and compliance with the requirements of this standard is dependent on that other equipment, one of the following shall be provided:

– the name or trademark of the manufacturer of the other electrical equipment with a MODEL OR TYPE REFERENCE of the specified other equipment adjacent to the relevant connection point;

– placing safety sign ISO 7010-M002 (see Table D.2, safety sign 10) adjacent to the relevant connection point and listing of the required details in the instructions for use; or

– using a special connector style that is not commonly available on the market and listing of the required details in the instructions for use.

See also 7.9.2.3, 8.2.1 and 16.3.

7.2.6 Connection to the SUPPLY MAINS

ME EQUIPMENT shall be marked with the following information:

– the RATED supply voltage(s) or RATED voltage range(s) to which it may be connected. A RATED supply voltage range shall have a hyphen (-) between the minimum and maximum

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voltages. Where multiple RATED supply voltages or multiple RATED supply voltage ranges are given, they shall be separated by a solidus (/);

EXAMPLE 1 RATED supply voltage range: 100-240 V. This means that the ME EQUIPMENT is designed to be connected to a SUPPLY MAINS having a NOMINAL voltage between 100 V and 240 V.

EXAMPLE 2 Multiple RATED supply voltage: 120/220/240 V. This means that the ME EQUIPMENT is designed to be switched to allow connection to a SUPPLY MAINS having a NOMINAL voltage of 120 V or 220 V or 240 V.

NOTE 1 Marking of RATED supply voltage is taken from IEC 61293[9)].

– nature of supply, for example, number of phases (except for single-phase supply) and type of current. Symbols IEC 60417-5032, 5032-1, 5032-2, 5031, and 5033 (all 2002-10) may be used for this purpose (see Table D.1, symbols 1, 2, 3, 4 and 5);

NOTE 2 For alternating current, the RATED frequency in hertz is sufficient to identify the type of current.

– the RATED supply frequency or RATED frequency range in hertz;

EXAMPLE 3 RATED supply frequency range: 50-60 Hz. This means that the ME EQUIPMENT is designed to be connected to a SUPPLY MAINS having a NOMINAL frequency between 50 Hz and 60Hz.

– For CLASS II ME EQUIPMENT, symbol IEC 60417-5172 (2003-02) (see Table D.1, symbol 9).

Except for PERMANENTLY INSTALLED ME EQUIPMENT, these markings shall appear on the outside of the part that contains the SUPPLY MAINS connection and preferably adjacent to the connection point. For PERMANENTLY INSTALLED ME EQUIPMENT, the NOMINAL supply voltage or voltage range to which it can be connected may be marked on the inside or the outside of the ME EQUIPMENT, preferably adjacent to the SUPPLY MAINS connection.

7.2.7 Electrical input power from the SUPPLY MAINS

The RATED input from the SUPPLY MAINS shall be marked on the ME EQUIPMENT. The RATED input shall be given in:

– amperes or volt-amperes, or

– if the power factor exceeds 0,9, in amperes, volt-amperes or watts.

In the case of ME EQUIPMENT for one or several RATED voltage ranges, the RATED input shall always be given for the upper and lower limits of the range or ranges, if the range(s) is/are greater than ± 10 % of the mean value of the given range.

In the case of range limits which do not differ by more than 10 % from the mean value, marking of the input at the mean value of the range is sufficient.

If the rating of ME EQUIPMENT includes both long-time and momentary current or volt-ampere ratings, the marking shall include both long-time and the most relevant momentary volt-ampere ratings, each plainly identified and indicated in the ACCOMPANYING DOCUMENTS.

The marked input of ME EQUIPMENT provided with means for the connection of supply conductors of other electrical equipment shall include the RATED (and marked) output of such means.

7.2.8 Output connectors

7.2.8.1 Mains power output

For MULTIPLE SOCKET-OUTLETS that are integral with ME EQUIPMENT, see 16.9.2.1 b).

7.2.8.2 Other power sources

With the exception of MULTIPLE SOCKET-OUTLETS or connectors intended only for specified equipment, equipment parts or ACCESSORIES, output connectors of ME EQUIPMENT intended to deliver power shall be marked with the following information:

– RATED output voltage;

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9) IEC 61293:1994, *Marking of electrical equipment with ratings related to electrical supply - Safety requirements*

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– RATED current or power (when applicable);

– output frequency (when applicable).

7.2.9 IP classification

ME EQUIPMENT or its parts shall be marked with a symbol, using the letters IP followed by the designations described in IEC 60529, according to the classification in 6.3 (see Table D.3, Code 2).

ME EQUIPMENT classified IPX0 or IP0X need not be marked as such.

7.2.10 * APPLIED PARTS

This requirement does not apply to parts that have been identified according to 4.6.

The degree of protection against electric shock as classified in 6.2 for all APPLIED PARTS shall be marked with the relevant symbol, i.e., TYPE B APPLIED PARTS with symbol IEC 60417-5840, TYPE BF APPLIED PARTS with symbol IEC 60417-5333 or TYPE CF APPLIED PARTS with symbol IEC 60417-5335 (all 2002-10) (see Table D.1, symbols 19, 20 and 21).

For DEFIBRILLATION-PROOF APPLIED PARTS, symbols IEC 60417-5841, IEC 60417-5334, or IEC 60417-5336 shall be used as applicable (all 2002-10) (see Table D.1, symbols 25, 26 and 27).

The relevant symbol shall be marked adjacent to or on the connector for the APPLIED PART, unless either:

– there is no such connector, in which case the marking shall be on the APPLIED PART; or

– the connector is used for more than one APPLIED PART and the different APPLIED PARTS have different classifications, in which case each APPLIED PART shall be marked with the relevant symbol.

For clear differentiation with symbol IEC 60417-5333, symbol IEC 60417-5840 shall not be applied in such a way as to give the impression of being inscribed within a square (see Table D.1, symbols 19 and 20).

If the protection against the effect of the discharge of a cardiac defibrillator is partly in the PATIENT cable, safety sign ISO 7010-W001, shall be placed near the relevant outlet (see Table D.2, safety sign 2). The instructions for use shall explain that protection of the ME EQUIPMENT against the effects of the discharge of a cardiac defibrillator is dependent upon the use of appropriate cables.

7.2.11 Mode of operation

If no marking is provided, ME EQUIPMENT is assumed to be suitable for CONTINUOUS OPERATION. For ME EQUIPMENT intended for non-CONTINUOUS OPERATION, the DUTY CYCLE shall be indicated using an appropriate marking giving the maximum activation (on) time and the minimum deactivation (off) time.

7.2.12 * Fuses

Where the fuse-holder is an ACCESSIBLE PART, the type and full rating of the fuse (voltage, current, operating speed and breaking capacity) shall be marked adjacent to the fuse-holder.

7.2.13 Physiological effects (safety signs and warning statements)

ME EQUIPMENT producing physiological effects that are not obvious to the OPERATOR and can cause HARM to the PATIENT or OPERATOR shall bear a suitable safety sign (see 7.5). The safety sign shall appear in a prominent location so that it will be CLEARLY LEGIBLE in NORMAL USE after the ME EQUIPMENT has been PROPERLY INSTALLED.

The instructions for use shall describe the nature of the HAZARD and the precautions for avoiding it or minimising the associated RISK.

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7.2.14 HIGH VOLTAGE TERMINAL DEVICES

HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT that are accessible without the use of a TOOL shall be marked with symbol IEC 60417-5036 (2002-10) (see Table D.1, symbol 24).

NOTE CREEPAGE DISTANCES and AIR CLEARANCES between the high voltage contacts and the standard test finger are subject to the requirements in 8.9.

7.2.15 Cooling conditions

Requirements for cooling provisions for ME EQUIPMENT (for example, supply of water or air) shall be marked.

7.2.16 Mechanical stability

For requirements on ME EQUIPMENT with a limited stability, see 9.4.

7.2.17 Protective packaging

If special handling measures have to be taken during transport or storage, the packaging shall be marked accordingly (see ISO 780).

The permissible environmental conditions for transport and storage shall be marked on the outside of the packaging (see 7.9.3.1 and ISO 15223-1).

Where premature unpacking of ME EQUIPMENT or its parts could result in an unacceptable RISK, the packaging shall be marked with a suitable safety sign (see 7.5).

EXAMPLE 1 Humidity sensitive ME EQUIPMENT.

EXAMPLE 2 ME EQUIPMENT containing hazardous substances and materials.

The packaging of ME EQUIPMENT or ACCESSORIES supplied sterile shall be marked as sterile and indicate the method of sterilization (see ISO 15223-1).

7.2.18 External pressure source

Adjacent to each input connector, the ME EQUIPMENT shall be marked with:

– the RATED maximum supply pressure from an external source, and

– the RATED flow rate if required to maintain BASIC SAFETY or ESSENTIAL PERFORMANCE.

7.2.19 FUNCTIONAL EARTH TERMINALS

A FUNCTIONAL EARTH TERMINAL shall be marked with symbol IEC 60417-5017 (2006-08) (see Table D.1, symbol 7).

7.2.20 Removable protective means

If ME EQUIPMENT has alternative applications that require the removal of a protective means to use a particular function, the protective means shall be marked to indicate the necessity for replacement when the relevant function is no longer needed. No marking is required when an interlock is provided.

Compliance with the requirements of 7.2 is checked by inspection and by application of the tests and criteria in 7.1.2 and 7.1.3.

7.2.21 * Mass of MOBILE ME EQUIPMENT

MOBILE ME EQUIPMENT shall be marked with its mass including its SAFE WORKING LOAD in kilograms. The marking shall be done in a way that it is obvious that it applies to the whole of the MOBILE ME EQUIPMENT when loaded with its SAFE WORKING LOAD and is separate and distinct from any markings related to maximum bin, shelf or drawer loading requirements.

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7.3 Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts (see also Table C.2)

7.3.1 Heating elements or lampholders

The maximum power loading of heating elements or lampholders designed for use with heating lamps shall be marked near the heater or in the heater itself.

For heating elements or lampholders designed for use with heating lamps that can be changed only by SERVICE PERSONNEL with the use of a TOOL, an identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS is sufficient.

7.3.2 * HIGH VOLTAGE parts

The presence of HIGH VOLTAGE parts shall be marked with symbol IEC 60417-5036 (2002-10) (see Table D.1, symbol 24) or with safety sign 3 (see Table D.2, safety sign 3). See also 7.5.

7.3.3 Batteries

The type of battery and the mode of insertion (if applicable) shall be marked (see 15.4.3.2).

For batteries intended to be changed only by SERVICE PERSONNEL with the use of a TOOL, an identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS is sufficient.

Where lithium batteries or fuel cells are incorporated and where incorrect replacement would result in an unacceptable RISK, a warning indicating that replacement by inadequately trained personnel could result in a HAZARD (such as excessive temperatures, fire or explosion) shall be given in addition to the identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS.

7.3.4 * Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES

Fuses and replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES that are accessible only by the use of a TOOL shall be identified either by specification adjacent to the component (voltage, current, operating speed, size, breaking capacity), or by a reference to information in the ACCOMPANYING DOCUMENTS.

The nomenclature of IEC 60127-1 may be used.

7.3.5 * PROTECTIVE EARTH TERMINALS

PROTECTIVE EARTH TERMINALS shall be marked with symbol IEC 60417-5019 (2006-08) (see Table D.1, symbol 6) unless the PROTECTIVE EARTH TERMINAL is in an APPLIANCE INLET according to IEC 60320-1.

Markings that are on or adjacent to PROTECTIVE EARTH TERMINALS shall not be affixed to parts that have to be removed to make the connection. They shall remain visible after the connection has been made.

7.3.6 FUNCTIONAL EARTH TERMINALS

FUNCTIONAL EARTH TERMINALS shall be marked with symbol IEC 60417-5017 (2006-08) (see Table D.1, symbol 7).

7.3.7 Supply terminals

Terminals for supply conductors shall be marked adjacent to the terminals unless it can be demonstrated that no unacceptable RISK an result if connections are interchanged.

If ME EQUIPMENT is so small that the terminal markings cannot be affixed, they shall be included in the ACCOMPANYING DOCUMENTS.

Terminals that are provided exclusively for the connection of the neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT shall be marked with the appropriate code from IEC 60445 (see Table D.3, Code 1).

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If marking for connection to a three-phase supply is necessary, it shall be according to IEC 60445.

Markings that are on or adjacent to electrical connection points shall not be affixed to parts that have to be removed to make the connection. They shall remain visible after the connection has been made.

7.3.8 Temperature of supply terminals

If any point within a terminal box or wiring compartment intended for connection of the power supply conductors for PERMANENTLY INSTALLED ME EQUIPMENT (including such conductors themselves), attains a temperature of more than 75 °C during NORMAL USE and NORMAL CONDITION at the maximum ambient operating temperature as indicated in the technical description (see 7.9.3.1), the ME EQUIPMENT shall be marked with the following or an equivalent statement:

"For supply connections, use wiring materials suitable for at least X °C."

where "X" is greater than the maximum temperature measured in the terminal box or wiring compartment in NORMAL USE and NORMAL CONDITION. This statement shall be located at or near the point where the supply connections are to be made. This statement shall not be affixed to parts that have to be removed to make the connection. It shall be CLEARLY LEGIBLE after the connections have been made.

Compliance with the requirements of 7.3 is checked by inspection and by application of the tests and criteria in 7.1.2 and 7.1.3.

7.4 Marking of controls and instruments (see also Table C.3)

7.4.1 * Power switches

Switches used to control power to ME EQUIPMENT or its parts, including mains switches, shall have their "on" and "off" positions:

– marked with symbols IEC 60417-5007 (2002-10) and IEC 60417-5008 (2002-10) (see Table D.1, symbols 12 and 13); or
– indicated by an adjacent indicator light; or
– indicated by other unambiguous means.

If a push button with bistable positions is used:

– it shall be marked with symbol IEC 60417-5010 (2002-10) (see Table D.1, symbol 14); and
– the status shall be indicated by an adjacent indicator light; or
– the status shall be indicated by other unambiguous means.

If a push button with momentary on position is used:

– it shall be marked with symbol 60417-5011 (2002-10) (see Table D.1, symbol 15); or
– the status shall be indicated by an adjacent indicator light; or
– the status shall be indicated by other unambiguous means.

7.4.2 * Control devices

Different positions of control devices and different positions of switches on ME EQUIPMENT shall be indicated by figures, letters or other visual means, e.g. by use of symbols IEC 60417-5264 (2002-10) and IEC 60417-5265 (2002-10) (see Table D.1, symbols 16 and 17).

If in NORMAL USE, the change of setting of a control could result in an unacceptable RISK to the PATIENT, such controls shall be provided with either:

– an associated indicating device, e.g. instruments or scale, or
– an indication of the direction in which the magnitude of the function changes. See also 15.4.6.2.

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A control device or switch that brings the ME EQUIPMENT into the "stand-by" condition may be indicated by use of symbol IEC 60417-5009 (2002-10) (see Table D.1, Symbol 29).

7.4.3 Units of measurement

Numeric indications of parameters on ME EQUIPMENT shall be expressed in SI units according to ISO 80000-1 except the base quantities listed in Table 1 may be expressed in the indicated units, which are outside the SI units system.

For application of SI units, their multiples and certain other units, ISO 80000-1 applies.

Compliance with the requirements of 7.4 is checked by inspection and by application of the tests and criteria in 7.1.2 and 7.1.3.

Table 1 – Units outside the SI units system that may be used on ME EQUIPMENT

Base quantity	Unit	
	Name	Symbol
Plane angle	revolution	r
	gon	gon or grade
	degree	°
	minute of angle	′
	second of angle	″
Time	minute	min
	hour	h
	day	d
Energy	electron volt	eV
Volume	litre	l [a]
Pressure of respiratory gases, blood, and other body fluids	millimetres of mercury	mmHg
	centimetres of water	cmH_2O
Pressure of gases	bar	bar
	millibar	mbar

[a] For consistency, in international standards only the symbol "l" is used for litre, although the symbol "L" is also given in ISO 80000-1.

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7.5 Safety signs

For the purpose of this clause, markings used to convey a warning, prohibition or mandatory action that mitigates a RISK that is not obvious to the OPERATOR shall be a safety sign selected from ISO 7010. If a safety sign with an established meaning is appropriately used, the use of the general warning sign ISO 7010:2003-W001 (see Table D.2, safety sign 2) is not required.

NOTE 1 In this context, warning is used to mean, "There is certain danger"; prohibition is used to mean, "You must not..."; and mandatory action is used to mean, "You must...".

Where a safety sign is not available to indicate a particular desired meaning, the meaning may be obtained by one of the following methods.

a) Constructing a safety sign according to ISO 3864-1:2002, Clause 7 (for the corresponding templates, see Table D.2, safety signs 1, 4 and 8).

b) Using the general warning sign ISO 7010:2003-W001 (see Table D.2, safety sign 2) placed together with a supplementary symbol or text. The text associated with the general warning sign shall be an affirmative statement (i.e., a safety notice) describing the principal RISK(S) foreseen (e.g. "Causes burns", "Risk of explosion", etc.).

c) Using the general prohibition sign ISO 7010:2003-P001 (see Table D.2, safety sign 4) placed together with a supplementary symbol or text. The text associated with the general prohibition sign shall be a statement (i.e. a safety notice) describing what is prohibited (e.g. "Do not open", "Do not drop", etc.).

d) Using the general mandatory action sign ISO 7010:2003-M001 (see Table D.2, safety sign 9) placed together with a supplementary symbol or text. The text associated with the general mandatory action sign shall be a command (i.e. a safety notice) describing required action (e.g. "Wear protective gloves", "Scrub before entering", etc.).

If there is insufficient space to place the affirmative statement together with the safety sign on the ME EQUIPMENT, it may be placed in the instructions for use.

NOTE 2 The colours for safety signs are specified in ISO 3864-1 and it is important to use the specified colour.

NOTE 3 A safety notice should include the appropriate precautions or include instructions on how to reduce the RISK (e.g. "Do not use for . . . ", "Keep away from . . .", etc.).

Safety signs, including any supplementary symbol or text, shall be explained in the instructions for use (see 7.9.2).

When supplementary text is placed together with safety signs, the supplementary text shall be in a language that is acceptable to the intended OPERATOR.

NOTE 4 In some countries, more than one language is required.

Compliance is checked by inspection.

7.6 Symbols

7.6.1 Explanation of symbols

The meanings of the symbols used for marking shall be explained in the instructions for use.

7.6.2 Symbols from Annex D

Symbols required by this standard shall conform to the requirements in the referenced IEC or ISO publication. Annex D provides the symbol graphic and description for these symbols as a quick reference.

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7.6.3 Symbols for controls and performance

Symbols used for controls and performance shall conform to the requirements of the IEC or ISO publication where the symbol is defined, when applicable. See also 7.2.13.

NOTE IEC 60878 [60] provides a survey of titles, descriptions and graphical representations of symbols for electrical equipment used in medical practice.

Compliance with the requirements of 7.6 is checked by inspection.

7.7 Colours of the insulation of conductors

7.7.1 PROTECTIVE EARTH CONDUCTOR

A PROTECTIVE EARTH CONDUCTOR shall be identified throughout its length by green and yellow coloured insulation.

7.7.2 PROTECTIVE EARTH CONNECTIONS

Any insulation on conductors inside ME EQUIPMENT that form PROTECTIVE EARTH CONNECTIONS shall be identified by the colours green and yellow at least at the termination of the conductors.

EXAMPLE Conductors of a multi-conductor cord that are connected in parallel, where the maximum allowed resistance of the PROTECTIVE EARTH CONNECTIONS would be exceeded if only the green and yellow coloured conductor were used.

7.7.3 Green and yellow insulation

Identification by green and yellow insulation shall only be used for:

– PROTECTIVE EARTH CONDUCTORS (see 8.6.2);

– conductors as specified in 7.7.2;

NOTE In other safety standards such as IEC 60950-1, internal connections between conductive parts and the main protective earth are called protective bonding conductors.

– POTENTIAL EQUALIZATION CONDUCTORS (see 8.6.7);

– FUNCTIONAL EARTH CONDUCTORS (see 8.6.9).

7.7.4 Neutral conductor

Conductors in POWER SUPPLY CORDS intended to be connected to the neutral conductor of the supply system shall be coloured “light blue” as specified in IEC 60227-1 or in IEC 60245-1.

7.7.5 POWER SUPPLY CORD conductors

Colours of conductors in POWER SUPPLY CORDS shall be in accordance with IEC 60227-1 or with IEC 60245-1.

Compliance with the requirements of 7.7 is checked by inspection.

7.8 * Indicator lights and controls

7.8.1 Colours of indicator lights

The colours of indicator lights and their meanings shall comply with Table 2.

NOTE IEC 60601-1-8 contains specific requirement for the colour, flashing frequency and DUTY CYCLE of alarm indicator lights.

Dot-matrix and other alphanumeric displays are not considered to be indicator lights.

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Table 2 – Colours of indicator lights and their meaning for ME EQUIPMENT

Colour	Meaning
Red	Warning – immediate response by the OPERATOR is required
Yellow	Caution – prompt response by the OPERATOR is required
Green	Ready for use
Any other colour	Meaning other than that of red, yellow or green

7.8.2 Colours of controls

The colour red shall be used only for a control by which a function is interrupted in case of emergency.

Compliance with the requirements of 7.8 is checked by inspection. See also 15.4.4.

7.9 ACCOMPANYING DOCUMENTS

7.9.1 * General (see also Table C.4)

ME EQUIPMENT shall be accompanied by documents containing at least the instructions for use and a technical description. The ACCOMPANYING DOCUMENTS shall be regarded as a part of the ME EQUIPMENT.

NOTE The purpose of the ACCOMPANYING DOCUMENTS is to promote the safe use of the ME EQUIPMENT during its EXPECTED SERVICE LIFE.

The ACCOMPANYING DOCUMENTS shall identify the ME EQUIPMENT by including, as applicable, the following:

– name or trade-name of the MANUFACTURER and contact information to which the RESPONSIBLE ORGANIZATION can refer;

– MODEL OR TYPE REFERENCE (see 7.2.2).

ACCOMPANYING DOCUMENTS may be provided electronically, e.g. electronic file format on CD-ROM. If the ACCOMPANYING DOCUMENTS are provided electronically, the USABILITY ENGINEERING PROCESS shall include consideration of which information also needs to be provided as hard copy or as markings on the ME EQUIPMENT (see 12.2).

EXAMPLE Information to cover emergency operation

NOTE ACCOMPANYING DOCUMENTS provided electronically might not be acceptable in all jurisdictions.

The ACCOMPANYING DOCUMENTS shall specify any special skills, training and knowledge required of the intended OPERATOR or the RESPONSIBLE ORGANIZATION and any restrictions on locations or environments in which the ME EQUIPMENT can be used.

The ACCOMPANYING DOCUMENTS shall be written at a level consistent with the education, training and any special needs of the person(s) for whom they are intended.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS, and, when provided electronically, as specified in IEC 60601-1-6.

7.9.2 Instructions for use (see also Table C.5)

7.9.2.1 * General

The instructions for use shall document:

– the use of the ME EQUIPMENT as intended by the MANUFACTURER,

– the frequently used functions;

– any known contraindication(s) to the use of the ME EQUIPMENT; and

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– those parts of the ME EQUIPMENT that shall not be serviced or maintained while in use with a PATIENT.

Where the PATIENT is an intended OPERATOR, the instructions for use shall indicate:

– the PATIENT is an intended OPERATOR;
– a warning against servicing and maintenance while the ME EQUIPMENT is in use;
– which functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and
– which maintenance the PATIENT can perform (e.g. changing batteries).

NOTE 1 For ME EQUIPMENT where the INTENDED USE includes the PATIENT partially or fully operating the ME EQUIPMENT, the PATIENT becomes an OPERATOR.

NOTE 2 For ME EQUIPMENT where the PATIENT is allowed to perform restricted maintenance, the PATIENT becomes SERVICE PERSONNEL.

The instructions for use shall indicate:

– the name or trademark and address of the MANUFACTURER;
– the MODEL OR TYPE REFERENCE.

The instructions for use shall include all applicable classifications specified in Clause 6, all markings specified in 7.2, and the explanation of safety signs and symbols (marked on the ME EQUIPMENT).

NOTE 3 The instructions for use are intended for the OPERATOR and the RESPONSIBLE ORGANIZATION and should contain only the information most likely to be useful to the OPERATOR or RESPONSIBLE ORGANIZATION. Additional details can be contained in the technical description. See also 7.9.3.

NOTE 4 Guidance on the preparation of instructions for use is found in IEC 62079 [25]. Guidance on the preparation of educational materials for ME EQUIPMENT is found in IEC/TR 61258 [24].

The instructions for use shall be in a language that is acceptable to the intended OPERATOR.

NOTE 5 In some countries, more than one language is required.

7.9.2.2 * Warning and safety notices

The instructions for use shall include all warning and safety notices.

NOTE General warnings and safety notices should be placed in a specifically identified section of the instructions for use. A warning or safety notice that applies only to a specific instruction or action should precede the instruction to which it applies.

For CLASS I ME EQUIPMENT, the instructions for use shall include a warning statement to the effect: “WARNING: To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.”

The instructions for use shall provide the OPERATOR or RESPONSIBLE ORGANIZATION with warnings regarding any significant RISKS of reciprocal interference posed by the presence of the ME EQUIPMENT during specific investigations or treatments.

The instructions for use shall include information regarding potential electromagnetic or other interference between the ME EQUIPMENT and other devices together with advice on ways to avoid or minimize such interference.

If the ME EQUIPMENT is provided with an integral MULTIPLE SOCKET-OUTLET, the instructions for use shall provide a warning statement that connecting electrical equipment to the MSO effectively leads to creating an ME SYSTEM and the result can be a reduced level of safety. For the requirements that are applicable to an ME SYSTEM, the RESPONSIBLE ORGANIZATION shall be referred to this standard.

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7.9.2.3 ME EQUIPMENT specified for connection to a separate power supply

If ME EQUIPMENT is intended for connection to a separate power supply, either the power supply shall be specified as part of the ME EQUIPMENT or the combination shall be specified as an ME SYSTEM. The instructions for use shall state this specification.

7.9.2.4 Electrical power source

For mains-operated ME EQUIPMENT with an additional power source not automatically maintained in a fully usable condition, the instructions for use shall include a warning statement referring to the necessity for periodic checking or replacement of such an additional power source.

If leakage from a battery would result in an unacceptable RISK, the instructions for use shall include a warning to remove the battery if the ME EQUIPMENT is not likely to be used for some time.

If an INTERNAL ELECTRICAL POWER SOURCE is replaceable, the instructions for use shall state its specification.

If loss of the power source would result in an unacceptable RISK, the instructions for use shall contain a warning that the ME EQUIPMENT must be connected to an appropriate power source.

EXAMPLE Internal or external battery, uninterruptible power supply (UPS) or institutional stand-by generator.

7.9.2.5 ME EQUIPMENT description

The instructions for use shall include:

– a brief description of the ME EQUIPMENT;

– how the ME EQUIPMENT functions; and

– the significant physical and performance characteristics of the ME EQUIPMENT.

If applicable, this description shall include the expected positions of the OPERATOR, PATIENT and other persons near the ME EQUIPMENT in NORMAL USE (see 9.2.2.3).

The instructions for use shall include information on the materials or ingredients to which the PATIENT or OPERATOR is exposed if such exposure can constitute an unacceptable RISK (see 11.7).

The instructions for use shall specify any restrictions on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected.

The instructions for use shall indicate any APPLIED PART.

7.9.2.6 * Installation

If installation of the ME EQUIPMENT or its parts is required, the instructions for use shall contain:

– a reference to where the installation instructions are to be found (e.g. the technical description), or

– contact information for persons designated by the MANUFACTURER as qualified to perform the installation.

7.9.2.7 * Isolation from the SUPPLY MAINS

If an APPLIANCE COUPLER or MAINS PLUG or other separable plug is used as the isolation means to satisfy 8.11.1 a), the instructions for use shall contain an instruction not to position the ME EQUIPMENT so that it is difficult to operate the disconnection device.

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7.9.2.8 Start-up PROCEDURE

The instructions for use shall contain the necessary information for the OPERATOR to bring the ME EQUIPMENT into operation including such items as any initial control settings, connection to or positioning of the PATIENT, etc.

The instructions for use shall detail any treatment or handling needed before the ME EQUIPMENT, its parts, or ACCESSORIES can be used.

EXAMPLE A pre-use checklist.

7.9.2.9 Operating instructions

The instructions for use shall contain all information necessary to operate the ME EQUIPMENT in accordance with its specification. This shall include explanation of the functions of controls, displays and signals, the sequence of operation, and connection and disconnection of detachable parts and ACCESSORIES, and replacement of material that is consumed during operation.

The meanings of figures, symbols, warning statements, abbreviations and indicator lights on ME EQUIPMENT shall be explained in the instructions for use.

7.9.2.10 Messages

The instructions for use shall list all system messages, error messages and fault messages that are generated, unless these messages are self-explanatory.

NOTE 1 These lists can be identified in groups.

The list shall include an explanation of messages including important causes, and possible action(s) by the OPERATOR, if any, that are necessary to resolve the situation indicated by the message.

NOTE 2 Requirements and guidelines for messages generated by an alarm system are found in IEC 60601-1-8.

7.9.2.11 Shutdown PROCEDURE

The instructions for use shall contain the necessary information for the OPERATOR to safely terminate the operation of the ME EQUIPMENT.

7.9.2.12 Cleaning, disinfection and sterilization

For ME EQUIPMENT parts or ACCESSORIES that can become contaminated through contact with the PATIENT or with body fluids or expired gases during NORMAL USE, the instructions for use shall contain:

– details about cleaning and disinfection or sterilization methods that may be used; and

– list the applicable parameters such as temperature, pressure, humidity, time limits and number of cycles that such ME EQUIPMENT parts or ACCESSORIES can tolerate.

See also 11.6.6 and 11.6.7.

This requirement does not apply to any material, component, ACCESSORY or ME EQUIPMENT that is marked as intended for a single use unless the MANUFACTURER specifies that the material, component, ACCESSORY or ME EQUIPMENT is to be cleaned, disinfected or sterilized before use (see 7.2.1).

7.9.2.13 Maintenance

The instructions for use shall instruct the OPERATOR or RESPONSIBLE ORGANIZATION in sufficient detail concerning preventive inspection, maintenance and calibration to be performed by them, including the frequency of such maintenance.

The instructions for use shall provide information for the safe performance of such routine maintenance necessary to ensure the continued safe use of the ME EQUIPMENT.

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Additionally, the instructions for use shall identify the parts on which preventive inspection and maintenance shall be performed by SERVICE PERSONNEL, including the periods to be applied, but not necessarily including details about the actual performance of such maintenance.

For ME EQUIPMENT containing rechargeable batteries that are intended to be maintained by anyone other than SERVICE PERSONNEL, the instructions for use shall contain instructions to ensure adequate maintenance.

7.9.2.14 ACCESSORIES, supplementary equipment, used material

The instructions for use shall include a list of ACCESSORIES, detachable parts and materials that the MANUFACTURER has determined are intended for use with the ME EQUIPMENT.

If ME EQUIPMENT is intended to receive its power from other equipment in an ME SYSTEM, the instructions for use shall sufficiently specify such other equipment to ensure compliance with the requirements of this standard (e.g. part number, RATED voltage, maximum or minimum power, protection class, intermittent or continuous duty).

NOTE What was referred to in the first and second editions of this standard as a "specified power supply" is considered either as another part of the same ME EQUIPMENT or as other equipment in an ME SYSTEM. Similarly, a battery charger is considered either as part of the ME EQUIPMENT or as other equipment in an ME SYSTEM.

7.9.2.15 Environmental protection

The instructions for use shall provide advice on the proper disposal of waste products, residues, etc. and of the ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE.

7.9.2.16 Reference to the technical description

The instructions for use shall contain the information specified in 7.9.3 or a reference to where the material specified in 7.9.3 is to be found (e.g. in a service manual).

7.9.2.17 ME EQUIPMENT emitting radiation

For ME EQUIPMENT emitting radiation for medical purposes, when appropriate, the instructions for use shall indicate the nature, type, intensity and distribution of this radiation.

7.9.2.18 ME EQUIPMENT and ACCESSORIES supplied sterile

The instructions for use for ME EQUIPMENT or ACCESSORIES supplied sterile shall indicate that they have been sterilized and indicate the method of sterilization.

The instructions for use shall indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization (see also 7.9.2.12).

7.9.2.19 * Unique version identifier

The instructions for use shall contain a unique version identifier such as its date of issue.

EXAMPLE Month and year.

Compliance with the requirements of 7.9.2 is checked by inspection of the instructions for use in a language of an intended OPERATOR.

7.9.3 Technical description (see also Table C.6)

7.9.3.1 * General

The technical description shall provide all data that is essential for safe operation, transport and storage, and measures or conditions necessary for installing the ME EQUIPMENT, and preparing it for use. This shall include:

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– the permissible environmental conditions of use including conditions for transport and storage. See also 7.2.17;

– all characteristics of the ME EQUIPMENT, including range(s), accuracy, and precision of the displayed values or an indication where they can be found;

– any special installation requirements such as the maximum permissible apparent impedance of SUPPLY MAINS;

NOTE 1 The apparent impedance of the SUPPLY MAINS is the sum of the impedance of the distribution network plus the impedance of the power source.

– if liquid is used for cooling, the permissible range of values of inlet pressure and flow, and the chemical composition of the cooling liquid;

– a description of the means of isolating the ME EQUIPMENT from the SUPPLY MAINS, if such means is not incorporated in the ME EQUIPMENT (see 8.11.1 b));

– if applicable, a description of the means for checking the oil level in partially sealed oil-filled ME EQUIPMENT or its parts (see 15.4.9);

– a warning statement that addresses the HAZARDS that can result from unauthorized modification of the ME EQUIPMENT, e.g. a statement to the effect:

- "WARNING: No modification of this equipment is allowed."
- "WARNING: Do not modify this equipment without authorization of the manufacturer."
- "WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment."

– information pertaining to ESSENTIAL PERFORMANCE and any necessary recurrent ESSENTIAL PERFORMANCE and BASIC SAFETY testing including details of the means, methods and recommended frequency.

NOTE 2 This information is directly derived from the ESSENTIAL PERFORMANCE identified by the MANUFACTURER in 4.3.

If the technical description is separable from the instructions for use, it shall contain:

– all applicable classifications specified in Clause 6, any warning and safety notices and the explanation of safety signs (marked on the ME EQUIPMENT);

– a brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and

– a unique version identifier such as its date of issue.

NOTE 3 The technical description is intended for the RESPONSIBLE ORGANIZATION and SERVICE PERSONNEL.

The MANUFACTURER may designate the minimum qualifications for SERVICE PERSONNEL. If present, these requirements shall be documented in the technical description.

NOTE 4 Some authorities with jurisdiction impose additional requirements for qualification of SERVICE PERSONNEL.

7.9.3.2 Replacement of fuses, POWER SUPPLY CORDS and other parts

The technical description shall contain, as applicable, the following:

– the required type and full rating of fuses used in the SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT, if the type and rating of these fuses are not apparent from the information concerning RATED current and mode of operation of ME EQUIPMENT;

– for ME EQUIPMENT having a non-DETACHABLE POWER SUPPLY CORD, a statement as to whether the POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and if so, instructions for correct connection and anchoring to ensure that the requirements of 8.11.3 will continue to be met;

– instructions for correct replacement of interchangeable or detachable parts that the MANUFACTURER specifies as replaceable by SERVICE PERSONNEL; and

– where replacement of a component could result in an unacceptable RISK, appropriate warnings that identify the nature of the HAZARD and, if the MANUFACTURER specifies the

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component as replaceable by SERVICE PERSONNEL, all information necessary to safely replace the component.

7.9.3.3 Circuit diagrams, component part lists, etc.

The technical description shall contain a statement that the MANUFACTURER will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist SERVICE PERSONNEL to repair those parts of ME EQUIPMENT that are designated by the MANUFACTURER as repairable by SERVICE PERSONNEL.

7.9.3.4 * Mains isolation

The technical description shall clearly identify any means used to comply with the requirements of 8.11.1.

Compliance with the requirements of 7.9.3 is checked by inspection of the technical description.

8 * Protection against electrical HAZARDS from ME EQUIPMENT

8.1 Fundamental rule of protection against electric shock

The limits specified in 8.4 shall not be exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL CONDITION or SINGLE FAULT CONDITION. For other HAZARDOUS SITUATIONS in SINGLE FAULT CONDITION, see 13.1.

a) * NORMAL CONDITION includes all of the following simultaneously:

– the presence on any SIGNAL INPUT/OUTPUT PART of any voltage or current from other electrical equipment that is permitted to be connected according to the ACCOMPANYING DOCUMENTS as specified in 7.9, or, if the ACCOMPANYING DOCUMENTS place no restrictions on such other electrical equipment, the presence of the MAXIMUM MAINS VOLTAGE as specified in 8.5.3;

– transposition of supply connections, for ME EQUIPMENT intended for connection to a SUPPLY MAINS by means of a MAINS PLUG;

– short circuit of any or all insulation that does not comply with the requirements of 8.8;

– short circuit of any or all CREEPAGE DISTANCES or AIR CLEARANCES that do not comply with the requirements of 8.9;

– open circuit of any or all earth connections that do not comply with the requirements of 8.6, including any functional earth connection.

b) * SINGLE FAULT CONDITION includes:

– short circuit of any one insulation that complies with the requirements for one MEANS OF PROTECTION as specified in 8.8;

NOTE This includes short circuiting of either constituent part of DOUBLE INSULATION that complies with 8.8.

– short circuit of any one CREEPAGE DISTANCE or AIR CLEARANCE that complies with the requirements for one MEANS OF PROTECTION as specified in 8.9;

– short circuit and open circuit of any component other than a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS that is connected in parallel with insulation, with an AIR CLEARANCE or with a CREEPAGE DISTANCE unless shorting can be shown not to be a failure mode for the component (see also 4.8 and 4.9);

– open circuit of any one PROTECTIVE EARTH CONDUCTOR or internal PROTECTIVE EARTH CONNECTION that complies with the requirements of 8.6: this does not apply to a PROTECTIVE EARTH CONDUCTOR of PERMANENTLY INSTALLED ME EQUIPMENT, which is considered unlikely to become disconnected;

– interruption of any one supply conductor, except for the neutral conductor of polyphase ME EQUIPMENT or PERMANENTLY INSTALLED ME EQUIPMENT;

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– interruption of any one power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES, if this condition might cause permitted limits to be exceeded;

– unintended movement of a component (see 8.10.1);

– accidental detachment of conductors and connectors where breaking free could lead to a HAZARDOUS SITUATION. See also 8.10.2.

Determination of which parts are ACCESSIBLE PARTS is performed in accordance with 5.9.

LEAKAGE CURRENTS are measured in accordance with 8.7.

8.2 Requirements related to power sources

8.2.1 Connection to a separate power source

If ME EQUIPMENT is specified for connection to a separate power source, other than the SUPPLY MAINS, either the separate power source shall be considered as part of the ME EQUIPMENT and all relevant requirements of this standard shall apply, or the combination shall be considered as an ME SYSTEM. See also 7.2.5, 7.9.2.14, 5.5 f) and Clause 16.

NOTE What was formerly referred to, in the first and second editions of this standard, as a "specified power supply" is now considered either as another part of the same ME EQUIPMENT or as another electrical equipment in an ME SYSTEM.

Compliance is checked by inspection and by testing as specified in 5.5 f). If a particular separate power supply is specified then the relevant tests are performed with the ME EQUIPMENT connected to it. If a generic separate power supply is specified, then the specification in the ACCOMPANYING DOCUMENTS is inspected.

8.2.2 Connection to an external d.c. power source

If ME EQUIPMENT is specified for power supplied from an external d.c. power source, then a connection with the wrong polarity shall not lead to the HAZARDOUS SITUATIONS described in 13.1. The ME EQUIPMENT, when connection is subsequently made with the correct polarity, shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.

Protective devices that can be reset by anyone without the use of a TOOL are acceptable provided the ME EQUIPMENT returns to NORMAL CONDITION on reset.

NOTE 1 See also 11.8.

NOTE 2 The external d.c. power source can be a SUPPLY MAINS or another item of electrical equipment. In the latter case, the combination is considered to be an ME SYSTEM as specified in 8.2.1.

8.3 Classification of APPLIED PARTS

a) * An APPLIED PART that is specified in the ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION shall be a TYPE CF APPLIED PART.

NOTE See the rationale for the definition of DIRECT CARDIAC APPLICATION (3.22) concerning the APPLIED PARTS that need to be TYPE CF APPLIED PARTS. Other restrictions can apply for cardiac applications.

Compliance is checked by inspection.

b) * An APPLIED PART that includes a PATIENT CONNECTION that is intended to deliver electrical energy or an electrophysiological signal to or from the PATIENT shall be a TYPE BF APPLIED PART or TYPE CF APPLIED PART.

Compliance is checked by inspection.

c) An APPLIED PART not covered by a) or b) shall be a TYPE B APPLIED PART, TYPE BF APPLIED PART or TYPE CF APPLIED PART.

Compliance is checked by inspection.

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8.4 Limitation of voltage, current or energy

8.4.1 * PATIENT CONNECTIONS intended to deliver current

The limits specified in 8.4.2 do not apply to currents that are intended to flow through the body of the PATIENT to produce a physiological effect during NORMAL USE.

8.4.2 ACCESSIBLE PARTS and APPLIED PARTS

a) The currents from, to or between PATIENT CONNECTIONS shall not exceed the limits for PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT specified in Table 3 and Table 4 when measured as specified in 8.7.4.

Compliance is checked by measurement according to 8.7.4.

b) * The LEAKAGE CURRENTS from, to or between ACCESSIBLE PARTS shall not exceed the limits for TOUCH CURRENT specified in 8.7.3 c) when measured as specified in 8.7.4.

Compliance is checked by measurement according to 8.7.4.

c) * The limits specified in b) above do not apply to the following parts if the probability of a connection to a PATIENT, either directly or through the body of the OPERATOR, through which a current exceeding the allowable TOUCH CURRENT could flow, is negligible in NORMAL USE, and the instructions for use instruct the OPERATOR not to touch the relevant part and the PATIENT simultaneously:

- accessible contacts of connectors;
- contacts of fuseholders that are accessible during replacement of the fuse;
- contacts of lampholders that are accessible after removal of the lamp;
- parts inside an ACCESS COVER that can be opened without the use of a TOOL, or where a TOOL is needed but the instructions for use instruct any OPERATOR other than SERVICE PERSONNEL to open the relevant ACCESS COVER.

EXAMPLE 1 Illuminated push-buttons

EXAMPLE 2 Indicator lamps

EXAMPLE 3 Recorder pens

EXAMPLE 4 Parts of plug-in modules

EXAMPLE 5 Batteries

For such parts, the voltage to earth or to other ACCESSIBLE PARTS shall not exceed 42,4 V peak a.c. or 60 V d.c. in NORMAL CONDITION or in SINGLE FAULT CONDITION. The d.c. limit of 60 V applies to d.c. with not more than 10 % peak-to-peak ripple. If the ripple exceeds that amount, the 42,4 V peak limit applies. The energy shall not exceed 240 VA for longer than 60 s or the stored energy available shall not exceed 20 J at a potential of 2 V or more.

NOTE If voltages higher than the limits specified in 8.4.2 c) are present, the LEAKAGE CURRENT limits referred to in 8.4.2 b) apply.

Compliance is checked by inspection of the instructions for use and by measurement.

d) * The voltage and energy limits specified in c) above also apply to:

- internal parts, other than contacts of plugs, connectors and socket-outlets, that can be touched by the test pin shown in Figure 8 inserted through an opening in an ENCLOSURE; and
- internal parts that can be touched by a metal test rod with a diameter of $4\ ^{0}_{-0,05}$ mm and a length of $100\ ^{+0,5}_{0}$ mm, inserted through any opening in the top of an ENCLOSURE or

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through any opening provided for the adjustment of pre-set controls that can be adjusted by the RESPONSIBLE ORGANIZATION in NORMAL USE by using a TOOL.

See also 8.9.4 concerning the measurement of CREEPAGE DISTANCES and AIR CLEARANCES through slots or openings in external parts to the standard test finger.

Compliance is checked by inserting the test pin or the test rod through relevant openings. The test pin is inserted in every possible position with minimal force (not more than 1 N).

The test rod is inserted in every possible position through openings provided for the adjustment of pre-set controls that can be adjusted by the RESPONSIBLE ORGANIZATION in NORMAL USE, in case of doubt with a force of 10 N.

If the instructions for use specify that a particular TOOL is to be used, the test is repeated with that TOOL.

The test rod is also freely and vertically suspended through any opening in the top of an ENCLOSURE.

Dimensions in millimetres

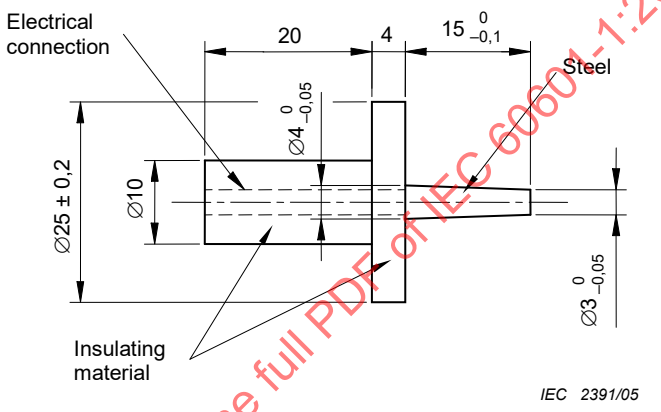


Figure 8 – Test pin
(see 8.4.2 d)

e) Where an ACCESS COVER that can be opened without the use of a TOOL gives access to parts that are at voltages above the levels permitted by this subclause, but these parts are automatically de-energized when the ACCESS COVER is opened, the device(s) used to de-energize the parts shall meet the requirements specified in 8.11.1 for mains isolating switches and shall remain effective in SINGLE FAULT CONDITION. If it is possible to prevent these devices from operating, a TOOL shall be required.

Compliance is checked by inspection.

8.4.3 * ME EQUIPMENT intended to be connected to a power source by a plug

ME EQUIPMENT or its parts intended to be connected to a power source by means of a plug shall be so designed that 1 s after disconnection of the plug the voltage between the pins of the plug and between either supply pin and the ENCLOSURE does not exceed 60 V or, if this value is exceeded, the stored charge does not exceed 45 μC.

Compliance is checked by the following test:

ME EQUIPMENT is operated at RATED voltage or at the upper limit of the RATED voltage range.

ME EQUIPMENT is disconnected from the power source with any relevant switch in the "On" and "Off" positions.

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Either the ME EQUIPMENT is disconnected from the power source by means of the plug, in which case the test is performed as many times as necessary to allow the worst case to be measured, or a triggering circuit is used to ensure that disconnection occurs at the peak of the supply voltage waveform.

The voltage between the pins of the plug and between any pin and the ENCLOSURE is measured 1 s after disconnection with an instrument the internal impedance of which does not affect the test significantly.

NOTE An example of a measuring arrangement that is considered acceptable is an oscilloscope and probe having an input impedance consisting of a resistance of 100 MΩ ± 5 MΩ in parallel with an input capacitance of 20 pF ± 5 pF.

The stored charge can be measured or calculated by any convenient method.

Where appropriate, a d.c. input voltage equal to the peak of the RATED SUPPLY MAINS voltage may be used.

8.4.4 * Internal capacitive circuits

Conductive parts of capacitive circuits that become accessible after ME EQUIPMENT has been de-energized and ACCESS COVERS as present in NORMAL USE have been removed immediately thereafter, shall not have a residual voltage exceeding 60 V, or, if this value is exceeded, shall not have a stored charge exceeding 45 μC.

If automatic discharging is not reasonably possible and ACCESS COVERS can be removed only with the aid of a TOOL, a device that is included and which permits manual discharging is acceptable. The capacitor(s) or the connected circuitry shall then be marked with symbol IEC 60417-5036 (2002-10) (see Table D.1, symbol 24) and the non-automatic discharging device shall be specified in the technical description.

Compliance is checked by the following test:

ME EQUIPMENT is operated at RATED voltage and then de-energized. Any ACCESS COVERS present in NORMAL USE are removed as quickly as normally possible. Immediately thereafter, the residual voltage on any accessible capacitors or circuit parts is measured and the stored charge calculated.

If a non-automatic discharging device is specified in the technical description, its inclusion and marking are ascertained by inspection.

8.5 Separation of parts

8.5.1 * MEANS OF PROTECTION (MOP)

8.5.1.1 General

ME EQUIPMENT shall have two MEANS OF PROTECTION to prevent APPLIED PARTS and other ACCESSIBLE PARTS from exceeding the limits specified in 8.4.

Each MEANS OF PROTECTION shall be categorized as a MEANS OF PATIENT PROTECTION or a MEANS OF OPERATOR PROTECTION, taking account of 4.6. See also Figure A.12.

Varnishing, enamelling, oxidation and similar protective finishes, as well as covering with sealing compounds that can replasticize at temperatures to be expected during operation (including sterilization), shall not be regarded as a MEANS OF PROTECTION.

NOTE Coatings and other insulation that are intended as a MEANS OF PROTECTION and that comply with IEC 60950-1:2005 may be used as a MEANS OF OPERATOR PROTECTION but not automatically as a MEANS OF PATIENT PROTECTION. For MEANS OF PATIENT PROTECTION, considerations can arise as a result of the RISK MANAGEMENT PROCESS.

Components and wiring forming a MEANS OF PROTECTION shall comply with the relevant requirements of 8.10.

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Any insulation, CREEPAGE DISTANCE, AIR CLEARANCES, component or earth connection that does not comply with the requirements of 8.5.1.2 and 8.5.1.3 shall not be considered as a MEANS OF PROTECTION. Failure of any or all such parts shall be regarded as NORMAL CONDITION.

Compliance is checked by the test in 8.5.1.3.

8.5.1.2 * MEANS OF PATIENT PROTECTION (MOPP)

Solid insulation forming a MEANS OF PATIENT PROTECTION shall comply with the dielectric strength test according to 8.8 at the test voltage specified in Table 6.

CREEPAGE DISTANCES and AIR CLEARANCES forming a MEANS OF PATIENT PROTECTION shall comply with the limits specified in Table 12.

PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION shall comply with the requirements and tests of 8.6.

A Y capacitor (Y1 or Y2 only) complying with IEC 60384-14 is considered equivalent to one MEANS OF PATIENT PROTECTION. Where two capacitors are used in series, they shall be identical in type (either both Y1 or both Y2) and shall have the same NOMINAL capacitance. The capacitor(s) shall meet the dielectric strength for the type of protection for which they are being used (i.e. one or two MEANS OF PATIENT PROTECTION).

Where the working voltage across a barrier forming a MEANS OF PATIENT PROTECTION is less than 42,4 V peak a.c. or 60 V d.c., a single Y1 capacitor is acceptable for two MEANS OF PATIENT PROTECTION.

Compliance is checked by the test in 8.5.1.3.

8.5.1.3 MEANS OF OPERATOR PROTECTION (MOOP)

Solid insulation forming a MEANS OF OPERATOR PROTECTION shall:

– comply with the dielectric strength test according to 8.8 at the test voltage specified in Table 6; or

– comply with the requirements of IEC 60950-1 for INSULATION CO-ORDINATION.

CREEPAGE DISTANCES and AIR CLEARANCES forming a MEANS OF OPERATOR PROTECTION shall:

– comply with the limits specified in Table 13 to Table 16 (inclusive); or

– comply with the requirements of IEC 60950-1 for INSULATION CO-ORDINATION.

PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION shall either:

– comply with the requirements of 8.6; or

– comply with the requirements and tests of IEC 60950-1 for protective earthing.

A Y capacitor (Y1 or Y2 only) complying with IEC 60384-14 is considered equivalent to one MEANS OF OPERATOR PROTECTION. Where two capacitors are used in series, they shall be identical in type (either both Y1 or both Y2) and shall have the same NOMINAL capacitance. The capacitor(s) shall meet the dielectric strength for the type of protection for which they are being used (i.e. one or two MEANS OF OPERATOR PROTECTION). A Y1 capacitor can be used for two MEANS OF OPERATOR PROTECTION.

Compliance is checked by examination of the physical and electrical configuration of the ME EQUIPMENT to identify points at which insulation, CREEPAGE DISTANCES, AIR CLEARANCES, impedances of components or PROTECTIVE EARTH CONNECTIONS prevent ACCESSIBLE PARTS or APPLIED PARTS from exceeding the limits specified in 8.4.

NOTE Such points typically include insulation between parts different from earth potential and ACCESSIBLE PARTS or APPLIED PARTS but can also include, for example, insulation between a floating circuit and earth or other circuits. A survey of insulation paths is found in Annex J.

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For each such point, it is determined whether:

– *solid insulation complies with the dielectric strength test according to 8.8 or, for a MEANS OF OPERATOR PROTECTION, with the requirements of IEC 60950-1 for INSULATION CO-ORDINATION;*

– *CREEPAGE DISTANCES and AIR CLEARANCES are as specified in 8.9 or, for a MEANS OF OPERATOR PROTECTION, with the requirements of IEC 60950-1 for INSULATION CO-ORDINATION;*

– *components that are connected in parallel with an insulation, with an AIR CLEARANCE or with a CREEPAGE DISTANCE comply with 4.8 and 8.10.1;*

– *PROTECTIVE EARTH CONNECTIONS comply with the requirements of 8.6 or, for a MEANS OF OPERATOR PROTECTION, with the requirements of IEC 60950-1 for protective earthing;*

and hence whether a failure at that point is to be regarded as a NORMAL CONDITION or as a SINGLE FAULT CONDITION.

Each MEANS OF PROTECTION is categorized in relation to the ME EQUIPMENT part(s) which it protects from exceeding permitted limits. It is a MEANS OF PATIENT PROTECTION if it protects APPLIED PARTS or parts that are identified according to 4.6 as needing to be subject to the same requirements as APPLIED PARTS. Otherwise it is a MEANS OF OPERATOR PROTECTION.

The WORKING VOLTAGE is determined by inspection, calculation or measurement, according to 8.5.4.

The voltage, current or energy that can appear between any ACCESSIBLE PART or APPLIED PART and any other ACCESSIBLE PART, APPLIED PART or earth in NORMAL CONDITION and in SINGLE FAULT CONDITION is determined by inspection or calculation or, where necessary, by measurement in the relevant conditions.

8.5.2 Separation of PATIENT CONNECTIONS

8.5.2.1 * F-TYPE APPLIED PARTS

The PATIENT CONNECTION(S) of any F-TYPE APPLIED PART shall be separated from all other parts, including the PATIENT CONNECTION(S) of other APPLIED PARTS, by means equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAXIMUM MAINS VOLTAGE and shall comply with the specified limit for PATIENT LEAKAGE CURRENT with 110 % of the MAXIMUM MAINS VOLTAGE applied.

A single F-TYPE APPLIED PART may include multiple functions, in which case separation between such functions is not required.

If there is no electrical separation between PATIENT CONNECTION(S) of the same or another function (e.g. between ECG electrode and pressure catheter), then these PATIENT CONNECTION(S) are treated as one APPLIED PART.

Whether multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS is as defined by the MANUFACTURER.

The classification as TYPE BF, TYPE CF or DEFIBRILLATION-PROOF applies to the whole of one APPLIED PART.

Compliance is checked by inspection, by the LEAKAGE CURRENT tests of 8.7.4, by the dielectric strength test of 8.8.3 and by measurement of relevant CREEPAGE DISTANCES and AIR CLEARANCES.

NOTE The separation means between an F-TYPE APPLIED PART and other parts are subject both to these tests, related to the MAXIMUM MAINS VOLTAGE, and to tests related to the voltages present within the respective circuits as specified in 8.5.4. Depending on the magnitude of the latter voltages, one set of tests or the other could be more stringent.

Any protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and the ENCLOSURE for the purpose of providing protection against excessive voltages shall not operate below 500 V r.m.s.

Compliance is checked by testing the operating voltage of the protective device.

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8.5.2.2 * TYPE B APPLIED PARTS

The PATIENT CONNECTION(S) of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED shall be separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS that are not PROTECTIVELY EARTHED, unless:

– the metal ACCESSIBLE PART is physically contiguous with the APPLIED PART and can be regarded as a part of the APPLIED PART; and

– the RISK that the metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low.

Compliance is checked by inspection, by the LEAKAGE CURRENT tests of 8.7.4, by the dielectric strength test of 8.8.3, by measurement of relevant CREEPAGE DISTANCES and AIR CLEARANCES, and by reference to the RISK MANAGEMENT FILE.

8.5.2.3 * PATIENT leads or PATIENT cables

Any connector for electrical connections on a PATIENT lead that:

– is at the end of the lead or cable that is remote from the PATIENT; and

– contains a conductive part that is not separated from all PATIENT CONNECTION(S) by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAXIMUM MAINS VOLTAGE.

shall be constructed so that the said part cannot become connected to earth or possible hazardous voltage while the PATIENT CONNECTION(S) contact the PATIENT.

NOTE Where the phrase "said part" is mentioned in this subclause, it refers to the "...conductive part of the connector that is not separated from all PATIENT CONNECTIONS...." from the first sentence of this subclause.

In particular:

– the said part shall not come into contact with a flat conductive plate of not less than 100 mm diameter;

– the AIR CLEARANCE between connector pins and a flat surface shall be at least 0,5 mm;

– if able to be plugged into a mains socket, the said part shall be protected from making contact with parts at MAINS VOLTAGE by insulating means providing a CREEPAGE DISTANCE of at least 1,0 mm and a dielectric strength of 1 500 V and complying with 8.8.4.1;

– the straight unjointed test finger with the same dimensions as the standard test finger of Figure 6 shall not make electrical contact with the said part if applied in the least favourable position against the access openings with a force of 10 N, unless the RISK MANAGEMENT PROCESS demonstrates that no unacceptable RISK exists from contact with objects other than a mains socket or a flat surface (e.g. corners or edges).

Compliance is checked by inspection and test as required.

8.5.3 * MAXIMUM MAINS VOLTAGE

The MAXIMUM MAINS VOLTAGE shall be determined as follows:

– for single-phase or d.c. SUPPLY MAINS powered ME EQUIPMENT, including INTERNALLY POWERED ME EQUIPMENT that also has a means of connection to a SUPPLY MAINS, the MAXIMUM MAINS VOLTAGE is the highest RATED supply voltage; unless this is less than 100 V, in which case the MAXIMUM MAINS VOLTAGE is 250 V;

– for polyphase ME EQUIPMENT, the MAXIMUM MAINS VOLTAGE is the highest RATED phase to neutral supply voltage;

– for other INTERNALLY POWERED ME EQUIPMENT, the MAXIMUM MAINS VOLTAGE is 250 V.

8.5.4 * WORKING VOLTAGE

The WORKING VOLTAGE for each MEANS OF PROTECTION shall be determined as follows:

– The input supply voltage to the ME EQUIPMENT shall be the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value.

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– For d.c. voltages with superimposed ripple, the WORKING VOLTAGE is the average value if the peak-to-peak ripple does not exceed 10 % of the average value or the peak voltage if the peak-to-peak ripple exceeds 10 % of the average value.

– The WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION is the voltage to which the DOUBLE INSULATION as a whole is subjected.

– For WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth, the situation in which the PATIENT is earthed (intentionally or accidentally) is regarded as a NORMAL CONDITION.

– The WORKING VOLTAGE between the PATIENT CONNECTION(S) of an F-TYPE APPLIED PART and the ENCLOSURE is taken as the highest voltage appearing across the insulation in NORMAL USE including earthing of any part of the APPLIED PART. See also 8.5.2.1.

– For DEFIBRILLATION-PROOF APPLIED PARTS, the WORKING VOLTAGE is determined without regard to the possible presence of defibrillation voltages. See also 8.5.5 and 8.9.1.15.

– In the case of motors provided with capacitors where a resonance voltage can occur between the point where a winding and a capacitor are connected together on the one hand and any terminal for external conductors on the other hand, the WORKING VOLTAGE shall be equal to the resonance voltage.

8.5.5 DEFIBRILLATION-PROOF APPLIED PARTS

8.5.5.1 * Defibrillation protection

The classification DEFIBRILLATION-PROOF APPLIED PART shall apply to the whole of one APPLIED PART.

See 8.9.1.15 for the requirements for CREEPAGE DISTANCES and AIR CLEARANCES associated with a DEFIBRILLATION-PROOF APPLIED PART.

Arrangements used to isolate the PATIENT CONNECTION(S) of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT shall be so designed that:

a) During a discharge of a cardiac defibrillator to a PATIENT connected to a DEFIBRILLATION-PROOF APPLIED PART, hazardous electrical energies, as determined by the peak voltage measured between the points Y_1 and Y_2 of Figure 9 and Figure 10 exceeding 1 V, do not appear on:

   – the ENCLOSURE, including connectors in PATIENT leads and cables when connected to the ME EQUIPMENT;

     NOTE 1 This requirement does not apply to a connecting lead from a DEFIBRILLATION-PROOF APPLIED PART or its connector when it is disconnected from the ME EQUIPMENT.

   – any SIGNAL INPUT/OUTPUT PART;

   – metal foil for test on which the ME EQUIPMENT is placed and which has an area at least equal to the base of the ME EQUIPMENT;

   – PATIENT CONNECTIONS of any other APPLIED PART (whether or not classified as a DEFIBRILLATION-PROOF APPLIED PART); or

   – any unused or disconnected connections of the APPLIED PART under test or any function of the same APPLIED PART. ME EQUIPMENT that is completely BODY-WORN (e.g. a Holter monitor) is exempt from this requirement.

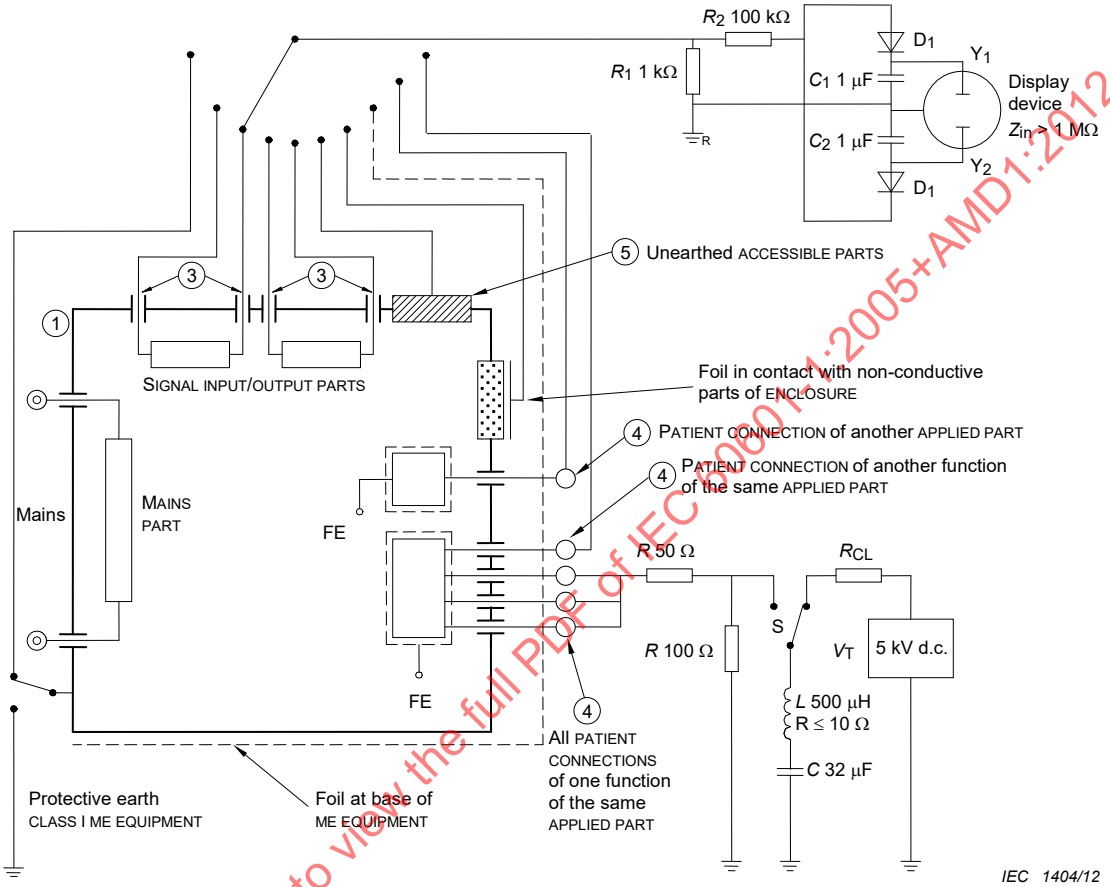
b) Following exposure to the defibrillation voltage, and any necessary recovery time stated in the ACCOMPANYING DOCUMENTS, the ME EQUIPMENT shall comply with relevant requirements of this standard and shall continue to provide BASIC SAFETY and ESSENTIAL PERFORMANCE.

Compliance is checked by the following tests, for each DEFIBRILLATION-PROOF APPLIED PART in turn.

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- ***Common-mode test***

The ME EQUIPMENT is connected to the test circuit as shown in Figure 9. The test voltage is applied to all the PATIENT CONNECTIONS of the DEFIBRILLATION-PROOF APPLIED PART connected together, excluding any that are PROTECTIVELY EARTHED or functionally earthed. If an APPLIED PART has multiple functions, the test voltage is applied to all the PATIENT CONNECTIONS of one function at a time with the other functions disconnected.



For legends, see Table 5.

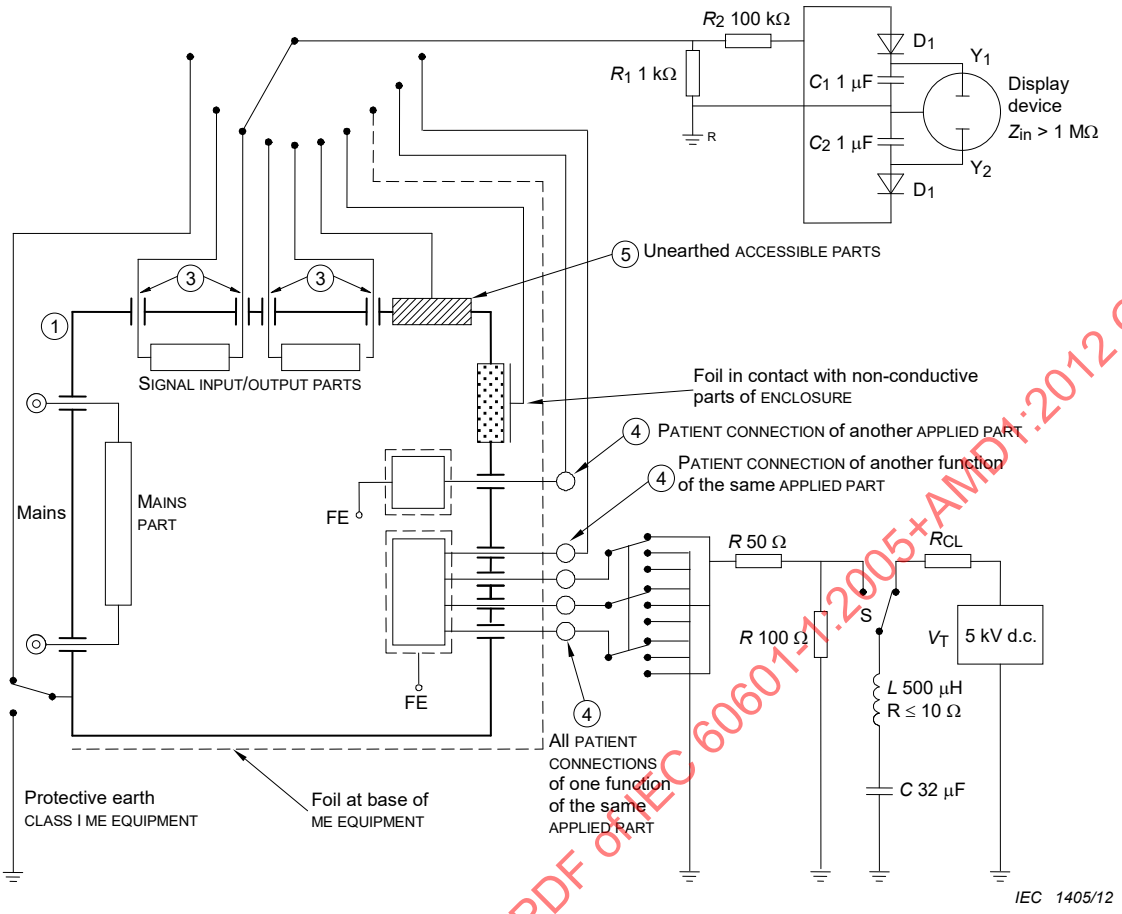
Components

V_T	Test voltage
S	Switch for applying the test voltage
R_1, R_2	Tolerance at ± 2 %, not less than 2 kV
R_{CL}	Current limiting resistor
D_1, D_2	Small signal silicon diodes

Other components toleranced at ± 5 %

Figure 9 – Application of test voltage to bridged PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS
(see 8.5.5.1)

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For legends, see Table 5.

Components

V_T	Test voltage
S	Switch for applying the test voltage
R_1, R_2	Tolerance at ± 2 %, not less than 2 kV
R_{CL}	Current limiting resistor
D_1, D_2	Small signal silicon diodes

Other components toleranced at ± 5 %

Figure 10 – Application of test voltage to individual PATIENT CONNECTIONS for DEFIBRILLATION-PROOF APPLIED PARTS
(see 8.5.5.1)

- ***Differential-mode test***

The ME EQUIPMENT is connected to the test circuit as shown in Figure 10. The test voltage is applied to each PATIENT CONNECTION of the DEFIBRILLATION-PROOF APPLIED PART in turn with all the remaining PATIENT CONNECTIONS of the same DEFIBRILLATION-PROOF APPLIED PART being connected to earth.

NOTE 2 The differential-mode test is not used when the APPLIED PART consists of a single PATIENT CONNECTION.

During the above tests:

– *except for PERMANENTLY INSTALLED ME EQUIPMENT, the ME EQUIPMENT is to be tested with and without the PROTECTIVE EARTH CONDUCTOR connected (i.e. two separate tests);*

– *insulating surfaces of APPLIED PARTS are covered with metal foil or, where appropriate, immersed in a 0,9 % saline solution;*

– *any external connection to a FUNCTIONAL EARTH TERMINAL is removed;*

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– *parts specified 8.5.5.1 a) that are not PROTECTIVELY EARTHED are connected in turn to a display device;*

– *the ME EQUIPMENT is connected to the SUPPLY MAINS and operated in accordance with the instructions for use*.

After the operation of S, the peak voltage between the points Y_1 and Y_2 is measured. Each test is repeated with V_T reversed.

After any recovery time stated in the ACCOMPANYING DOCUMENTS, determine that the ME EQUIPMENT continues to provide BASIC SAFETY and ESSENTIAL PERFORMANCE.

8.5.5.2 Energy reduction test

DEFIBRILLATION-PROOF APPLIED PARTS or PATIENT CONNECTIONS of DEFIBRILLATION-PROOF APPLIED PARTS shall incorporate a means so that the defibrillator energy delivered to a 100 Ω load is at least 90 % of the energy delivered to this load with the ME EQUIPMENT disconnected.

Compliance is checked by the following test:

The test circuit is shown in Figure 11. For this test, the ACCESSORIES such as cables, electrodes and transducers that are recommended in the instructions for use (see 7.9.2.14) are used. The test voltage is applied to each PATIENT CONNECTION or APPLIED PART in turn with all the remaining PATIENT CONNECTIONS of the same APPLIED PART being connected to earth (differential mode). Other DEFIBRILLATION PROOF APPLIED PARTS, if any, are tested separately, in turn.

The PROCEDURE is as follows.

a) *Connect the APPLIED PART or PATIENT CONNECTION to the test circuit. The parts described in 8.5.5.1 a) are connected to earth.*

b) *Charge capacitor C to 5 kV d.c. with switch S in position A.*

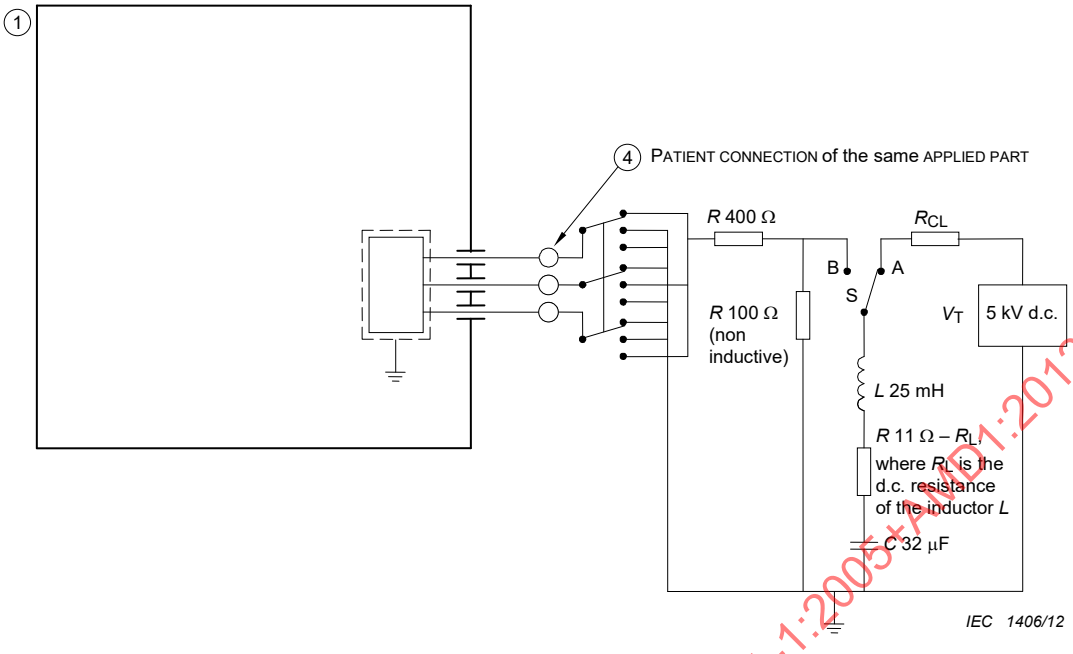
c) *Discharge capacitor C by actuating the switch S to position B, and measure the energy E_1 delivered to the 100 Ω load.*

d) *Remove the ME EQUIPMENT under test from the test circuit and repeat steps b) and c) above, measuring the energy E_2 delivered to the 100 Ω load.*

e) *Verify that the energy E_1 is at least 90 % of E_2.*

f) *Repeat the test with V_T reversed.*

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For legends, see Table 5.

Components

S	Switch for applying the test energy
A, B	Switch positions
R_{CL}	Current limiting resistor

Components toleranced at ± 5 %

Figure 11 – Application of test voltage to test the delivered defibrillation energy
(see 8.5.5.2)

8.6 * Protective earthing, functional earthing and potential equalization of ME EQUIPMENT

8.6.1 * Applicability of requirements

The requirements of 8.6.2 to 8.6.8 (inclusive) apply unless the parts concerned comply with the requirements and tests of IEC 60950-1 for protective earthing and serve as MEANS OF OPERATOR PROTECTION but not as MEANS OF PATIENT PROTECTION.

8.6.2 * PROTECTIVE EARTH TERMINAL

The PROTECTIVE EARTH TERMINAL of ME EQUIPMENT shall be suitable for connection to an external protective earthing system either by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and, where appropriate, by a suitable plug, or by a FIXED PROTECTIVE EARTH CONDUCTOR.

The clamping means of the PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS shall comply with the requirements of 8.11.4.3. It shall not be possible to loosen the clamping means without the aid of a TOOL.

Screws for internal PROTECTIVE EARTH CONNECTIONS shall be completely covered or protected against accidental loosening from the outside of ME EQUIPMENT.

Where an APPLIANCE INLET forms the supply connection to ME EQUIPMENT, the earth pin of the APPLIANCE INLET shall be regarded as the PROTECTIVE EARTH TERMINAL.

The PROTECTIVE EARTH TERMINAL shall not be used for the mechanical connection between different parts of the ME EQUIPMENT or the fixing of any component not related to protective earthing or functional earthing.

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Compliance is checked by inspection of materials and construction, by manual tests, and by the test of 8.11.4.3.

8.6.3 * Protective earthing of moving parts

Any PROTECTIVE EARTH CONNECTION shall not be used for a moving part unless the MANUFACTURER demonstrates that the connection will remain reliable during the EXPECTED SERVICE LIFE of the ME EQUIPMENT.

Compliance is checked by inspection of the ME EQUIPMENT and if necessary inspection of the RISK MANAGEMENT FILE.

8.6.4 Impedance and current-carrying capability

a) * PROTECTIVE EARTH CONNECTIONS shall be able to carry fault currents reliably and without excessive voltage drop.

For PERMANENTLY INSTALLED ME EQUIPMENT, the impedance between the PROTECTIVE EARTH TERMINAL and any part that is PROTECTIVELY EARTHED shall not exceed 100 mΩ, except as allowed by 8.6.4 b).

For ME EQUIPMENT with an APPLIANCE INLET the impedance between the earth pin in the APPLIANCE INLET and any part that is PROTECTIVELY EARTHED shall not exceed 100 mΩ, except as allowed by 8.6.4 b).

For ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD the impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED shall not exceed 200 mΩ, except as allowed by 8.6.4 b).

Additionally, the impedance between the protective earth pin in the MAINS PLUG of any DETACHABLE POWER SUPPLY CORD supplied or specified by the MANUFACTURER, when attached to the ME EQUIPMENT, and any part of the ME EQUIPMENT that is PROTECTIVELY EARTHED shall not exceed 200 mΩ, except as allowed by 8.6.4 b).

Where a DETACHABLE POWER SUPPLY CORD is neither supplied nor specified, testing shall be carried out using a 3 m long cord of appropriate cross sectional area based on 8.11.3.3 and Table 17.

Compliance is checked by the following test:

A current of 25 A or 1,5 times the highest RATED current of the relevant circuit(s), whichever is greater (± 10 %), from a current source with a frequency of 50 Hz or 60 Hz and with a no-load voltage not exceeding 6 V, is passed for 5 s to 10 s through the PROTECTIVE EARTH TERMINAL or the protective earth contact in the APPLIANCE INLET or the protective earth pin in the MAINS PLUG and each PROTECTIVELY EARTHED part.

Alternatively, d.c. may be used for this test.

The voltage drop between the parts described is measured and the impedance determined from the current and voltage drop.

Where the product of the test current as specified above and the total impedance (i.e. the impedance being measured plus the impedance of the test leads and the contact impedances) would exceed 6 V, the impedance is first measured with a no-load voltage not exceeding 6 V.

If the measured impedance is within the permitted limit, either the impedance measurement is then repeated using a current source with a no-load voltage sufficient to deliver the specified current into the total impedance, or the current-carrying ability of the relevant protective earth conductor and protective earth connection is confirmed by checking that their cross sectional area is at least equal to that of the relevant current-carrying conductors.

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b) * The impedance of PROTECTIVE EARTH CONNECTIONS is allowed to exceed the values specified above if the relevant circuits have limited current capability such that, in case of short circuit of relevant insulation, the allowable values of the TOUCH CURRENT and the PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION are not exceeded.

Compliance is checked by inspection and if necessary by measurement of LEAKAGE CURRENT in the relevant SINGLE FAULT CONDITION. Transient currents occurring during the first 50 ms following the short circuit are disregarded.

8.6.5 Surface coatings

Conductive elements of ME EQUIPMENT that have surface coatings of poorly conducting material such as paint, and between which electrical contact is essential to a PROTECTIVE EARTH CONNECTION, shall have the coatings removed at the point of contact unless an investigation of the joint construction and the manufacturing PROCESS has demonstrated that the requirements for impedance and current-carrying capacity are assured without the removal of the surface coating.

Compliance is checked by inspection.

8.6.6 Plugs and sockets

Where the connection between the SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT that can be operated by persons other than SERVICE PERSONNEL is made via a plug and socket device, the PROTECTIVE EARTH CONNECTION shall be made before and interrupted after the supply connections are made or interrupted. This applies also where interchangeable parts are PROTECTIVELY EARTHED.

Compliance is checked by inspection.

8.6.7 * POTENTIAL EQUALIZATION CONDUCTOR

If ME EQUIPMENT is provided with a terminal for the connection of a POTENTIAL EQUALIZATION CONDUCTOR, the following requirements apply.

– The terminal shall be accessible to the OPERATOR with the ME EQUIPMENT in any position of NORMAL USE.

– Accidental disconnection shall be avoided in NORMAL USE.

– The terminal shall allow the conductor to be detached without the use of a TOOL.

– The terminal shall not be used for a PROTECTIVE EARTH CONNECTION.

– The terminal shall be marked with symbol IEC 60417-5021 (2002-10) (see Table D.1, symbol 8).

– The instructions for use shall contain information on the function and use of the POTENTIAL EQUALIZATION CONDUCTOR together with a reference to the requirements of this standard for ME SYSTEMS.

The POWER SUPPLY CORD shall not incorporate a POTENTIAL EQUALIZATION CONDUCTOR.

Compliance is checked by inspection.

8.6.8 FUNCTIONAL EARTH TERMINAL

A FUNCTIONAL EARTH TERMINAL of ME EQUIPMENT shall not be used to provide a PROTECTIVE EARTH CONNECTION.

Compliance is checked by inspection.

8.6.9 * CLASS II ME EQUIPMENT

If CLASS II ME EQUIPMENT with isolated internal screens is supplied with a POWER SUPPLY CORD having three conductors, the third conductor (connected to the protective earth contact of the MAINS PLUG) shall be used only as the functional earth connection to a FUNCTIONAL EARTH

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TERMINAL for these screens and shall be coloured green and yellow. In such a case, the ACCOMPANYING DOCUMENTS shall state that the third conductor in the POWER SUPPLY CORD is only a functional earth.

The insulation between internal screens, including internal wiring connected to them and ACCESSIBLE PARTS, shall provide two MEANS OF PROTECTION.

Compliance is checked by inspection and measurement. The insulation is tested as described in 8.8.

8.7 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

8.7.1 General requirements

a) The electrical isolation providing protection against electric shock shall be of such quality that currents flowing through it are limited to the values specified in 8.7.3.

b) The specified values of the EARTH LEAKAGE CURRENT, the TOUCH CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT apply in any combination of the following conditions:

- at operating temperature and following the humidity preconditioning treatment, as described in 5.7;
- after any required sterilization PROCEDURE (see 11.6.7);
- in NORMAL CONDITION and in the SINGLE FAULT CONDITIONS specified in 8.7.2;
- with ME EQUIPMENT energized in stand-by condition and fully operating and with any switch in the MAINS PART in any position;
- with the highest RATED supply frequency;
- with a supply equal to 110 % of the highest RATED MAINS VOLTAGE.

8.7.2 * SINGLE FAULT CONDITIONS

The allowable values specified in 8.7.3 apply in the SINGLE FAULT CONDITIONS specified in 8.1 b) except that:

- where insulation is used in conjunction with a PROTECTIVE EARTH CONNECTION, short circuit of the insulation applies only in the circumstances specified in 8.6.4 b);
- the only SINGLE FAULT CONDITION for the EARTH LEAKAGE CURRENT is the interruption of one supply conductor at a time;
- LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT are not measured in the SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION.

SINGLE FAULT CONDITIONS shall not be applied at the same time as the special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS (8.7.4.7 b)) and non-PROTECTIVELY EARTHED parts of the ENCLOSURE (8.7.4.7 d)).

8.7.3 * Allowable values

a) The allowable values specified in 8.7.3 b), c) and d) apply to currents flowing through the network of Figure 12 a) and measured as shown in this figure (or by a device measuring the frequency contents of the currents as defined in Figure 12 b)). The values apply to d.c. and a.c. and composite waveforms. Unless stated otherwise they may be d.c. or r.m.s.

b) The allowable values of the PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS are stated in Table 3 and Table 4. The values of a.c. apply to currents having a frequency not less than 0,1 Hz.

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c) The allowable values of the TOUCH CURRENT are 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION.

d) The allowable values of the EARTH LEAKAGE CURRENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION. For PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit that supplies only this ME EQUIPMENT, a higher value of EARTH LEAKAGE CURRENT is allowed.

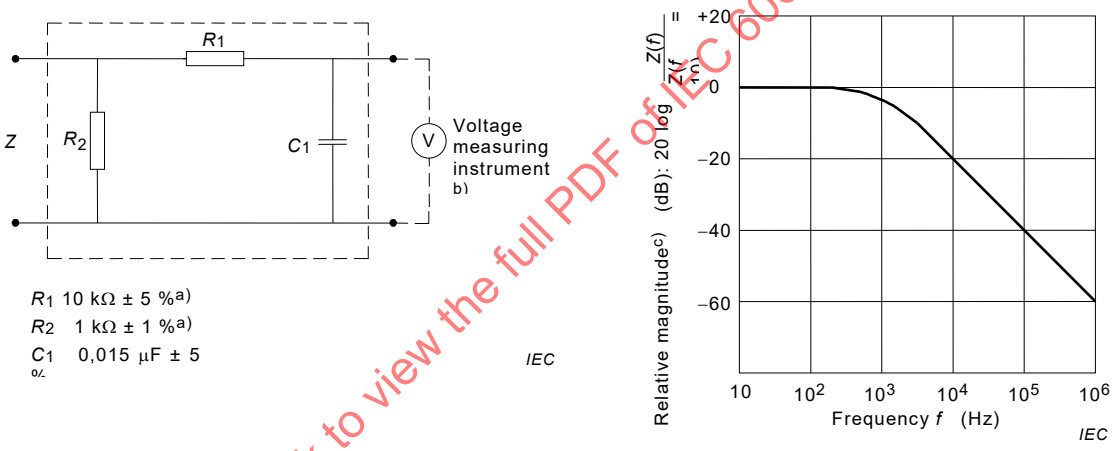
NOTE 1 Local regulation can establish limits for protective earth currents of the installation. See also IEC 60364-7-710 [10].

NOTE 2 The EARTH LEAKAGE CURRENT in NORMAL CONDITION can become TOUCH CURRENT in SINGLE FAULT CONDITION unless the ME EQUIPMENT is PERMANENTLY INSTALLED or the protective earth is not accessible from outside the ME EQUIPMENT.

e) Additionally, regardless of waveform and frequency, no LEAKAGE CURRENT shall exceed 10 mA r.m.s. in NORMAL CONDITION or in SINGLE FAULT CONDITION when measured with a non-frequency-weighted device.

f) *. The allowable values of LEAKAGE CURRENTS that can flow in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION.

NOTE 3 Subclause 16.6.1 requires that when ME EQUIPMENT is included in an ME SYSTEM, the TOUCH CURRENTS from any part of the ME SYSTEM cannot exceed 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION.



a) Measuring device

b) Frequency characteristics

NOTE The network and voltage measuring instrument above are replaced by the symbol 

in the following figures.

a) Non-inductive components
b) Resistance ≥ 1 MΩ and capacitance ≤ 150 pF
c) $Z(f)$ is the transfer impedance of the network, i.e. V_{out}/I_{in}, for a current of frequency f.

Figure 12 – Example of a measuring device and its frequency characteristics
(see 8.7.3)

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Table 3 – * Allowable values of PATIENT LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS under NORMAL CONDITION and SINGLE FAULT CONDITION

Current in μA

Current	Description	Reference	Measuring Circuit		TYPE B APPLIED PART		TYPE BF APPLIED PART		TYPE CF APPLIED PART	
					NC	SFC	NC	SFC	NC	SFC
PATIENT AUXILIARY CURRENT		8.7.4.8	Figure 19	d.c.	10	50	10	50	10	50
				a.c.	100	500	100	500	10	50
PATIENT LEAKAGE CURRENT	From PATIENT CONNECTION to earth	8.7.4.7 a)	Figure 15	d.c.	10	50	10	50	10	50
				a.c.	100	500	100	500	10	50
	Caused by an external voltage on a SIP/SOP	8.7.4.7 c)	Figure 17	d.c.	10	50	10	50	10	50
				a.c.	100	500	100	500	10	50
Total PATIENT LEAKAGE CURRENT [a]	With the same types of APPLIED PART connected together	8.7.4.7 a) and 8.7.4.7 h)	Figure 15 and Figure 20	d.c.	50	100	50	100	50	100
				a.c.	500	1 000	500	1 000	50	100
	Caused by an external voltage on a SIP/SOP	8.7.4.7 c) and 8.7.4.7 h)	Figure 17 and Figure 20	d.c.	50	100	50	100	50	100
				a.c.	500	1 000	500	1 000	50	100

Key
NC = NORMAL CONDITION
SFC = SINGLE FAULT CONDITION

NOTE 1 For EARTH LEAKAGE CURRENT see 8.7.3 d).

NOTE 2 For TOUCH CURRENT see 8.7.3 c).

[a] Total PATIENT LEAKAGE CURRENT values are only applicable to equipment having multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS shall comply with the PATIENT LEAKAGE CURRENT values.

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Table 4 – * Allowable values of PATIENT LEAKAGE CURRENTS under the special test conditions identified in 8.7.4.7

Current in μA

Current	Description [a]	Reference	Measuring Circuit	TYPE B APPLIED PART	TYPE BF APPLIED PART	TYPE CF APPLIED PART
PATIENT LEAKAGE CURRENT	Caused by an external voltage on the PATIENT CONNECTION of an F-TYPE APPLIED PART	8.7.4.7 b)	Figure 16	Not applicable	5 000	50
	Caused by an external voltage on a metal ACCESSIBLE PART not PROTECTIVELY EARTHED	8.7.4.7 d)	Figure 18	500	500	– [c]
Total PATIENT LEAKAGE CURRENT [b]	Caused by an external voltage on the PATIENT CONNECTION of an F-TYPE APPLIED PART	8.7.4.7 b) and 8.7.4.7 h)	Figure 16 and Figure 20	Not applicable	5 000	100
	Caused by an external voltage on a metal ACCESSIBLE PART not PROTECTIVELY EARTHED	8.7.4.7 d) and 8.7.4.7 h)	Figure 18 and Figure 20	1 000	1 000	– [c]

[a] The condition referred to in Table IV of the second edition as "MAINS VOLTAGE on APPLIED PART", and treated in that edition as a SINGLE FAULT CONDITION, is treated in this edition as a special test condition. The test with MAXIMUM MAINS VOLTAGE on a non-PROTECTIVELY EARTHED ACCESSIBLE PART is also a special test condition, but the allowable values are the same as for SINGLE FAULT CONDITION. See also the rationales for 8.5.2.2 and 8.7.4.7 d).

[b] Total PATIENT LEAKAGE CURRENT values are only applicable to equipment having multiple APPLIED PARTS. See 8.7.4.7 h). The individual APPLIED PARTS shall comply with the PATIENT LEAKAGE CURRENT values.

[c] This condition is not tested with TYPE CF APPLIED PARTS because it is covered by the test with MAXIMUM MAINS VOLTAGE on the APPLIED PART. See also the rationale for 8.7.4.7 d).

8.7.4 Measurements

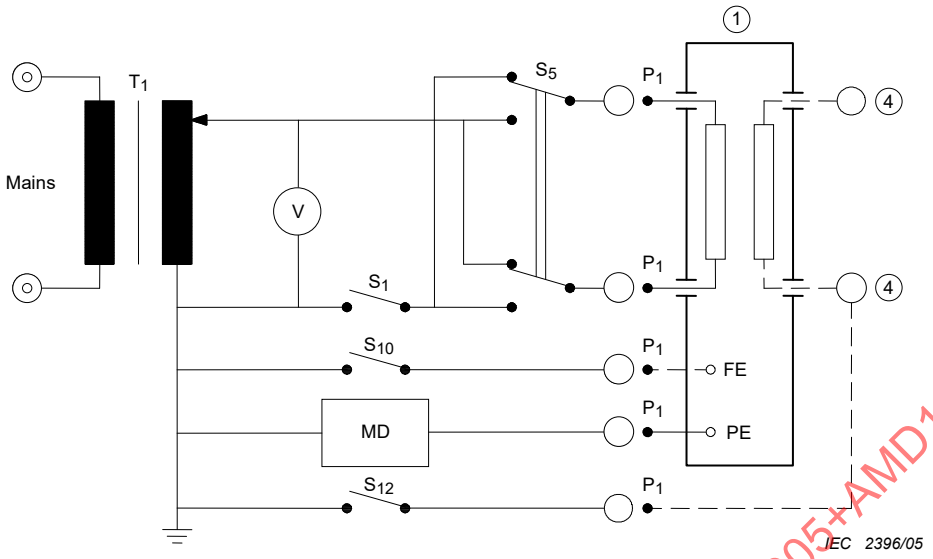
8.7.4.1 General

The LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT test figures referenced in 8.7.4.5 to 8.7.4.8 (Figure 13 to Figure 19 inclusive) show suitable test configurations for use in conjunction with the test PROCEDURES specified in these subclauses. It is recognized that other test figures can yield accurate results. However if the test results are close to the allowed values or if there is any doubt as to the validity of the test results, the applicable test figure is to be used as the deciding factor.

a) The EARTH LEAKAGE CURRENT, the TOUCH CURRENT, the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT are measured after the ME EQUIPMENT has been brought up to operating temperature in accordance with the requirements of 11.1.3 c).

b) Where examination of the circuit arrangement and the arrangement of components and material of the ME EQUIPMENT shows no possibility of any HAZARDOUS SITUATION described in 13.1, the number of tests can be reduced.

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For legends, see Table 5.

Key

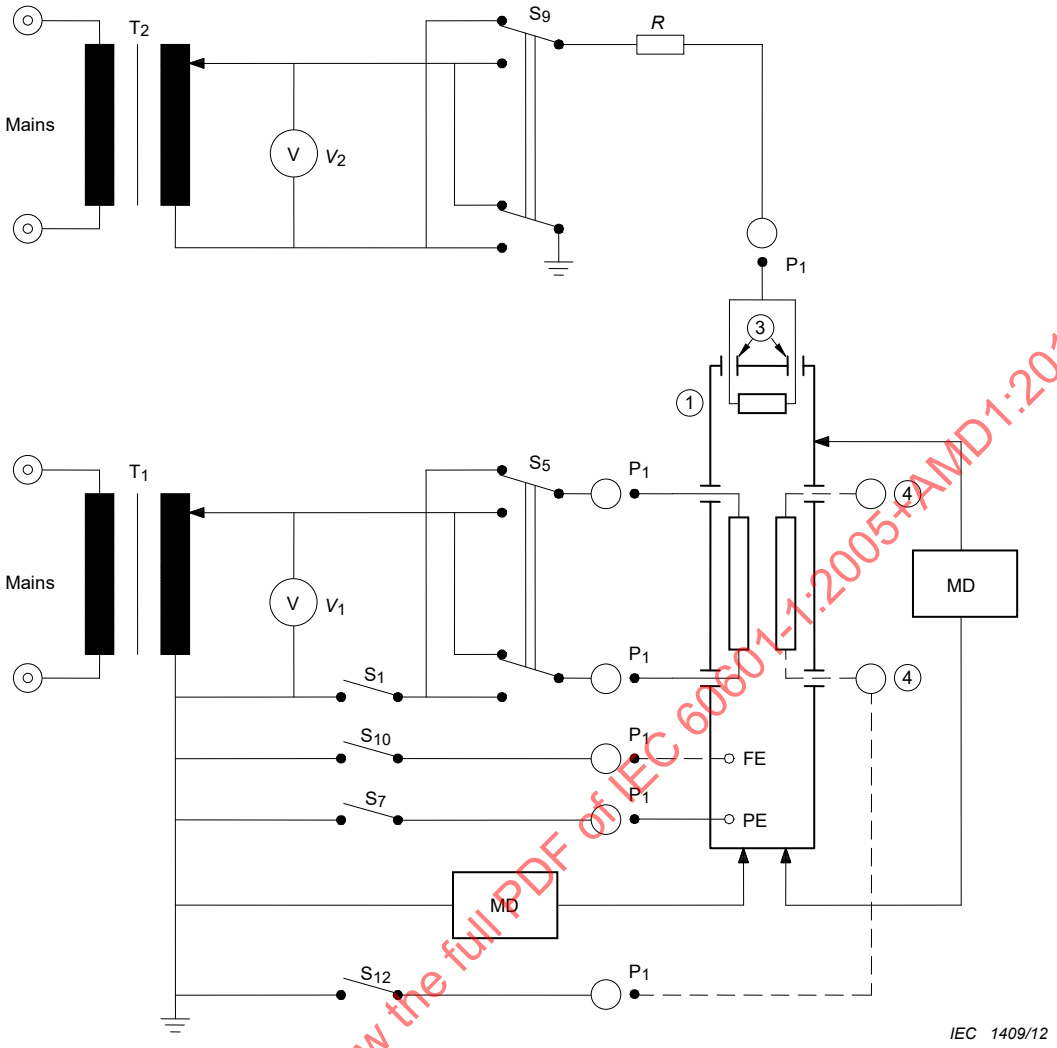
Measure in all possible combinations of positions of S_5, S_{10} and S_{12} with:

S_1 closed (NORMAL CONDITION), and
S_1 open (SINGLE FAULT CONDITION).

Example with the measuring supply circuit of Figure F.1

Figure 13 – Measuring circuit for EARTH LEAKAGE CURRENT of CLASS I ME EQUIPMENT, with or without APPLIED PART
(see 8.7.4.5)

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For legends, see Table 5.

Key

Measure (with S_7 closed if CLASS I ME equipment) under all possible combinations of positions of S_1, S_5, S_9, S_{10}, and S_{12}.

S_1 open is SINGLE FAULT CONDITION.

CLASS I ME equipment only:
Measure with S_7 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of S_5, S_9, S_{10} and S_{12}.

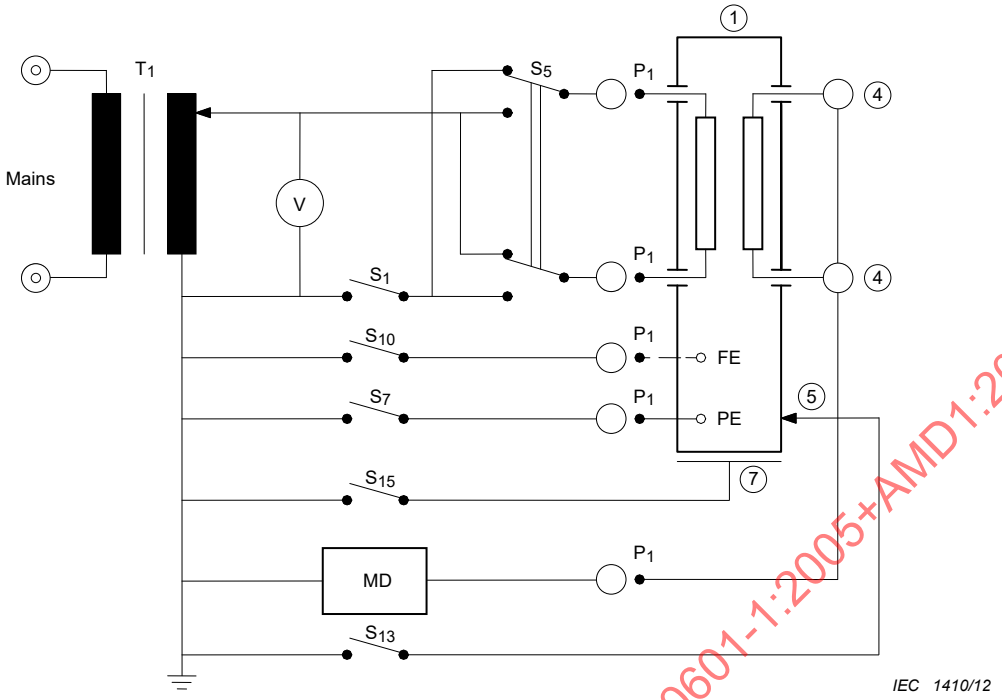
For CLASS II ME equipment, the PROTECTIVE EARTH CONNECTION and S_7 are not used.

Transformer T_2 is used if required (see 8.1 a))

Example with the measuring supply circuit of Figure F.1.

Figure 14 – Measuring circuit for TOUCH CURRENT
(see 8.7.4.6)

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For legends, see Table 5.

Key

Measure (with S_7 closed if CLASS I ME EQUIPMENT) under all possible combinations of positions of S_1, S_5, S_{10}, S_{13} and S_{15}.

S_1 open is SINGLE FAULT CONDITION.

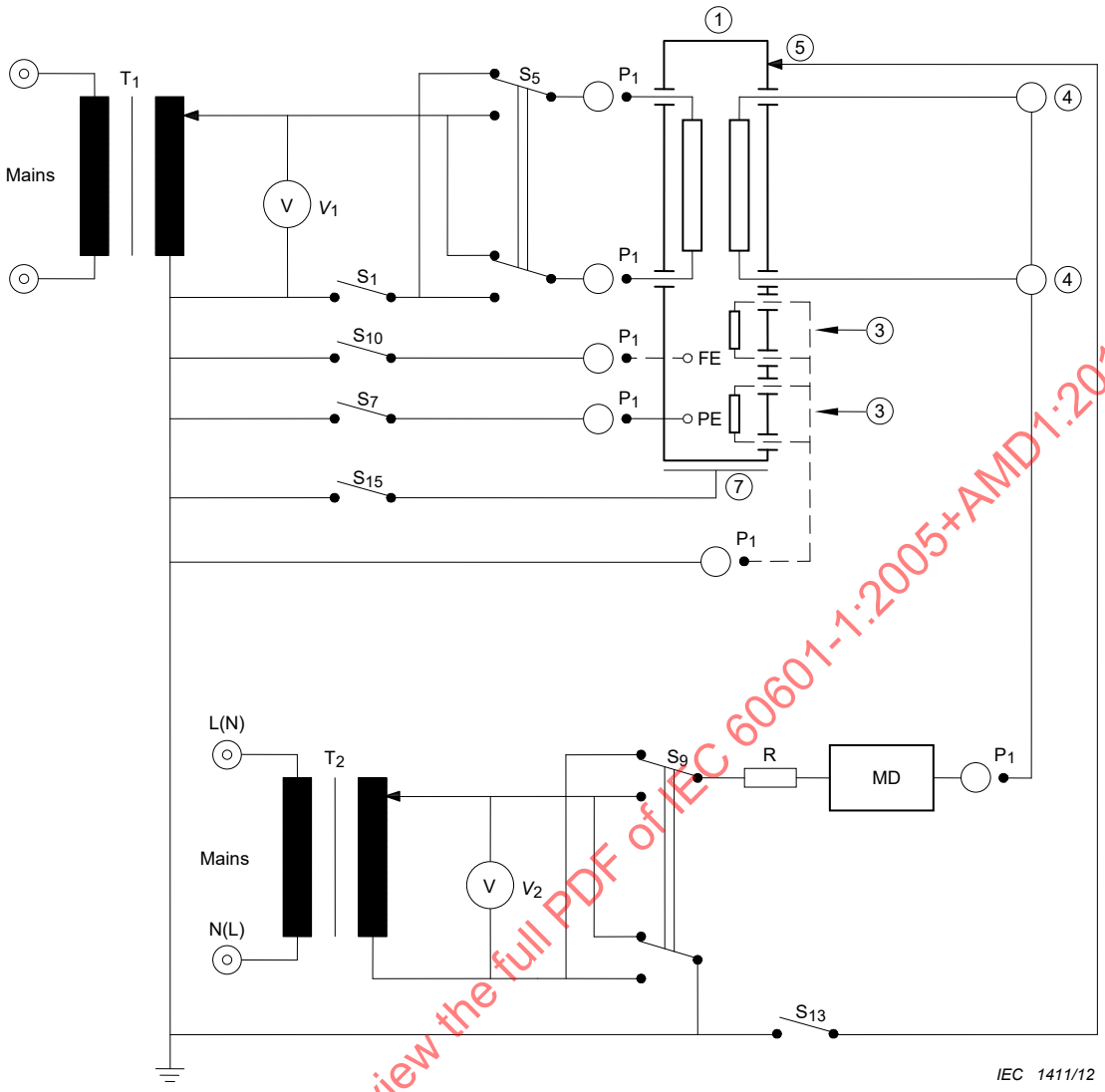
CLASS I ME EQUIPMENT only:
Measure with S_7 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of S_5, S_{10}, S_{13} and S_{15}.

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S_7 are not used.

Example with the measuring supply circuit of Figure F.1.

Figure 15 – Measuring circuit for PATIENT LEAKAGE CURRENT from the PATIENT CONNECTION to earth
(see 8.7.4.7 a))

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For legends, see Table 5.

Key

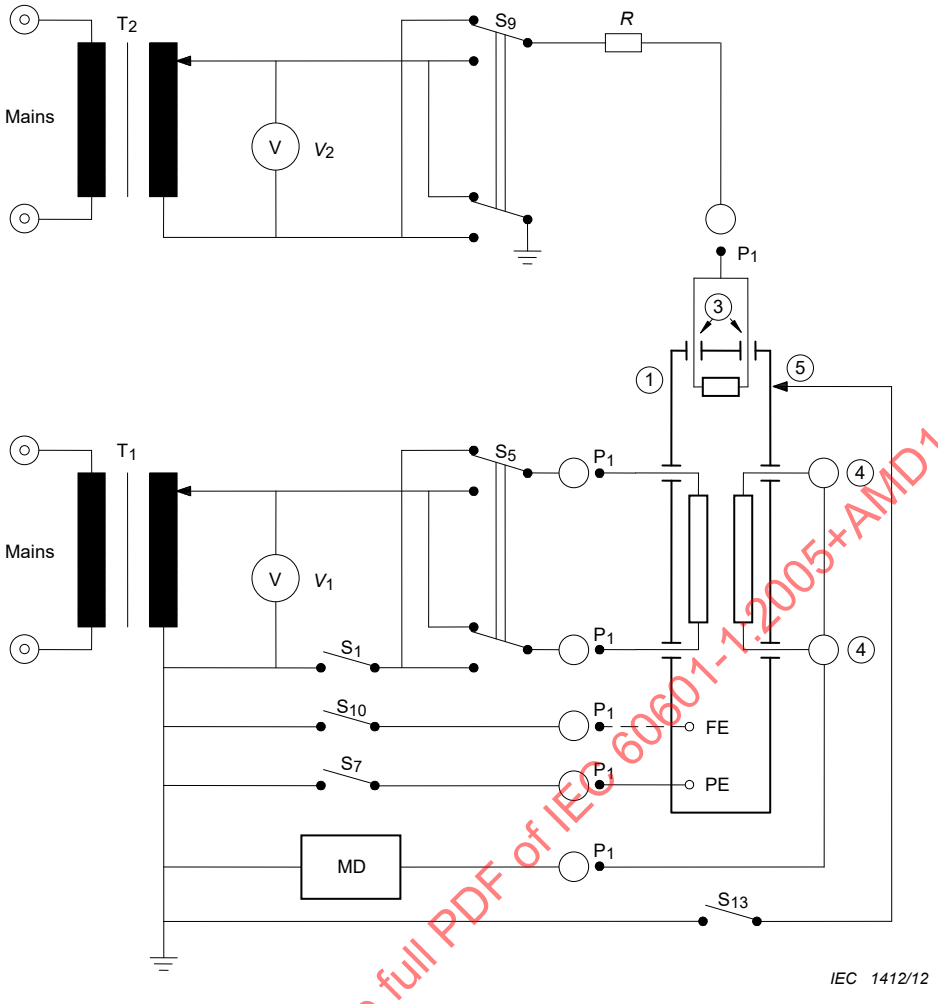
Measure (with S_7 closed, if CLASS I ME EQUIPMENT) WITH S_1 closed under all possible combinations of positions of S_5, S_9, S_{10} and S_{13}.

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S_7 are not used.

Example with the measuring supply circuit of Figure F.1.

Figure 16 – Measuring circuit for PATIENT LEAKAGE CURRENT via the PATIENT CONNECTION(S) of an F-TYPE APPLIED PART to earth caused by an external voltage on the PATIENT CONNECTION(S)
(see 8.7.4.7 b))

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For legends, see Table 5.

Key

Measure (with S_7 closed, if CLASS I ME EQUIPMENT) under all possible combinations of positions of S_1, S_5, S_9, S_{10} and S_{13} (S_1 open is SINGLE FAULT CONDITION).

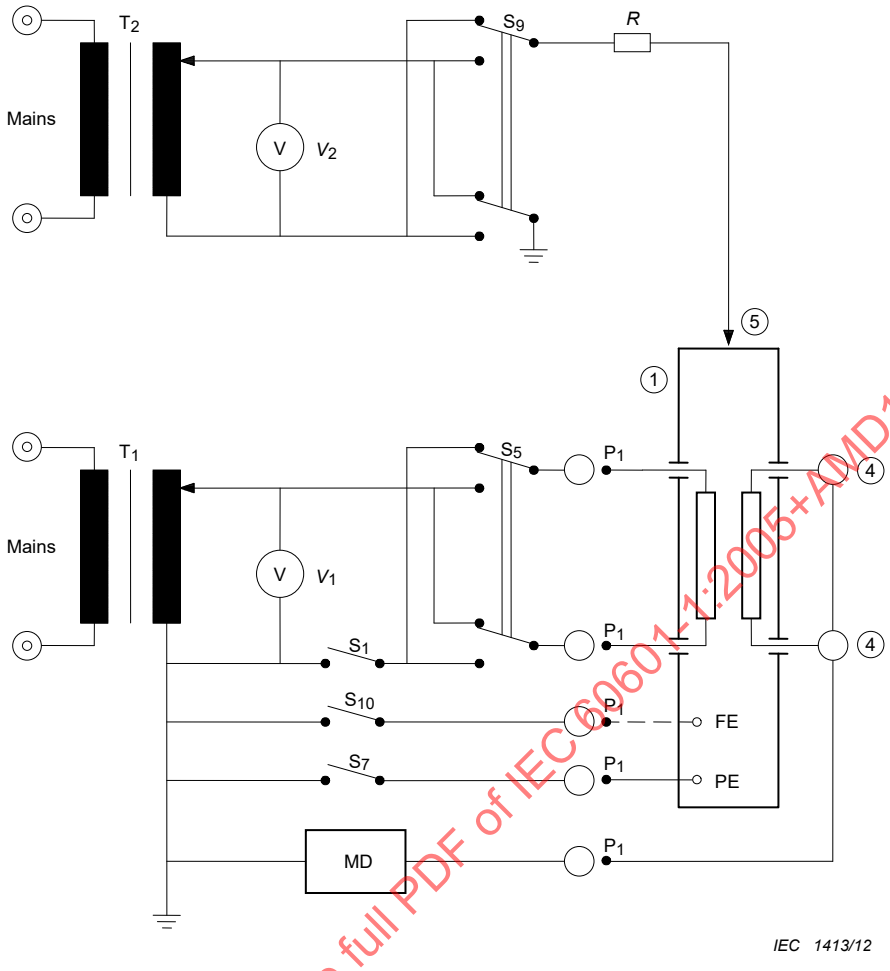
CLASS I ME EQUIPMENT only:
Measure with S_7 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of S_5, S_9, S_{10} and S_{13}.

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S_7 are not used.

Example with the measuring supply circuit of Figure F.1.

Figure 17 – Measuring circuit for PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(S) to earth caused by an external voltage on a SIGNAL INPUT/OUTPUT PART
(see 8.7.4.7 c))

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For legends, see Table 5.

Key

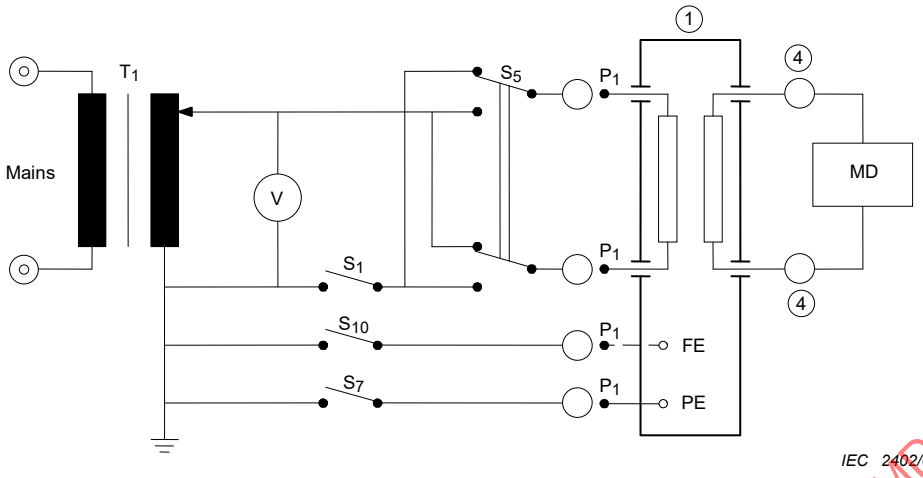
Measure with S_1 closed (and with S_7 closed, if CLASS I ME EQUIPMENT) under all possible combinations of positions of S_5, S_9 and S_{10}

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S_7 are not used.

Example with the measuring supply circuit of Figure F.1.

Figure 18 – Measuring circuit for PATIENT LEAKAGE CURRENT from PATIENT CONNECTION(S) to earth caused by an external voltage on a metal ACCESSIBLE PART that is not PROTECTIVELY EARTHED
(see 8.7.4.7 d))

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For legends, see Table 5.

Key

Measure (with S_7 closed if CLASS I ME EQUIPMENT) under all possible combinations of positions of S_1, S_5, and S_{10}.

S_1 open is a SINGLE FAULT CONDITION.

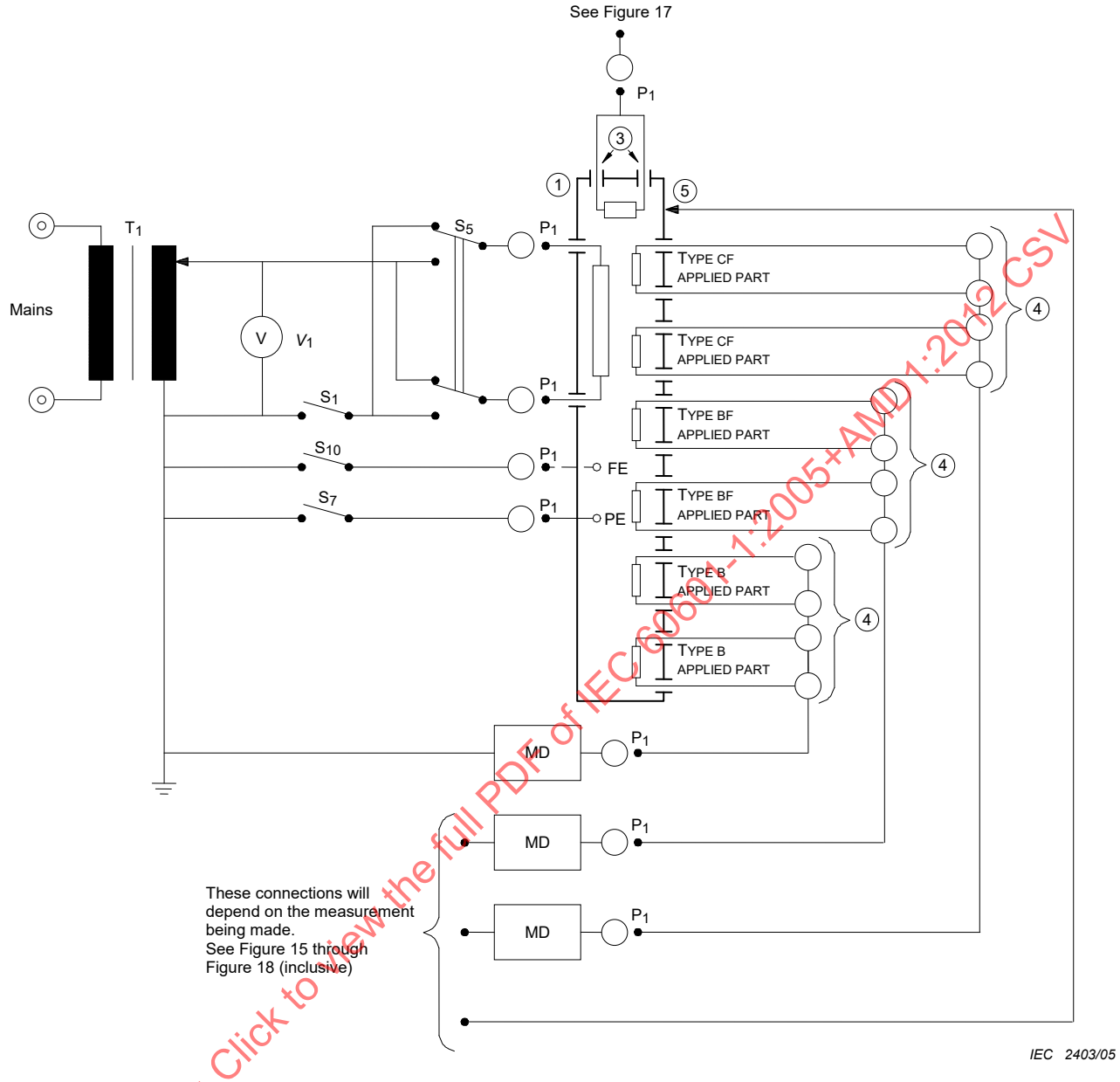
CLASS I ME EQUIPMENT only:
Measure with S_7 open (SINGLE FAULT CONDITION) and with S_1 closed under all possible combinations of positions of S_5, and S_{10}.

For CLASS II ME EQUIPMENT, the PROTECTIVE EARTH CONNECTION and S_7 are not used.

Example with the measuring supply circuit of Figure F.1.

Figure 19 – Measuring circuit for PATIENT AUXILIARY CURRENT
(see 8.7.4.8)

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For legends, see Table 5.

Key

For the position of S_1, S_5, S_7 and S_{10}, see Figure 15, Figure 16, Figure 17 or Figure 18

Figure 20 – Measuring circuit for total PATIENT LEAKAGE CURRENT with all PATIENT CONNECTIONS of all APPLIED PARTS of the same type (TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS) connected together
(see 8.7.4.7 h))

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Table 5 – Legends of symbols for Figure 9 to Figure 11, Figure 13 to Figure 20, Figure A.15, Annexes E and F

1	ME EQUIPMENT ENCLOSURE
2	Separate power supply unit or other electrical equipment in an ME SYSTEM that supplies power to the ME EQUIPMENT (see 5.5 f) and Annex F)
3	SIGNAL INPUT/OUTPUT PART short circuited or loaded
4	PATIENT CONNECTIONS
5	Metal ACCESSIBLE PART not PROTECTIVELY EARTHED In case of a non-conductive ENCLOSURE and PATIENT LEAKAGE CURRENT measurement, connection is replaced by a metal foil of maximum 20 cm × 10 cm in intimate contact with the ENCLOSURE or relevant parts of the ENCLOSURE and connected to the reference earth
6	PATIENT circuit
7	Metal plate under a non-conductive ENCLOSURE with dimensions at least equal to the plan projection of the ENCLOSURE connected to the reference earth
T_1, T_2	Single- or polyphase isolation transformers with sufficient power rating and adjustable output voltage (See also the rationale for 8.7.4.2 and 8.7.4.3.)
$V_{(1,2,3)}$	Voltmeter indicating r.m.s. value, using, if relevant and possible, one meter with a commutator switch
S_1, S_2, S_3	Single-pole switches, simulating the interruption of a power supply conductor (SINGLE FAULT CONDITION) (See Annex F)
S_5, S_9	Commutator switches to reverse the polarity of the MAINS VOLTAGE
S_7	Single-pole switch, simulating the interruption of a single PROTECTIVE EARTH CONDUCTOR to the ME EQUIPMENT (SINGLE FAULT CONDITION)
S_8	Single pole switch simulating the interruption of a single PROTECTIVE EARTH CONDUCTOR to a separate power supply unit or other electrical equipment in an ME SYSTEM that supplies power to the ME EQUIPMENT (SINGLE FAULT CONDITION) (see Figure F.5)
S_{10}	Switch for connecting a FUNCTIONAL EARTH TERMINAL to the earthed point of the measuring supply system
S_{12}	Switch for connecting a PATIENT CONNECTION to the earthed point of the measuring supply circuit
S_{13}	Switch for connecting to earth a metal ACCESSIBLE PART not PROTECTIVELY EARTHED
S_{14}	Switch to connect/disconnect PATIENT CONNECTION to/from earth
S_{15}	Switch for connecting to earth a metal plate under a non-conductive ENCLOSURE
P_1	Sockets, plugs or terminals for the supply connection of the ME EQUIPMENT
P_2	Sockets, plugs or terminals for the connection to a separate power supply or other electrical equipment in an ME SYSTEM that supplies power to the ME EQUIPMENT (see Figure F.5)
MD	Measuring device (see Figure 12)
FE	FUNCTIONAL EARTH TERMINAL
PE	PROTECTIVE EARTH TERMINAL
R	Impedance to protect the circuitry and the person performing the test, but low enough to accept currents higher than the allowable values of the LEAKAGE CURRENT to be measured (optional)
- - - -	Optional connection
	Reference earth (for LEAKAGE CURRENT and PATIENT AUXILLARY CURRENT measurements and for testing of DEFIBRILLATION-PROOF APPLIED PARTS, not connected to protective earth of the SUPPLY MAINS)
	SUPPLY MAINS voltage source

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8.7.4.2 * Measuring supply circuits

ME EQUIPMENT specified for connection to a SUPPLY MAINS is connected to an appropriate power source. For single-phase ME EQUIPMENT, the polarity of the supply is reversible and tests are conducted at both polarities. INTERNALLY POWERED ME EQUIPMENT is tested without any connection to a measuring supply circuit.

NOTE Figure F.1 to Figure F.5 (inclusive) show some suitable arrangements but do not cover all possibilities, for example, delta-connected 3-phase supplies.

8.7.4.3 * Connection to the measuring supply circuit

a) *ME EQUIPMENT provided with a POWER SUPPLY CORD is tested using this cord.*

b) *ME EQUIPMENT provided with an APPLIANCE INLET is tested while connected to the measuring supply circuit via a DETACHABLE POWER SUPPLY CORD having a length of 3 m or a length and type specified in the instructions for use.*

c) *PERMANENTLY INSTALLED ME EQUIPMENT is tested while connected to the measuring supply circuit by the shortest possible connection.*

d) *Measuring arrangement*

1) *APPLIED PARTS, including PATIENT cables (when present), are placed on an insulating surface with a dielectric constant of approximately 1 (for example, expanded polystyrene) and approximately 200 mm above an earthed metal surface.*

NOTE 1 The measuring supply circuit and the measuring circuit should be positioned as far as possible away from unscreened power source leads. Placing the ME EQUIPMENT on or near a large earthed metal surface should be avoided.

NOTE 2 Where APPLIED PARTS are such that the test results can depend upon how they are placed on the insulating surface, the test is repeated as necessary to determine the worst possible positioning.

2) *If an isolating transformer is not used for LEAKAGE CURRENT measurements (e.g. when measuring LEAKAGE CURRENT for very high input power ME EQUIPMENT), the reference earth of the measuring circuits is connected to protective earth of the SUPPLY MAINS.*

8.7.4.4 Measuring device (MD)

a) *The measuring device loads the source of LEAKAGE CURRENT or PATIENT AUXILIARY CURRENT with a resistive impedance of approximately 1 000 Ω for d.c., a.c. and composite waveforms with frequencies up to and including 1 MHz.*

b) *The evaluation of current or current components according to 8.7.3 a) is obtained automatically if a measuring device according to Figure 12 a) or a similar circuit with the same frequency characteristic is used. This allows measurement of the total effect of all frequencies with a single instrument.*

If currents or current components with frequencies exceeding 1 kHz might exceed the 10 mA limit specified in 8.7.3 *e), these are measured by other appropriate means such as a 1 kΩ non-inductive resistor and suitable measuring instrument.*

c) *The voltage measuring instrument as shown in Figure 12 a) has an input resistance of at least 1 MΩ and input capacitance of no more than 150 pF. It indicates the true r.m.s. value of the voltage being d.c., a.c. or a composite waveform having components with frequencies from 0,1 Hz up to and including 1 MHz, with an indicating error not exceeding ± 5 % of the indicated value.*

The scale can indicate the current through the measuring device including automatic evaluation of components with frequencies above 1 kHz so as to enable direct comparison of the reading with the limit values specified in 8.7.3.

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These requirements can be limited to a frequency range with an upper limit lower than 1 MHz if it can be proven (for example, by the use of an oscilloscope) that frequencies above such an upper limit do not occur in the measured current.

8.7.4.5 * Measurement of the EARTH LEAKAGE CURRENT and current in functional earth connection

a) *CLASS I ME EQUIPMENT is tested according to Figure 13. CLASS II ME EQUIPMENT with a functional earth connection according to 8.6.9 is tested as if it were CLASS I ME EQUIPMENT.*

b) *If ME EQUIPMENT has more than one PROTECTIVE EARTH CONDUCTOR (for example, one connected to the main ENCLOSURE and one to a separate power supply unit), then the current to be measured is the aggregate current that would flow into the protective earthing system of the installation.*

c) *For FIXED ME EQUIPMENT that can have connections to earth through the building structure, the MANUFACTURER specifies a suitable test PROCEDURE and configuration for measurement of EARTH LEAKAGE CURRENT.*

8.7.4.6 * Measurement of the TOUCH CURRENT

a) *ME EQUIPMENT is tested according to Figure 14, using an appropriate measuring supply circuit.*

Measure with MD between earth and each part of the ENCLOSURE(S) that is not PROTECTIVELY EARTHED.

Measure with MD between parts of the ENCLOSURE(S) that are not PROTECTIVELY EARTHED.

In the SINGLE FAULT CONDITION of interruption of any one PROTECTIVE EARTH CONDUCTOR (when applicable, see 8.1 b)), measure with MD between earth and any part of the ENCLOSURE(S) that is normally PROTECTIVELY EARTHED.

NOTE It is not necessary to make separate measurements from more than one part that is PROTECTIVELY EARTHED.

INTERNALLY POWERED ME EQUIPMENT is investigated for TOUCH CURRENT but only between parts of the ENCLOSURE, not between the ENCLOSURE and earth unless 8.7.4.6 c) applies.

b) *If ME EQUIPMENT has an ENCLOSURE or a part of the ENCLOSURE made of insulating material, metal foil of maximum 20 cm x 10 cm is applied in intimate contact with the ENCLOSURE or relevant part of the ENCLOSURE.*

The metal foil is shifted, if possible, to determine the highest value of the TOUCH CURRENT. The metal foil should not touch any metal parts of the ENCLOSURE that are possibly PROTECTIVELY EARTHED; however, metal parts of the ENCLOSURE that are not PROTECTIVELY EARTHED can be covered partly or totally by the metal foil.

Where it is intended to measure the TOUCH CURRENT in the SINGLE FAULT CONDITION of interruption of a PROTECTIVE EARTH CONDUCTOR, the metal foil is arranged to contact parts of the ENCLOSURE that are normally PROTECTIVELY EARTHED.

Where the surface of the ENCLOSURE contacted by the PATIENT or OPERATOR is larger than 20 cm x 10 cm, the size of the foil is increased corresponding to the area of contact.

c) *ME EQUIPMENT with a SIGNAL INPUT/OUTPUT PART is, when required (see 8.1 a)), additionally tested using transformer T_2.*

The value of the voltage set at the transformer T_2 is equal to 110 % of the MAXIMUM MAINS VOLTAGE. The specific pin configuration used when applying the external voltage is determined to be worst case based on testing or circuit analysis.

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8.7.4.7 Measurement of the PATIENT LEAKAGE CURRENT

See Annex K, which contains simplified PATIENT LEAKAGE CURRENT diagrams, for supplemental explanatory detail.

a) *ME EQUIPMENT with an APPLIED PART is tested according to Figure 15.*

An ENCLOSURE, other than an APPLIED PART, made of insulating material is placed in any position of NORMAL USE upon a flat metal surface connected to earth with dimensions at least equal to the plan-projection of the ENCLOSURE.

b) * *ME EQUIPMENT with an F-TYPE APPLIED PART is additionally tested according to Figure 16.*

SIGNAL INPUT/OUTPUT PARTS are connected to earth, if not already permanently earthed in the ME EQUIPMENT.

The value of the voltage to be set at the transformer T_2 in Figure 16 is equal to 110 % of the MAXIMUM MAINS VOLTAGE.

For this measurement, non-PROTECTIVELY EARTHED metal ACCESSIBLE PARTS including PATIENT CONECTIONS of other APPLIED PARTS (if present) are connected to earth.

c) * *ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART is, when required (see 8.1 a)), additionally tested according to Figure 17.*

The value of the voltage set at the transformer T_2 is equal to 110 % of the MAXIMUM MAINS VOLTAGE. The specific pin configuration used when applying the external voltage is to be worst case based on testing or circuit analysis.

d) * *ME EQUIPMENT with a PATIENT CONNECTION of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED or a TYPE BF APPLIED PART and with metal ACCESSIBLE PARTS that are not PROTECTIVELY EARTHED is additionally tested according to Figure 18.*

The value of the voltage set at the transformer T_2 is equal to 110 % of the MAXIMUM MAINS VOLTAGE.

This test need not be conducted if it can be demonstrated that there is adequate separation of the parts involved.

e) *An APPLIED PART consisting of a surface made of insulating material is tested using metal foil as mentioned under 8.7.4.6. Alternatively a 0,9 % saline solution is used in which the APPLIED PART is immersed.*

Where the surface of the APPLIED PART intended to contact the PATIENT is considerably larger than that of a foil of 20 cm x 10 cm, the size of the foil is increased to correspond to the area of contact.

Such metal foil or saline solution is considered as the only PATIENT CONNECTION for the APPLIED PART concerned.

f) *Where the PATIENT CONNECTION is formed by a fluid which contacts the PATIENT, the fluid is replaced by 0,9 % saline solution, an electrode is placed in the saline solution and this electrode is considered as the PATIENT CONNECTION for the APPLIED PART concerned.*

g) *The PATIENT LEAKAGE CURRENT is measured (see also Annex E):*

- *for TYPE B APPLIED PARTS, from all PATIENT CONNECTIONS connected directly together.*
- *for TYPE BF APPLIED PARTS, from and to all PATIENT CONNECTIONS of a single function either connected directly together or loaded as in NORMAL USE.*
- *for TYPE CF APPLIED PARTS, from and to every PATIENT CONNECTION in turn.*

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If the instructions for use specifies alternatives for a detachable part of the APPLIED PART (for example, PATIENT leads or PATIENT cables and electrodes), the PATIENT LEAKAGE CURRENT measurements are made with the least favourable specified detachable part. See also 7.9.2.14.

h) * *The total PATIENT LEAKAGE CURRENT is measured from and to all PATIENT CONNECTIONS of all APPLIED PARTS of the same type (TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS) connected together. See Figure 20. If necessary, a functional earth may be disconnected before conducting this test.*

NOTE Measurement of total PATIENT LEAKAGE CURRENT of TYPE B APPLIED PARTS is only necessary if there are two or more PATIENT CONNECTION that belong to different functions and that are not electrically connected directly together.

i) *If the PATIENT CONNECTIONS of the APPLIED PART are loaded in NORMAL USE, the measuring device is connected to each PATIENT CONNECTION in turn.*

8.7.4.8 Measurement of the PATIENT AUXILIARY CURRENT

ME EQUIPMENT with an APPLIED PART is tested according to Figure 19 using an appropriate measuring supply circuit unless the ME EQUIPMENT has only a single PATIENT CONNECTION.

The PATIENT AUXILIARY CURRENT is measured between any single PATIENT CONNECTION and all other PATIENT CONNECTIONS, either connected directly together or loaded as in NORMAL USE (see also Annex E).

8.7.4.9 * ME EQUIPMENT with multiple PATIENT CONNECTIONS

ME EQUIPMENT with multiple PATIENT CONNECTIONS is investigated to ensure that the PATIENT LEAKAGE CURRENT and the PATIENT AUXILIARY CURRENT do not exceed the allowable values for NORMAL CONDITION while one or more PATIENT CONNECTIONS are:

– disconnected from the PATIENT; and

– disconnected from the PATIENT and earthed.

Testing is performed if an examination of the ME EQUIPMENT circuit indicates that the PATIENT LEAKAGE CURRENT or the PATIENT AUXILIARY CURRENT can increase to excessive levels under the above conditions. Actual measurements should be limited to a representative number of combinations.

8.8 Insulation

8.8.1 * General

Only insulation that is relied upon as a MEANS OF PROTECTION, including REINFORCED INSULATION, shall be subject to testing.

Insulation forming part of a component is exempt provided that the component complies with 4.8.

Insulation forming MEANS OF OPERATOR PROTECTION is exempt from the tests of 8.8 if it complies with the requirements and tests of IEC 60950-1 for INSULATION CO-ORDINATION.

8.8.2 * Distance through solid insulation or use of thin sheet material

Solid insulation which forms SUPPLEMENTARY INSULATION or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V shall either:

a) have a distance through insulation of at least 0,4 mm, or

b) not form part of an ENCLOSURE and not be subject to handling or abrasion during NORMAL USE, and comprise:

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– at least two layers of material, each of which will pass the appropriate dielectric strength test; or

– three layers of material, for which all combinations of two layers together will pass the appropriate dielectric strength test.

The appropriate dielectric strength test for the one or two layers is the test for one MEANS OF PROTECTION in the case of SUPPLEMENTARY INSULATION or the test for two MEANS OF PROTECTION in the case of REINFORCED INSULATION, respectively.

NOTE 1 There is no minimum thickness requirement for BASIC INSULATION, nor for insulation operating at WORKING VOLTAGE up to 71 V.

NOTE 2 There is no requirement for all layers of insulation to be of the same material.

Compliance is checked by inspection, by measurement of thickness and by the dielectric strength test of 8.8.3.

For wound components, where BASIC INSULATION, SUPPLEMENTARY INSULATION or REINFORCED INSULATION is required between windings, they shall be separated by interleaved insulation complying with a) or b) immediately above, or both, unless one of the following wire constructions is used:

c) wire that has solid insulation, other than solvent based enamel, complying with a) above;

d) wire that has multi-layer extruded or spirally wrapped insulation (where the layers can be individually tested for dielectric strength) complying with b) above and passes the tests of Annex L;

e) wire that has multi-layer extruded or spirally wrapped insulation (where only the finished wire can be tested) and passes the tests of Annex L. The minimum number of constructional layers applied to the conductor shall be as follows:

– BASIC INSULATION: two wrapped layers or one extruded layer;

– SUPPLEMENTARY INSULATION: two layers, wrapped or extruded;

– REINFORCED INSULATION: three layers, wrapped or extruded.

In both d) and e), for spirally wrapped insulation where the CREEPAGE DISTANCES between layers, as wrapped, are less than those given in Table 12 or Table 16 (for Pollution Degree 1) depending on the type of insulation in question, the path between layers shall be sealed as for a cemented joint in 8.9.3.3 and the test voltages of the TYPE TESTS in L.3 are increased to 1,6 times their normal values.

NOTE 3 One layer of material wound with more than 50 % overlap is considered to constitute two layers.

Where two insulated wires or one bare and one insulated wire are in contact inside the wound component, crossing each other at an angle between 45° and 90° and subject to winding tension, protection against mechanical stress shall be provided. This protection can be achieved, for example, by providing physical separation in the form of insulating sleeving or sheet material, or by using double the required number of insulation layers.

The finished component shall pass routine tests for dielectric strength using the appropriate test voltages in 8.8.3.

Compliance is checked by inspection and measurement and, if applicable, as specified in Annex L. However, the tests of Annex L are not repeated if the material data sheets confirm compliance.

8.8.3 * Dielectric strength

The dielectric strength of solid electrical insulation of ME EQUIPMENT shall be capable of withstanding the test voltages as specified in Table 6. Only insulation with a safety function need be subject to testing (see 8.8.1).

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Compliance is checked by applying the test voltage specified in Table 6 for 1 min:

– *immediately after the humidity preconditioning treatment (as described in 5.7) with the ME EQUIPMENT de-energized during the test, and*

– *after any required sterilization PROCEDURE (see 11.6.7, 7.9.2.12 and the instructions for use) with the ME EQUIPMENT de-energized, and*

– *after reaching a temperature equivalent to the steady state operating temperature reached during the heating test of 11.1.1.*

Initially, not more than half the test voltage is applied, and then it is gradually raised over a period of 10 s to the full value, which is maintained for 1 min, after which it is gradually lowered over a period of 10 s to less than half the full value.

The test conditions are as follows:

a) * *The test voltage has a waveform and frequency such that the dielectric stress on the insulation is at least equal to that occurring in NORMAL USE. The waveform and frequency of the test voltage can differ from the voltage applied in NORMAL USE if it can be demonstrated that the dielectric stress on the insulation tested will not be diminished.*

Where the voltage to which the relevant insulation is subjected in NORMAL USE is non-sinusoidal a.c., the test may be performed using a sinusoidal 50 Hz or 60 Hz test voltage.

Alternatively, a d.c. test voltage equal to the peak value of the a.c. test voltage may be used.

The test voltage, for the WORKING VOLTAGE to which the insulation is subjected is greater than or equal to the value specified in Table 6.

b) *During the test, breakdown constitutes a failure. Insulation breakdown is considered to have occurred when the current which flows as a result of the application of the test voltage rapidly increases in an uncontrolled manner, that is, the insulation does not restrict the flow of the current. Corona discharge or a single momentary flashover is not regarded as insulation breakdown.*

c) *If it is not possible to test individual solid insulations, it is then necessary to test a large part of the ME EQUIPMENT or even the whole ME EQUIPMENT. In this case, it is important not to overstress different types and levels of insulation and the following must be taken into account.*

– *Where an ENCLOSURE or part of ENCLOSURE consists of non-conductive surfaces, metal foil is applied. Care is taken that the metal foil is positioned in such a manner that flashover does not occur at the edges of insulation linings. If applicable, the metal foil is moved so as to test all parts of the surface.*

– *The circuits on either side of the insulation under test should be connected or short circuited such that components within these circuits do not get stressed during the test. For example, the terminals of the MAINS PART, the SIGNAL INPUT/OUTPUT PART and the PATIENT CONNECTION(S) (if applicable) respectively are short circuited during the test.*

– *Where there are capacitors across the insulation under test (e.g. radio-frequency filter capacitors), they may be disconnected during the test, if they are certified to IEC 60384-14.*

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Table 6 – Test voltages for solid insulation forming a MEANS OF PROTECTION

PEAK WORKING VOLTAGE (*U*) V peak	PEAK WORKING VOLTAGE (*U*) V d.c.	A.C. test voltages in V r.m.s.							
		MEANS OF OPERATOR PROTECTION				MEANS OF PATIENT PROTECTION			
		Protection from MAINS PART		Protection from SECONDARY CIRCUITS		Protection from MAINS PART		Protection from SECONDARY CIRCUITS	
		One MOOP	Two MOOP	One MOOP	Two MOOP	One MOPP	Two MOPP	One MOPP	Two MOPP
$U < 42{,}4$	$U < 60$	1 000	2 000	No test	No test	1 500	3 000	500	1 000
$42{,}4 < U \leq 71$	$60 < U \leq 71$	1 000	2 000	See Table 7	See Table 7	1 500	3 000	750	1 500
$71 < U \leq 184$	$71 < U \leq 184$	1 000	2 000	See Table 7	See Table 7	1 500	3 000	1 000	2 000
$184 < U \leq 212$	$184 < U \leq 212$	1 500	3 000	See Table 7	See Table 7	1 500	3 000	1 000	2 000
$212 < U \leq 354$	$212 < U \leq 354$	1 500	3 000	See Table 7	See Table 7	1 500	4 000	1 500	3 000
$354 < U \leq 848$	$354 < U \leq 848$	See Table 7	3 000	See Table 7	See Table 7	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)
$848 < U \leq 1\,414$	$848 < U \leq 1\,414$	See Table 7	3 000	See Table 7	See Table 7	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)	$\sqrt{2}U$ + 1 000	2 x ($\sqrt{2}U$ + 1 500)
$1\,414 < U \leq 10\,000$	$1\,414 < U \leq 10\,000$	See Table 7	See Table 7	See Table 7	See Table 7	$U/\sqrt{2}$ + 2 000	$\sqrt{2}U$ + 5 000	$U/\sqrt{2}$ + 2 000	$\sqrt{2}U$ + 5 000
$10\,000 < U \leq 14\,140$	$10\,000 < U \leq 14\,140$	1,06 x $U/\sqrt{2}$	1,06 x $U/\sqrt{2}$	1,06 x $U/\sqrt{2}$	1,06 x $U/\sqrt{2}$	$U/\sqrt{2}$ + 2 000	$\sqrt{2}U$ + 5 000	$U/\sqrt{2}$ + 2 000	$\sqrt{2}U$ + 5 000
$U > 14\,140$	$U > 14\,140$	If necessary, to be prescribed by particular standards							

NOTE 1 For a barrier according to:

– Figure J.6, use the column MEANS OF PATIENT PROTECTION – Protection from SECONDARY CIRCUITS – Two MOPP.

– 8.5.2.1 and Figure J.7, use the column MEANS OF PATIENT PROTECTION – Protection from MAINS PART – One MOPP.

NOTE 2 See the rationale for 8.8.3.

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Table 7 – Test voltages for MEANS OF OPERATOR PROTECTION

Test voltage in V r.m.s.

PEAK WORKING VOLTAGE (*U*) V peak or V d.c.	One MOOP	Two MOOP	PEAK WORKING VOLTAGE (*U*) V peak or V d.c.	One MOOP	Two MOOP	PEAK WORKING VOLTAGE (*U*) V peak or V d.c.	One MOOP	Two MOOP
34	500	800	250	1 261	2 018	1 750	3 257	3 257
35	507	811	260	1 285	2 055	1 800	3 320	3 320
36	513	821	270	1 307	2 092	1 900	3 444	3 444
38	526	842	280	1 330	2 127	2 000	3 566	3 566
40	539	863	290	1 351	2 162	2 100	3 685	3 685
42	551	882	300	1 373	2 196	2 200	3 803	3 803
44	564	902	310	1 394	2 230	2 300	3 920	3 920
46	575	920	320	1 414	2 263	2 400	4 034	4 034
48	587	939	330	1 435	2 296	2 500	4 147	4 147
50	598	957	340	1 455	2 328	2 600	4 259	4 259
52	609	974	350	1 474	2 359	2 700	4 369	4 369
54	620	991	360	1 494	2 390	2 800	4 478	4 478
56	630	1 008	380	1 532	2 451	2 900	4 586	4 586
58	641	1 025	400	1 569	2 510	3 000	4 693	4 693
60	651	1 041	420	1 605	2 567	3 100	4 798	4 798
62	661	1 057	440	1 640	2 623	3 200	4 902	4 902
64	670	1 073	460	1 674	2 678	3 300	5 006	5 006
66	680	1 088	480	1 707	2 731	3 400	5 108	5 108
68	690	1 103	500	1 740	2 784	3 500	5 209	5 209
70	699	1 118	520	1 772	2 835	3 600	5 309	5 309
72	708	1 133	540	1 803	2 885	3 800	5 507	5 507
74	717	1 147	560	1 834	2 934	4 000	5 702	5 702
76	726	1 162	580	1 864	2 982	4 200	5 894	5 894
78	735	1 176	588	1 875	3 000	4 400	6 082	6 082
80	744	1 190	600	1 893	3 000	4 600	6 268	6 268
85	765	1 224	620	1 922	3 000	4 800	6 452	6 452
90	785	1 257	640	1 951	3 000	5 000	6 633	6 633
95	805	1 288	660	1 979	3 000	5 200	6 811	6 811
100	825	1 319	680	2 006	3 000	5 400	6 987	6 987
105	844	1 350	700	2 034	3 000	5 600	7 162	7 162
110	862	1 379	720	2 060	3 000	5 800	7 334	7 334
115	880	1 408	740	2 087	3 000	6 000	7 504	7 504
120	897	1 436	760	2 113	3 000	6 200	7 673	7 673
125	915	1 463	780	2 138	3 000	6 400	7 840	7 840
130	931	1 490	800	2 164	3 000	6 600	8 005	8 005
135	948	1 517	850	2 225	3 000	6 800	8 168	8 168
140	964	1 542	900	2 285	3 000	7 000	8 330	8 330
145	980	1 568	950	2 343	3 000	7 200	8 491	8 491
150	995	1 593	1 000	2 399	3 000	7 400	8 650	8 650
152	1 000	1 600	1 050	2 454	3 000	7 600	8 807	8 807
155	1 000	1 617	1 100	2 508	3 000	7 800	8 964	8 964
160	1 000	1 641	1 150	2 560	3 000	8 000	9 119	9 119
165	1 000	1 664	1 200	2 611	3 000	8 200	9 273	9 273
170	1 000	1 688	1 250	2 661	3 000	8 400	9 425	9 425
175	1 000	1 711	1 300	2 710	3 000	8 600	9 577	9 577
180	1 000	1 733	1 350	2 758	3 000	8 800	9 727	9 727
184	1 000	1 751	1 400	2 805	3 000	9 000	9 876	9 876
185	1 097	1 755	1 410	2 814	3 000	9 200	10 024	10 024
190	1 111	1 777	1 450	2 868	3 000	9 400	10 171	10 171
200	1 137	1 820	1 500	2 934	3 000	9 600	10 317	10 317
210	1 163	1 861	1 550	3 000	3 000	9 800	10 463	10 463
220	1 189	1 902	1 600	3 065	3 065	10 000	10 607	10 607
230	1 214	1 942	1 650	3 130	3 130			
240	1 238	1 980	1 700	3 194	3 194			

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8.8.4 Insulation other than wire insulation

8.8.4.1 * Mechanical strength and resistance to heat

The resistance to heat shall be retained by all types of insulation, including insulating partition walls, during the EXPECTED SERVICE LIFE of the ME EQUIPMENT.

Compliance is checked by inspection of the ME EQUIPMENT and the design documentation, and, if necessary, inspection of the RISK MANAGEMENT FILE in conjunction with the following tests:

– *resistance to moisture, etc. (see 11.6);*

– *dielectric strength (see 8.8.3);*

– *mechanical strength (see 15.3).*

Resistance to heat is established by the following tests, which need not be performed if satisfactory evidence of compliance is provided.

a) *For parts of the ENCLOSURE and other external insulating parts, the deterioration of which could result in an unacceptable RISK, by the ball-pressure test:*

ENCLOSURES and other external parts of insulating material, except the insulation of flexible cords and parts of ceramic material, are subjected to a ball-pressure test using the test apparatus shown in Figure 21. The surface of the part to be tested is placed in the horizontal position and a steel ball of 5 mm diameter is pressed against the surface with a force of 20 N. The test is performed in a heating cabinet at a temperature of 75 °C ± 2 °C or the ambient temperature indicated in the technical description (see 7.9.3.1) ± 2 °C plus the temperature rise of the relevant part of insulating material measured during the test of 11.1, whichever is the higher.

The ball is withdrawn after 1 h and the diameter of the impression made by the ball is measured. An impression greater than 2 mm in diameter constitutes a failure.

b) *For parts of insulating material that support uninsulated parts of the MAINS PART, the deterioration of which could influence the safety of the ME EQUIPMENT, by the ball-pressure test:*

A test is performed as described in a) above, but at a temperature of 125 °C ± 2 °C or at the ambient temperature indicated in the technical description (see 7.9.3.1) ± 2 °C plus the temperature rise that was determined during the test of 11.1 of the relevant part, whichever is the higher.

The test is not performed on parts of ceramic material, insulating parts of commutators, brush-caps and the like, and on coil formers not used as REINFORCED INSULATION.

NOTE For SUPPLEMENTARY INSULATION and REINFORCED INSULATION of thermoplastic materials, see also 13.1.2.

8.8.4.2 Resistance to environmental stress

The insulating characteristics and mechanical strength of any MEANS OF PROTECTION shall be so designed or protected that it is not likely to be impaired by environmental stresses including deposition of dirt or by dust resulting from wear of parts within the ME EQUIPMENT to such an extent that CREEPAGE DISTANCES and AIR CLEARANCES are reduced below the values specified in 8.9.

Ceramic material not tightly sintered, and the like, and beads alone shall not be used as SUPPLEMENTARY INSULATION or REINFORCED INSULATION.

Insulating material in which heating conductors are embedded may be considered as one MEANS OF PROTECTION but shall not be used as two MEANS OF PROTECTION.

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Compliance is checked by inspection, by measurement and for natural latex rubber by the following test:

Parts of natural latex rubber are aged in an atmosphere of oxygen under pressure. The samples are suspended freely in an oxygen cylinder, the effective capacity of the cylinder is at least 10 times the volume of the samples. The cylinder is filled with commercial oxygen not less than 97 % pure, to a pressure of 2,1 MPa ± 70 kPa.

The samples are kept in the cylinder at a temperature of 70 °C ± 2 °C for 96 h. Immediately afterwards, they are taken out of the cylinder and left at room temperature for at least 16 h. After the test, the samples are examined. Cracks visible to the naked eye constitute a failure.

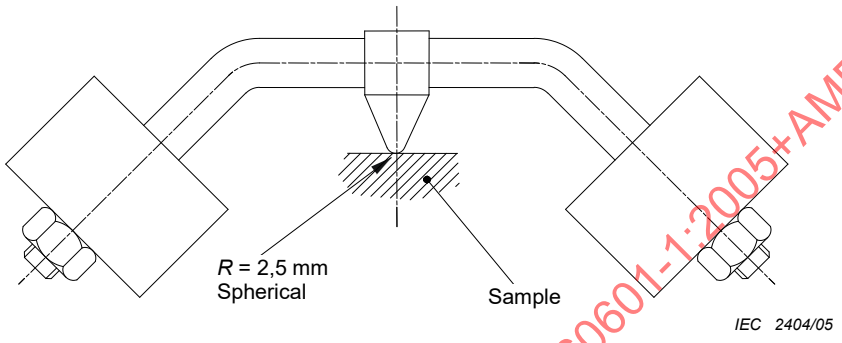


Figure 21 – Ball-pressure test apparatus
(see 8.8.4.1)

8.9 * CREEPAGE DISTANCES and AIR CLEARANCES

8.9.1 * Values

8.9.1.1 General

CREEPAGE DISTANCES and AIR CLEARANCES of ME EQUIPMENT shall be equal to or greater than the values of:

– for insulation between parts of opposite polarity of the MAINS PART on the SUPPLY MAINS side of any mains fuse or OVER-CURRENT RELEASE, one MEANS OF OPERATOR PROTECTION in accordance with Table 13, Table 14 and Table 16; and

– for insulation providing at least a MEANS OF PROTECTION, in accordance with Table 12 to Table 16 (inclusive) except as specified in 8.9.1.2 to 8.9.1.15. See also 8.9.2 to 8.9.4.

8.9.1.2 CREEPAGE DISTANCES and AIR CLEARANCES complying with IEC 60950-1

The values of Table 12 to Table 16 (inclusive) do not apply to CREEPAGE DISTANCES and AIR CLEARANCES forming MEANS OF OPERATOR PROTECTION that comply with the requirements of IEC 60950-1 for INSULATION CO-ORDINATION and are used in the conditions (e.g. overvoltage category, pollution degree) under which compliance was tested.

8.9.1.3 CREEPAGE DISTANCES across glass, mica, ceramic and similar materials

For CREEPAGE DISTANCES across glass, mica, ceramic and other inorganic insulating materials with similar tracking characteristics, the specified minimum value of AIR CLEARANCE shall be applied as the minimum CREEPAGE DISTANCE.

8.9.1.4 Minimum CREEPAGE DISTANCE

If the minimum CREEPAGE DISTANCE derived from Table 12 to Table 16 (inclusive) is less than the applicable minimum AIR CLEARANCE, that value of minimum AIR CLEARANCE shall be applied as the minimum CREEPAGE DISTANCE.

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8.9.1.5 ME EQUIPMENT RATED for high altitudes

Unless otherwise declared by the MANUFACTURER, ME EQUIPMENT is RATED to operate at an altitude ≤ 2 000 m. Where ME EQUIPMENT is intended to be operated in a pressurized environment, e.g. aircraft, the operating altitude corresponding to the air pressure concerned shall be used in determining multiplication factor from Table 8. The AIR CLEARANCE is then multiplied by this factor. CREEPAGE DISTANCES are not subject to the multiplication factors but shall always be at least as large as the resulting value for AIR CLEARANCE.

Table 8 – Multiplication factors for AIR CLEARANCES for altitudes up to 5 000 m

RATED operating altitude (*a*) m	Normal barometric pressure kPa	Multiplication factor for MOOP	Multiplication factor for MOPP
a ≤ 2 000	80,0	1,00	1,00
2 000 < *a* ≤ 3 000	70,0	1,14	1,00
3 000 < *a* ≤ 4 000	62,0	1,29	1,14
4 000 < *a* ≤ 5 000	54,0	1,48	1,29
NOTE 1 The multiplication factors for MEANS OF OPERATOR PROTECTION relate to IEC 60950-1, which specifies AIR CLEARNACES for altitudes up to 2 000 m. NOTE 2 The multiplication factors for MEANS OF PATIENT PROTECTION relate to the second edition of IEC 60601-1, which specified spacing AIR CLEARANCES for altitudes up to 3 000 m. NOTE 3 The multiplication factors for MOOPs (column 3) are derived from IEC 60664-1:2007.			

8.9.1.6 * Interpolation

If the WORKING VOLTAGE has a value between those given in Table 12 to Table 16 (inclusive):

– for determining CREEPAGE DISTANCES, linear interpolation is permitted between the nearest two values, the calculated spacing being rounded to the next higher 0,1 mm increment;

– for determining AIR CLEARANCES for PEAK WORKING VOLTAGES above 2 800 V peak or d.c., linear interpolation is permitted between the nearest two values, the calculated spacing being rounded to the next higher 0,1 mm increment;

– for determining AIR CLEARANCES for PEAK WORKING VOLTAGE up to 2 800 V peak or d.c., the higher of the two values shall be applied.

8.9.1.7 Material groups classification

Material groups are classified as shown in Table 9.

Table 9 – Material group classification

Material group	Comparative tracking index (CTI)
I	600 ≤ CTI
II	400 ≤ CTI < 600
IIIa	175 ≤ CTI < 400
IIIb	100 ≤ CTI < 175

The material group is verified by evaluation of the test data for the material according to IEC 60112 using 50 drops of solution A.

If the material group is not known, material group IIIb shall be assumed.

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8.9.1.8 Pollution degree classification

Pollution degrees are classified as follows:

– Pollution degree 1 is used to describe a micro-environment that is sealed so as to exclude dust and moisture.

NOTE 1 An example of such a micro-environment is a sealed or potted component or assembly.

– Pollution degree 2 is used to describe a micro-environment where only non-conductive pollution occurs except that occasionally a temporary conductivity caused by condensation is to be expected.

– Pollution degree 3 is used to describe a micro-environment that is subject to conductive pollution, or to dry non-conductive pollution that could become conductive due to expected condensation.

– Pollution degree 4 is used to describe a micro-environment where continuous conductivity occurs due to conductive dust, rain or other wet conditions.

NOTE 2 This type of environment can occur inside commutating motors which generate carbon dust from the brushes.

Pollution degree 4 is not acceptable for insulation providing a MEANS OF PROTECTION. However, in the case where insulation between the MAINS PART and earth might be compromised, it is necessary to provide measures, such as planned maintenance, to ensure that the micro-environment is mitigated to a lower pollution degree.

Annex M specifies measures that may be used to reduce the pollution degree.

8.9.1.9 Overvoltage category classification

The applicable value of the MAINS TRANSIENT VOLTAGE shall be determined from the overvoltage category according to IEC 60664-1 and the NOMINAL a.c. MAINS VOLTAGE using Table 10.

8.9.1.10 AIR CLEARANCE for MAINS PARTS

For MAINS PARTS operating on RATED MAINS VOLTAGES up to 300 V, the required AIR CLEARANCE shall be the value in Table 13 for the r.m.s. or d.c. RATED MAINS VOLTAGE plus the additional AIR CLEARANCE in Table 14 for the PEAK WORKING VOLTAGE.

8.9.1.11 SUPPLY MAINS overvoltage

This standard relates to overvoltage category II according to IEC 60664-1. If ME EQUIPMENT is intended to be used in locations where the SUPPLY MAINS is overvoltage category III, the values specified in Table 13 to Table 15 (inclusive) will be inadequate for clearance. Therefore the values given in the next MAINS TRANSIENT VOLTAGE column upwards shall be used. Whilst it is not envisaged that PATIENT protection (Table 12) will be required for use of ME EQUIPMENT on overvoltage category III SUPPLY MAINS, should this be necessary, guidance is given on the values required in the rationale for Subclause 8.9.

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Table 10 – MAINS TRANSIENT VOLTAGE

NOMINAL a.c. SUPPLY MAINS voltage line-to-neutral up to and including V r.m.s.	MAINS TRANSIENT VOLTAGE V peak			
	Overvoltage Category			
	I	II	III	IV
50	330	500	800	1 500
100	500	800	1 500	2 500
150 [a]	800	1 500	2 500	4 000
300 [b]	1 500	2 500	4 000	6 000
600 [c]	2 500	4 000	6 000	8 000
NOTE 1 In Norway, due to the IT power distribution system used, the a.c SUPPLY MAINS voltage is considered to be equal to the line-to-line voltage, and will remain 230 V in case of a single earth fault. NOTE 2 In Japan, the value of the MAINS TRANSIENT VOLTAGES for the NOMINAL a.c. SUPPLY MAINS voltage of 100 V is determined from columns applicable to the NOMINAL a.c. SUPPLY MAINS voltage of 150 V.				
[a] Including 120/208 or 120/240 V. [b] Including 230/400 or 277/480 V. [c] Including 400/690 V.				

8.9.1.12 SECONDARY CIRCUITS

A SECONDARY CIRCUIT derived from a SUPPLY MAINS will normally be overvoltage category I according to IEC 60664-1 if the MAINS PART is overvoltage category II; the maximum transients for various SUPPLY MAINS voltages in overvoltage category I are shown in the column headings of Table 15.

Where the SECONDARY CIRCUIT is earthed or the ME EQUIPMENT is INTERNALLY POWERED, Table 15 applies.

Where a SECONDARY CIRCUIT is not earthed and is derived from a SUPPLY MAINS, the circuit shall be subjected to the requirements for primary circuits in Table 13 and Table 14.

If the SECONDARY CIRCUIT is separated from the MAINS PART by a functionally earthed or PROTECTIVELY EARTHED metal screen or transients in the SECONDARY CIRCUIT are below the levels expected for overvoltage category I, (for example due to being attenuated by connecting a component, such as a capacitor, between the SECONDARY CIRCUIT and earth), the values in Table 15 apply.

The column for circuits not subject to transient overvoltages applies to:

– d.c. SECONDARY CIRCUITS that are reliably connected to earth and have capacitive filtering which limits the peak-to-peak ripple to 10 % of the d.c. voltage; and

– circuits in INTERNALLY POWERED ME EQUIPMENT.

8.9.1.13 PEAK WORKING VOLTAGES above 1 400 V peak or d.c.

The values in Table 15 for PEAK WORKING VOLTAGES above 1 400 V peak or d.c. do not apply if all the following conditions are satisfied:

– the AIR CLEARANCE is at least 5 mm;

– the insulation involved passes a dielectric strength test according to 8.8.3 using:

  • an a.c. test voltage whose r.m.s. value is equal to 1,06 times the PEAK WORKING VOLTAGE or

  • a d.c. test voltage equal to the peak value of the a.c. test voltage prescribed above;

  and

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– the AIR CLEARANCE path is partly or entirely through air or along the surface of an insulating material of material group I.

If the AIR CLEARANCE path is also partly along the surface of a material that is not material group I, the dielectric strength test is conducted only across the part(s) of the path that are through air.

8.9.1.14 Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION

Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION are obtained by doubling the values shown in Table 16 for one MEANS OF OPERATOR PROTECTION.

8.9.1.15 * CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS

CREEPAGE DISTANCES and AIR CLEARANCES needed to satisfy 8.5.5.1 for DEFIBRILLATION-PROOF APPLIED PARTS shall not be less than 4 mm.

NOTE In Table 12, which detail the spacing for PATIENT protection, the CREEPAGE DISTANCE and AIR CLEARANCE are both related to r.m.s. or d.c. WORKING VOLTAGES. In Table 13, Table 14 and Table 15, which detail the spacing for OPERATOR protection, the AIR CLEARANCE is related to peak or d.c. WORKING VOLTAGE and the CREEPAGE DISTANCE is related to r.m.s. or d.c. WORKING VOLTAGE.

Table 11 – Not used

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Table 12 – Minimum CREEPAGE DISTANCES and AIR CLEARANCES providing MEANS OF PATIENT PROTECTION

WORKING VOLTAGE V d.c. up to and including	WORKING VOLTAGE V r.m.s. up to and including	Spacing providing one MEANS OF PATIENT PROTECTION		Spacing providing two MEANS OF PATIENT PROTECTION	
		CREEPAGE DISTANCE mm	AIR CLEARANCE mm	CREEPAGE DISTANCE mm	AIR CLEARANCE mm
17	12	1,7	0,8	3,4	1,6
43	30	2	1	4	2
85	60	2,3	1,2	4,6	2,4
177	125	3	1,6	6	3,2
354	250	4	2,5	8	5
566	400	6	3,5	12	7
707	500	8	4,5	16	9
934	660	10,5	6	21	12
1 061	750	12	6,5	24	13
1 414	1 000	16	9	32	18
1 768	1 250	20	11,4	40	22,8
2 263	1 600	25	14,3	50	28,6
2 828	2 000	32	18,3	64	36,6
3 535	2 500	40	22,9	80	45,8
4 525	3 200	50	28,6	100	57,2
5 656	4 000	63	36,0	126	72,0
7 070	5 000	80	45,7	160	91,4
8 909	6 300	100	57,1	200	114,2
11 312	8 000	125	71,4	250	142,8
14 140	10 000	160	91,4	320	182,8

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Table 13 – Minimum AIR CLEARANCES providing MEANS OF OPERATOR PROTECTION from the MAINS PART

AIR CLEARANCE in mm

WORKING VOLTAGE up to and including		NOMINAL MAINS VOLTAGE ≤ 150 V (MAINS TRANSIENT VOLTAGE 1 500 V)				150 V < NOMINAL MAINS VOLTAGE ≤ 300 V (MAINS TRANSIENT VOLTAGE 2 500 V)		300 V < NOMINAL MAINS VOLTAGE ≤ 600 V (MAINS TRANSIENT VOLTAGE 4 000V)	
Voltage peak or d.c.	Voltage r.m.s (sinusoidal)	Pollution degrees 1 and 2		Pollution degree 3		Pollution degrees 1, 2 and 3		Pollution degrees 1, 2 and 3	
V	V	One MOOP	Two MOOP	One MOOP	Two MOOP	One MOOP	Two MOOP	One MOOP	Two MOOP
210	150	1,0	2,0	1,3	2,6	2,0	4,0	3,2	6,4
420	300	1 MOOP 2,0 2 MOOP 4,0						3,2	6,4
840	600	1 MOOP 3,2 2 MOOP 6,4							
1 400	1 000	1 MOOP 4,2 2 MOOP 6,4							
2 800	2 000	1 or 2 MOOP 8,4							
7 000	5 000	1 or 2 MOOP 17,5							
9 800	7 000	1 or 2 MOOP 25							
14 000	10 000	1 or 2 MOOP 37							
28 000	20 000	1 or 2 MOOP 80							
AIR CLEARANCES for WORKING VOLTAGES above 20 kV r.m.s. or 28 kV d.c. can be prescribed by particular standards if necessary.									
NOTE AIR CLEARNACES are a function of peak voltage in the circuit. The r.m.s. voltage column is provided for the special case where the voltage has a sinusoidal waveform.									

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Table 14 – Additional AIR CLEARANCES for insulation in MAINS PARTS with PEAK WORKING VOLTAGES exceeding the peak value of the NOMINAL MAINS VOLTAGE [a]
(see 8.9.1.10)

NOMINAL MAINS VOLTAGE ≤ 150 V r.m.s. or 210 V d.c.		150 V r.m.s. or 210 V dc < NOMINAL MAINS VOLTAGE ≤ 300 V r.m.s. or 420 V d.c.	Additional AIR CLEARANCE mm	
Pollution degrees 1 and 2	Pollution degree 3	Pollution degrees 1, 2 and 3		
PEAK WORKING VOLTAGE V	PEAK WORKING VOLTAGE V	PEAK WORKING VOLTAGE V	One MOOP	Two MOOP
210	210	420	0	0
298	294	493	0,1	0,2
386	379	567	0,2	0,4
474	463	640	0,3	0,6
562	547	713	0,4	0,8
650	632	787	0,5	1,0
738	715	860	0,6	1,2
826	800	933	0,7	1,4
914		1 006	0,8	1,6
1 002		1 080	0,9	1,8
1 090		1 153	1,0	2,0
		1 226	1,1	2,2
		1 300	1,2	2,4

[a] When using this table, select the appropriate column for the RATED MAINS VOLTAGE and pollution degree and choose the row in that column which covers the actual PEAK WORKING VOLTAGE. Read the additional AIR CLEARANCE required from the relevant right hand column (for one or two MEANS OF OPERATOR PROTECTION and add this to the minimum AIR CLEARANCE from Table 13 to give the total minimum AIR CLEARANCE.

NOTE For voltage values above the PEAK WORKING VOLTAGE values given in the table, linear extrapolation is permitted.

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Table 15 – Minimum AIR CLEARANCES for MEANS OF OPERATOR PROTECTION in SECONDARY CIRCUITS
(see 8.9.1.12)

AIR CLEARANCES in mm

WORKING VOLTAGE up to and including		Transient value for SECONDARY CIRCUIT ≤ 800 V (NOMINAL MAINS VOLTAGE ≤ 150 V)				Transient value for SECONDARY CIRCUIT ≤ 1 500 V (150 V < NOMINAL MAINS VOLTAGE ≤ 300 V)				Transient value for SECONDARY CIRCUIT ≤ 2 500 V (300 V < NOMINAL MAINS VOLTAGE ≤600 V)		Circuit not subject to transient overvoltages	
Voltage V peak or V d.c.	Voltage V r.m.s. (sinu-soidal)	Pollution degrees 1 and 2		Pollution degree 3		Pollution degrees 1 and 2		Pollution degree 3		Pollution degrees 1, 2 and 3		Pollution degrees 1 and 2 only	
		One MOOP	Two MOOP	One MOOP	Two MOOP	One MOOP	Two MOOP	One MOOP	Two MOOP	One MOOP	Two MOOP	One MOOP	Two MOOP
71	50	0,7	1,4	1,3	2,6	1,0	2,0	1,3	2,6	2,0	4,0	0,4	0,8
140	100	0,7	1,4	1,3	2,6	1,0	2,0	1,3	2,6	2,0	4,0	0,7	1,4
210	150	0,9	1,8	1,3	2,6	1,0	2,0	1,3	2,6	2,0	4,0	0,7	1,4
280	200	One MOOP 1,4; two MOOP 2,8								2,0	4,0	1,1	2,2
420	300	One MOOP 1,9; two MOOP 3,8								2,0	4,0	1,4	2,8
700	500	One MOOP 2,5; two MOOP 5,0											
840	600	One MOOP 3,2; two MOOP 5,0											
1 400	1 000	One MOOP 4,2; two MOOP 5,0											
2 800	2 000	One or two MOOP 8,4, but see 8.9.1.13											
7 000	5 000	One or two MOOP 17,5, but see 8.9.1.13											
9 800	7 000	One or two MOOP 25, but see 8.9.1.13											
14 000	10 000	One or two MOOP 37, but see 8.9.1.13											
28 000	20 000	One or two MOOP 80, but see 8.9.1.13											
42 000	30 000	One or two MOOP 130, but see 8.9.1.13											

NOTE AIR CLEARANCES are a function of peak voltage in the circuit. The r.m.s voltage column is provided for the special case where the voltage has a sinusoidal waveform.

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Table 16 – Minimum CREEPAGE DISTANCES providing MEANS OF OPERATOR PROTECTION [a]

CREEPAGE DISTANCE in mm

WORKING VOLTAGE V r.m.s or d.c.	Spacing for one MEANS OF OPERATOR PROTECTION						
	Pollution degree 1	Pollution degree 2			Pollution degree 3		
	Material group	Material group			Material group		
	I, II, IIIa, IIIb	I	II	IIIa or IIIb	I	II	IIIa or IIIb
25	Use the AIR CLEARANCE from the appropriate table	0,5	0.5	0,5	1,3	1,3	1,3
50		0,6	0,9	1,2	1,5	1,7	1,9
100		0,7	1,0	1,4	1,8	2,0	2,2
125		0,8	1,1	1,5	1,9	2,1	2,4
150		0,8	1,1	1,6	2,0	2,2	2,5
200		1,0	1,4	2,0	2,5	2,8	3,2
250		1,3	1,8	2,5	3,2	3,6	4,0
300		1,6	2,2	3,2	4,0	4,5	5,0
400		2,0	2,8	4,0	5,0	5,6	6,3
600		3,2	4,5	6,3	8,0	9,6	10,0
800		4.0	5,6	8,0	10,0	11,0	12,5
1 000		5,0	7,1	10,0	12,5	14,0	16,0

NOTE 1 Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION are obtained by doubling the values in this table.

NOTE 2 A CREEPAGE DISTANCE cannot be less than the required air clearance. See 8.9.1.4.

NOTE 3 For WORKING VOLTAGE values greater than 1 000 V, refer to Table A.2.

[a] CREEPAGE DISTANCES within this table apply to all situations.

8.9.2 * Application

a) * For insulation in the MAINS PART between parts of opposite polarity, the minimum CREEPAGE DISTANCES and AIR CLEARANCES are not required if short circuiting of each single one of these CREEPAGE DISTANCES and AIR CLEARANCES in turn does not result in a HAZARDOUS SITUATION described in 13.1.

b) The contribution to the CREEPAGE DISTANCES of any groove or air gap less than 1 mm wide shall be limited to its width (see Figure 23 to Figure 31 [inclusive]).

c) If AIR CLEARANCE provides a MEANS OF PROTECTION, the relative positioning shall be such that the relevant parts are rigid and located by moulding or the design shall be otherwise such that there is no reduction of a distance below the specified value by deformation or movement of the parts.

Where limited movement of one of the relevant parts is normal or likely, this shall be taken into account when computing the minimum AIR CLEARANCE.

8.9.3 * Spaces filled by insulating compound

8.9.3.1 General

Where distances between conductive parts are filled with insulating compound, including where insulation is reliably cemented together with insulating compound, so that AIR CLEARANCES and CREEPAGE DISTANCES do not exist, only the requirements for solid insulation apply.

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NOTE Examples of such treatment include potting, encapsulation and vacuum impregnation, components or subassemblies that are treated with an insulating compound that fills voids; and internal insulation between adjacent tracks on one layer of a multi-layer printed board.

Compliance is checked by inspection, measurement and test of samples. Requirements for CREEPAGE DISTANCES and AIR CLEARANCES do not apply if samples pass the thermal cycling, humidity preconditioning and dielectric strength tests specified in either 8.9.3.2 and 8.9.3.4 or 8.9.3.3 and 8.9.3.4.

8.9.3.2 Insulating compound forming solid insulation between conductive parts

For situations where insulating compound forms solid insulation between conductive parts, a single finished sample is tested. The sample is subjected to the thermal cycling PROCEDURE as specified in 8.9.3.4, followed by humidity preconditioning according to 5.7 except for 48 hours only, followed by a dielectric strength test according to 8.8.3 except that the test voltage is multiplied by 1,6. The tests are followed by inspection, including sectioning, and measurement. Cracks or voids in the insulating compound such as would affect the homogeneity of the material constitute a failure.

8.9.3.3 Insulating compound forming a cemented joint with other insulating parts

For situations where insulating compound forms a cemented joint with other insulating parts, the reliability of the joint is checked by testing three samples. If a winding of solvent-based enamelled wire is used, it is replaced for the test by a metal foil or by a few turns of bare wire, placed close to the cemented joint. The three samples are then tested as follows.

– *One of the samples is subjected to the thermal cycling PROCEDURE as specified in 8.9.3.4. Immediately after the last period at highest temperature during thermal cycling it is subjected to a dielectric strength test according to 8.8.3 except that the test voltage is multiplied by 1,6;*

– *The other two samples are subjected to humidity preconditioning according to 5.7 except for 48 hours only, followed by a dielectric strength test according to 8.8.3 except that the test voltage is multiplied by 1,6.*

8.9.3.4 Thermal cycling

The sample is subjected 10 times to the following sequence of temperature cycles:

68 h at T_1 ± 2 °C;

1 h at 25 °C ± 2 °C;

2 h at 0 °C ± 2 °C;

not less than 1 h at 25 °C ± 2 °C,

where T_1 is the higher of

– *10 °C above the maximum temperature of the relevant part as determined according to 11.1.1, or*

– *85 °C.*

However, the 10 °C margin is not added if the temperature is measured by an embedded thermocouple.

The period of time taken for the transition from one temperature to another is not specified, but the transition is permitted to be gradual.

8.9.4 * Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES

Compliance is checked by measurement taking into account the rules in Figure 22 to Figure 31 *(inclusive). In each figure, the dashed line (– – –) represents* AIR CLEARANCE *and the shaded bar (▒▒▒▒▒▒▒▒▒▒▒▒▒▒▒▒)represents* CREEPAGE DISTANCE.

The minimum spacing (X) for grooves transverse to the CREEPAGE DISTANCE in Figure 23 to Figure 25 and Figure 27 to Figure 31 (inclusive) that are considered a MEANS OF OPERATOR

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PROTECTION may be adjusted based on pollution degree if the minimum AIR CLEARANCE is 3 mm or more. The minimum width of the groove is:

- *0,25 mm for pollution degree 1*
- *1,0 mm for pollution degree 2*
- *1,5 mm for pollution degree 3*

If the specified minimum AIR CLEARANCE is less than 3 mm, the minimum spacing (X) for grooves transverse to the CREEPAGE DISTANCE is the lesser of:

- *the relevant value specified in the previous paragraph, or*
- *one third of the specified minimum AIR CLEARANCE.*

The minimum spacing (X) for a groove transverse to a CREEPAGE DISTANCE that is considered a MEANS OF PATIENT PROTECTION is 1 mm for pollution degree 1 and pollution degree 2, and 1,5 mm for pollution degree 3.

Any corner with included angle less than 80° is assumed to be bridged with an insulating link of 1 mm moved into the least favourable position (see Figure 25).

Where the distance across the top of a groove is 1 mm or more, no CREEPAGE DISTANCE exists across the air space (see Figure 24).

CREEPAGE DISTANCES and AIR CLEARANCES between parts moving relative to each other are measured with the parts in their least favourable positions.

Computed CREEPAGE DISTANCE is never less than measured AIR CLEARANCE.

Coatings of varnish, enamel or oxide are ignored. Coverings of any insulating material, however, are considered as insulation, if the covering is equivalent to a sheet of insulating material of equal thickness with respect to its electrical, thermal and mechanical properties.

If CREEPAGE DISTANCES or AIR CLEARANCES for one or two MEANS OF PROTECTION are interrupted by one or more floating conductive parts, the minimum values specified in Table 12 to Table 16 (inclusive) apply to the sum of the sections, except that distances less than 1 mm are not taken into consideration.

If there are grooves transverse to the CREEPAGE DISTANCE, the wall of the groove is counted as CREEPAGE DISTANCE only if the width of the groove is more than 1 mm (see Figure 24). In all other cases the groove is neglected.

In the case of a barrier placed on the surface of insulation or held in a recess, the CREEPAGE DISTANCES are measured over the barrier only if the latter is so affixed that dust and moisture cannot penetrate into the joint or recess.

For ME EQUIPMENT provided with an APPLIANCE INLET, the measurements are made with an appropriate connector inserted. For other ME EQUIPMENT incorporating POWER SUPPLY CORDS, they are made with supply conductors of the largest cross-sectional area specified by the MANUFACTURER and also without conductors.

Movable parts are placed in the least favourable position; nuts and screws with non-circular heads are tightened in the least favourable position.

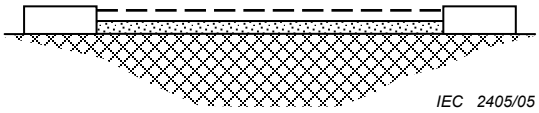
CREEPAGE DISTANCES and AIR CLEARANCES through slots or openings in external parts are measured to the standard test finger of Figure 6. If necessary, a force is applied to any point on bare conductors and to the outside of metal ENCLOSURES in an endeavour to reduce the CREEPAGE DISTANCES and AIR CLEARANCES while taking the measurements.

The force is applied by means of a standard test finger having a tip as shown in Figure 6 and has a value of:

2 N for bare conductors;
30 N for ENCLOSURES.

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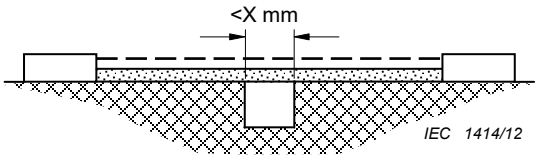
CREEPAGE DISTANCE and AIR CLEARANCES are measured after use of the test hook according to 5.9.2.2, if relevant.



Condition: Path under consideration is a flat surface.

Rule: CREEPAGE DISTANCE and AIR CLEARANCE are measured directly across the surface.

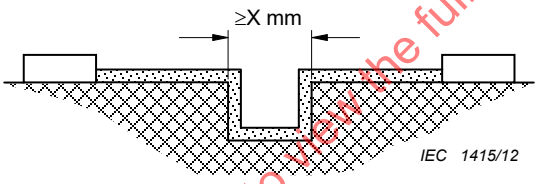
Figure 22 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 1



Condition: Path under consideration includes a parallel- or converging-sided groove of any depth with a width less than X mm.

Rule: CREEPAGE DISTANCE and AIR CLEARANCE are measured directly across the groove as shown.

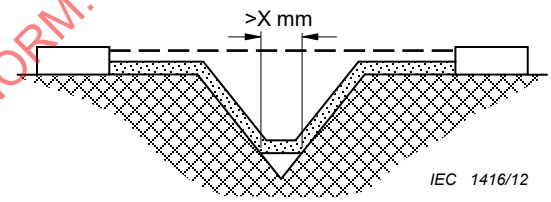
Figure 23 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 2



Condition: Path under consideration includes a parallel-sided groove of any depth and equal to or more than X mm.

Rule: AIR CLEARANCE is the "line of sight" distance. CREEPAGE DISTANCE path follows the contour of the groove.

Figure 24 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 3

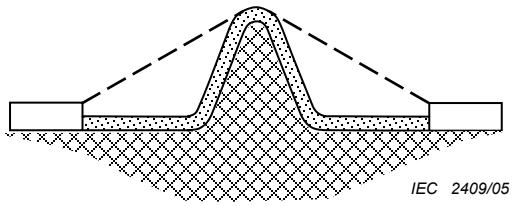


Condition: Path under consideration includes a V-shaped groove with a width greater than X mm and an internal angle of less than 80°.

Rule: AIR CLEARANCE is the "line of sight" distance. CREEPAGE DISTANCE path follows the contour of the groove but "short circuits" the bottom of the groove by a X mm link.

Figure 25 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 4

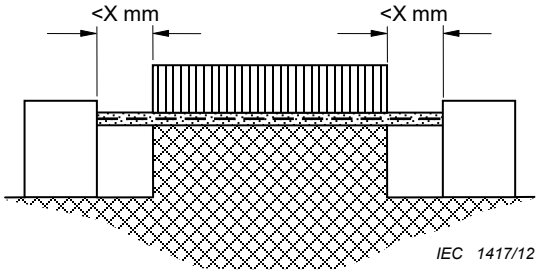
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Condition: Path under consideration includes a rib.

Rule: AIR CLEARANCE is the shortest direct air path over the top of the rib. CREEPAGE DISTANCE path follows the contour of the rib.

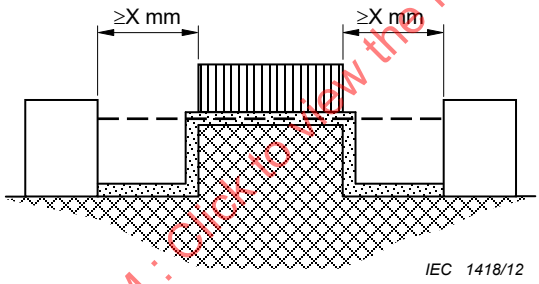
Figure 26 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 5



Condition: Path under consideration includes an uncemented joint (see 8.9.3) with grooves less than X mm wide on each side.

Rule: CREEPAGE DISTANCE and AIR CLEARANCE path are the "line of sight" distance shown.

Figure 27 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 6

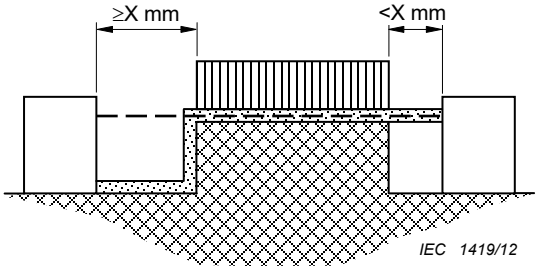


Condition: Path under consideration includes an uncemented joint (see 8.9.3) with grooves equal to or more that X mm wide on each side.

Rule: AIR CLEARANCE is the "line of sight" distance. CREEPAGE DISTANCE path follows the contour of the groove.

Figure 28 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 7

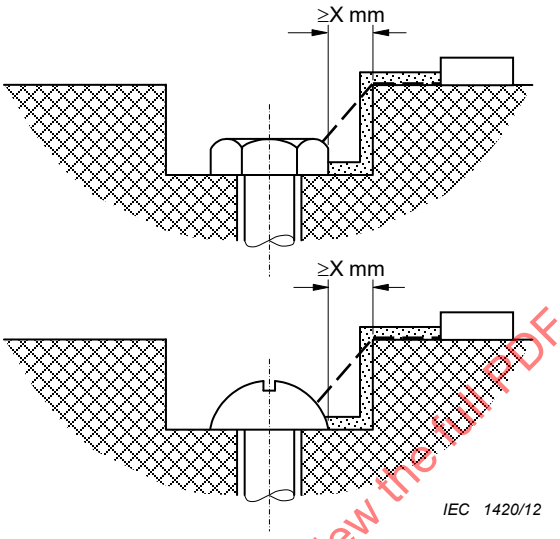
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Condition: Path under consideration includes an uncemented joint (see 8.9.3) with a groove on one side less than X mm wide and the groove on the other side equal to or more than X mm wide.

Rule: AIR CLEARANCE and CREEPAGE DISTANCE are as shown.

Figure 29 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 8

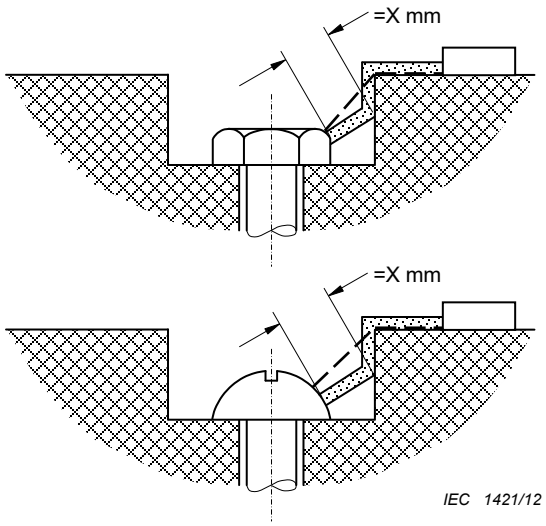


Condition: Gap between head of screw and wall of recess wide enough to be taken into account.

Rule: The AIR CLEARNACE is the shortest distance to any point on the head of the screw. CREEPAGE DISTANCE path follows the surface.

Figure 30 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 9

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Condition: Gap between head of screw and wall of recess too narrow to be taken into account.

Rule: Measurement of CREEPAGE DISTANCE is from screw to wall at any point where the distance is equal to X mm. The AIR CLEARNACE is the shortest distance to any point on the head of the screw.

Figure 31 – CREEPAGE DISTANCE and AIR CLEARANCE – Example 10

8.10 Components and wiring

8.10.1 * Fixing of components

Components of ME EQUIPMENT, the unwanted movement of which could result in an unacceptable RISK, shall be mounted securely to prevent such movement.

Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE.

8.10.2 * Fixing of wiring

Conductors and connectors of ME EQUIPMENT shall be so secured or insulated that accidental detachment shall not result in a HAZARDOUS SITUATION. They are not considered to be adequately secured if on breaking free at their joint and moving about their support point they are capable of touching parts resulting in a HAZARDOUS SITUATION described in 13.1.

Breaking free of one means of mechanical restraint shall be considered a SINGLE FAULT CONDITION.

Stranded conductors shall not be solder-coated if they are affixed by any clamping means and poor contact could result in a HAZARDOUS SITUATION described in 13.1.

Compliance is checked by inspection of the ME EQUIPMENT.

8.10.3 Connections between different parts of ME EQUIPMENT

Flexible cords detachable without the use of a TOOL that are used for interconnection of different parts of ME EQUIPMENT shall be provided with means for connection such that compliance of metal ACCESSIBLE PARTS with 8.4 is not compromised when a connection is loosened or broken due to the disengagement of one of the connecting means.

Compliance is checked by inspection and measurement and, if necessary, by a test with the standard test finger according to 5.9.2.1.

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8.10.4 * Cord-connected HAND-HELD parts and cord-connected foot-operated control devices (see also 15.4.7)

8.10.4.1 Limitation of operating voltages

Cord-connected HAND-HELD and foot-operated control devices of ME EQUIPMENT and their associated connection cords shall contain only conductors and components operating at voltages not exceeding 42,4 V peak a.c. or 60 V d.c. in circuits isolated from the MAINS PART by two MEANS OF PROTECTION. The d.c. limit of 60 V applies to d.c. with not more than 10 % peak-to-peak ripple. If the ripple exceeds that amount, the 42,4 V peak limit applies.

Compliance is checked by inspection and, if necessary, voltage measurements.

8.10.4.2 Connection cords

The connection and anchorage at both ends of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT shall comply with the requirements specified for POWER SUPPLY CORDS in 8.11.3, if breaking free or shorting between the conductors could result in a HAZARDOUS SITUATION described in 13.1. This requirement also applies to other HAND-HELD parts if disturbance or breaking of one or more of the connections could result in a HAZARDOUS SITUATION described in 13.1.

Compliance is checked by performance of the tests of 8.11.3.

8.10.5 * Mechanical protection of wiring

a) Internal cables and wiring shall be adequately protected against contact with a moving part or from friction at sharp corners and edges where damage to insulation could result in a HAZARDOUS SITUATION described in 13.1.

b) ME EQUIPMENT shall be so designed that wiring, cord forms or components are not likely to be damaged during assembly or the opening or closing of ACCESS COVERS where such damage could result in a HAZARDOUS SITUATION described in 13.1.

Compliance is checked by inspection and, where appropriate, by manual test.

8.10.6 Guiding rollers for insulated conductors

Guiding rollers of insulated conductors of ME EQUIPMENT shall be constructed in such a manner that movable insulated conductors in NORMAL USE are not bent round a radius of less than five times the outer diameter of the lead concerned.

Compliance is checked by inspection and measurement of the relevant dimensions.

8.10.7 * Insulation of internal wiring

a) If insulating sleeving is needed on internal wiring of ME EQUIPMENT, it shall be adequately secured. Sleeving that can only be removed by breaking or cutting or that is secured at both ends may be used to satisfy this requirement.

b) Inside ME EQUIPMENT the sheath of a flexible cord shall not be used as a MEANS OF PROTECTION if it is subject to mechanical or thermal stresses outside its RATED characteristics.

c) Insulated conductors of ME EQUIPMENT that in NORMAL USE are subject to temperatures exceeding 70 °C shall have insulation of heat-resistant material if compliance with this standard is likely to be impaired by deterioration of the insulation.

Compliance is checked by inspection and, if necessary, by special tests. Temperatures are determined as indicated in 11.1.

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8.11 MAINS PARTS, components and layout

8.11.1 Isolation from the SUPPLY MAINS

a) * ME EQUIPMENT shall have means to isolate its circuits electrically from the SUPPLY MAINS on all poles simultaneously.

PERMANENTLY INSTALLED ME EQUIPMENT connected to a polyphase SUPPLY MAINS may be provided with a device that does not interrupt the neutral conductor, provided that local installation conditions are such that in NORMAL CONDITION the voltage on the neutral conductor can be expected not to exceed the limits specified in 8.4.2 c).

For PERMANENTLY INSTALLED ME EQUIPMENT, the means provided to isolate its circuits electrically from the SUPPLY MAINS shall be capable of being locked in the off position if:

– reconnection would result in a HAZARDOUS SITUATION; or

– any OPERATOR including SERVICE PERSONNEL is unable to view the means of isolation from their intended position.

The locking mechanism may be in a SUPPLY MAINS switch provided by the RESPONSIBLE ORGANIZATION.

The requirements for the isolation device shall be specified in the ACCOMPANYING DOCUMENTS.

b) Means for isolation either shall be incorporated in ME EQUIPMENT or, if external, shall be described in the technical description (see 7.9.3.1).

c) * A SUPPLY MAINS switch that is used to comply with 8.11.1 a) shall comply with the CREEPAGE DISTANCES and AIR CLEARANCES as specified in IEC 61058-1 for a MAINS TRANSIENT VOLTAGE of 4 kV.

NOTE Table 22 in IEC 61058-1:2000 specifies different values for contact separation depending on the MAINS TRANSIENT VOLTAGE , which is referred to in that table as the “rated impulse withstand voltage.”

d) A SUPPLY MAINS switch shall not be incorporated in a POWER SUPPLY CORD or any other external, flexible lead.

e) The actuator of a SUPPLY MAINS switch that is used to comply with 8.11.1 a) shall comply with IEC 60447.

f) In non-PERMANENTLY INSTALLED ME EQUIPMENT that has no SUPPLY MAINS switch, a suitable plug device used to isolate ME EQUIPMENT from the SUPPLY MAINS shall be considered as complying with the requirements of 8.11.1 a). An APPLIANCE COUPLER or a flexible cord with a MAINS PLUG may be used.

g) A fuse or a semiconductor device shall not be used as an isolating means in the sense of this subclause.

h) * ME EQUIPMENT shall not include a device that causes disconnection of the ME EQUIPMENT from the SUPPLY MAINS by producing a short circuit that results in operation of an over-current protection device.

i) * Any part within the ENCLOSURE of ME EQUIPMENT with a circuit voltage exceeding 42,4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device that is accessible at all times shall be protected against being touched even after opening of the ENCLOSURE by an additional covering or, in the case of a spatially separated arrangement, shall be marked clearly as exceeding the permitted voltage for parts that can be touched. The use of the symbol ISO 7000-0434 (see Table D.1, symbol 10) is not sufficient. A warning notice on the outside of the ME EQUIPMENT may be used.

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Compliance is checked by inspection.

For a part that cannot be disconnected from the supply by an external switch or a plug device that is accessible at all times, compliance is checked by inspection of the required cover or warning notice (if present) and, if necessary, by application of the standard test finger of Figure 6.

8.11.2 * MULTIPLE SOCKET-OUTLETS

MULTIPLE SOCKET-OUTLETS that are integral with ME EQUIPMENT shall comply with the requirements of 16.2 d), second dash, and 16.9.2.1.

Compliance is checked by inspection.

8.11.3 POWER SUPPLY CORDS

8.11.3.1 Application

The MAINS PLUG of ME EQUIPMENT shall not be fitted with more than one POWER SUPPLY CORD.

Compliance is checked by inspection.

8.11.3.2 Types

Any POWER SUPPLY CORD of ME EQUIPMENT shall be not less robust than ordinary tough rubber-sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, designation 53).

A polyvinyl chloride insulated POWER SUPPLY CORD shall not be used for ME EQUIPMENT having external metal parts with a temperature exceeding 75 °C and which can be touched in NORMAL USE by the cord, unless it is RATED for that temperature. See also Table 22.

Compliance is checked by inspection and measurement.

8.11.3.3 Cross-sectional area of POWER SUPPLY CORD conductors

The NOMINAL cross-sectional area of conductors of any POWER SUPPLY CORD of ME EQUIPMENT shall be not less than that shown in Table 17.

Compliance is checked by inspection.

Table 17 – NOMINAL cross-sectional area of conductors of a POWER SUPPLY CORD

RATED current (*I*) of ME EQUIPMENT A	NOMINAL cross-sectional area mm² Cu
$I \leq 6$	0,75
$6 < I \leq 10$	1
$10< I \leq 16$	1,5
$16< I \leq 25$	2,5
$25< I \leq 32$	4
$32< I \leq 40$	6
$40< I \leq 63$	10

8.11.3.4 * APPLIANCE COUPLERS

APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6.

Compliance is checked by inspection of the documentation demonstrating that the APPLIANCE COUPLER conforms to the requirements of IEC 60320-1.

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8.11.3.5 * Cord anchorage

a) The conductors of a POWER SUPPLY CORD shall be relieved from strain, including twisting, and the insulation of the conductors shall be protected from abrasion at the point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage.

b) If a total insulation failure of the POWER SUPPLY CORD could cause conductive ACCESSIBLE PARTS that are not PROTECTIVELY EARTHED to exceed the limits specified in 8.4, the cord anchorage of a POWER SUPPLY CORD shall be made:

- of insulating material, or
- of metal, insulated from conductive ACCESSIBLE PARTS not PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or
- of metal provided with an insulating lining, which shall be affixed to the cord anchorage, unless it is a flexible bushing that forms part of the cord guard specified in 8.11.3.6, and which shall comply with the requirements for one MEANS OF PROTECTION.

c) The cord anchorage of a POWER SUPPLY CORD shall be so designed that the cord is not clamped by a screw that bears directly on the cord insulation.

d) Screws, if any, that have to be operated when replacing the POWER SUPPLY CORD shall not serve to fix any component other than parts of the cord anchorage.

e) Conductors of the POWER SUPPLY CORD shall be so arranged that if the cord anchorage fails the PROTECTIVE EARTH CONDUCTOR is not subject to strain as long as the phase conductors are in contact with their terminals.

f) The cord anchorage shall prevent the POWER SUPPLY CORD from being pushed into the ME EQUIPMENT or MAINS CONNECTOR.

Compliance is checked by inspection and by the following tests:

ME EQUIPMENT, if designed for a POWER SUPPLY CORD, is tested with the cord supplied by the MANUFACTURER.

The POWER SUPPLY CORD conductors are, if possible, disconnected from the terminals or from the MAINS CONNECTOR.

The cord is subjected 25 times to a pull on the sheath of the value shown in Table 18. The pulls are applied in the most unfavourable direction without jerks, each time for 1 s.

Immediately afterwards, the cord is subjected for 1 min to a torque of the value shown in Table 18.

Table 18 – Testing of cord anchorages

Mass (*m*) of ME EQUIPMENT kg	Pull N	Torque Nm
$m \leq 1$	30	0,1
$1 < m \leq 4$	60	0,25
$m > 4$	100	0,35

A cord anchorage that allows the cord sheath to be longitudinally displaced by more than 2 mm or the conductor ends to move over a distance of more than 1 mm from their normally connected position is considered to fail.

CREEPAGE DISTANCES and AIR CLEARANCES that are reduced below the values specified in 8.9 constitutes a failure.

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Attempt to push the cord into the ME EQUIPMENT or the MAINS CONNECTOR. If the cord can be pushed into the ME EQUIPMENT or the MAINS CONNECTOR to such an extent that the cord or internal parts are damaged, the cord anchorage is considered to fail.

8.11.3.6 * Cord guards

POWER SUPPLY CORDS of other than STATIONARY ME EQUIPMENT shall be protected against excessive bending at the inlet opening of the equipment or of the MAINS CONNECTOR by means of a cord guard of insulating material or by means of an appropriately shaped opening in the ME EQUIPMENT.

Compliance is checked by inspection and by either the test described in IEC 60335-1:2001, subclause 25.14 or the following test. An arrangement that passes either test is considered to comply with the requirement.

ME EQUIPMENT having a cord guard or opening is so placed that the axis of the cord guard, where the cord leaves it, projects at an angle of 45° when the cord is free from stress. A mass equal to 10 x D^2 gram is then attached to the free end of the cord, where D is the overall diameter of, or for flat cords, the minor overall dimension of the POWER SUPPLY CORD in millimetres.

If the cord guard is of temperature-sensitive material, the test is made at 23 °C ± 2 °C.

Flat cords are bent in the plane of least resistance.

If the radius of curvature of the cord, immediately after the mass has been attached, is anywhere less than 1,5 x D, the cord guard is considered to fail.

8.11.4 MAINS TERMINAL DEVICES

8.11.4.1 * General requirements for MAINS TERMINAL DEVICES

PERMANENTLY INSTALLED ME EQUIPMENT and ME EQUIPMENT having a non-DETACHABLE POWER SUPPLY CORD that is replaceable by SERVICE PERSONNEL shall be provided with MAINS TERMINAL DEVICES that ensure reliable connection.

Reliance shall not be placed upon the terminals alone to maintain the conductors in position, unless barriers are provided such that CREEPAGE DISTANCES and AIR CLEARANCES that serve as a MEANS OF PROTECTION cannot be reduced to less than the values specified in 8.9, if any conductor breaks away. See also 8.10.2.

Terminals of components other than terminal blocks may be used as terminals intended for external conductors if they comply with the requirements of this subclause and are properly marked according to 7.3.7.

Screws and nuts that clamp external conductors shall not serve to fix any other component, except that they may also clamp internal conductors if these are so arranged that they are unlikely to be displaced when fitting the supply conductors.

Compliance is checked by inspection.

8.11.4.2 Arrangement of MAINS TERMINAL DEVICES

a) * For ME EQUIPMENT with rewirable cords where terminals are provided for the connection of external cords or POWER SUPPLY CORDS, these terminals together with any PROTECTIVE EARTH TERMINAL shall be closely grouped, so as to provide a convenient means of connection.

   Compliance is checked by inspection.

b) For details of PROTECTIVE EARTH CONDUCTOR connections, see 8.6.

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c) For marking of MAINS TERMINAL DEVICES, see 7.3.

d) MAINS TERMINAL DEVICES shall not be accessible without the use of a TOOL.

Compliance is checked by inspection.

e) MAINS TERMINAL DEVICES shall be so located or shielded that, if a wire of a stranded conductor escapes when the conductors are fitted, short circuiting a MEANS OF PROTECTION is unlikely.

Compliance is checked by inspection and, if necessary, by the following test:

The end of a flexible conductor having the NOMINAL cross-sectional area specified in Table 17 is stripped of its insulation for a length of 8 mm.

A single wire of the stranded conductor is left free and the rest of the conductor is secured to the terminal.

The free wire is bent in every possible direction without pulling back the insulating sheath and without making sharp bends around partitions.

Contact between the free wire and any other part such that a MEANS OF PROTECTION is short circuited constitutes a failure.

8.11.4.3 Fixing of mains terminals

Terminals shall be FIXED such that, when the means for clamping the conductors are tightened or loosened, the internal wiring is not subjected to stress and CREEPAGE DISTANCES and AIR CLEARANCES are not reduced below the values specified in 8.9.

Compliance is checked by inspection and by measurement after fastening and loosening a conductor of the largest cross-sectional area specified 10 times.

8.11.4.4 * Connections to mains terminals

Terminals with clamping means for a rewirable flexible cord shall not require special preparation of the conductors in order to effect correct connection, and they shall be so designed or placed that the conductors are not damaged and cannot slip out when the clamping means are tightened. See also 8.10.2.

Compliance is checked by inspection of the terminals and of the conductors after the test of 8.11.3.4.

8.11.4.5 Accessibility of the connection

The space inside ME EQUIPMENT designed for FIXED wiring or a rewirable POWER SUPPLY CORD shall be adequate to allow conductors to be easily introduced and connected, and covers, if any, to be fitted without damage to the conductors or their insulation. It shall be possible to check that the conductors are correctly connected and positioned before the ACCESS COVER is fitted. See also 8.10.5.

Compliance is checked by inspection and by an installation test.

8.11.5 * Mains fuses and OVER-CURRENT RELEASES

A fuse or OVER-CURRENT RELEASE shall be provided in each supply lead for CLASS I ME EQUIPMENT and for CLASS II ME EQUIPMENT having a functional earth connection according to 8.6.9, and in at least one supply lead for other single-phase CLASS II ME EQUIPMENT, except that:

– for PERMANENTLY INSTALLED ME EQUIPMENT, the neutral conductor shall not be fused;

– if examination shows that two MEANS OF PROTECTION are present between all parts of opposite polarity within the MAINS PART, and between all parts of the MAINS PART and earth,

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then the fuses or OVER-CURRENT RELEASES may be omitted. These insulation requirements shall be continued up to and within any component. The effect of short-circuit fault conditions in other circuits shall be VERIFIED before eliminating fuses or OVER-CURRENT RELEASES.

A PROTECTIVE EARTH CONDUCTOR shall not incorporate a fuse or OVER-CURRENT RELEASE.

Protective devices shall have adequate breaking capacity to interrupt the maximum fault current (including short-circuit current) which can flow.

NOTE If fuses complying with IEC 60127[10)] are used and the prospective short-circuit current exceeds 35 A or 10 times the current rating of the fuse, whichever is greater, the fuses should have high breaking capacity (1 500 A).

Justification for omission of fuses or OVER-CURRENT RELEASES shall be documented.

Compliance is checked by inspection of the ME EQUIPMENT and the MANUFACTURER'S documentation.

8.11.6 Internal wiring of the MAINS PART

a) Internal wiring in a MAINS PART between the MAINS TERMINAL DEVICE or the APPLIANCE INLET and the protective devices shall have a cross-sectional area not less than the minimum required for the POWER SUPPLY CORD as specified in 8.11.3.3.

Compliance is checked by inspection.

b) The cross-sectional area of other wiring in the MAINS PART and the sizes of tracks on printed wiring circuits of ME EQUIPMENT shall be sufficient to prevent fire in case of possible fault currents.

When necessary, compliance is checked by connecting the ME EQUIPMENT to a specified SUPPLY MAINS from which the most unfavourable short-circuit current expected can be drawn in the event of a fault in the MAINS PART. Subsequently, a fault in a single insulation in the MAINS PART is simulated so that the fault current is the least favourable. The occurrence of any HAZARDOUS SITUATIONS listed in 13.1.2 constitutes a failure.

9 * Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

9.1 MECHANICAL HAZARDS of ME EQUIPMENT

For general requirements on design and manufacture of ME EQUIPMENT, see Clause 4 and 15.3.

Table 19 identifies the subclauses that address the MECHANICAL HAZARDS.

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10) IEC 60127 series, *Miniature fuses*

Table 19 – MECHANICAL HAZARDS covered by this clause

MECHANICAL HAZARD	Covered by subclause
Crushing HAZARD	9.2, 9.4 and 9.8
Shearing HAZARD	9.2 and 9.8
Cutting or severing HAZARD	9.2, 9.3 and 9.8
Entanglement HAZARD	9.2
Trapping HAZARD	9.2
Stabbing or puncturing HAZARD	9.2, 9.3 and 9.8
Friction or abrasion HAZARD	9.2 and 9.3
Expelled parts HAZARD	9.5
High pressure fluid ejection HAZARD	9.7
Falling HAZARD	9.8
Instability HAZARD	9.4
Impact HAZARD	9.2 and 9.8
Moving and positioning of PATIENT	9.2 and 9.4
Vibration and noise	9.6

9.2 * MECHANICAL HAZARDS associated with moving parts

9.2.1 * General

ME EQUIPMENT with moving parts shall be designed, built and laid out so that, when PROPERLY INSTALLED and used as indicated in the ACCOMPANYING DOCUMENTS or under reasonably foreseeable misuse, the RISKS associated with those moving parts are reduced to an acceptable level.

The RISK from contact with the moving parts shall be reduced to an acceptable level by use of RISK CONTROL measures, bearing in mind the ease of access, the ME EQUIPMENT'S function, the shape of the parts, the energy and speed of the motion and the benefits to the PATIENT.

The RESIDUAL RISK associated with moving parts is considered acceptable if exposure is needed for the ME EQUIPMENT to perform its intended function, and RISK CONTROL measures have been implemented (e.g. warnings).

NOTE 1 Requirements for parts subject to wear are found in 15.2.

NOTE 2 See ISO 14971:2007, subclauses 6.2 and 6.5.

9.2.2 TRAPPING ZONE

9.2.2.1 General

Where feasible, ME EQUIPMENT with a TRAPPING ZONE shall comply with the requirements of one or more of the following:

– gaps as specified in 9.2.2.2; or

– safe distances as specified in 9.2.2.3; or

– GUARDS and other RISK CONTROL measures as specified in 9.2.2.4; or

– continuous activation as specified in 9.2.2.5.

If implementation of the above RISK CONTROL measures would be inconsistent with the INTENDED USE of the ME EQUIPMENT or the ME SYSTEM, control of the relevant motion shall comply with 9.2.2.6.

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9.2.2.2 Gaps

A TRAPPING ZONE is considered not to present a MECHANICAL HAZARD if the gaps of the TRAPPING ZONE comply with the dimensions specified in Table 20.

NOTE In general the values for adults should be used. However, in the case of devices specifically designed for use with children, the dimensions given for children should be applied.

9.2.2.3 Safe distances

A TRAPPING ZONE is considered not to present a MECHANICAL HAZARD if the distances separating the OPERATOR, PATIENT and other persons from the TRAPPING ZONES exceed the values specified in ISO:13857:2008. The distances are measured from the expected positions of the OPERATOR, PATIENT and other persons near the ME EQUIPMENT in NORMAL USE or under reasonably foreseeable misuse.

9.2.2.4 * GUARDS and other RISK CONTROL measures

9.2.2.4.1 Access to TRAPPING ZONES

A TRAPPING ZONE is considered not to present a MECHANICAL HAZARD if GUARDS or other RISK CONTROL measures (e.g. electro-mechanical):

– are of robust construction;

– are not easy to bypass or render non-operational;

– do not introduce any additional unacceptable RISK.

NOTE RISK CONTROL measures (e.g. electro-mechanical) addressed by this subclause are intended to include collision detection or collision avoidance systems, such as those employing light barrier(s) and similar feedback control(s).

Compliance is checked by the applicable tests of 15.3 for ENCLOSURES.

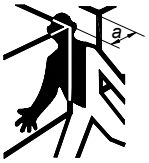
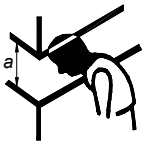
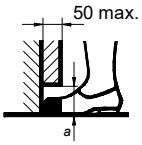
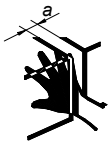
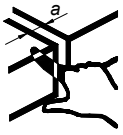
9.2.2.4.2 FIXED GUARDS

FIXED GUARDS shall be securely held in place by systems that cannot be dismantled without the use of a TOOL.

Compliance is checked by inspection.

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Table 20 – Acceptable gaps [a]

Part of body	Adult gap *a* mm	Children gap *a* mm	Illustration
Body	>500	>500	
Head	>300 or <120	>300 or <60	
Leg	>180	>180	
Foot	>120 or <35	>120 or <25	
Toes	>50	>50	
Arm	>120	>120	
Hand, wrist, fist	>100	>100	
Finger	> 25 or < 8	> 25 or < 4	
[a] The values in this table are taken from ISO13857:2008.			

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9.2.2.4.3 Movable GUARDS

Movable GUARDS that can be opened without the use of a TOOL:

– shall remain attached to the ME EQUIPMENT when the GUARD is open;

– shall be associated with an interlock device that prevents the relevant moving parts from starting to move while the TRAPPING ZONE is accessible and stops movement when the GUARD is opened;

– shall be so designed that the absence or failure of one of their components prevents starting, and stops moving parts.

Compliance is checked by inspection of the ME EQUIPMENT and by conducting any applicable tests.

9.2.2.4.4 Other RISK CONTROL measures

Protective measures shall be designed and incorporated into the control system so that:

– moving parts cannot start to move while they are in the reach of persons;

Other RISK CONTROL measures (e.g. electro-mechanical) shall be designed and incorporated into the control system so that:

– once the ME EQUIPMENT has started to move, if the TRAPPING ZONE is reached, system movement shall stop; and

– if the RISK CONTROL measure is defeated in a SINGLE FAULT CONDITION, a second RISK CONTROL measure shall be provided, such as one or more emergency stopping device(s) (see 9.2.4), or the ME EQUIPMENT shall otherwise be SINGLE FAULT SAFE (see 4.7).

Compliance is checked by the following as necessary:

– *inspection of the ME EQUIPMENT;*

– *examination of the construction and circuits;*

– *conducting any applicable tests including, if necessary, tests under SINGLE FAULT CONDITION.*

9.2.2.5 * Continuous activation

Where it is impractical to make the TRAPPING ZONE inaccessible, continuous activation may be used as a RISK CONTROL measure.

A TRAPPING ZONE is not considered to present a MECHANICAL HAZARD if:

a) the movement is in the OPERATOR'S field of view;

Compliance is checked by inspection.

b) movement of the ME EQUIPMENT or its parts is possible only by the continuous activation of the control by the OPERATOR as long as the response of the OPERATOR to deactivate the device can be relied on to prevent HARM;

NOTE Manually operated movements are also considered to comply with this clause, as long as mass and velocity allow adequate control of positioning without causing an unacceptable RISK.

Compliance is checked by inspection.

c) the continuous activation system is defeated in a SINGLE FAULT CONDITION, then a second RISK CONTROL measure shall be provided, such as one or more emergency stopping device(s) (see 9.2.4), or the ME EQUIPMENT shall otherwise be SINGLE FAULT SAFE (see 4.7).

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Compliance is checked by the following as necessary:

– *inspection of the ME EQUIPMENT;*

– *examination of the construction and circuits;*

– *conducting any applicable tests including, if necessary, tests under SINGLE FAULT CONDITION.*

9.2.2.6 * Speed of movement(s)

The speed of movement(s) that position parts of the ME EQUIPMENT or PATIENT, where contact with the ME EQUIPMENT could result in an unacceptable RISK, shall be limited so that the OPERATOR will have adequate control of the movement.

The overtravel (stopping distance) of such movement, occurring after operation of a control to stop the movement, shall not result in an unacceptable RISK.

Compliance is checked by the following as necessary:

– *inspection of the overtravel (stopping distance) calculations and evaluation;*

– *any functional tests*.

NOTE The overtravel (stopping distance) calculations and evaluation are part of the RISK MANAGEMENT FILE.

9.2.3 * Other MECHANICAL HAZARDS associated with moving parts

9.2.3.1 Unintended movement

Controls shall be so positioned, recessed, or protected by other means so that they cannot be accidentally actuated, unless for the intended PATIENT, the USABILITY ENGINEERING PROCESS concludes otherwise (e.g. PATIENT with special needs) or activation does not result in an unacceptable RISK.

Compliance is checked by inspection of ME EQUIPMENT, and, if the control is part of the PRIMARY OPERATING FUNCTIONS, inspection of the USABILITY ENGINEERING FILE.

9.2.3.2 Overtravel end stops

Overtravel past range limits of ME EQUIPMENT parts shall be prevented. End stops or other stopping means shall be provided to act as the ultimate travel limiting measure.

Such means shall have the mechanical strength to withstand the intended loading in NORMAL USE and reasonably foreseeable misuse.

Compliance is checked by inspection of the ME EQUIPMENT and the following test:

The ME EQUIPMENT is

– *loaded with the SAFE WORKING LOAD,*

– *unloaded, or*

– *loaded to any intermediate level that is likely to provide the most severe test result.*

The moving part is to be driven against each end stop or other mechanical means for the number of cycles, operating speed and test conditions as specified in Table 33. The end stops or other mechanical means required shall be capable of performing their intended function upon completion of the test.

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Table 33 – Test conditions for overtravel end stop test

Construction	Number of cycles	Test condition
1. Motor driven: No range limit system provided [a]	6 000	Run at maximum speed
2. Motor driven: Non-independent range limit system or systems provided [a, b]	50	Defeat all switches simultaneously, and run at maximum speed
3. Motor driven: Two or more independent range limit systems [a, b]	1	Defeat all switches simultaneously, and run at maximum speed
4. Manually driven or manually driven, power assisted	50	Run at any speed, including reasonably foreseeable misuse

[a] A range limit system consists of all components required to stop motion, for example, it may consist of (1) a limit switch, (2) sensing circuits, and (3) related mechanical actuating mechanism.

[b] To qualify as an independent range limit system, each system shall, in addition to the criteria in footnote [a], comply with both of the following:

1. the system is capable of de-energizing the motor(s) directly; that is, the switch or motor controller circuit interrupts the motor's rotor or stator current, or both, and
2. the system provides a means by which a malfunction of one range limit system is made obvious to the OPERATOR. This may be an audible, visual or otherwise discernible indicator.

9.2.4 * Emergency stopping devices

Where it is considered necessary to have one or more emergency stopping device(s), the emergency stopping device shall comply with all the following requirements.

a) The emergency stopping device shall reduce the RISK to an acceptable level.

b) The proximity and response of the OPERATOR to actuate the emergency stopping device can be relied on to prevent HARM.

c) The emergency stopping device actuator shall be readily accessible to the OPERATOR.

d) Emergency stopping device(s) shall not be part of the normal operation of the ME EQUIPMENT.

e) Operation of an emergency switching or stopping means shall neither introduce a further MECHANICAL HAZARD nor interfere with the complete operation necessary to remove the original HAZARD.

f) Emergency stopping device(s) shall be able to break the full load of the relevant circuit, taking into account possible stalled motor currents and the like.

g) Means for stopping of movements shall operate as a result of one single action.

h) The emergency stopping device shall have an actuator coloured red designed to be distinctive and easily identifiable from that of other controls.

i) An actuator that interrupts/opens mechanical movements shall be marked on, or immediately adjacent to, the face of the actuator with symbol IEC 60417-5638 (2002-10) (see Table D.1, symbol 18) or the word "STOP".

NOTE If the actuator is a switch that interrupts all power, compliance with the above marking requirement is not required.

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j) The emergency stopping device, once actuated, shall maintain the ME EQUIPMENT in the disabled condition until a deliberate action, different from that used to actuate it, is performed.

k) The emergency stopping device shall be shown to be suitable for its application.

Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE, and by functional tests.

9.2.5 * Release of PATIENT

Means shall be provided to permit the release of the PATIENT quickly and safely in the event of breakdown of the ME EQUIPMENT or failure of the power supply (see 11.8), activation of a RISK CONTROL measure or emergency stopping. Special attention shall be given to the following.

– Uncontrolled or unintended movement of the ME EQUIPMENT that could result in an unacceptable RISK shall be prevented.

– Situations where the PATIENT is subjected to unacceptable RISKS due to the proximity of moving parts, removal of normal exit routes, or other HAZARDS, shall be prevented.

– When, after removal of counterbalanced parts, other parts of the ME EQUIPMENT can move in a hazardous way, measures shall be provided to reduce the RISK to an acceptable level.

Compliance is checked by inspection of the ME EQUIPMENT and the RISK MANAGEMENT FILE, and by functional tests.

9.3 * MECHANICAL HAZARD associated with surfaces, corners and edges

Rough surfaces, sharp corners and edges of ME EQUIPMENT that could cause injury or damage shall be avoided or covered.

In particular, attention shall be paid to flange or frame edges and the removal of burrs.

Compliance is checked by inspection of the ME EQUIPMENT.

NOTE 1 If inspection is insufficient to determine sharpness of edges or burrs, the rationale for 9.3 provides a reference to an optional functional test.

NOTE 2 A sharp edge MECHANICAL HAZARD could cut wire insulation which could lead to an electrical HAZARD. This requirement is intended to cover all these HAZARDS.

9.4 * Instability HAZARDS

9.4.1 General

ME EQUIPMENT and its parts, other than FIXED ME EQUIPMENT, intended to be placed on a surface such as a floor or a table in NORMAL USE shall not overbalance (tip over) or move unexpectedly.

NOTE HAND-HELD parts of FIXED ME EQUIPMENT are intended to be tested.

Compliance is checked by the tests in 9.4.2 to 9.4.4 (inclusive). Each test is performed separately.

9.4.2 * Instability – overbalance

9.4.2.1 Instability in transport position

ME EQUIPMENT or its parts shall not overbalance when placed in any transport position of NORMAL USE on a plane inclined at an angle of 10° from the horizontal plane.

NOTE The meaning of transport in this subclause is moving ME EQUIPMENT from room to room during NORMAL USE.

Compliance is checked by the following test:

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Prior to the test the ME EQUIPMENT is prepared as indicated in the ACCOMPANYING DOCUMENTS (or, if not specified, as in 9.4.2.2). The ME EQUIPMENT or its parts is placed on a plane inclined at an angle 10° from the horizontal plane. If the ME EQUIPMENT or its parts overbalances, it constitutes a failure.

9.4.2.2 Instability excluding transport position

ME EQUIPMENT or its parts shall not overbalance when placed in any position of NORMAL USE, excluding any transport positions, on a plane inclined at an angle of 5° from the horizontal plane.

If the ME EQUIPMENT or its parts overbalances when placed in any position of NORMAL USE, excluding any transport positions, on a plane inclined at an angle of 10° from the horizontal plane, it shall carry a warning notice stating that transport should only be undertaken in a certain condition that shall be clearly described in the instructions for use or marked on the ME EQUIPMENT with an indication of the RESIDUAL RISK if the ME EQUIPMENT or its parts overbalances.

NOTE For warning notice requirements, see 7.9.2.2.

Compliance is checked by the following test:

Prior to conducting the test, the ME EQUIPMENT is prepared as follows:

a) *ME EQUIPMENT is provided with all specified connection leads, the POWER SUPPLY CORD and any interconnecting cords. It is provided with the least favourable combination of possible detachable parts, ACCESSORIES and load as specified in NORMAL USE.*

b) *ME EQUIPMENT having an APPLIANCE INLET is provided with the specified DETACHABLE POWER SUPPLY CORD.*

c) *The connection leads are laid down on the inclined plane in the position most unfavourable for stability.*

d) *If castors/wheels are present, they are temporarily immobilized, if necessary by blocking, in their most disadvantageous position.*

e) *Doors, drawers, shelves and the like are placed in the most disadvantageous position and fully loaded or unloaded whichever represents "worst case" as specified in NORMAL USE according to the ACCOMPANYING DOCUMENTS.*

f) *ME EQUIPMENT having containers for liquids is tested with these containers completely or partly filled or empty, whichever is least favourable.*

g) *The ME EQUIPMENT is not connected to the SUPPLY MAINS.*

The test floor surface is to be hard and flat (e.g. concrete floor covered with 2 mm to 4 mm thick vinyl flooring material).

The ME EQUIPMENT or the ME EQUIPMENT parts is placed on a plane inclined at an angle of 10° from the horizontal plane, or, if a warning notice is present, compliance is checked by inspection of the warning notice and the ME EQUIPMENT or its parts is placed on a plane inclined at an angle of 5° from the horizontal plane. If the ME EQUIPMENT or its parts overbalances, it constitutes a failure.

9.4.2.3 Instability from horizontal and vertical forces

a) * ME EQUIPMENT or its parts having a mass of 25 kg or more other than FIXED ME EQUIPMENT that is intended to be used on the floor shall be permanently marked with a CLEARLY LEGIBLE warning of this RISK, e.g. by use of safety sign ISO 7010-P017 (see Table

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D.2, safety sign 5), or it shall not overbalance due to being pushed, leaned, rested upon etc.

If marking is provided because the ME EQUIPMENT overbalances, the marking shall be visible during NORMAL USE, but not on surfaces for which pushing is associated with NORMAL USE (e.g. surfaces with handles).

Compliance is checked by inspection of the marking provided or the following test:

Prior to the test, the ME EQUIPMENT is prepared as described in 9.4.2.2. The ME EQUIPMENT is placed on a horizontal plane and a force equal to 15 % of its weight, but not more than 150 N, is applied in any direction, except a direction having an upward component. Unless otherwise marked, the force is applied at any point of the ME EQUIPMENT but not exceeding 1,5 m from the floor. The ME EQUIPMENT is prevented from sliding on the floor by a horizontal obstruction, not exceeding 20 mm height, which is fastened flat on the floor. If the application of the test force results in lateral movement of the ME EQUIPMENT, increase the height of the obstruction to the minimum extent necessary to prevent lateral movement. ME EQUIPMENT without marking shall not overbalance.

b) ME EQUIPMENT or its parts, other than FIXED ME EQUIPMENT, that is intended to be used on the floor or on a table shall be permanently marked with a CLEARLY LEGIBLE warning of this RISK, e.g. by use of safety signs ISO 7010-P018 or ISO 7010-P019 as appropriate (see Table D.2, safety signs 6 and 7), or it shall not overbalance due to being sat or stepped upon.

NOTE Requirements for PATIENT support surfaces are found in 9.8.3.

If marking is provided because the ME EQUIPMENT overbalances, the marking shall be visible during potential stepping or sitting misuse.

Compliance is checked by inspection of the marking provided or by the following test:

Prior to the test the ME EQUIPMENT is prepared as described in 9.4.2.2. The ME EQUIPMENT is placed on a horizontal plane and a constant downward force of 800 N is applied at the point of maximum moment to any working surface, excluding PATIENT support surfaces, offering an obvious foothold or sitting surface of a minimum 20 cm by 20 cm area, and at a height not exceeding 1 m from the floor. ME EQUIPMENT without marking shall not overbalance.

9.4.2.4 * Castors and wheels

9.4.2.4.1 General

The means used for transportation of MOBILE ME EQUIPMENT, e.g. castors or wheels, shall not result in an unacceptable RISK when the MOBILE ME EQUIPMENT is moved or parked in NORMAL USE.

9.4.2.4.2 Force for propulsion

The force required for moving MOBILE ME EQUIPMENT along a hard and flat horizontal surface shall not exceed 200 N unless the instructions for use state that more than one person is needed.

Compliance is checked by placing the ME EQUIPMENT on a hard flat horizontal floor (e.g. concrete floor covered with 2 mm to 4 mm thick vinyl flooring material) and measuring the force needed to propel the ME EQUIPMENT at a speed of 0,4 m/s ± 0,1 m/s. The force is applied at a height of 1 m above the floor or at the highest point on the ME EQUIPMENT if its height is less than 1 m.

9.4.2.4.3 * Movement over a threshold

MOBILE ME EQUIPMENT exceeding 45 kg shall be able to pass over a 10 mm threshold. Passing over a 10 mm threshold shall not result in overbalancing.

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Compliance is checked by the following test:

The ME EQUIPMENT is configured in transport position with any SAFE WORKING LOAD *in place as indicated in the* ACCOMPANYING DOCUMENTS. *The ME EQUIPMENT is moved as in NORMAL USE 10 times in forward direction over (up and down) a solid vertical plane obstruction that is affixed flat on the floor. The obstruction shall have a rectangular cross section of 10 mm ± 0,5 mm high and at least 80 mm wide with a radius of 2 mm ± 0,1 mm at the top edges. The method of passing over the obstruction has to be applied in accordance with the instructions in the ACCOMPANYING DOCUMENTS, or if no instructions are given, by the following test.*

All wheels and castors are to impact the obstruction at a speed of 0,8 m/s ± 0,1 m/s for manual MOBILE ME EQUIPMENT, or, for motor driven MOBILE ME EQUIPMENT, the maximum speed capable of being maintained. Manual MOBILE ME EQUIPMENT is propelled by a force acting at its handle.

It is unacceptable for ME EQUIPMENT to be unable to go over (up) the obstruction (due to small wheel diameter, for example). Overbalancing constitutes a failure. BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained.

NOTE Examples of damage that can affect BASIC SAFETY include the reduction of CREEPAGE DISTANCES and AIR CLEARANCES below those specified in 8.9, access to parts which exceed limits in 8.4, or access to moving parts which could cause HARM.

Assessment criteria that can be useful in determining if this test has resulted in a loss of BASIC SAFETY include:

– those in Clause 8 and 11.6;

– the dielectric strength test as specified in 8.8.3 to evaluate the integrity of solid insulation providing a MEANS OF PROTECTION; and

– measurement of CREEPAGE DISTANCES or AIR CLEARANCES to compare the values with the minimum distances specified in 8.9. Small chips that do not adversely affect the protection against electric shock or moisture can normally be ignored.

9.4.3 * Instability from unwanted lateral movement (including sliding)

9.4.3.1 Instability in transport position

a) Brakes of power-driven MOBILE ME EQUIPMENT shall be designed so that they are normally activated and can only be released by continuous actuation of a control.

Compliance is checked by inspection.

b) MOBILE ME EQUIPMENT shall be fitted with means (such as locking devices) intended to prevent any unwanted movement of the ME EQUIPMENT or its parts in the transport position.

Compliance is checked by inspection.

c) * MOBILE ME EQUIPMENT shall be provided with wheel locks or with a braking system to prevent unwanted movement on an incline of 10° when in its transport position.

Compliance is checked by the following test:

Prior to the test, the ME EQUIPMENT is prepared as described in 9.4.2.2. The MOBILE ME EQUIPMENT is placed in its transport position (or in the worst case NORMAL USE position) with the SAFE WORKING LOAD in place, and the locking device (e.g. brakes) activated, on a hard flat surface inclined at 10° from the horizontal plane. If castors are incorporated, they are positioned in their worst-case position. Following the initial elastic movement, initial creepage, and initial pivoting of castors, any further movement of the MOBILE ME EQUIPMENT greater than 50 mm (in relation to the inclined plane) constitutes a failure.

9.4.3.2 Instability excluding transport position

a) MOBILE ME EQUIPMENT shall be provided with wheel locks or with a braking system to prevent unwanted movement on an incline of 5° when in any position excluding transport position.

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Compliance is checked by the following test:

Prior to the test, the ME EQUIPMENT is prepared as described in 9.4.2.2. The MOBILE ME EQUIPMENT with the SAFE WORKING LOAD in place is positioned on a hard flat surface inclined at an angle of 5° from the horizontal plane with wheels locks on or braking system activated. Following the initial elastic movement, initial creepage, and initial pivoting of castors, any further movement of the ME EQUIPMENT greater than 50 mm (in relation to the inclined surface) constitutes a failure.

b) MOBILE ME EQUIPMENT shall be provided with wheel locks or with a braking system to prevent unwanted movement from lateral forces.

Compliance is checked by the following test:

Prior to the test, the ME EQUIPMENT is prepared as described in 9.4.2.2. The ME EQUIPMENT is placed on a horizontal plane with the SAFE WORKING LOAD in place, and the locking device (e.g. brakes) activated. If castors are incorporated, they are positioned in their worst-case position. A force equal to 15 % of the weight of the unit, but not more than 150 N, is applied in any direction, except a direction having an upwards component, at the highest point of the ME EQUIPMENT that does not lead to overbalancing but not exceeding 1,5 m from the floor. Following the initial elastic movement, initial creepage, and initial pivoting of castors, any further movement of the ME EQUIPMENT greater than 50 mm (in relation to the horizontal plane) constitutes a failure.

9.4.4 Grips and other handling devices

a) ME EQUIPMENT other than PORTABLE ME EQUIPMENT or its part with a mass of more than 20 kg that needs to be lifted in NORMAL USE or transport shall either be provided with suitable handling devices (for example handles, lifting eyes, etc.) or the ACCOMPANYING DOCUMENTS shall indicate the points where it can be lifted safely, unless the method of handling is obvious and no unacceptable RISK can develop when this is done. If the means for lifting are handles, they shall be suitably placed to enable the ME EQUIPMENT or its part to be carried by two or more persons.

Compliance is checked by weighing (if necessary) and by inspection of the ME EQUIPMENT or its part or the ACCOMPANYING DOCUMENTS.

b) ME EQUIPMENT specified by the MANUFACTURER as PORTABLE ME EQUIPMENT with a mass of more than 20 kg shall have one or more carrying-handles suitably placed to enable the ME EQUIPMENT to be carried by two or more persons.

Compliance is checked by carrying.

c) Carrying handles or grips furnished on PORTABLE ME EQUIPMENT shall withstand loading as described in the following test:

The handles and their means of attachment are subjected to a force equal to four times the weight of the ME EQUIPMENT in any direction of NORMAL USE and transport.

If more than one handle is furnished on PORTABLE ME EQUIPMENT, the force is distributed between the handles. The distribution of forces is determined by measuring the percentage of the ME EQUIPMENT weight sustained by each handle with the ME EQUIPMENT in the normal carrying position. If the ME EQUIPMENT is furnished with more than one handle but is so designed that it can readily be carried by only one handle, then each handle is to be capable of sustaining the total force.

The force is applied uniformly over a 7 cm length of the handle at the centre, starting at zero and gradually increasing so that the test value will be attained in 5 s to 10 s and maintained for a period of 1 min.

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Handles that break loose from the ME EQUIPMENT or exhibit any permanent distortion, cracking or other evidence of breakdown constitutes a failure.

9.5 * Expelled parts HAZARD

9.5.1 Protective means

Where expelled parts could result in an unacceptable RISK, the ME EQUIPMENT shall be provided with a means for protecting against such RISK.

Compliance is checked by assessment of the suitability of the protective means and by inspection of the RISK MANAGEMENT FILE.

9.5.2 Cathode ray tubes

Any cathode ray tube shall comply with the applicable requirements of IEC 60065:2001, Clause 18; or IEC 61965.

Compliance is checked by inspection of a certificate of compliance or by the relevant tests of IEC 60065:2001, Clause 18.

9.6 Acoustic energy (including infra- and ultrasound) and vibration

9.6.1 * General

ME EQUIPMENT shall be designed so that human exposure to acoustic energy and vibration shall not result in an unacceptable RISK.

Compliance is checked by the tests in 9.6.2 and 9.6.3, and, if necessary, by inspection of the RISK MANAGEMENT FILE (taking into account the audibility of auditory alarm signals and PATIENT sensitivity).

9.6.2 * Acoustic energy

9.6.2.1 Audible acoustic energy

In NORMAL USE, the PATIENT, OPERATOR and other persons shall not be exposed to acoustic energy from ME EQUIPMENT, except sound from auditory ALARM SIGNALS, exceeding the levels specified below.

– 80 dBA for a cumulative exposure of 24 h over a 24 h period; an offset of 3 dBA is to be added to this value when halving the cumulative exposure time over a 24 h period (e.g. 83 dBA for 12 h over a 24 h period);

– 140 dBC (peak) sound pressure level for impulsive or impact acoustic energy (noise).

NOTE 1 Interpolation or extrapolation is allowed for exposure times in accordance with the following formula, $80 - 10 * \log_{10}(h/24)$, in dBA, where h is cumulative exposure time over a 24 h period.

NOTE 2 Since PATIENTS might have a higher sensitivity to acoustic energy (noise), a lower level could be more appropriate. Consideration should also be given to perception of auditory ALARM SIGNALS. The World Health Organization has recommended a maximum impulse or impact acoustic energy (noise) level for children of 120 dB.

NOTE 3 If the A-weighted sound pressure level exceeds 80 dBA, noise protection measure should be considered.

Compliance is checked by measuring the maximum A-weighted sound pressure level at the minimum distances of PATIENT, OPERATOR and other persons from the source of acoustic energy (*noise) in NORMAL USE, and if necessary, calculating the A-weighted sound pressure level produced by the ME EQUIPMENT in accordance with ISO 3746, ISO 9614-1 or IEC 61672-1. The following conditions apply.*

a) The ME EQUIPMENT is operated under worst-case NORMAL CONDITION.

b) Any protective means provided or called for in ACCOMPANYING DOCUMENTS are to be in place during sound measurement.

c) Sound level meters used in the measurement conform to IEC 61672-1 and IEC 61672-2.

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d) The test room is semi-reverberant with a hard reflecting floor. The distance between any wall or other object and the surface of the ME EQUIPMENT *is not less than 3 m.*

e) When sound measurements in a test room are not feasible (e.g. for a large PERMANENTLY INSTALLED ME EQUIPMENT*), measurements may be done* in situ.

9.6.2.2 Infrasound and ultrasound energy

When applicable, the MANUFACTURER shall address the RISKS associated with infrasound or ultrasound in the RISK MANAGEMENT PROCESS.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

9.6.3 * Hand-transmitted vibration

Except for vibrations directly required to carry out the INTENDED USE of the ME EQUIPMENT, means shall be provided to protect the PATIENT, OPERATOR and other persons if in NORMAL USE the hand-transmitted frequency-weighted r.m.s. acceleration generated by the ME EQUIPMENT exceeds the value below:

– 2,5 m/s^2 for a cumulative time of 8 h during a 24 h period.

– Allowable accelerations for different times are inversely proportional to the square root of the time (e.g. the allowable acceleration for 2 h would be 5,0 m/s^2).

NOTE Interpolation or extrapolation is allowed for allowable acceleration in accordance with the following formula, 2,5 x $\sqrt{(8 / t)}$, in m/s^2, where t is the cumulative time over a 24 h period.

Compliance is checked by measurements at points of equipment in hand contact with PATIENT, OPERATOR *or other persons. Measurements are made in accordance with ISO 5349-1.*

9.7 * Pressure vessels and parts subject to pneumatic and hydraulic pressure

9.7.1 General

The requirements of this subclause apply to vessels and parts of ME EQUIPMENT subject to pressure, the rupture of which could result in an unacceptable RISK.

The parts of a pneumatic or hydraulic system that are used as a support system shall additionally comply with the requirements in 9.8.

9.7.2 Pneumatic and hydraulic parts

Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES shall be so designed that:

– no unacceptable RISK results from loss of pressure or loss of vacuum;

– no unacceptable RISK results from a fluid jet caused by leakage or a component failure;

– elements of the ME EQUIPMENT or an ACCESSORY, and especially pipes and hoses, that can lead to an unacceptable RISK shall be protected against harmful external effects;

– reservoirs and similar vessels (e.g. hydro-pneumatic accumulators) that can lead to an unacceptable RISK are automatically depressurized when the ME EQUIPMENT is isolated from its power supply (e.g. pulling out the pneumatic plug at the connector mounted on the facility wall). If this is not possible, means shall be provided for the isolation (e.g. cutting off from the peripheral circuit), or local depressurizing of reservoirs and similar vessels, and pressure indication;

– all elements that can remain under pressure after isolation of the ME EQUIPMENT or an ACCESSORY from its power supply and that could result in an unacceptable RISK shall be provided with clearly identified exhaust devices, and a warning label drawing attention to the necessity of depressurizing these elements before any setting or maintenance activity on the ME EQUIPMENT or ACCESSORIES.

Compliance is checked by inspection and examination of RISK MANAGEMENT FILE.

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9.7.3 Maximum pressure

The maximum pressure to which a part of ME EQUIPMENT can be subjected in NORMAL CONDITION and SINGLE FAULT CONDITION shall be considered to be whichever is the highest of the following:

a) the RATED maximum supply pressure from an external source;

b) the pressure setting of a pressure-relief device provided as part of the assembly;

c) the maximum pressure that can be developed by a source of pressure that is part of the assembly, unless the pressure is limited by a pressure-relief device.

9.7.4 Pressure rating of ME EQUIPMENT parts

The maximum pressure to which a part of ME EQUIPMENT can be subjected in NORMAL CONDITION and SINGLE FAULT CONDITION shall not exceed the MAXIMUM PERMISSIBLE WORKING PRESSURE for the part, except as allowed for pressure relief devices in 9.7.7.

Compliance is checked by inspection of the MANUFACTURER'S data for the component, inspection of the ME EQUIPMENT, and where necessary, by functional test.

9.7.5 * Pressure vessels

A pressure vessel shall withstand a HYDRAULIC TEST PRESSURE if both the following conditions are met:

– the pressure is greater than 50 kPa; and

– the product of pressure and volume is greater than 200 kPa · l.

Compliance is checked by the following tests:

The HYDRAULIC TEST PRESSURE is the MAXIMUM PERMISSIBLE WORKING PRESSURE multiplied by a factor obtained from Figure 32.

The pressure is raised gradually to the specified test value and is held at that value for 1 min. A sample that bursts or suffers from permanent (plastic) deformation or leaks constitutes a failure. Leakage at a gasket during this test is not considered to constitute failure unless it occurs at a pressure below 40 % of the required test value, or below the MAXIMUM PERMISSIBLE WORKING PRESSURE, whichever is greater.

No leakage is allowed for pressure vessels intended for toxic, flammable or otherwise hazardous substances. For other pressure vessels, no leakage is allowed that will otherwise result in an unacceptable RISK (e.g. high pressure fluid jet).

Where unmarked pressure vessels and pipes (e.g. those with no national certification) cannot be hydraulically tested, integrity is verified by other suitable tests, e.g. pneumatic using suitable media, at the same test pressure as for the hydraulic test.

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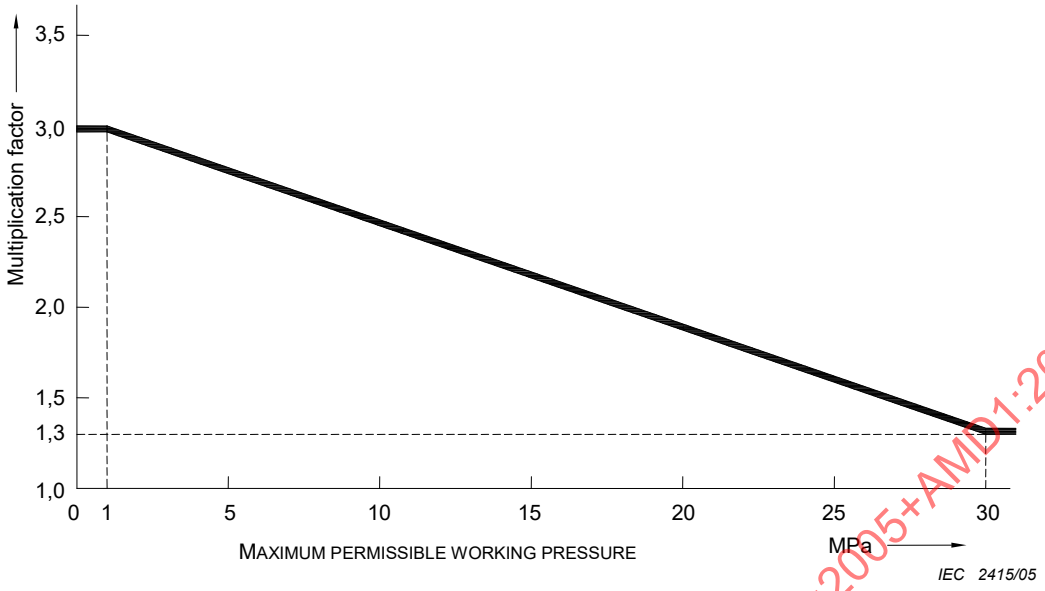


Figure 32 – Ratio between HYDRAULIC TEST PRESSURE and MAXIMUM PERMISSIBLE WORKING PRESSURE
(see 9.7.5)

9.7.6 Pressure-control device

In ME EQUIPMENT for which 9.7.7 requires a pressure-relief device, any pressure-control device responsible for regulating the pressure shall be capable of performing under RATED load for 100 000 cycles of operation and shall prevent the pressure from exceeding 90 % of the setting of the pressure-relief device under any condition of NORMAL USE.

Compliance is checked by inspection of the MANUFACTURER'S data for the component, inspection of the ME EQUIPMENT, and where necessary, by functional test.

9.7.7 Pressure-relief device

ME EQUIPMENT shall incorporate pressure-relief device(s) where the MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded.

A pressure-relief device shall comply with all of the following requirements:

a) it shall be connected as close as reasonably practical to the pressure vessel or parts of the system that it is intended to protect;

b) it shall be so installed that it is readily accessible for inspection, maintenance and repair;

c) it shall not be capable of being adjusted or rendered inoperative without the use of a TOOL;

d) it shall have its discharge opening so located and directed that the released material is not directed towards any person;

e) it shall have its discharge opening so located and directed that operation of the device will not deposit material on parts that could result in an unacceptable RISK;

f) it shall be of adequate discharge capacity to ensure that the pressure will not exceed the MAXIMUM PERMISSIBLE WORKING PRESSURE of the system to which it is connected by more than 10 % in the event of a failure in the control of the supply pressure;

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g) there shall be no shut-off valve between a pressure-relief device and the parts that it is intended to protect;

h) the minimum number of cycles of operation shall be 100 000, except for one-time use devices such as bursting disks.

Compliance is checked by inspection of the MANUFACTURER'S data for the component, inspection of the ME EQUIPMENT, inspection of the RISK MANAGEMENT FILE, and where necessary, by functional test.

9.7.8 RATED maximum supply pressure

See 7.2.18.

9.8 * MECHANICAL HAZARDS associated with support systems

9.8.1 General

Where ME EQUIPMENT parts are designed to support loads or to provide actuating forces, the following requirements shall be applied if a mechanical fault could constitute an unacceptable RISK.

– The construction of the support, suspension or actuation system shall be designed based upon Table 21 and the TOTAL LOAD.

– Means of attachment of ACCESSORIES shall be designed such that any possibility of incorrect attachment that could result in an unacceptable RISK is avoided.

– The RISK ANALYSIS of support systems shall consider MECHANICAL HAZARDS arising from static, dynamic, vibration, impact and pressure loading, foundation and other movements, temperature, environmental, manufacture and service conditions.

– All likely failure effects shall be considered in the RISK ANALYSIS. These include excessive deflection, plastic deformation, ductile or brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep, material deterioration and residual stresses resulting from the manufacturing PROCESSES, e.g. machining, assembling, welding, heat treatment or surface coating.

– The ACCOMPANYING DOCUMENTS shall contain instructions on attachment of structures to a floor, wall, ceiling, etc. making adequate allowances for quality of the materials used to make the connection and shall list the required materials. Additionally there shall be advice on checking the adequacy of the surface of the structure to which the parts will be attached.

9.8.2 * TENSILE SAFETY FACTOR

Support systems shall maintain structural integrity during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. TENSILE SAFETY FACTORS shall not be less than those shown in Table 21 unless an alternative method demonstrates structural integrity throughout the EXPECTED SERVICE LIFE of the ME EQUIPMENT, or the support is a foot rest. The requirements for foot rests are in 9.8.3.2 a).

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Table 21 – Determination of TENSILE SAFETY FACTOR

Situation			Minimum TENSILE SAFETY FACTOR [a]	
No.	**System Part**	**Elongation**	**A [b]**	**B [c]**
1	Support system parts not impaired by wear	Metallic material [d] having a specific elongation at break equal to or greater than 5 %	2,5	4
2	Support system parts not impaired by wear	Metallic material [d] having a specific elongation at break of less than 5 %	4	6
3	Support system parts impaired by wear [e] and no MECHANICAL PROTECTIVE DEVICE	Metallic material [d] having a specific elongation at break equal to or greater than 5 %	5	8
4	Support system parts impaired by wear [e] and no MECHANICAL PROTECTIVE DEVICE	Metallic material [d] having a specific elongation at break of less than 5 %	8	12
5	Support system parts impaired by wear [e] and with MECHANICAL PROTECTIVE DEVICE (or primary system of multiple support systems)	Metallic material [d] having a specific elongation at break equal to or greater than 5 %	2,5	4
6	Support system parts impaired by wear [e] and with MECHANICAL PROTECTIVE DEVICE (or primary system of multiple support systems)	Metallic material [d] having a specific elongation at break of less than 5 %	4	6
7	MECHANICAL PROTECTIVE DEVICE (or back-up system of multiple support system)		2,5	4

[a] The TENSILE SAFETY FACTORS are intended to take account of conditions defined in 15.3.7 (i.e. environmental effects, impairing effects of wear, corrosion, material fatigue or ageing).

[b] Case A = The material TENSILE STRENGTH and all external forces to be expected are quantifiable and known accurately.

[c] Case B = Other than case A; specifically, the material TENSILE STRENGTH and all external forces to be expected are known approximately, but not with sufficient accuracy to justify the TENSILE SAFETY FACTOR for case A.

[d] For non-metallic materials, particular standards can prescribe adequate TENSILE SAFETY FACTORS (see rationale in Annex A, Subclause 9.8).

[e] Components considered impaired by wear include: chains, cables (wire rope), belts, jack screw nuts, springs, pneumatic or hydraulic hoses, gaskets or rings of pneumatic or hydraulic pistons.

Compliance with 9.8.1 and 9.8.2 is checked by inspection of the ME EQUIPMENT, the RISK MANAGEMENT FILE, the specifications of materials used and the processing specifications for these materials.

If testing is needed to demonstrate compliance with 9.8.1 or 9.8.2, a test load equal to the TOTAL LOAD times the required TENSILE SAFETY FACTOR is gradually applied to the support assembly under test. The support assembly under test is to be in equilibrium after 1 min, or otherwise not result in an unacceptable RISK.

NOTE 1 It might be necessary to support assemblies that are connected to the assembly under test but do not require such a high safety factor, e.g. assembly under test requires TENSILE SAFETY FACTOR = 8 and assembly supporting it is designed with a TENSILE SAFETY FACTOR = 4. Use of additional support should be explained in the test report.

NOTE 2 The 1 min time period might need to be longer for materials which might have creep type problems, such as plastics or other non-metallic materials.

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9.8.3 * Strength of PATIENT or OPERATOR support or suspension systems

9.8.3.1 General

ME EQUIPMENT parts serving for support or immobilization of PATIENTS shall be designed and manufactured so there is no unacceptable RISK of physical injuries or of accidental loosening of fixings.

The SAFE WORKING LOAD of ME EQUIPMENT or its parts serving for support or suspension of PATIENTS or OPERATORS shall be the sum of the mass of the PATIENTS or the mass of the OPERATORS plus the mass of ACCESSORIES intended by MANUFACTURERS to be supported or suspended by the ME EQUIPMENT or ME EQUIPMENT parts.

Unless otherwise stated by the MANUFACTURER, supporting and suspending parts for adult human PATIENTS or OPERATORS shall be designed for a PATIENT or OPERATOR having a minimum mass of 135 kg and ACCESSORIES having a minimum mass of 15 kg.

Where a MANUFACTURER specifies particular applications (e.g. paediatric use), the maximum mass of the PATIENT included in the SAFE WORKING LOAD of the ME EQUIPMENT or its parts serving for support or suspension of PATIENTS may be adapted. When the maximum allowable value of the mass of the PATIENT is less than 135 kg, that value shall be marked on the ME EQUIPMENT and described in ACCOMPANYING DOCUMENTS. When the maximum allowable value of the mass of the PATIENT is more than 135 kg, that value shall be described in ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection of the ME EQUIPMENT (including markings), the ACCOMPANYING DOCUMENTS, the MANUFACTURER'S data for the component, the RISK MANAGEMENT FILE, and, where necessary, functional test.

9.8.3.2 * Static forces due to loading from persons

In analyzing loading forces and torques on support assemblies, the part of the SAFE WORKING LOAD representing the mass of the PATIENTS or OPERATORS is distributed on the support/suspension surface in a manner representing the human body (see the example in Figure A.19).

NOTE 1 The position of the human body varies depending on the configuration of the support/suspension system and therefore the load acting on different sections will vary and should be taken into account.

In analyzing loading forces and torques on support assemblies, the part of the SAFE WORKING LOAD representing the mass of ACCESSORIES shall be deployed as in NORMAL USE or, if not defined, at the worst case position permitted by the configuration or ACCESSORIES attachment on the support/suspension parts.

a) For a foot rest that is intended to temporarily support a standing PATIENT or OPERATOR, the whole mass of the PATIENT or OPERATOR is distributed over an area of 0,1 m^2.

   Compliance is checked by inspection of the ME EQUIPMENT, the specifications of materials used and the processing specifications for these materials, and the following test:

   Prior to performing these tests, the PATIENT support/suspension system is positioned horizontally in its most disadvantageous position in NORMAL USE.

   A mass equal to two times 135 kg or two times the intended person load, whichever is greater is applied to the foot rest over an area of 0,1 m^2 for 1 min. After the test, a foot rest and its fixings that shows any damage or permanent deflection from normal greater than 5° constitutes a failure. BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained.

   NOTE 2 Examples of damage that can affect BASIC SAFETY include the reduction of CREEPAGE DISTANCES and AIR CLEARANCES below those specified in 8.9, access to parts that exceed limits in 8.4, or access to moving parts that could cause HARM.

   Assessment criteria that can be useful in determining if this test has resulted in a loss of BASIC SAFETY include:

   – those in Clause 8 and 11.6;

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– the dielectric strength test as specified in 8.8.3 to evaluate the integrity of solid insulation providing a MEANS OF PROTECTION; and

– measurement of CREEPAGE DISTANCES or AIR CLEARANCES to compare the values with the minimum distances specified in 8.9. Small chips that do not adversely affect the protection against electric shock or moisture can normally be ignored.

b) For an area of support/suspension where a PATIENT or OPERATOR can sit, deflection of a support surface from PATIENT or OPERATOR loading shall not result in an unacceptable RISK.

Compliance is checked by inspection of the ME EQUIPMENT, the specifications of materials used and the processing specifications for these materials, and the following test:

Prior to performing these tests, the PATIENT support/suspension system is positioned horizontally in its most disadvantageous position in NORMAL USE.

A mass of 60 % of the part of the SAFE WORKING LOAD representing the PATIENT or OPERATOR, as defined in the instructions for use, or a minimum 80 kg, is placed on the support/suspension system with the centre of the load 60 mm from the outer edge of the support/suspension system for at least one minute. Any permanent deflection of the support/suspension system from normal greater than 5° constitutes a failure. BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained.

NOTE 3 Examples of damage that can affect BASIC SAFETY include the reduction of CREEPAGE DISTANCES and AIR CLEARANCES below those specified in 8.9, access to parts that exceed limits in 8.4, or access to moving parts that could cause HARM.

Assessment criteria that can be useful in determining if this test has resulted in a loss of BASIC SAFETY include:

– those in Clause 8 and 11.6;

– the dielectric strength test as specified in 8.8.3 to evaluate the integrity of solid insulation providing a MEANS OF PROTECTION; and

– measurement of CREEPAGE DISTANCES or AIR CLEARANCES to compare the values with the minimum distances specified in 8.9. Small chips that do not adversely affect the protection against electric shock or moisture can normally be ignored.

9.8.3.3 * Dynamic forces due to loading from persons

Where dynamic forces (due to sitting down, standing up, PATIENT handling PROCESS or the like) can be exerted on ME equipment parts intended to support or suspend a PATIENT or OPERATOR in NORMAL USE, the ME EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.

Compliance is checked by the following test:

Prior to performing this test, the PATIENT support/suspension system is positioned horizontally in its most disadvantageous position in NORMAL USE.

For the area of support/suspension where a PATIENT or OPERATOR can sit, the top reservoir of the body upper-carriage module described in Figure 33 is loaded with the appropriate mass to obtain the SAFE WORKING LOAD representing the PATIENT or OPERATOR as defined in the ACCOMPANYING DOCUMENTS. The *body upper-carriage module with appropriate mass is dropped from a distance of 150 mm above the seat area. BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained.*

NOTE Examples of damage that can affect BASIC SAFETY include the reduction of CREEPAGE DISTANCES and AIR CLEARANCES below those specified in 8.9, access to parts that exceed limits in 8.4, or access to moving parts which could cause HARM.

Assessment criteria that can be useful in determining if this test has resulted in a loss of BASIC SAFETY include:

– those in Clause 8 and 11.6;

– the dielectric strength test as specified in 8.8.3 to evaluate the integrity of solid providing a MEANS OF PROTECTION; and

– measurement of CREEPAGE DISTANCES or AIR CLEARANCES to compare the values with the minimum distances specified in 8.9. Small chips that do not adversely affect the protection against electric shock or moisture can normally be ignored.

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9.8.4 * Systems with MECHANICAL PROTECTIVE DEVICES

9.8.4.1 General

a) A MECHANICAL PROTECTIVE DEVICE shall be provided when a support system or any of its parts impaired by wear have a TENSILE SAFETY FACTOR greater than or equal to the values specified in rows 5 and 6 but less than those in rows 3 and 4 of Table 21.

b) The MECHANICAL PROTECTIVE DEVICE shall:

- be designed on the basis of TOTAL LOAD, which shall include the effects of the SAFE WORKING LOAD when applicable;
- have TENSILE SAFETY FACTORS for all parts not less than those in row 7 of Table 21;
- activate before travel (movement) produces an unacceptable RISK;
- take into account 9.2.5 and 9.8.4.3.

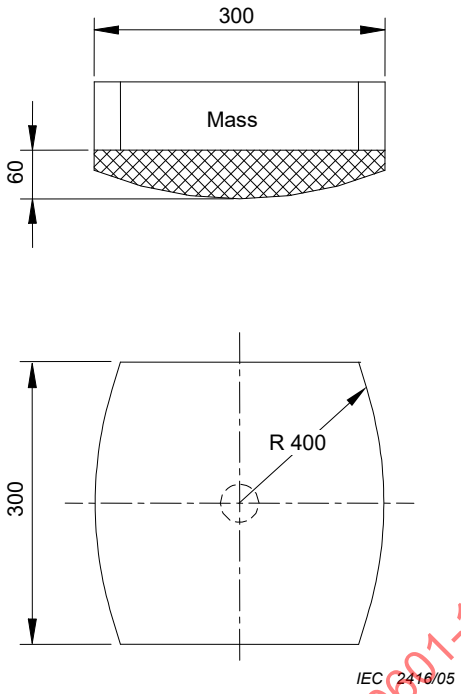
Compliance is checked by the following as necessary:

- *inspection of the overtravel (stopping distance from the time of engagement of the MECHANICAL PROTECTIVE DEVICE to the time of no further movement) calculations and evaluation;*
- *any functional tests*.

NOTE The overtravel (stopping distance from the time of engagement of the MECHANICAL PROTECTIVE DEVICE to the time of no further movement) calculations and evaluation are part of the RISK MANAGEMENT FILE.

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Dimensions in millimetres



NOTE The top reservoir of the body upper-carriage module is formed of wood, metal or a similar material. The reservoir is intended to retain the appropriate human body mass, typically with high density material (e.g. lead). The bottom portion is foam. The resiliency or spring factor of the foam (ILD or IFD ratings) is not specified, as with a large mass being dropped, the foam properties are likely inconsequential. The foam is cylindrical, rather than spherical.

Figure 33 – Body upper-carriage module

9.8.4.2 Use after activation of a MECHANICAL PROTECTIVE DEVICE

If ME EQUIPMENT can still be used after failure of the suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE such as a secondary cable (wire rope), it shall become obvious to the OPERATOR that the MECHANICAL PROTECTIVE DEVICE has been activated.

The MECHANICAL PROTECTIVE DEVICE shall require the use of a TOOL to be reset or replaced.

Compliance is checked by inspection of the ME EQUIPMENT.

9.8.4.3 MECHANICAL PROTECTIVE DEVICE intended for single activation

If a MECHANICAL PROTECTIVE DEVICE is intended to function only once, the following requirements shall be fulfilled:

– Further use of the ME EQUIPMENT shall be impossible until the MECHANICAL PROTECTIVE DEVICE has been replaced.

– The ACCOMPANYING DOCUMENTS shall instruct that once the MECHANICAL PROTECTIVE DEVICE has been activated, SERVICE PERSONNEL are to be called, and the MECHANICAL PROTECTIVE DEVICE must be replaced before the ME EQUIPMENT can be used again.

– The ME EQUIPMENT shall be permanently marked with safety sign ISO 7010-W001 (see Table D.2, safety sign 2).

– The marking shall be adjacent to the MECHANICAL PROTECTIVE DEVICE or so located that its relation to the MECHANICAL PROTECTIVE DEVICE is obvious to the person performing service or repair.

NOTE See also 15.3.7.

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Compliance is checked as follows:

– *by inspection of the ME EQUIPMENT, the ACCOMPANYING DOCUMENTS and the specifications of materials used and the processing specifications for these materials;*

– *a chain, cable (wire rope), band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, is defeated (to test the MECHANICAL PROTECTIVE DEVICE) by any convenient means, thereby causing the maximum normal load to fall from the most adverse position permitted by the construction of the ME EQUIPMENT. If the system supports a PATIENT or OPERATOR, the load is to include the SAFE WORKING LOAD defined in 9.8.3.1.*

Any evidence of damage to a MECHANICAL PROTECTIVE DEVICE that would affect its ability to perform its intended function constitutes a failure.

9.8.5 Systems without MECHANICAL PROTECTIVE DEVICES

A MECHANICAL PROTECTIVE DEVICE is not required if:

– the support system parts are not impaired by wear and have TENSILE SAFETY FACTORS greater than or equal to the values specified in rows 1 and 2 of Table 21; or

– the support system parts are impaired by wear but have TENSILE SAFETY FACTORS greater than or equal to the values specified in rows 3 and 4 of Table 21.

Compliance is checked by inspection of the ME EQUIPMENT, the design documentation and the RISK MANAGEMENT FILE.

10 * Protection against unwanted and excessive radiation HAZARDS

10.1 X-Radiation

10.1.1 * ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation

For ME EQUIPMENT not intended to produce X-radiation for diagnostic or therapeutic purposes, but which might produce ionizing radiation, the AIR KERMA rate shall not exceed 5 μGy/h at a distance of 5 cm from a surface of the ME EQUIPMENT taking account of the background radiation.

If the INTENDED USE of the ME EQUIPMENT requires a permanent proximity to a PATIENT, the resulting annual exposure should be made acceptable taking into account the irradiated body part and national regulations and/or international recommendations.

NOTE 1 The dose-rate value appears in ICRP 60 [39].

NOTE 2 In the member countries of CENELEC, the amount of ionizing radiation is regulated by European Council Directive 96/29/Euratom of 13 May 1996. This Directive requires that at any point 10 cm from the surface of the equipment, the dose-rate shall not exceed 1 μSv/h (0,1 mR/h) taking account of the background level.

Compliance is checked by following test:

The amount of radiation is determined by means of a radiation monitor of the ionizing chamber type with an effective area of 10 cm^2 or by measuring equipment of other types giving equivalent results.

The ME EQUIPMENT is operated at the most unfavourable RATED MAINS VOLTAGE and with any controls adjusted so as to give maximum radiation whilst maintaining the ME EQUIPMENT in NORMAL USE.

Internal preset controls not intended to be adjusted during the EXPECTED SERVICE LIFE of the ME EQUIPMENT are not considered.

Measurements are made at a distance of 5 cm from any surface to which OPERATORS other than SERVICE PERSONNEL:

– *can gain access without the use of a TOOL;*

– *is deliberately provided with the means of access; or*

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– *is instructed to enter regardless of whether or not a TOOL is needed to gain access.*

Any measurement exceeding 5 μGy/h adjusted for the level of background radiation constitutes a failure.

NOTE 3 This test PROCEDURE is equivalent to that in Annex H of IEC 60950-1:2005.

10.1.2 ME EQUIPMENT intended to produce diagnostic or therapeutic X-radiation

Unintended X-radiation from ME EQUIPMENT designed to produce diagnostic or therapeutic X-radiation shall be reduced as far as possible by application of applicable particular and collateral standards, or in the absence of these standards by application of the RISK MANAGEMENT PROCESS.

For intended X-radiation, also see 12.4.5.2 and 12.4.5.3.

Compliance is checked by application of applicable particular and collateral standards or inspection of the RISK MANAGEMENT FILE.

10.2 Alpha, beta, gamma, neutron and other particle radiation

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with alpha, beta, gamma, neutron and other particle radiation.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

10.3 Microwave radiation

The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz shall not exceed 10 W/m^2 at any point 50 mm away from a surface of the ME EQUIPMENT under reference test conditions. This requirement does not apply to parts of the apparatus where microwave radiation is propagated intentionally, for example, at waveguide output ports.

NOTE This requirement is equivalent to that in subclause 12.4 of IEC 61010-1:2001.

Compliance is checked by review of MANUFACTURER'S calculations and, if necessary, the following test:

The ME EQUIPMENT is operated at the most unfavourable RATED MAINS VOLTAGE and with any control adjusted so as to give maximum microwave radiation whilst maintaining the ME EQUIPMENT in NORMAL USE.

Internal pre-set controls not intended to be adjusted during the expected SERVICE LIFE of the ME EQUIPMENT are not considered.

Measurements are made at a distance of 50 mm from any surface to which OPERATORS other than SERVICE PERSONNEL:

– *can gain access without the use of a TOOL;*

– *are deliberately provided with the means of access; or*

– *are instructed to enter regardless of whether or not a TOOL is needed to gain access.*

Any measurement exceeding 10 W/m^2 under reference test conditions constitutes a failure.

10.4 * Lasers

For lasers that produce or amplify electromagnetic radiation in the wavelength range from 180 nm to 1 mm, the relevant requirements of IEC 60825-1:2007 shall apply. If laser light barriers or similar products are used within equipment, they shall comply with the requirements of IEC 60825-1:2007.

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NOTE For laser equipment that is intended for use on humans or animals for surgical, therapeutic, medical diagnostic, cosmetic, or veterinary applications and classified as a Class 3b or Class 4 laser product as defined in IEC 60825-1, see also IEC 60601-2-22 [59].

Compliance is checked by following the relevant PROCEDURES of IEC 60825-1:2007.

10.5 Other visible electromagnetic radiation

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with visible electromagnetic radiation, other than that produced by lasers and light emitting diodes (see 10.4).

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

10.6 Infrared radiation

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with infrared radiation, other than that produced by lasers and light emitting diodes (see 10.4).

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

10.7 Ultraviolet radiation

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with ultraviolet radiation, other than that produced by lasers and light emitting diodes (see 10.4).

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

11 Protection against excessive temperatures and other HAZARDS

11.1 * Excessive temperatures in ME EQUIPMENT

11.1.1 * Maximum temperature during NORMAL USE

When ME EQUIPMENT is operated in worst-case NORMAL USE including the maximum ambient operating temperature specified in the technical description (see 7.9.3.1):

– ME EQUIPMENT parts shall not reach temperatures exceeding the values given in Table 22 and Table 23;

– the ME EQUIPMENT shall not cause the surfaces of the test corner to exceed 90 °C; and

– THERMAL CUT-OUTS shall not operate in NORMAL CONDITION.

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Table 22 – Allowable maximum temperatures of parts

Parts	Maximum Temperature °C
Insulation, including winding insulation [a]	
- of Class A Material	105
- of Class E Material	120
- of Class B Material	130
- of Class F Material	155
- of Class H Material	180
Parts with T marking	T [b]
Other components and materials	[c]
Parts in contact with flammable liquid with flash-point of T °C	T-25
Wood	90

[a] The classification of insulating materials is in accordance with IEC 60085. Any incompatibility of the materials of an insulating system that could reduce the maximum temperature limit of the system below the limits of the individual materials shall be considered.

[b] T marking refers to the marked maximum operating temperature.

[c] For each material and component, account shall be taken of the temperature ratings for each material or component to determine the appropriate maximum temperature. Each component shall be used in accordance with its temperature rating. Where doubt exists, the ball pressure test of 8.8.4.1 should be performed.

Table 23 – Allowable maximum temperatures for ME EQUIPMENT parts that are likely to be touched

ME EQUIPMENT and its parts		Maximum temperature [a] °C		
		Metal and liquids	Glass, porcelain, vitreous material	Moulded material, plastic, rubber, wood
External surfaces of ME EQUIPMENT that are likely to be touched for a time "*t*"	*t* < 1 s	74	80	86
	1 s ≤ *t* < 10 s	56	66	71
	10 s ≤ *t* < 1 min	51	56	60
	1 min ≤ *t*	48	48	48

[a] These temperature limit values are applicable for touching the healthy skin of adults. They are not applicable when large areas of the skin (10 % of total body surface or more) can be in contact with a hot surface. This also applies in the case of skin contact with over 10 % of the head surface. Where this is the case, appropriate limits shall be determined and documented in the RISK MANAGEMENT FILE.

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Table 24 – Allowable maximum temperatures for skin contact with ME EQUIPMENT APPLIED PARTS

APPLIED PARTS of ME EQUIPMENT		Maximum temperature [a] [b] °C		
		Metal and liquids	Glass, porcelain, vitreous material	Moulded material, plastic, rubber, wood
APPLIED PART having contact with the PATIENT for a time "*t*"	*t* < 1 min	51	56	60
	1 min ≤ *t* < 10 min	48	48	48
	10 min ≤ *t*	43	43	43

[a] These temperature limit values are applicable for the healthy skin of adults. They are not applicable when large areas of the skin (10 % of total body surface or more) can be in contact with a hot surface. They are not applicable in the case of skin contact with over 10 % of the head surface. Where this is the case, appropriate limits shall be determined and documented in the RISK MANAGEMENT FILE.

[b] Where it is necessary for APPLIED PARTS to exceed the temperature limits of Table 24 in order to provide clinical benefit, the RISK MANAGEMENT FILE shall contain documentation showing that the resulting benefit exceeds any associated increase in RISK.

11.1.2 * Temperature of APPLIED PARTS

11.1.2.1 APPLIED PARTS intended to supply heat to a PATIENT

The temperature (hot or cold surfaces) or (where appropriate) the clinical effects shall be determined and documented in the RISK MANAGEMENT FILE. The temperatures and clinical effects shall be disclosed in the instructions for use.

11.1.2.2 * APPLIED PARTS not intended to supply heat to a PATIENT

The limits of Table 24 shall apply in both NORMAL CONDITION and SINGLE FAULT CONDITION. If the surface temperature of an APPLIED PART exceeds 41 °C:

– the maximum temperature shall be disclosed in the instructions for use;

– the conditions for safe contact, e.g. duration or condition of the PATIENT, shall be disclosed; and

– the clinical effects with respect to characteristics such as body surface, maturity of PATIENTS, medications being taken or surface pressure shall be determined and documented in the RISK MANAGEMENT FILE.

Where 41°C is not exceeded, no justification is required.

If analyses documented in the RISK MANAGEMENT FILE demonstrate that APPLIED PART temperatures cannot be affected by operation of the ME EQUIPMENT including in SINGLE FAULT CONDITIONS, measurement of APPLIED PART temperature according to 11.1.3 is not required.

Surfaces of APPLIED PARTS that are cooled below ambient temperatures can also result in an unacceptable RISK and shall be evaluated as part of the RISK MANAGEMENT PROCESS.

11.1.3 * Measurements

Where engineering judgement by the MANUFACTURER indicates that temperature limits cannot be exceeded, no measurement is required. Where such judgements indicate that the test corner will not impact the measurements, it may be omitted. However, the rationale for such judgement shall be documented in the RISK MANAGEMENT FILE. If the test corner is used, its surfaces shall not exceed 90 °C.

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For ME EQUIPMENT parts that are likely to be touched and for APPLIED PARTS, the probability of occurrence of contact and of the duration of contact is determined and documented in the RISK MANAGEMENT FILE.

Compliance with the requirements of 11.1.1 and 11.1.2 is checked by inspection of the RISK MANAGEMENT FILE and the instructions for use, operation of ME EQUIPMENT and temperature measurements as follows:

a) Positioning

1) ME EQUIPMENT is tested in the position(s) of NORMAL USE.

2) ME EQUIPMENT is placed in a test corner. The test corner consists of two walls at right angles, a floor and, if necessary, a ceiling, all of dull black painted plywood of 20 mm thickness. The linear dimensions of the test corner are at least 115 % of the linear dimensions of the ME EQUIPMENT under test.

The ME EQUIPMENT is positioned in the test corner as follows:

- *ME EQUIPMENT normally used on a floor or a table is placed as near to the walls as is likely to occur in NORMAL USE.*
- *ME EQUIPMENT normally affixed to a wall is mounted on one of the walls, as near to the other wall and to the floor or ceiling as is likely to occur in NORMAL USE.*
- *ME EQUIPMENT normally affixed to a ceiling is mounted on the ceiling as near to the walls as is likely to occur in NORMAL USE.*

3) HAND-HELD ME EQUIPMENT is suspended in its normal position, in still air.

4) ME EQUIPMENT intended for installation in a cabinet or wall is built in as required by the technical description (see 7.9.3.1), using dull black painted plywood walls, 10 mm thick when representing cabinet walls if the technical description so specify and 20 mm thick when representing building walls.

b) Supply

- *ME EQUIPMENT having heating elements is operated as in NORMAL USE, with all heating elements energized unless prevented by switching interlocks, the supply voltage being equal to 110 % of the maximum RATED voltage.*
- *Motor operated ME EQUIPMENT is operated under normal load and normal DUTY CYCLE and the least favourable voltage between 90 % of the minimum RATED voltage and 110 % of the maximum RATED voltage.*
- *Combined heating and motor operated and other ME EQUIPMENT is tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.*
- *When modules are tested separately, the configuration for testing simulates the worst case conditions of NORMAL USE that might affect the test result.*

c) Thermal stabilization

- *For ME EQUIPMENT intended for non-CONTINUOUS OPERATION:*

  After operating in standby/quiescent mode until THERMAL STABILITY is reached, the ME EQUIPMENT is operated in NORMAL USE over consecutive cycles until THERMAL STABILITY is again achieved, or for 7 h, whichever is shorter. The "on" and "off" periods for each cycle are the RATED "on" and "off" periods;

- *For ME EQUIPMENT for CONTINUOUS OPERATION:*

  The ME EQUIPMENT is operated until THERMAL STABILITY is reached.

d) Temperature measurement

- *Resistance method (for windings):*

  The value of the temperature rise of a copper winding is calculated from the formula:

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$$\Delta T = \frac{R_2 - R_1}{R_1}(234{,}5 + T_1) - (T_2 - T_1)$$

where:

ΔT is the temperature rise in °C;

R_1 is the resistance at the beginning of the test in Ω;

R_2 is the resistance at the end of the test in Ω;

T_1 is the room temperature at the beginning of the test in °C;

T_2 is the room temperature at the end of the test in °C.

At the beginning of the test, windings are to be at room temperature.

NOTE When the resistance method is used, it is recommended that the resistance of windings at the end of the test be determined by taking measurements as soon as possible after switching off, and then at short intervals so that a curve of resistance against time can be plotted for ascertaining the value at the instant of switching off.

– *Thermocouple and other methods (for all measurements):*

Measurement is made by devices or sensors so chosen and positioned that they have a negligible effect on the temperature of the part under test.

When thermocouples are used to determine the temperature of windings, the temperature limits of Table 22 are to be reduced by 10 °C.

The temperature of electrical insulation, other than that of windings, is determined on the surface of the insulation at places where failure could cause a short circuit, bridging of a MEANS OF PROTECTION, bridging of insulation or reduction of CREEPAGE DISTANCES or AIR CLEARANCES below the values specified for the insulation type in 8.9.

The point of separation of cores of a multicore cord and where insulated wires enter lampholders are examples of places where temperatures might be measured.

e) Test criteria

During the test THERMAL CUT-OUTS are not de-activated.

The maximum temperature of a part is determined by measuring the temperature rise of the part under test and adding it to the maximum allowed ambient temperature specified in the technical description (see 7.9.3.1). Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE.

11.1.4 GUARDS

GUARDS intended to prevent contact with hot or cold accessible surfaces of ME EQUIPMENT shall be removable only with the aid of a TOOL.

Compliance is checked by inspection.

11.2 * Fire prevention

11.2.1 * Strength and rigidity required to prevent fire in ME EQUIPMENT

ENCLOSURES shall have the strength and rigidity necessary to avoid a fire that could occur as a result of a total or partial collapse caused by reasonably foreseeable misuse.

Compliance is checked by the mechanical strength tests for ENCLOSURES (see 15.3).

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11.2.2 * ME EQUIPMENT and ME SYSTEMS used in conjunction with OXYGEN RICH ENVIRONMENTS

11.2.2.1 RISK of fire in an OXYGEN RICH ENVIRONMENT

In ME EQUIPMENT and ME SYSTEMS, the RISK of fire in an OXYGEN RICH ENVIRONMENT shall be reduced as far as possible under NORMAL CONDITION or SINGLE FAULT CONDITIONS (as identified in 11.2.3). An unacceptable RISK of fire is considered to exist in an OXYGEN RICH ENVIRONMENT when a source of ignition is in contact with ignitable material and there is no means that would limit the spread of a fire.

NOTE 1 For oxygen concentrations up to 25 % at one atmosphere or partial pressures up to 27,5 kPa for higher atmospheric pressures, the requirements in 13.1.1 are considered to be sufficient.

a) * A source of ignition is considered to exist in an OXYGEN RICH ENVIRONMENT when any of the following conditions exist in NORMAL CONDITION and SINGLE FAULT CONDITIONS (including voltage and current):

1) the temperature of the material is raised to its ignition temperature;

2) temperatures could affect solder or solder joints causing loosening, short circuiting or other failures that could result in sparking or raising the temperature of the material to its ignition temperature;

3) parts affecting safety crack or change their outer shape exposing temperatures exceeding 300 °C or sparks (see 4) and 5) below) due to overheating;

4) temperatures of parts or components could exceed 300 °C;

5) sparks provide adequate energy for ignition by exceeding the limits of Figure 35 to Figure 37 (inclusive).

Items 4) and 5) address the worst case where the atmosphere is 100 % oxygen, the contact material (for item 5) is solder and the fuel is cotton. Available fuels and oxygen concentrations should be taken into consideration when applying these specific requirements. Where deviations from these worst case limits are made (based on lower oxygen concentrations or less flammable fuels) they shall be justified and documented in the RISK MANAGEMENT FILE.

As an alternative to 11.2.2.1 a) 5), the following test may be used to determine whether a source of ignition exists.

First, the place(s) within the ME EQUIPMENT where sparking might cause ignition are identified. Then the material(s) of the parts between which sparks can occur is identified. Samples of the same material are then used to construct the contact pins for the test apparatus (see Figure 34).

Other parameters for the test are: oxygen concentration, fuel, electrical parameters (current, voltage, capacitance, inductance or resistance). These parameters are chosen such that they represent the worst case for the ME EQUIPMENT.

NOTE 2 For ME EQUIPMENT that includes a circuit not addressed in Figure 35 to Figure 37 (inclusive), either the test voltage or current may be set at three times the worst case values with the other parameter set at the worst case value for determining whether ignition can occur.

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Two contact pins made of the material to be considered are placed in opposition (see Figure 34). One pin has a diameter of 1 mm, the other of 3 mm. The electrical source is connected to the pins as shown in Figure 35 to Figure 37. A piece of cotton is placed close to the contact surfaces of the two pins. The contacts are constantly flushed by oxygen with a speed of less than 0,5 m/s via a tube. The cathode is moved to the anode to close the contacts and pulled back to open them again. A minimum of 300 trials has to be performed before it can be decided that the sparks do not ignite. If the sparks get smaller because of bad surfaces of the electrodes, the electrodes are cleaned with a file. If the cotton gets black because it became oxidized then it is replaced. In Figure 36 and Figure 37, the resistance used to control current flowing into the inductor and the time constant for charging the capacitor is chosen such that it has minimal impact on the energy of the spark. This is tested by visual inspection without the capacitor in place or with the inductor shorted.

The situation with the highest voltage or current respectively and no ignition defines the upper limit. A safe upper limit is given by dividing the upper limit of voltage or current respectively with the safety margin factor of three.

NOTE 3 The safety margin factor is considered to cover the uncertainty of sparking experiments and the variability of the underlying parameters like pressure, quality of cotton or of the contact materials.

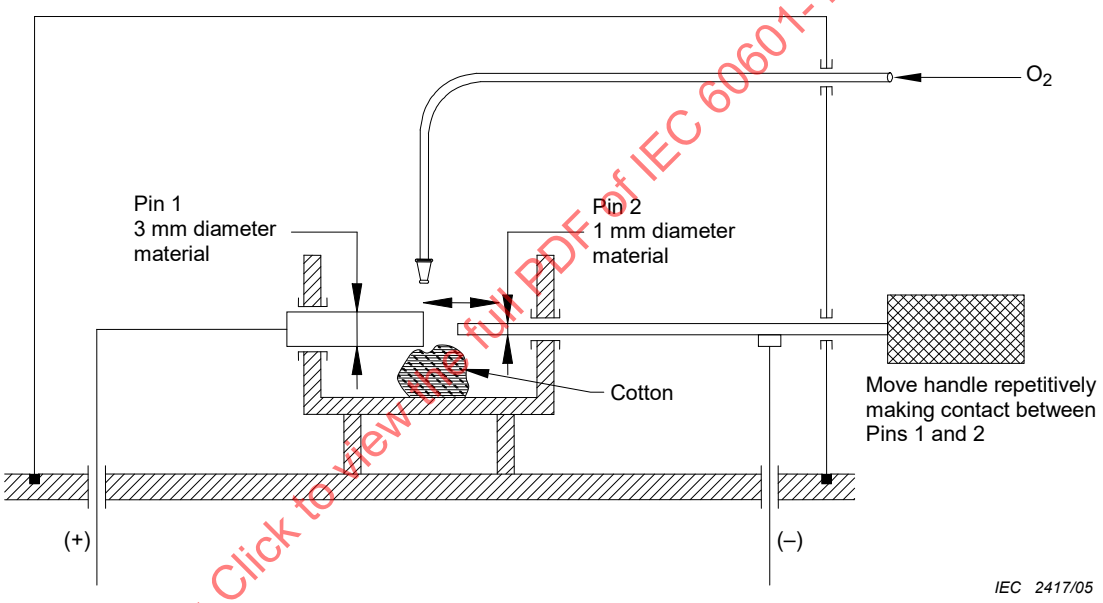


Figure 34 – Spark ignition test apparatus
(see 11.2.2.1)

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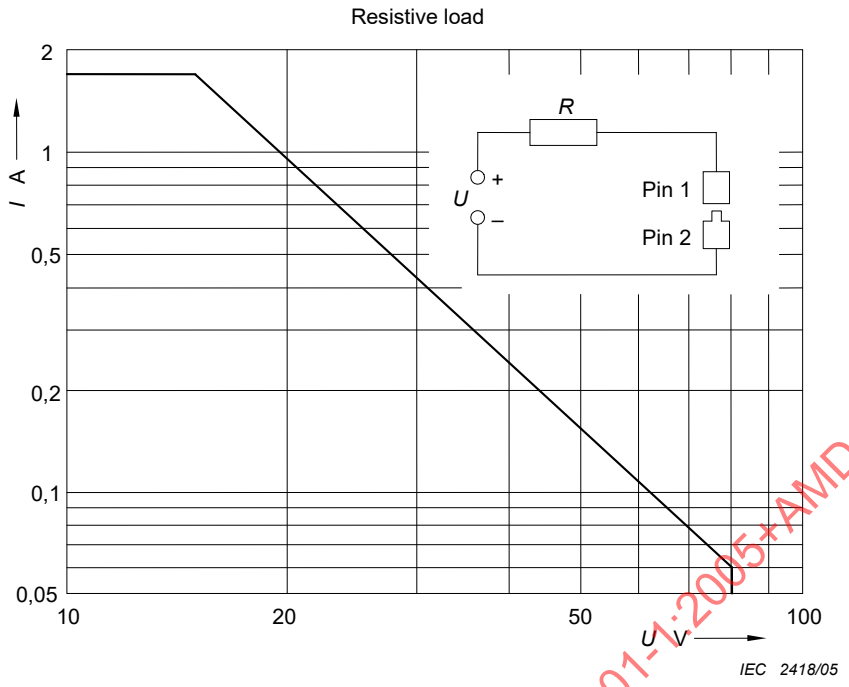


Figure 35 – Maximum allowable current *I* as a function of the maximum allowable voltage *U* measured in a purely resistive circuit in an OXYGEN RICH ENVIRONMENT
(see 11.2.2.1)

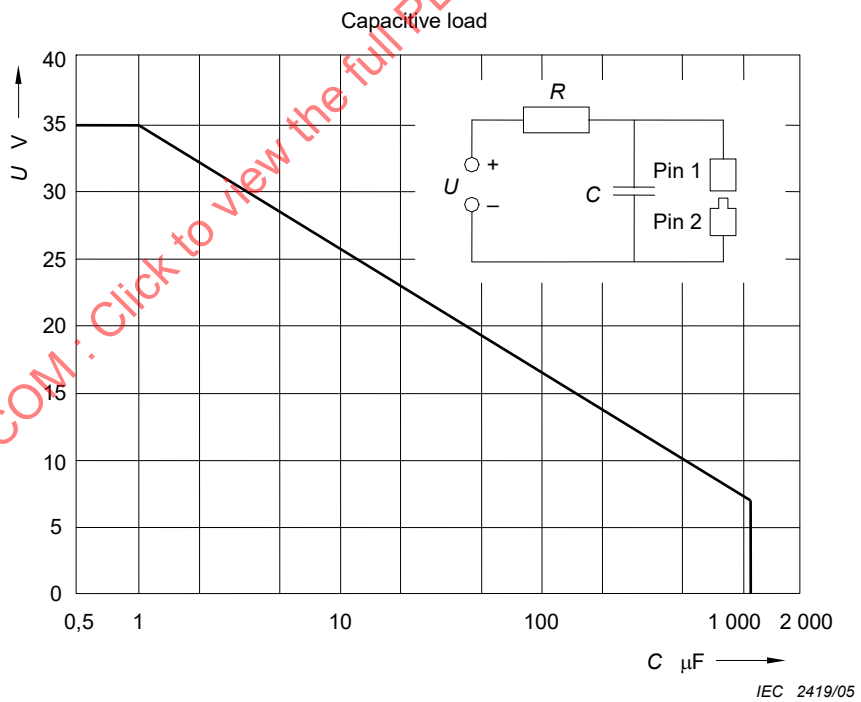


Figure 36 – Maximum allowable voltage *U* as a function of the capacitance *C* measured in a capacitive circuit used in an OXYGEN RICH ENVIRONMENT
(see 11.2.2.1)

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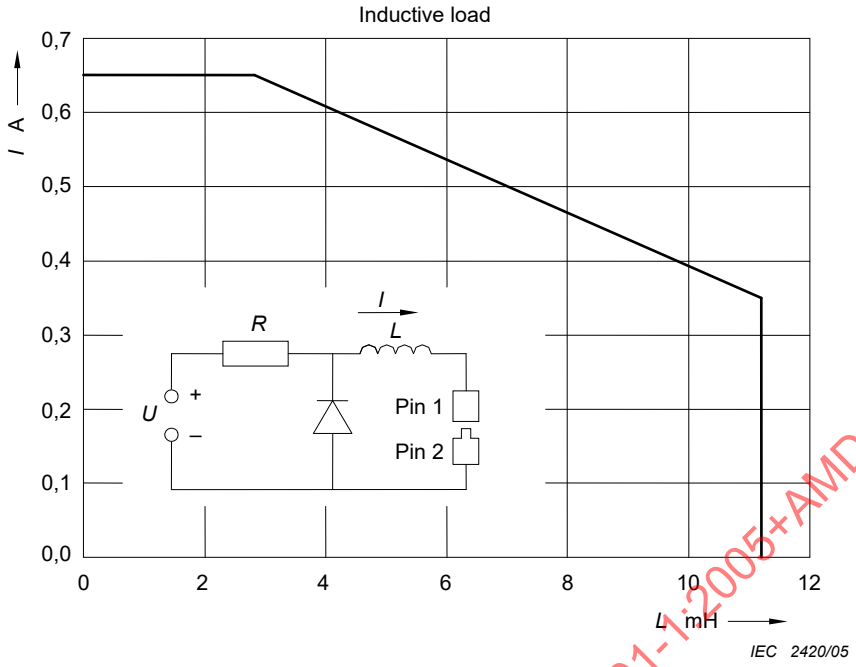


Figure 37 – Maximum allowable current *I* as a function of the inductance *L* measured in an inductive circuit in an OXYGEN RICH ENVIRONMENT
(see 11.2.2.1)

b) The following configurations, alone or in combination as appropriate (as determined by the application of the RISK MANAGEMENT PROCESS), are considered to provide an acceptable RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT.

1) Electrical components in a compartment with an OXYGEN RICH ENVIRONMENT shall have power supplies with limited energy levels. Those energy levels shall be less than those which are considered to be sufficient for ignition (see 11.2.2.1 a)).

Compliance is checked by inspection of the design and measurement or calculation of power, energy and temperature values in NORMAL CONDITION and SINGLE FAULT CONDITION (as identified in 11.2.3).

or

2) * Compartments that contain parts or components that can be a source of ignition (as defined in 11.2.2.1 a)) only under SINGLE FAULT CONDITION (as identified in 11.2.3) and that can be penetrated by oxygen (e.g. because of an undetected leak) shall be ventilated such that the oxygen concentration will not exceed 25 %.

Compliance is checked by the following test:

The oxygen concentration is measured for such a period that the highest possible concentration of oxygen occurs. The least favourable control settings are selected. The leaking conditions of oxygen are selected such that they provide the minimum leak that could be detected by the OPERATOR (e.g. because of a failure of the function of the device). If the concentration of oxygen exceeds 25 % in the presence of parts or components that could be a source of ignition including at the moment energy is applied, it constitutes a failure.

or

3) * A compartment that contains parts or components that can be a source of ignition (as defined in 11.2.2.1 a)) only under SINGLE FAULT CONDITION (as identified in 11.2.3) IS separated from another compartment that contains an OXYGEN RICH ENVIRONMENT by

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sealing all joints and any holes for cables, shafts or for other purpose. The effect of possible leaks and failures under SINGLE FAULT CONDITION (as identified in 11.2.3) that could cause ignition shall be evaluated using a RISK ASSESSMENT to determine the appropriate maintenance intervals.

Compliance is checked by visual inspection and by inspection of the documentation provided by the MANUFACTURER including the RISK MANAGEMENT FILE.

or

4) Electrical components in a compartment containing an OXYGEN RICH ENVIRONMENT that can become a source of ignition (as defined in 11.2.2.1 a)) only under SINGLE FAULT CONDITIONS (as identified in 11.2.3) shall be enclosed in such a way that should ignition occur within the ENCLOSURE, the fire would self-extinguish rapidly and no hazardous amount of toxic gases would reach the PATIENT.

Compliance shall be checked by starting a fire in the ENCLOSURE. If it is not evident that toxic gases cannot reach the PATIENT, the gas that could reach the PATIENT is analyzed.

11.2.2.2 * External exhaust outlets for OXYGEN RICH ENVIRONMENT

External exhaust outlets of an OXYGEN RICH ENVIRONMENT shall not be located so that RISK of ignition occurs because of any electrical component (which could cause a spark in NORMAL USE or SINGLE FAULT CONDITION as identified in 11.2.3) mounted on the outside of the ME EQUIPMENT or an ME SYSTEM. RISK of ignition is considered to be sufficiently low if oxygen concentration in the immediate surroundings of the electrical component does not exceed 25 % under the least favourable conditions of operation.

Compliance is checked by inspection.

11.2.2.3 Electrical connections in OXYGEN RICH ENVIRONMENTS

Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE shall not produce sparks because of loosening or breaking unless they are limited in power and energy to the values identified in 11.2.2.1 a) 5).

Prevention of loosening or breaking is accomplished by the following or equivalent methods.

– Screw-attachments shall be protected against loosening during use by methods such as varnishing, the use of spring washers or application of adequate torques.
– Soldered, crimped and pin-and-socket connections of cables that exit the ENCLOSURE shall include additional mechanical fixing.

Compliance is checked by visual inspection.

11.2.3 SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS in conjunction with ME EQUIPMENT and ME SYSTEMS

– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2).
– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3).
– Failure of a component that creates a source of ignition (as defined in 11.2.2.1 a)).
– Failure of insulation (whether solid material or spacing) providing the equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION (as described in 8.8 and 8.9) that could create a source of ignition (as defined in 11.2.2.1 a)).
– Failure of a pneumatic component that results in leakage of oxygen-enriched gas.

11.3 * Constructional requirements for fire ENCLOSURES of ME EQUIPMENT

This subclause provides an alternative means of compliance with selected HAZARDOUS SITUATIONS and fault conditions as identified in 13.1.2. In doing so, the following constructional

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requirements shall be met or specifically analyzed in the RISK MANAGEMENT FILE and if not met, specific justification shall also be given.

a) Insulated wire within the fire ENCLOSURE shall have a flammability classification equivalent FV-1, or better, according to the appropriate parts of the IEC 60695 series. Connectors, printed circuit boards and insulating material on which components are mounted shall have a flammability classification FV-2, or better, according to IEC 60695-11-10.

Compliance is checked by inspection of data on materials, or by performing the FV tests specified in IEC 60695-11-10 on three samples of the relevant parts being tested. The samples can be any of the following:

1) *complete parts; or*
2) *sections of a part, including the area with the least wall thickness and any ventilation openings.*

Components certified in accordance with IEC 60695-11-10 need not be tested.

b) The fire ENCLOSURE shall meet the following requirements:

1) The bottom shall have no openings or, to the extent specified in Figure 39, shall be constructed with baffles as specified in Figure 38, or be made of metal, perforated as specified in Table 25, or be a metal screen with a mesh not exceeding 2 mm × 2 mm centre to centre and a wire diameter of at least 0,45 mm.

2) The sides shall have no openings within the area that is included within the inclined line C in Figure 39.

3) The ENCLOSURE, and any baffle or flame barrier, shall be made of metal (except magnesium) or of non-metallic materials, except for constructions according to Table 25 and constructions with a mesh, having a flammability classification of FV-2 (or better) for TRANSPORTABLE ME EQUIPMENT and FV-1 (or better) for FIXED ME EQUIPMENT or STATIONARY ME EQUIPMENT in accordance with IEC 60695-11-10.

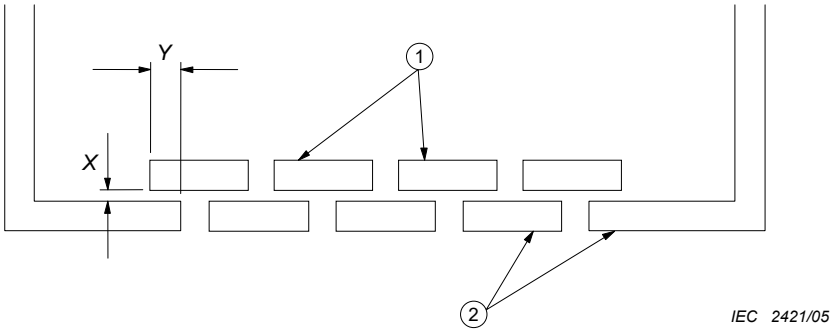
The ENCLOSURE, and any baffle or flame barrier, shall have adequate rigidity.

Conformity is checked by inspection. In case of doubt, the flammability classification of requirement b) 3) is checked as in a).

Table 25 – Acceptable perforation of the bottom of an ENCLOSURE

Minimum thickness mm	Maximum diameter of holes mm	Minimum spacing of holes centre to centre mm
0,66	1,14	1,70 (233 holes/645 mm^2)
0,66	1,19	2,36
0,76	1.15	1,70
0,76	1,19	2,36
0,81	1,91	3,18 (72 holes/645 mm^2)
0,89	1,90	3,18
0,91	1,60	2,77
0,91	1,98	3,18
1,00	1,60	2,77
1,00	2,00	3,00

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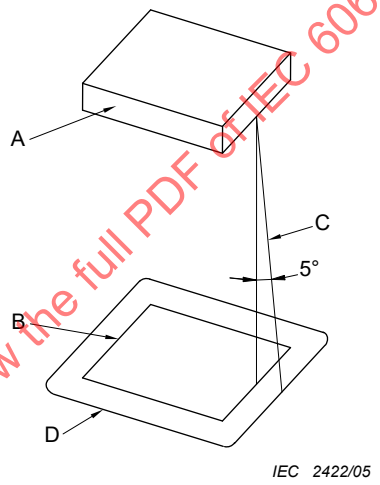


Y = twice X but never less than 25 mm

(1) Baffle plates (may be below the bottom of the ENCLOSURE)

(2) Bottom of the ENCLOSURE

Figure 38 – Baffle
(see 11.3)



Key

A Part or component of the ME EQUIPMENT that is considered to be a source of fire. This consists of an entire component or part of the ME EQUIPMENT if it is not otherwise shielded, or the unshielded portion of a component that is partially shielded by its casing.

B Projection of the outline of A on the horizontal plane.

C Inclined line that traces out the minimum area of the bottom and sides to be constructed as specified in 11.3 b) 1*)* and 11.3 b) 2). This line projects at a 5° angle from the vertical at every point around the perimeter of A and is oriented so as to trace out the maximum area.

D Minimum area of the bottom to be constructed as specified in 11.3 b) 1).

Figure 39 – Area of the bottom of an ENCLOSURE as specified in 11.3 b) 1)
(see 11.3)

11.4 * ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics

ME EQUIPMENT, ME SYSTEMS or their parts described in the ACCOMPANYING DOCUEMNTS for use with flammable anaesthetics (CATEGORY AP) or flammable anaesthetics with oxidants (CATEGORY APG) shall meet the applicable requirements of Annex G.

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11.5 * ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents

The MANUFACTURER'S RISK MANAGEMENT PROCESS shall address the possibility of fire and associated mitigations.

Compliance is determined by inspection of the RISK MANAGEMENT FILE.

11.6 Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT

11.6.1 General

The construction of ME EQUIPMENT and ME SYSTEMS shall ensure a sufficient degree of protection against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization as well as compatibility with substances used with the ME EQUIPMENT.

11.6.2 * Overflow in ME EQUIPMENT

If ME EQUIPMENT incorporates a reservoir or liquid storage chamber that is liable to be overfilled or to overflow in NORMAL USE, liquid overflowing from the reservoir or chamber shall not wet any MEANS OF PROTECTION that is liable to be adversely affected by such a liquid, nor result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE.

If the maximum fill level is indicated by marking on the ME EQUIPMENT and a warning or safety notice is given, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow shall develop if the reservoir or liquid storage chamber is filled to its maximum capacity and the TRANSPORTABLE ME EQUIPMENT is tilted through an angle of 10°, or for MOBILE ME EQUIPMENT exceeding 45 kg, if it is moved over a threshold as described in 9.4.2.4.3.

If no warning or safety notice is given regarding the maximum fill level, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow shall develop if the reservoir or liquid storage chamber is filled to 15 % above the maximum capacity and the TRANSPORTABLE ME EQUIPMENT is tilted through an angle of 10°, or in MOBILE ME EQUIPMENT exceeding 45 kg, if it is moved over a threshold as described in 9.4.2.4.3.

Compliance is checked by the following:

If warnings or safety notices regarding overfilling are marked on the TRANSPORTABLE ME EQUIPMENT, the liquid reservoir is filled to the indicated maximum level.

If there is no warning or safety notice regarding overfilling marked on the TRANSPORTABLE ME EQUIPMENT, the liquid reservoir is filled completely and subsequently a further quantity equal to 15 % of the capacity of the reservoir is added poured in steadily over a period of 1 min.

TRANSPORTABLE ME EQUIPMENT is subsequently tilted through an angle of 10° in the least favourable direction(s) (if necessary with refilling) starting from the position of NORMAL USE.

MOBILE ME EQUIPMENT exceeding 45 kg is moved over a threshold as described in 9.4.2.4.3.

After these PROCEDURES, the ME EQUIPMENT is to pass the appropriate dielectric strength and LEAKAGE CURRENT tests and is to show no signs of wetting of uninsulated electrical parts or electrical insulation of parts that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION (based on a visual inspection).

11.6.3 * Spillage on ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT and ME SYSTEMS requiring the handling of liquids in NORMAL USE, including ME EQUIPMENT or ME SYSTEMS used in an environment where the PROCESS has determined

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that spillage on the ME EQUIPMENT is likely to occur, shall be so constructed that spillage does not wet parts that are likely to result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE .

Compliance is checked by inspection of the RISK MANAGEMENT FILE and by the following test:

The ME EQUIPMENT is positioned according to 5.4 a). A quantity of liquid is poured steadily on a point on the top of the ME EQUIPMENT. The type of liquid, volume, duration of the spill, and location (point) are determined through RISK ANALYSIS. Test conditions that simulate the worst case for spillage shall be documented in the RISK MANAGEMENT FILE.

After these PROCEDURES, the ME EQUIPMENT is to pass the appropriate dielectric strength and LEAKAGE CURRENT tests and is to show no signs of wetting of uninsulated electrical parts or electrical insulation of parts that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION (based on a visual inspection).

11.6.4 * Leakage

See 13.2.6.

11.6.5 * Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

ENCLOSURES of ME EQUIPMENT and ME SYSTEMS designed to give a specified degree of protection against harmful ingress of water or particulate matter shall provide this protection in accordance with the classification of IEC 60529. See also 7.2.9.

Compliance is checked by the tests of IEC 60529 with the ME EQUIPMENT placed in the least favourable position of NORMAL USE and by inspection.

After these PROCEDURES, the ME EQUIPMENT is to show no signs of bridging of insulation (or electrical components) that is likely to result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION (based on a visual inspection) followed by the appropriate dielectric strength and LEAKAGE CURRENT tests.

11.6.6 Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT, ME SYSTEMS and their parts, including APPLIED PARTS and ACCESSORIES, shall be capable of withstanding, without damage or deterioration of safety provisions, the cleaning or disinfection PROCESSES specified in the instructions for use. See also 7.9.2.12.

The MANUFACTURER shall evaluate the effects of multiple cleanings/disinfections as indicated in the instructions for use during the EXPECTED SERVICE LIFE of the ME EQUIPMENT, ME SYSTEM, their parts and ACCESSORIES and assure that these PROCESSES do not result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE.

Where compliance with this standard could be effected by cleaning or disinfecting the ME EQUIPMENT, ME SYSTEM and their parts and ACCESSORIES, they are cleaned or disinfected once in accordance with the methods specified including any cooling or drying period. After these PROCEDURES, the ME EQUIPMENT, ME EQUIPMENT parts or ACCESSORIES are to show no signs of deterioration that could result in an unacceptable RISK (visual inspection) followed by the appropriate dielectric strength and LEAKAGE CURRENT tests. The RISK MANAGEMENT FILE is inspected to verify that the MANUFACTURER has evaluated the affects of multiple cleanings.

11.6.7 Sterilization of ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized shall be assessed and documented according to ISO 11135-1, ISO 11137-1 or ISO 17665-1 as appropriate. See also 7.9.2.12.

After these PROCEDURES, the ME EQUIPMENT, ME SYSTEM and their parts or ACCESSORIES are to show no signs of deterioration that could result in an unacceptable RISK (visual inspection)

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followed by the appropriate dielectric strength and LEAKAGE CURRENT tests and by inspection of the RISK MANAGEMENT FILE.

11.6.8 * Compatibility with substances used with the ME EQUIPMENT

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with compatibility with substances used with the ME EQUIPMENT. Such RISKS may be addressed through the application of appropriate ISO or IEC standards (giving the presumption of acceptable RISK according to 4.2) such as ISO 15001 [70] for components that contain oxygen at pressures greater than 50 kPa or through the MANUFACTURER'S own testing and RISK CONTROL measures.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

11.7 Biocompatibility of ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT, ME SYSTEM and their parts or ACCESSORIES intended to come into direct or indirect contact with biological tissues, cells or body fluids shall be assessed and documented according to the guidance and principles given in the ISO 10993 series of standards.

Compliance is checked by inspection of the information provided by the MANUFACTURER.

11.8 * Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

ME EQUIPMENT shall be so designed that an interruption and restoration of the power supply shall not result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE.

NOTE This can require testing at several durations and ME EQUIPMENT states.

Compliance is checked by interruption and restoration of relevant power supplies.

12 * Accuracy of controls and instruments and protection against hazardous outputs

12.1 Accuracy of controls and instruments

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with accuracy of controls and instruments.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

12.2 USABILITY of ME EQUIPMENT

The MANUFACTURER shall address the RISK(S) of poor USABILITY, including those associated with identification, marking and documents, through a USABILITY ENGINEERING PROCESS complying with IEC 60601-1-6.

Compliance is checked as specified in IEC 60601-1-6.

12.3 ALARM SYSTEMS

If the MANUFACTURER has implemented an ALARM SYSTEM, this ALARM SYSTEM shall comply with IEC 60601-1-8.

Compliance is checked as specified in IEC 60601-1-8.

12.4 Protection against hazardous output

12.4.1 * Intentional exceeding of safety limits

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with hazardous output arising from the intentional exceeding of safety limits.

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Compliance is checked by inspection of the RISK MANAGEMENT FILE.

12.4.2 Indication relevant to safety

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the need to indicate any hazardous output.

EXAMPLE 1 Prior to the delivery of energy or substances to a PATIENT the energy, rate or volume is indicated quantitively.

EXAMPLE 2 During activation of an X-ray output, a flashing yellow light is displayed.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

12.4.3 * Accidental selection of excessive output values

Where ME EQUIPMENT is a multi-purpose unit designed for providing both low-intensity and high-intensity outputs for different treatments, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with accidental selection of excessive output values.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

12.4.4 Incorrect output

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with incorrect output.

EXAMPLE The RISKS associated with incorrect delivery of energy or substances to a PATIENT can be addressed by providing an alarm to alert the OPERATOR to any significant departure from the set level of delivery.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

12.4.5 Diagnostic or therapeutic radiation

12.4.5.1 Limits

For ME EQUIPMENT designed to produce radiation for diagnostic or therapeutic purposes, adequate provisions shall be made to protect PATIENTS, OPERATORS, other persons and sensitive devices in the vicinity, from unwanted or excessive radiation emitted by the ME EQUIPMENT.

NOTE Radiation from ME EQUIPMENT intended for application to PATIENTS for diagnostic or therapeutic purpose under medical supervision could exceed limits normally acceptable for the population as a whole.

As appropriate, particular standards shall specify requirements, limits and compliance tests to ensure radiation safety.

12.4.5.2 Diagnostic X-ray equipment

ME EQUIPMENT and ME SYSTEMS designed to produce X-radiation for diagnostic imaging purposes shall comply with IEC 60601-1-3.

Compliance is checked as specified in IEC 60601-1-3.

12.4.5.3 Radiotherapy equipment

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with radiotherapy.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

12.4.5.4 Other ME EQUIPMENT producing diagnostic or therapeutic radiation

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with ME EQUIPMENT producing diagnostic or therapeutic radiation other than for diagnostic X-rays and radiotherapy (see 12.4.5.2 and 12.4.5.3).

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Compliance is checked by inspection of the RISK MANAGEMENT FILE.

12.4.6 Diagnostic or therapeutic acoustic pressure

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with diagnostic or therapeutic acoustic pressure.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

13 * HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

13.1 Specific HAZARDOUS SITUATIONS

13.1.1 * General

When applying the SINGLE FAULT CONDITIONS as described in 4.7 and listed in 13.2, one at a time, none of the HAZARDOUS SITUATIONS in 13.1.2 to 13.1.4 (inclusive) shall occur in the ME EQUIPMENT.

The failure of any one component at a time, which could result in a HAZARDOUS SITUATION, is described in 4.7.

13.1.2 * Emissions, deformation of ENCLOSURE or exceeding maximum temperature

The following HAZARDOUS SITUATIONS shall not occur:

– emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities;

– deformation of ENCLOSURES to such an extent that compliance with 15.3.1 is impaired;

– temperatures of APPLIED PARTS exceeding the allowed values identified in Table 24 when measured as described in 11.1.3;

– temperatures of ME EQUIPMENT parts that are not APPLIED PARTS but are likely to be touched, exceeding the allowable values in Table 23 when measured and adjusted as described in 11.1.3;

– exceeding the allowable values for “other components and materials” identified in Table 22 times 1,5 minus 12,5 °C. Limits for windings are found in Table 26, Table 27 and Table 31. In all other cases, the allowable values of Table 22 apply.

Temperatures shall be measured using the method described in 11.1.3.

The SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2 and 13.2.2, with regard to the emission of flames, molten metal or ignitable substances, shall not be applied to parts and components where:

– The construction of the supply circuit limits the power dissipation in SINGLE FAULT CONDITION to less than 15 W or the energy dissipation to less than 900 J.

Compliance is checked by drawing 15 W from the supply circuit for 1 min. If, after 1 min. the supply circuit can not supply 15 W, the circuit shall be considered to limit power dissipation to less than 15 W. The related design documentation is also reviewed.

or

– Secondary circuits meet all of the following conditions:

- mounted on material with a flammability classification of FV1 in accordance with IEC 60695-11-10 or better;
- they are energized at a voltage of 60 V d.c. or 42,2 V peak or less in NORMAL and SINGLE FAULT CONDITION;
- they are limited to 100 VA or are limited to 6 000 J in SINGLE FAULT CONDITION;
- they employ wire insulation of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide.

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Compliance is checked by evaluation of the design documentation.

or

– The component is a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS as described in 4.9.

Compliance is checked by evaluation of the design documentation.

or

– They are completely contained within a fire ENCLOSURE.

Compliance is checked by inspection and evaluation of the design documentation to assure that the ENCLOSURE is constructed in accordance with 11.3.

NOTE The tests according to this subclause should be performed in the sequence indicated in Annex B.

After the tests of this clause, THERMAL CUT-OUTS and OVER-CURRENT RELEASES are inspected to determine that their setting has not changed (by heating, vibration or other causes) sufficiently to affect their safety function.

13.1.3 Exceeding LEAKAGE CURRENT or voltage limits

The following HAZARDOUS SITUATIONS shall not occur:

– exceeding the limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION as indicated in 8.7.3;

– exceeding the voltage limits for the ACCESSIBLE PARTS including APPLIED PARTS indicated in 8.4.2.

13.1.4 Specific MECHANICAL HAZARDS

For specific MECHANICAL HAZARDS, see 9.1 to 9.8 (inclusive).

13.2 SINGLE FAULT CONDITIONS

13.2.1 General

During the application of the SINGLE FAULT CONDITIONS listed in 13.2.2 to 13.2.13 (inclusive), the NORMAL CONDITIONS identified in 8.1 a) shall also be applied in the least favourable combination.

13.2.2 Electrical SINGLE FAULT CONDITION

Requirements and tests relating to this SINGLE FAULT CONDITION are found in 8.1.

13.2.3 Overheating of transformers in ME EQUIPMENT

Requirements and tests relating to this SINGLE FAULT CONDITION are found in 15.5.

13.2.4 Failure of THERMOSTATS

Requirements and tests relating to this SINGLE FAULT CONDITION are found in 13.2.13 and 15.4.2 for overloading situations.

THERMOSTATS are short circuited or interrupted, whichever is less favourable.

13.2.5 Failure of temperature limiting devices

Requirements and tests relating to this SINGLE FAULT CONDITION are found in 13.2.13 and 15.4.2 for overloading situations.

THERMOSTATS are short circuited or interrupted, whichever is less favourable.

13.2.6 Leakage of liquid

ME EQUIPMENT shall be so constructed that liquid that might escape in a SINGLE FAULT CONDITION does not result in an unacceptable RISK.

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Since only small amounts of liquid will escape when they leak, sealed rechargeable batteries are exempted from this requirement.

A RISK MANAGEMENT PROCESS shall be used to determine the appropriate test conditions for the ME EQUIPMENT.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

13.2.7 Impairment of cooling that could result in a HAZARDOUS SITUATION

ME EQUIPMENT shall be so designed that it remains SINGLE FAULT SAFE during the failure of cooling systems to operate as intended.

Impairments of cooling that can occur are simulated, for example:

– *single ventilation fans are locked consecutively;*
– *ventilation through openings in top and sides is impaired by covering of openings in the top of the ENCLOSURE or positioning of ME EQUIPMENT against walls;*
– *blocking of filters is simulated;*
– *the flow of a cooling agent is interrupted.*

Temperatures that exceed the limits set in 13.1.2 constitute a failure.

Compliance is checked utilizing the test methods of 11.1, which are applied as far as possible.

13.2.8 Locking of moving parts

ME EQUIPMENT shall be so designed that it remains SINGLE FAULT SAFE when moving parts become jammed.

Moving parts are locked if ME EQUIPMENT:

– *has moving ACCESSIBLE PARTS including APPLIED PARTS liable to be jammed, or*
– *is liable to be operated while unattended (this includes ME EQUIPMENT that is automatically or remotely controlled), or*
– *has one or more motors with a locked rotor torque smaller than the full load torque.*

If ME EQUIPMENT has more than one moving part as described above, only one part at a time is locked. If a SINGLE FAULT CONDITION can lock multiple motors, then all motors are locked simultaneously. For further test criteria see 13.2.10.

13.2.9 * Interruption and short circuiting of motor capacitors

ME EQUIPMENT shall be so designed that it remains SINGLE FAULT SAFE during the short circuit and open circuit of motor capacitors.

Compliance is checked by performing the following test:

Motors with a capacitor in the circuit of an auxiliary winding are operated according to 13.2.10 with a locked rotor, with the capacitor short circuited or open circuited in turn. Capacitor voltages are measured with one side disconnected (open circuit). A measured voltage that exceeds the RATED value constitutes a failure.

The test with a short-circuited capacitor is not performed if the motor is provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT is not intended for unattended use (including automatic or remote control).

For additional test criteria, see 13.2.10.

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13.2.10 * Additional test criteria for motor operated ME EQUIPMENT

For every test in the SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, taking into account the exemptions stated in 13.1.2, motor-operated ME EQUIPMENT is operated starting from COLD CONDITION, at RATED voltage or at the upper limit of the RATED voltage range for the following periods of time:

a) *30 s for:*

- *HAND-HELD ME EQUIPMENT;*
- *ME EQUIPMENT that has to be kept switched on by hand;*
- *ME EQUIPMENT that has to be kept under physical load by hand;*

b) *5 min for other ME EQUIPMENT intended only for attended use (attended use excludes automated or remotely controlled ME EQUIPMENT that could operate when the OPERATOR is not present);*

c) *for the maximum period of a timer, if such a device terminates the operation, for ME EQUIPMENT not listed under a) or b);*

d) *as long as necessary to establish THERMAL STABILITY for all the remaining ME EQUIPMENT.*

Temperatures of windings are determined at the end of the specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices and the like.

Temperatures are measured as specified in 11.1.3 d).

Temperatures that exceed the limits of Table 26 constitute a failure.

13.2.11 Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS

Requirements and tests relating to these SINGLE FAULT CONDITIONS are found in 11.2.2.

13.2.12 Failure of parts that might result in a MECHANICAL HAZARD

Requirements and tests relating to these SINGLE FAULT CONDITIONS are found in Clause 9 and 15.3.

Table 26 – * Temperature limits of motor windings

Temperature in °C

Type of ME EQUIPMENT	Insulation class				
	Class A	Class B	Class E	Class F	Class H
ME EQUIPMENT provided with a timer and not intended for unattended use and ME EQUIPMENT to be operated for 30 s or 5 min	200	225	215	240	260
Other ME EQUIPMENT					
– if impedance-protected, maximum value	150	175	165	190	210
– if protected by protection devices that operate during the first hour, maximum value	200	225	215	240	260
– after the first hour, maximum value	175	200	190	215	235
– after the first hour, arithmetic average	150	175	165	190	210
NOTE The temperature limits in this table were derived from IEC 61010-1:2001 [22].					

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13.2.13 * Overload

13.2.13.1 * General overload test conditions

After the tests of 13.2.13.2 to 13.2.13.4 (inclusive), the ME EQUIPMENT, when cooled down to within 3 °C of the temperature in the test environment, shall remain safe.

Compliance is determined by inspection of the ME EQUIPMENT or the appropriate tests (such as dielectric strength of motor insulation according to 8.8.3).

For insulation of thermoplastic materials that is relied upon as a MEANS OF PROTECTION (see 8.8), the ball-pressure test specified in 8.8.4.1 a) is performed at a temperature 25 °C higher than the temperature of the insulation measured during the tests of 13.2.13.2 to 13.2.13.4 (inclusive).

13.2.13.2 ME EQUIPMENT with heating elements

a) ME EQUIPMENT having heating elements is checked for compliance as follows:

1) for thermostatically controlled ME EQUIPMENT having heating elements that is intended for built-in or for unattended operation or that has a capacitor not protected by a fuse or the like connected in parallel with the contacts of the THERMOSTAT: by the tests of 13.2.13.2 b) and 13.2.13.2 c);

2) for ME EQUIPMENT having heating elements RATED for non-CONTINUOUS OPERATION: by the tests of 13.2.13.2 b) and 13.2.13.2 c);

3) for other ME EQUIPMENT having heating elements: by the test of 13.2.13.2 b).

If more than one of the tests is applicable to the same ME EQUIPMENT, these tests are performed consecutively.

If, in any of the tests, a non-SELF-RESETTING THERMAL CUT-OUT operates, a heating element or an intentionally weak part ruptures, or if the current is otherwise interrupted before THERMAL STABILITY is established without the possibility of automatic restoration, the heating period is ended. However, if the interruption is due to the rupture of a heating element or of an intentionally weak part, the test is repeated on a second sample. Open circuiting of a heating element or of an intentionally weak part in the second sample does not in itself entail a failure to comply. However, if either sample fails to comply with the conditions specified in 13.1.2, it constitutes a failure.

b) ME EQUIPMENT having heating elements is tested under the conditions specified in 11.1, but without adequate heat discharge, the supply voltage being 90 % or 110 % of the RATED supply voltage, whichever is the least favourable.

If a non-SELF-RESETTING THERMAL CUT-OUT operates, or if the current is otherwise interrupted without the possibility of automatic restoration before THERMAL STABILITY is established, the operating period is ended. If interruption of the current does not occur, ME EQUIPMENT is switched off as soon as THERMAL STABILITY is established and is allowed to cool to approximately room temperature.

For ME EQUIPMENT RATED for non-CONTINUOUS OPERATION, the duration of the test is equal to the RATED operating time.

c) Heating parts of ME EQUIPMENT are tested with the ME EQUIPMENT operated in NORMAL CONDITION, at a supply voltage 110 % of the RATED supply voltage and as specified in 11.1. The following test conditions are met.

1) Any control that serves to limit the temperature in NORMAL CONDITION, except a THERMAL CUT-OUT, is disabled.

2) If the ME EQUIPMENT is provided with more than one control, they are disabled in turn.

3) The ME EQUIPMENT is operated at the RATED DUTY CYCLE until THERMAL STABILITY is achieved, irrespective of the RATED operating time.

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13.2.13.3 ME EQUIPMENT with motors

a) ME EQUIPMENT having motors is checked for compliance as follows:

1) For the motor part of the ME EQUIPMENT, compliance is checked by the tests of 13.2.8 to 13.2.10 (inclusive), 13.2.13.3 b), 13.2.13.3 c) and 13.2.13.4, as applicable. For motors located in circuits with a voltage not exceeding 42,4 V peak a.c. or 60 V d.c. and where difficulty is experienced in obtaining accurate temperature measurements due to the small size or design of the motor, it is permitted to use the following test instead of temperature measurement in order to determine compliance with 13.2.9 and 13.2.10.

The motor is covered with a single layer of cheesecloth with the following characteristics:

- *bleached cotton material;*
- *26–28 m^2 per kg mass; and*
- *13 threads per cm in one direction and 11 threads per cm in the other.*

Ignition of the cheesecloth during the test or at its conclusion constitutes a failure.

2) For ME EQUIPMENT that also contains heating parts, the tests are performed at the prescribed voltage, with the motor part and the heating part operated simultaneously so as to produce the least favourable condition.

3) If more than one of the tests is applicable for the same ME EQUIPMENT, these tests are performed consecutively.

b) Motors are checked for running overload protection if they are:

1) intended to be remotely controlled or automatically controlled (by a single control device without redundant protection), or

2) likely to be subjected to CONTINUOUS OPERATION whilst unattended.

Compliance is determined by operating the ME EQUIPMENT under normal load conditions at RATED voltage or at the maximum of the RATED voltage range, until THERMAL STABILITY is achieved (see 11.1.3).

The load is then increased so that the current is increased in appropriate steps, the supply voltage being maintained at its original value.

When THERMAL STABILITY is established, the load is again increased. The load is thus progressively increased in appropriate steps until the overload protection operates, or until no further temperature rise is noted.

The motor winding temperature is determined during each steady period. If the maximum value recorded exceeds the value in Table 27, it constitutes a failure.

Table 27 – Maximum motor winding steady-state temperature

Insulation class	Maximum temperature °C
A	140
B	165
E	155
F	180
H	200

If the load cannot be changed in appropriate steps in ME EQUIPMENT, the motor is removed from the ME EQUIPMENT in order to perform the test.

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The running overload test for motors located in circuits with a voltage not exceeding 42,4 V peak a.c. or 60 V d.c. is performed only if a possibility of an overload occurring is determined by inspection or by review of the design. The test need not be performed, for example, where electronic drive circuits maintain a substantially constant drive current.

c) ME EQUIPMENT with three-phase motors is operated with normal load, connected to a three-phase (SUPPLY MAINS) with one phase disconnected. Periods of operation are according to 13.2.10.

13.2.13.4 * ME EQUIPMENT RATED for non-CONTINUOUS OPERATION

ME EQUIPMENT RATED for non-CONTINUOUS OPERATION other than:

– *HAND-HELD ME EQUIPMENT*;

– *ME EQUIPMENT that has to be kept switched on manually;*

– *ME EQUIPMENT that has to be kept under physical load by hand;*

– *ME EQUIPMENT with a timer and a back-up timer system*

is operated under normal load and at RATED voltage or at the upper limit of the RATED voltage range until the peak temperature does not increase by more than 5 °C in one hour, or until any protective device operates.

Motor winding temperatures are determined when THERMAL STABILITY is established or immediately before the operation of the protective device. Motor winding temperatures that exceed the values specified in 13.2.10 constitute a failure.

If in NORMAL USE a load-reducing device in the ME EQUIPMENT operates, the test is continued with the ME EQUIPMENT running idle.

14 * PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

14.1 * General

The requirements in 14.2 to 14.12 (inclusive) shall apply to PEMS unless:

– none of the PROGRAMMABLE ELECTRONIC SUBSYSTEM (PESS) provides functionality necessary for BASIC SAFETY or ESSENTIAL PERFORMANCE; or

– the application of RISK MANAGEMENT as described in 4.2 demonstrates that the failure of any PESS does not lead to an unacceptable RISK.

The requirements in 14.13 are applicable to any PEMS intended to be incorporated into an IT-NETWORK whether or not the requirements in 14.2 to 14.12 apply.

NOTE 1 This clause requires that a PROCESS be followed throughout the PEMS DEVELOPMENT LIFE-CYCLE and that a RECORD of that PROCESS be produced. The concepts of RISK MANAGEMENT and a PEMS DEVELOPMENT LIFE-CYCLE are the basis of such a PROCESS. However, because a RISK MANAGEMENT PROCESS is already required by this standard, this clause will define the minimum elements of the PEMS DEVELOPMENT LIFE-CYCLE and only the additional elements for the PEMS that needs to be considered as part of the RISK MANAGEMENT PROCESS (see 4.2).

NOTE 2 If a RISK CONTROL measure is implemented within the PEES, it is necessary to apply Clause 14 to demonstrate that the failure of the PEES does not lead to an unacceptable RISK.

NOTE 3 It is recognized that the MANUFACTURER might not be able to follow all the PROCESSES identified in Clause 14 for each constituent component of the PEMS, such as software of unknown provenance (SOUP), subsystems of non-medical origin, and legacy devices. In this case, the MANUFACTURER should take special account of the need for additional RISK CONTROL measures. SOUP is defined in IEC 62304:2006 as a “software item that is already developed and generally available and that has not been developed for the purpose of being incorporated into the medical device (also known as 'off-the-shelf software') or software previously developed for which adequate RECORDS of the development PROCESSES are not available”.

Compliance is determined by inspection of all documentation required, and when necessary, assessment of the requirements in 14.2 to 14.13 (inclusive).

NOTE 4 This assessment could be performed by internal audit.

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When the requirements in 14.2 to 14.13 apply, the requirements in subclause 4.3, Clause 5, Clause 7, Clause 8 and Clause 9 of IEC 62304:2006 shall also apply to the development or modification of software for each PESS.

Compliance is determined by inspection and assessment as required by subclause 1.4 of IEC 62304:2006.

NOTE 5 The software development PROCESS required for compliance with this standard does not include the post-production monitoring and maintenance required by Clause 6 of IEC 62304:2006.

14.2 * Documentation

The documents required by Clause 14 shall be reviewed, approved, issued and changed in accordance with a formal document control PROCEDURE.

14.3 * RISK MANAGEMENT plan

The RISK MANAGEMENT plan required by 4.2.2 shall also include a reference to the PEMS VALIDATION plan (see 14.11).

14.4 * PEMS DEVELOPMENT LIFE-CYCLE

A PEMS DEVELOPMENT LIFE-CYCLE shall be documented.

NOTE Clause H.2 explains PEMS DEVELOPMENT LIFE-CYCLE in more detail.

The PEMS DEVELOPMENT LIFE-CYCLE shall include a set of defined milestones.

At each milestone, the activities to be completed and the VERIFICATION methods to be applied to those activities shall be defined.

Each activity shall be defined including its inputs and outputs.

Each milestone shall identify the RISK MANAGEMENT activities that must be completed before that milestone.

The PEMS DEVELOPMENT LIFE-CYCLE shall be tailored for a specific development by making plans which detail activities, milestones and schedules.

The PEMS DEVELOPMENT LIFE-CYCLE shall include documentation requirements.

14.5 * Problem resolution

Where appropriate, a documented system for problem resolution within and between all phases and activities of the PEMS DEVELOPMENT LIFE-CYCLE shall be developed and maintained.

Depending on the type of product, the problem resolution system may:

– be documented as a part of the PEMS DEVELOPMENT LIFE-CYCLE;

– allow the reporting of potential or existing problems affecting BASIC SAFETY or ESSENTIAL PERFORMANCE;

– include an assessment of each problem for associated RISKS;

– identify the criteria that must be met for the issue to be closed;

– identify the action to be taken to resolve each problem.

14.6 RISK MANAGEMENT PROCESS

14.6.1 * Identification of known and foreseeable HAZARDS

When compiling the list of known or foreseeable HAZARDS, the MANUFACTURER shall consider those HAZARDS associated with software and hardware aspects of the PEMS including those associated with the incorporation of the PEMS into an IT-NETWORK, components of third-party origin and legacy subsystems.

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NOTE In addition to the material given in Annex E of ISO 14971:2007, the list of possible causes for HAZARDS associated with PEMS can include:

– undesired feedback [physical and data] (possibilities include: unsolicited input, out of range or inconsistent input, and input originating from electromagnetic interference);
– unavailable data;
– lack of integrity of data;
– incorrect data;
– incorrect timing of data.
– unintended interactions within and among PESS;
– unknown aspects or quality of third-party software;
– unknown aspects or quality of third-party PESS;
– lack of data security, including its effects on data privacy, and particularly vulnerability to tampering, unintended interaction with other programs and viruses.
– failure of the IT-NETWORK to provide the characteristics necessary for the PEMS to achieve its BASIC SAFETY or ESSENTIAL PERFORMANCE. See Annex H.7.2 for examples.

14.6.2 * RISK CONTROL

The following requirements for PEMS supplement 4.2.2.

Suitably validated tools and PROCEDURES shall be selected and identified to implement each RISK CONTROL measure. These tools and PROCEDURES shall be appropriate to assure that each RISK CONTROL measure satisfactorily reduces the identified RISK(S).

14.7 * Requirement specification

For the PEMS and each of its subsystems (e.g. for a PESS) there shall be a documented requirement specification.

NOTE Example structures of a PEMS are given in H.1.

The requirement specification for a system or subsystem shall include and distinguish any ESSENTIAL PERFORMANCE and any RISK CONTROL measures implemented by that system or subsystem.

14.8 * Architecture

For the PEMS and each of its subsystems, an architecture shall be specified that shall satisfy the requirement specification.

Where appropriate, to reduce the RISK to an acceptable level, the architecture specification shall make use of:

a) COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS;
b) fail-safe functions;
c) redundancy;
d) diversity;
e) * partitioning of functionality;
f) defensive design, e.g. limits on potentially hazardous effects by restricting the available output power or by introducing means to limit the travel of actuators.

The architecture specification shall take into consideration:

g) * allocation of RISK CONTROL measures to subsystems and components of the PEMS;

NOTE Subsystems and components include sensors, actuators, PESS and interfaces.

h) failure modes of components and their effects;
i) common cause failures;
j) systematic failures;
k) test interval duration and diagnostic coverage;

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l) maintainability;

m) protection from reasonably foreseeable misuse;

n) the IT-NETWORK specification, if applicable.

14.9 * Design and implementation

Where appropriate, the design shall be decomposed into subsystems, each having both a design and test specification.

Descriptive data regarding the design environment shall be documented.

NOTE See H.4 a) for examples of design environment elements.

14.10 * VERIFICATION

VERIFICATION is required for all functions that implement BASIC SAFETY, ESSENTIAL PERFORMANCE or RISK CONTROL measures.

A VERIFICATION plan shall be produced to show how these functions shall be verified. The plan shall include:

– at which milestone(s) VERIFICATION is to be performed for each function;

– the selection and documentation of VERIFICATION strategies, activities, techniques, and the appropriate level of independence of the personnel performing the VERIFICATION;

– the selection and utilization of VERIFICATION tools;

– coverage criteria for VERIFICATION.

NOTE Examples of methods and techniques are:

– walkthroughs;

– inspections;

– static analysis;

– dynamic analysis;

– white box testing;

– black box testing;

– statistical testing.

The VERIFICATION shall be performed according to the VERIFICATION plan. The results of the VERIFICATION activities shall be documented.

14.11 * PEMS VALIDATION

A PEMS VALIDATION plan shall include the validation of BASIC SAFETY and ESSENTIAL PERFORMANCE.

Methods used for PEMS VALIDATION shall be documented.

The PEMS VALIDATION shall be performed according to the PEMS VALIDATION plan. The results of PEMS VALIDATION activities shall be documented.

The person having the overall responsibility for the PEMS VALIDATION shall be independent of the design team. The MANUFACTURER shall document the rationale for the level of independence.

No member of a design team shall be responsible for the PEMS VALIDATION of their own design.

All professional relationships of the members of the PEMS VALIDATION team with members of the design team shall be documented in the RISK MANAGEMENT FILE.

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14.12 * Modification

If any or all of a design results from a modification of an earlier design then either all of this clause applies as if it were a new design or the continued validity of any previous design documentation shall be assessed under a documented modification/change PROCEDURE.

When software is modified, the requirements in subclause 4.3, Clause 5, Clause 7, Clause 8 and Clause 9 of IEC 62304:2006 shall also apply to the modification.

14.13 * PEMS intended to be incorporated into an IT-NETWORK

If the PEMS is intended to be incorporated into an IT-NETWORK that is not validated by the PEMS MANUFACTURER, the MANUFACTURER shall make available instructions for implementing such connection including the following:

a) the purpose of the PEMS's connection to an IT-NETWORK;

b) the required characteristics of the IT-NETWORK incorporating the PEMS;

c) the required configuration of the IT-NETWORK incorporating the PEMS;

d) the technical specifications of the network connection of the PEMS including security specifications;

e) the intended information flow between the PEMS, the IT-NETWORK and other devices on the IT-NETWORK, and the intended routing through the IT-NETWORK; and

NOTE 1 This can include aspects of effectiveness and data and system security as related to BASIC SAFETY and ESSENTIAL PERFORMANCE (see also Clause H.6 and IEC 80001-1:2010).

f) a list of the HAZARDOUS SITUATIONS resulting from a failure of the IT-NETWORK to provide the characteristics required to meet the purpose of the PEMS connection to the IT-NETWORK.

NOTE 2 Connecting a PEMS to another piece of equipment for the purpose of transferring data creates a two-node IT-NETWORK. For example, connecting a PEMS to a printer creates an IT-NETWORK. If the MANUFACTURER has validated the PEMS with the printer, the resulting network would be considered within the control of the MANUFACTURER.

Compliance is checked by inspection of the instructions.

In the ACCOMPANYING DOCUMENTS, the MANUFACTURER shall instruct the RESPONSIBLE ORGANIZATION that:

– connection of the PEMS to an IT-NETWORK that includes other equipment could result in previously unidentified RISKS to PATIENTS, OPERATORS or third parties;

– the RESPONSIBLE ORGANIZATION should identify, analyze, evaluate and control these RISKS;

NOTE 3 IEC 80001-1:2010 provides guidance for the RESPONSIBLE ORGANIZATION to address these RISKS.

– subsequent changes to the IT-NETWORK could introduce new RISKS and require additional analysis; and

– changes to the IT-NETWORK include:

- changes in the IT-network configuration;
- connection of additional items to the IT-NETWORK;
- disconnecting items from the IT-NETWORK;
- update of equipment connected to the IT-NETWORK; and
- upgrade of equipment connected to the IT-NETWORK.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

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15 Construction of ME EQUIPMENT

15.1 * Arrangements of controls and indicators of ME EQUIPMENT

When applicable, the MANUFACTURER shall address the RISKS associated with the arrangement of controls and indicators of ME EQUIPMENT in the USABILITY ENGINEERING PROCESS. See 12.2.

Compliance is checked as specified in IEC 60601-1-6.

15.2 * Serviceability

Parts of ME EQUIPMENT subject to mechanical wear, electrical and environmental degradation or ageing that could result in an unacceptable RISK if allowed to continue unchecked for too long a period shall be accessible for inspection, replacement and maintenance.

Parts of ME EQUIPMENT that are likely to be replaced or adjusted shall be so located and secured as to permit inspection, servicing, replacement and adjustment without damage to, or interference with, adjacent parts or wiring.

Compliance is checked by inspection of the parts mentioned above in this subclause and of their location.

15.3 Mechanical strength

15.3.1 General

ME EQUIPMENT or its parts shall have adequate mechanical strength and shall not result in loss of BASIC SAFETY or ESSENTIAL PERFORMANCE due to moulding stress or when subjected to mechanical stress caused by pushing, impact, dropping, and rough handling.

Compliance is checked by application of the tests in Table 28. The tests are not applied to handles, levers, knobs, the face of cathode ray tubes (see 9.5.2), or to transparent or translucent covers of indicating or measuring devices unless with the handle, lever, knob, or cover removed there is an unacceptable RISK of electric shock.

NOTE Examples of damage that can affect BASIC SAFETY include the reduction of CREEPAGE DISTANCES and AIR CLEARANCES below those specified in 8.9, access to parts which exceed limits in 8.4, or access to moving parts which could cause HARM.

Assessment criteria that can be useful in determining if this test has resulted in loss of BASIC SAFETY include:

– those in Clause 8 and 11.6;

– the dielectric strength test as specified in 8.8.3 to evaluate the integrity of solid INSULATION providing a MEANS OF PROTECTION; and

– measurement of CREEPAGE DISTANCES or AIR CLEARANCES to compare the values with the minimum distances specified in 8.9. Small chips that do not adversely affect the protection against electric shock or moisture can normally be ignored.

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Table 28 – Mechanical strength test applicability

ME EQUIPMENT type	Test
HAND-HELD	Push (15.3.2)
	Drop (15.3.4.1)
	Moulding stress relief (15.3.6)
BODY-WORN	Push (15.3.2)
	Impact (15.3.3)
	Drop (15.3.4.1)
	Moulding stress relief (15.3.6)
PORTABLE	Push (15.3.2)
	Impact (15.3.3)
	Drop (15.3.4.2)
	Moulding stress relief (15.3.6)
MOBILE	Push (15.3.2)
	Impact (15.3.3)
	Rough handling (15.3.5)
	Moulding stress relief (15.3.6)
FIXED or STATIONARY	Push (15.3.2)
	Impact (15.3.3)
	Moulding stress relief (15.3.6)

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15.3.2 * Push test

ENCLOSURES of ME EQUIPMENT shall have sufficient rigidity to protect against unacceptable RISK.

Compliance is checked by the following test.

External parts of an ENCLOSURE are subject to a steady force of 250 N ± 10 N for a period of 5 s, applied by means of a suitable test tool providing contact over a circular plane surface 30 mm in diameter. However, this test is not applied to the bottom of an ENCLOSURE of ME EQUIPMENT having a mass of more than 18 kg.

After the test, any damage sustained that results in an unacceptable RISK constitutes a failure.

NOTE See the compliance criteria in 15.3.1.

15.3.3 * Impact test

ENCLOSURES of ME EQUIPMENT shall have sufficient resistance to impact to protect against unacceptable RISK.

Compliance is checked by the following test.

Except for HAND-HELD ME EQUIPMENT and ME EQUIPMENT parts that are HAND-HELD, ENCLOSURES and other external insulating parts, the deterioration of which could result in unacceptable RISK, are tested as indicated below.

A sample consisting of the complete ENCLOSURE, or a portion thereof representing the largest unreinforced area, is supported in its normal position. A solid smooth steel ball, approximately 50 mm in diameter and with a mass of 500 g ± 25 g, is permitted to fall freely from a 1,3 m height once onto each relevant part of the test sample.

To test vertical surfaces, the steel ball is suspended by a cord and allowed to swing like a pendulum in order to apply a horizontal impact, dropping though a vertical distance of 1,3 m once against each relevant part of the test sample.

The test is not applied to flat panel displays, to the platen glass of ME EQUIPMENT (for example film scanners), or to cathode ray tubes (see 9.5.2).

After the test, any damage sustained that results in an unacceptable RISK constitutes a failure.

NOTE See the compliance criteria in 15.3.1.

15.3.4 * Drop test

15.3.4.1 HAND-HELD ME EQUIPMENT

HAND-HELD ME EQUIPMENT, ACCESSORIES and ME EQUIPMENT parts shall not result in an unacceptable RISK as a result of a free fall.

Compliance is checked by the following test.

The sample to be tested, with any SAFE WORKING LOAD in place, is allowed to fall freely once from each of three different starting orientations encountered during NORMAL USE from the height at which the ME EQUIPMENT, ACCESSORY or ME EQUIPMENT part is used (as specified in the ACCOMPANYING DOCUMENTS), or from a height of 1 m, whichever is greater, onto a 50 mm ± 5 mm thick hardwood board (hardwood > 600 kg/m³) lying flat on a concrete or a similar rigid base.

After the test, the HAND-HELD ME EQUIPMENT, ACCESSORY or ME EQUIPMENT part shall not result in an unacceptable RISK.

15.3.4.2 * PORTABLE ME EQUIPMENT

PORTABLE ME EQUIPMENT, ACCESSORIES and ME EQUIPMENT parts shall withstand the stress caused by a free fall from the height indicated in Table 29 onto a hard surface.

Compliance is checked by the following test.

The sample to be tested, with the SAFE WORKING LOAD in place, is lifted to a height as indicated in Table 29 above a 50 mm ± 5 mm thick hardwood board (for example, > 600 kg/m3) that lies flat on a concrete floor or a similar rigid base. The dimensions of the board are at least those of the sample tested. The sample is dropped three times from each orientation in which it can be placed during NORMAL USE.

Table 29 – Drop height

Mass (*m*) of PORTABLE ME EQUIPMENT or its parts kg	**Drop height** cm
$m \leq 10$	5
$10 < m \leq 50$	3
$m > 50$	2

After the test, any damage sustained that results in a unacceptable RISK constitutes a failure.

NOTE See the compliance criteria in 15.3.1.

15.3.5 * Rough handling test

MOBILE ME EQUIPMENT and ME EQUIPMENT parts that are MOBILE shall withstand the stress caused by rough handling and movement and shall not result in an unacceptable RISK.

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Compliance is checked by the following tests.

The sample is tested in transport position with any SAFE WORKING LOAD in place and in the most adverse condition permitted in NORMAL USE. During the test, suitable precautions shall be taken to prevent over-balance caused by the rough handling stress/shock.

a) Ascending step shock

The sample is pushed three times in its normal direction of travel at a speed of 0,8 m/s ± 0,1 m/s, or, for motor-driven MOBILE ME EQUIPMENT, at the maximum speed capable of being maintained, against a solid hardwood plane obstruction with a face of 40 mm that is rigidly attached to an otherwise flat floor. The direction of movement is perpendicular to the face of the obstacle. The sample need not go over the 40 mm obstruction.

b) Descending step shock

The sample is pushed three times in its normal direction of travel at a speed of 0,8 m/s ± 0,1 m/s, or, for motor-driven MOBILE ME EQUIPMENT, at the maximum speed capable of being maintained, in order to fall over a vertical step having a height of 40 mm affixed flat on a rigid base (e.g. concrete). The direction of movement is perpendicular to the face of the descending step.

During performance of the descending step shock test, if a part other than the castor comes in contact with the obstruction before the castor touches the ground, the ME EQUIPMENT continues to be pushed until it has fully descended.

c) Door frame shock

The sample is moved three times in its normal direction of travel at a speed of 0,8 m/s ± 0,1 m/s, or, for motor driven MOBILE ME EQUIPMENT, the maximum speed capable of being maintained, against a hardwood vertical obstacle having a width and thickness of 40 mm affixed to a vertical rigid support (e.g. concrete). The height of the vertical obstacle must be higher than the ME EQUIPMENT contact point(s). The direction of movement is perpendicular to the face of the obstacle.

After each test, any damage sustained that results in an unacceptable RISK constitutes a failure.

NOTE 1 See compliance criteria in 15.3.1.

NOTE 2 Instability of ME EQUIPMENT, when the ME EQUIPMENT remains undamaged from the rough handling shock/stress, is evaluated in accordance with 9.4.

15.3.6 * Mould stress relief test

ENCLOSURES of moulded or formed thermoplastic materials shall be so constructed that any shrinkage or distortion of the material due to release of internal stresses caused by the moulding or forming operation does not result in an unacceptable RISK.

Compliance is checked by inspection of the construction and available data were appropriate or by the following test.

One sample consisting of the complete ME EQUIPMENT, or of the ENCLOSURE together with any supporting framework, is placed in a circulating air oven at a temperature 10 °C higher than the maximum temperature observed on the ENCLOSURE during the test of 11.1.3, but not less than 70 °C, for a period of 7 h, then permitted to cool to room temperature.

NOTE Relative humidity need not be maintained at a specific value during this conditioning.

For large ME EQUIPMENT where it is not practical to condition a complete ENCLOSURE, it is permitted to use a portion of the ENCLOSURE representative of the complete assembly with regard to thickness and shape, including any mechanical support members.

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Any damage that results in an unacceptable RISK constitutes a failure.

15.3.7 * Environmental influences

The selection and treatment of materials used in the construction of ME EQUIPMENT shall take account of the INTENDED USE, the EXPECTED SERVICE LIFE and the conditions for transport and storage.

The ME EQUIPMENT shall be so designed and constructed that during its EXPECTED SERVICE LIFE any corrosion, ageing, mechanical wear, or degradation of biological materials due to the influence of bacteria, plants, animals and the like, shall not reduce its mechanical properties in a way that results in an unacceptable RISK. See also 15.2.

Compliance is checked by inspection:

– *of the ME EQUIPMENT, of the ACCOMPANYING DOCUMENTS and of the MANUFACTURER'S specifications of materials used and of the processing specifications for these materials;*

– *of the MANUFACTURER'S relevant tests or calculations.*

15.4 ME EQUIPMENT components and general assembly

15.4.1 Construction of connectors

Design and construction of electrical, hydraulic, pneumatic and gas connection terminals and connectors of ME EQUIPMENT shall be such that incorrect connection of accessible connectors, removable without the use of a TOOL, shall be prevented where an unacceptable RISK would otherwise exist. In particular:

a) Plugs for connection of PATIENT leads or PATIENT cables shall be so designed that they cannot be connected to outlets on the same ME EQUIPMENT intended for other functions, unless it can be proven that no unacceptable RISK can result.

Compliance is checked by inspection of PATIENT leads, PATIENT cables, connectors and outlets and, if interchange of the leads, cables, connectors or outlets is possible, by inspection of the RISK MANAGEMENT FILE.

b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE shall not be interchangeable. See also ISO 407 [27].

Compliance is checked by inspection of all medical gas connectors.

15.4.2 Temperature and overload control devices

15.4.2.1 Application

a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting shall not be used in ME EQUIPMENT if their use could lead to a HAZARDOUS SITUATION described in 13.1 by such resetting.

Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE.

b) THERMAL CUT-OUTS with a safety function that have to be reset by a soldering operation that can affect the operating value shall not be fitted in ME EQUIPMENT.

Compliance is checked by inspection of the design documentation.

c) In ME EQUIPMENT, where a failure of a THERMOSTAT could lead to a HAZARDOUS SITUATION described in 13.1, an independent non-SELF-RESETTING THERMAL CUT-OUT shall additionally be provided. The temperature of operation of the additional device shall be outside that attainable at the extreme setting of the normal control device (THERMOSTAT) but shall be within the safe temperature limit for the intended function of the ME EQUIPMENT .

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Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE.

d) Loss of function of the ME EQUIPMENT caused by operation of a THERMAL CUT-OUT or OVER-CURRENT RELEASE shall not result in the loss of ESSENTIAL PERFORMANCE or any of the HAZARDOUS SITUATIONS described in 13.1.

Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE.

e) Capacitors or other spark-suppression devices of ME EQUIPMENT shall not be connected between the contacts of THERMAL CUT-OUTS.

Compliance is checked by inspection.

f) The use of a THERMAL CUT-OUT or OVER-CURRENT RELEASE in the design shall not affect the safety of the ME EQUIPMENT.

Compliance is checked by inspection and, if applicable, by the following tests.

Verify compliance of positive temperature coefficient devices (PTC's) with IEC 60730-1:2010, clauses 15, 17, J.15 and J.17 as applicable.

THERMAL CUT-OUTS and OVER-CURRENT RELEASES are tested by operating the ME EQUIPMENT under the conditions described in Clause 13.

SELF-RESETTING THERMAL CUT-OUTS and self-resetting OVER-CURRENT RELEASES including circuits that perform equivalent functions (other than PTC's) are caused to operate 200 times unless approved to the appropriate IEC component standard.

Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES are caused to operate 10 times, if they are not approved to the appropriate IEC component standard (see 4.5) or the MANUFACTURER has not provided adequate data to demonstrate the reliability of the component to perform its safety-related function.

Thermal protection devices can be tested separately from ME EQUIPMENT where engineering judgement indicates that doing so would not impact the test results.

g) ME EQUIPMENT that incorporates a fluid filled container having heating facilities shall be provided with a protection device to safeguard against overheating in the event of the heater being switched on with the container empty. An unacceptable RISK shall not occur from overheating.

Compliance is checked by operating the relevant ME EQUIPMENT with an empty container until the protection device activates.

h) ME EQUIPMENT that incorporates tubular heating elements shall have protection against overheating in both leads where a conductive connection to earth could result in overheating.

Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE.

15.4.2.2 Temperature settings

Where means are provided for varying the temperature setting of THERMOSTATS in ME EQUIPMENT, the temperature setting shall be clearly indicated.

Compliance is checked by inspection.

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15.4.3 * Batteries

15.4.3.1 Housing

In ME EQUIPMENT, housings containing batteries from which gases can escape during charging or discharging shall be ventilated so that there is no unacceptable RISK from the accumulation of gases and possible ignition is prevented.

Battery compartments of ME EQUIPMENT shall be designed to prevent accidental short circuiting of the battery where such short circuits could result in the HAZARDOUS SITUATIONS described in 13.1.

Compliance is checked by inspection of the design documentation and the RISK MANAGEMENT FILE.

15.4.3.2 Connection

If a HAZARDOUS SITUATION might develop by the incorrect connection or replacement of a battery, ME EQUIPMENT shall be fitted with a means of preventing incorrect polarity of connection. See also 7.3.3 and 8.2.2.

Compliance is checked by inspection.

15.4.3.3 Protection against overcharging

Where overcharging of any battery of ME EQUIPMENT could result in an unacceptable RISK, the design shall prevent overcharging.

Compliance is checked by inspection of the design documentation.

15.4.3.4 Lithium batteries

Primary lithium batteries shall comply with the requirements of IEC 60086-4. Secondary lithium batteries shall comply with the requirements of IEC 62133. See also 7.3.3.

NOTE Batteries includes both single cells and assemblies of cells, i.e. battery packages.

Compliance is checked by inspection of the battery design documentation or by performance of the tests identified in IEC 60086-4 for primary lithium batteries and IEC 62133 for secondary lithium batteries.

15.4.3.5 * Excessive current and voltage protection

An INTERNAL ELECTRICAL POWER SOURCE in ME EQUIPMENT shall be provided with an appropriately RATED device for protection against fire caused by excessive currents if the cross-sectional area and layout of the internal wiring or the rating of connected components can give rise to a fire in case of a short circuit. Protective devices shall have adequate breaking capacity to interrupt the maximum fault current (including short-circuit current) which can flow. Justification for omission of fuses or OVER-CURRENT RELEASES shall be documented.

The short circuit test between the positive pole and the negative pole of an INTERNAL ELECTRICAL POWER SOURCE in the area between the INTERNAL ELECTRICAL POWER SOURCE output contacts and the subsequent protection device may be omitted if two MEANS OF OPERATOR PROTECTION are provided. Alternatively, a short-circuit test shall not result in any of the HAZARDOUS SITUATIONS in 13.1.2.

Compliance is checked by inspection for the presence of protective means, and if necessary, by inspection of the design documentation. Alternatively, conduct the short-circuit test and none of the HAZARDOUS SITUATIONS in 13.1.2 shall occur.

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15.4.4 * Indicators

Unless it is otherwise apparent to the OPERATOR from the normal operating position, indicator lights shall be provided to indicate that ME EQUIPMENT is ready for NORMAL USE. The marking of 7.4.1 is not sufficient for this purpose.

If equipped with a stand-by state or a warm-up state whose duration exceeds 15 s, the ME EQUIPMENT shall be provided with an additional indicator light unless it is otherwise apparent to the OPERATOR from the normal operating position.

Indicator lights shall be provided on ME EQUIPMENT incorporating non-luminous heaters to indicate that the heaters are operational, if a HAZARDOUS SITUATION could exist unless it is otherwise apparent to the OPERATOR from the normal operating position.

NOTE This does not apply to heated stylus-pens for recording purposes.

Indicator lights shall be provided on ME EQUIPMENT to indicate that an output exists where an accidental or prolonged operation of the output circuit could constitute a HAZARDOUS SITUATION.

Colours of indicator lights are described in 7.8.1.

In ME EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE, the charging mode shall be visibly indicated to the OPERATOR.

Compliance is checked by inspection of the presence and function of indicating means visible from the position of NORMAL USE.

15.4.5 Pre-set controls

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with pre-set controls.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

15.4.6 Actuating parts of controls of ME EQUIPMENT

15.4.6.1 Fixing, prevention of maladjustment

a) All actuating parts of ME EQUIPMENT shall be so secured that they cannot be pulled off or work loose during NORMAL USE.

b) Controls shall be so secured that the indication of any scale always corresponds with the position of the control.

c) Incorrect connection of the indicating device to the relevant component shall be prevented by an adequate construction, if it can be separated without the use of a TOOL.

Compliance is checked by inspection and tests. For rotating controls, the torques as shown in Table 30 are applied between the control knob and the shaft for not less than 2 s in each direction alternately. The test is repeated 10 times.

A knob that rotates with respect to the shaft constitutes a failure.

If an axial pull is required in NORMAL USE, compliance is checked by applying for 1 min an axial force of 60 N for electrical components and 100 N for other components.

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Table 30 – Test torques for rotating controls

Gripping diameter (*d*) of control knob mm [a]	Torque Nm
10 ≤ *d* < 23	1,0
23 ≤ *d* < 31	2,0
31 ≤ *d* < 41	3,0
41 ≤ *d* < 56	4,0
56 ≤ *d* ≤ 70	5,0
d > 70	6,0
[a] The gripping diameter (*d*) is the maximum width of a control knob regardless of its shape (e.g. control knob with pointer).	

15.4.6.2 Limitation of movement

Stops of adequate mechanical strength shall be provided on rotating or movable parts of controls of ME EQUIPMENT, where necessary to prevent an unexpected change from maximum to minimum, or vice-versa, of the controlled parameter.

Compliance is checked by inspection and manual tests. For rotating controls, the torques as shown in Table 30 are applied for not less than 2 s in each direction alternately. The test is repeated 10 times.

If an axial pull is likely to be applied to the rotating or movable parts of controls of ME EQUIPMENT in NORMAL USE there shall be no unexpected change of the controlled parameter.

Compliance is checked by applying for 1 min an axial force of 60 N for electrical components and 100 N for other components.

15.4.7 Cord-connected HAND-HELD and foot-operated control devices (see also 8.10.4)

15.4.7.1 Mechanical strength

a) HAND-HELD control devices of ME EQUIPMENT shall comply with 15.3.4.1.

b) Foot-operated control devices of ME EQUIPMENT shall be able to support the weight of an adult human being.

Compliance is checked by application to the foot-operated control device, in its position of NORMAL USE, of an actuating force of 1 350 N for 1 min. The force is applied over an area of 30 mm diameter. There shall be no damage to the device resulting in an unacceptable RISK.

15.4.7.2 Accidental operation of ME EQUIPMENT

HAND-HELD and foot-operated control devices shall not result in an unacceptable RISK by changing their control setting when accidentally placed in an abnormal position.

Compliance is checked by turning the control device in all possible abnormal positions and placing it on a flat surface. Any inadvertent change of control setting resulting in an unacceptable RISK constitutes a failure.

15.4.7.3 * Entry of liquids

a) Foot-operated control devices of ME EQUIPMENT shall be at least IPX1 according to IEC 60529.

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Compliance is checked by the tests of IEC 60529.

b) In ME EQUIPMENT, ENCLOSURES of foot operated control devices used in areas such as emergency rooms or operating theatres where liquids are likely to be present at floor level and that contain electrical circuits shall be classified at least IPX6 according to IEC 60529.

Compliance is determined by inspection of the ACCOMPANYING DOCUMENTS, the design documentation and by performing the appropriate tests of IEC 60529.

15.4.8 Internal wiring of ME EQUIPMENT

Aluminium wires of less than 16 mm^2 cross-section shall not be used in ME EQUIPMENT.

Compliance is checked by inspection.

15.4.9 Oil containers

a) Oil containers in PORTABLE ME EQUIPMENT shall be adequately sealed to prevent loss of oil in any position. The container design shall allow for the expansion of the oil.

b) Oil containers in MOBILE ME EQUIPMENT shall be sealed to prevent the loss of oil during transport but may be fitted with a pressure-release device that can operate during NORMAL USE.

c) Partially sealed oil-filled ME EQUIPMENT or its parts shall be provided with means for checking the oil level so that leakage can be detected (see 7.9.3.1).

Compliance is checked by inspection of the ME EQUIPMENT, the technical description, and by manual test.

15.5 * MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5

15.5.1 Overheating

15.5.1.1 * Transformers

Transformers of ME EQUIPMENT shall be protected against overheating in the event of short circuit or overload of any output winding.

Compliance is checked by the tests of 15.5.1.2 and 15.5.1.3 as appropriate under the following conditions:

Each winding is tested, in turn, with the following parameters at the most adverse value:

– *primary voltage maintained between 90 % to 110 % of RATED voltage*

– *RATED input frequency*

– *loads on other windings between no load and their NORMAL USE load*

Short circuit or resistive load, as appropriate, is applied at the ends of the windings or at the first point that can be short circuited under SINGLE FAULT CONDITION.

Components intended to prevent overheating of the transformer during short circuit and overload conditions are included as part of the tests of 15.5.1.2 and 15.5.1.3 provided that:

– *the component is one with high-integrity characteristics, and*

– *two MEANS OF OPERATOR PROTECTION are provided between the output contacts of the transformer up to the COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS.*

During the tests, no winding are to open, no HAZARDOUS SITUATION occurs, and the maximum temperatures of windings are not to exceed the values in Table 31. After the short circuit and

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overload tests, the transformer is to pass the dielectric strength test (as described in 8.8.3) between primary and secondary windings, between the primary windings and the frame and between the secondary windings and the frame. The tests are performed under the conditions specified in 11.1, either in the ME EQUIPMENT or under simulated conditions on the bench.

Table 31 – Maximum allowable temperatures of transformer windings under overload and short-circuit conditions at 25 °C (± 5 °C) ambient temperature

Parts	Maximum temperature °C
Windings and core laminations in contact therewith, if the winding insulation is:	
– of Class A material	150
– of Class B material	175
– of Class E material	165
– of Class F material	190
– of Class H material	210

15.5.1.2 Short-circuit test

The output winding under test is short circuited. The test is continued until the protective device operates or THERMAL STABILITY is achieved. For transformers not tested according to the 5X frequency and 5X voltage test of 15.5.2 a) or the 2X frequency and 2X voltage test of 15.5.2 b), the short circuit is applied directly across the output windings.

15.5.1.3 Overload test

Windings with more than one protective device could require multiple overload tests in order to fully evaluate worst-case NORMAL USE loading and fusing.

The overload test may be applied after rectification.

If the short-circuit test is completed without operation of a protective device (such as a current limiting circuit), the overload test is not required.

a) This test (a) is performed if the current at which the protective device operates cannot be determined based on a review of the provided protective devices and their performance data; otherwise test b) is performed.

The winding under test is loaded to its NORMAL USE load until THERMAL STABILITY is reached. The load is then progressively adjusted in appropriate steps to approach the minimum current at which the protective device operates. Each adjustment of the load is followed by a sufficient time to reach THERMAL STABILITY, and the load current and temperature are to be noted.

Following operation of a protective device, b) is performed.

b) If the protective device that operated in a) is external to the transformer, it is shunted. The winding under test is loaded based on the type of protective device as follows.

– *Fuse in accordance with IEC 60127-1:*

30 min at the appropriate test current determined from Table 32.

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Table 32 – Test current for transformers

Marked value of RATED current (*I*) of protecting fuse-link A	Ratio between test current and RATED current of the fuse-link
$I \leq 4$	2,1
$4 < I \leq 10$	1,9
$10 < I \leq 25$	1,75
$I > 25$	1,6

– *Fuses not in accordance with IEC 60127-1:*

30 min at the current according to the characteristics supplied by the fuse manufacturer, specifically the 30 min clearing-time current. If no 30 min clearing-time current data is available, the test current from Table 32 is used until THERMAL STABILITY is achieved.

– *Other protective device:*

until THERMAL STABILITY at a current just below that which caused the device to operate in a).

This portion of the overload test is concluded at the specified time or when a second protective device opens.

15.5.2 * Dielectric strength

This subclause is not applicable to transformers operating at a frequency above 1 kHz, which are tested in accordance with 8.8.3.

ME EQUIPMENT transformer windings shall have adequate insulation to prevent internal short-circuits that could cause overheating where such overheating could result in a HAZARDOUS SITUATION.

The dielectric strength of the electrical insulation between turns and layers of each winding of a transformer of ME EQUIPMENT where failure of the transformer could result in a HAZARDOUS SITUATION shall be such that after the humidity preconditioning treatment (see 5.7) it passes the following tests.

a) *Transformer windings having a RATED voltage ≤ 500 V or RATED frequency ≤ 60 Hz are tested with a voltage across the winding of five times the RATED voltage or five times the upper limit of the RATED voltage range of that winding and a frequency not less than five times the RATED frequency (where RATED frequency is the normal operating frequency of the transformer input voltage).*

b) *Transformer windings having a RATED voltage exceeding 500 V or RATED frequency exceeding 60 Hz are tested with a voltage across that winding of twice the RATED voltage or twice the upper limit of the RATED voltage range of that winding and a frequency not less than twice the RATED frequency (where RATED frequency is the normal operating frequency of the transformer input voltage).*

In the two cases above, however, the stress on the turn and layer insulation of any winding of the transformer is to be such that the test voltage appearing at the winding with the highest RATED voltage does not exceed the test voltage specified in Table 6, for one MEANS OF PROTECTION, if the RATED voltage of such a winding is considered as the WORKING VOLTAGE. If this should occur, the test voltage on the primary winding is reduced accordingly. The test frequency can be adapted to produce in the core approximately the magnetic induction present in NORMAL USE. Where the core of the transformer is isolated from all external conductive connections (such as in most toroidal transformers), connections to the core described below may be omitted.

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– *Three-phase transformers can be tested by means of a three-phase testing device or by three consecutive tests using a single-phase testing device.*

– *The value of the test voltage with respect to the core and to any screen between primary and secondary windings is in accordance with the specification of the relevant transformer. If the primary winding has an identified connection point for the neutral of the SUPPLY MAINS such a point is connected to the core (and screen if present) unless the core (and screen) are specified for connection to an unearthed part of the circuit. To simulate this, the core (and screen) are connected to a source with an appropriate voltage and frequency with respect to the identified connection point.*

  If such a connection point has not been identified, each side of the primary winding in turn is connected to the core (and screen if present) unless the core (and screen) are specified for connection to an unearthed part of the circuit.

  To simulate this, the core (and screen) are connected to a source with an appropriate voltage and frequency with respect to each side of the primary winding in turn.

– *During the test, all windings not intended for connection to the SUPPLY MAINS are left unloaded (open circuit). Windings intended to be earthed at a point or to be operated with a point nearly at earth potential are to have such a point connected to the core, unless the core is specified for connection to an unearthed part of the circuit.*

  To simulate this, the core is connected to a source with an appropriate voltage and frequency with respect to such windings.

– *Initially not more than half the prescribed voltage is applied, then, it is raised over a period of 10 s to the full value, which is then maintained for 1 min, after which the voltage is reduced gradually and switched off.*

– *Tests are not conducted at resonant frequencies.*

Compliance is checked by the following:

During the test, any flashover or breakdown of any part of the insulation constitutes a failure. There is to be no detectable deterioration of the transformer after the test.

Slight corona discharges are neglected, provided that they cease when the test voltage is temporarily dropped to a lower value, that this value is higher than the WORKING VOLTAGE and that the discharges do not provoke a drop in test voltage.

15.5.3 * Construction of transformers used to provide separation as required by 8.5

Transformers of ME EQUIPMENT that form MEANS OF PROTECTION as required by 8.5 shall comply with the following:

– Means shall be provided to prevent displacement of end turns beyond the interwinding insulation.

– If a protective earthed screen has only one turn, it shall have an insulated overlap of not less than 3 mm. The width of the screen shall be at least equal to the axial winding length of the primary winding.

– The exit of the wires from the internal windings of toroidal transformers shall be provided with double sleeving complying with the requirements for two MEANS OF PROTECTION and having a total wall thickness of at least 0,3 mm, extending at least 20 mm outside the winding.

– The insulation between primary and secondary windings shall comply with 8.8.2.

– CREEPAGE DISTANCES and AIR CLEARANCES shall comply with 8.9.4 with the following exceptions:

  • Enamelled or lacquered winding wires are considered as contributing 1 mm each to the CREEPAGE DISTANCES specified in 8.9.4 for MEANS OF PATIENT PROTECTION.

  • CREEPAGE DISTANCES are measured through the joint between two parts of an insulation barrier, except when:

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– either the two parts forming the joint are bonded by heat sealing or other similar means at the place where this is of importance;

or

– the joint is completely filled with adhesive at the necessary places and the adhesive bonds to the surfaces of the insulating barrier so that humidity cannot be sucked into the joint.

- CREEPAGE DISTANCES within moulded transformers are considered not to exist if it can be shown that no gas bubbles are present and the thickness of the insulation between enamelled or lacquered primary and secondary windings is at least 1 mm for reference voltages *U* not exceeding 250 V and increased proportionally for higher reference voltages.

Compliance is checked by inspection of the transformer construction and measurement of required distances.

16 * ME SYSTEMS

16.1 * General requirements for the ME SYSTEMS

After installation or subsequent modification, an ME SYSTEM shall not result in an unacceptable RISK.

Only HAZARDS arising from combining various equipment to constitute an ME SYSTEM shall be considered.

NOTE RESPONSIBLE ORGANIZATIONS are reminded that the assembly of ME SYSTEMS and modifications during the actual service life require evaluation to the requirements of this standard.

An ME SYSTEM shall provide:

– within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with this standard; and

– outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective IEC or ISO safety standards.

Tests shall be performed:

– in NORMAL CONDITION unless otherwise specified, and

– under the operating conditions specified by the MANUFACTURER of the ME SYSTEM.

Safety tests that have already been performed on individual equipment of the ME SYSTEM according to relevant standards shall not be repeated.

The MANUFACTURER of an ME SYSTEM that is (re)configurable by the RESPONSIBLE ORGANIZATION or OPERATOR may use RISK MANAGEMENT methods to determine which configurations constitute the highest RISKS and which measures are needed to ensure that the ME SYSTEM in any possible configuration does not present an unacceptable RISK.

Non-ME EQUIPMENT, when used in an ME SYSTEM, shall comply with IEC or ISO safety standards that are relevant to that equipment.

Equipment in which protection against electric shock relies only on BASIC INSULATION shall not be used in an ME SYSTEM.

Compliance is checked by inspection of appropriate documents or certificates.

16.2 * ACCOMPANYING DOCUMENTS of an ME SYSTEM

An ME SYSTEM, (including a modified ME SYSTEM), shall be accompanied by documents containing all the data necessary for the ME SYSTEM to be used as intended by the MANUFACTURER, and an address to which the RESPONSIBLE ORGANIZATION can refer. The ACCOMPANYING DOCUMENTS shall be regarded as a part of the ME SYSTEM.

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NOTE ACCOMPANYING DOCUMENTS can be provided electronically, e.g. electronic file format or CD-ROM, for an ME SYSTEM capable of displaying or printing those documents.

These documents shall include:

a) the ACCOMPANYING DOCUMENTS for each item of ME EQUIPMENT that is provided by the MANUFACTURER (see 7.8.2);

b) the ACCOMPANYING DOCUMENTS for each item of non-ME EQUIPMENT that is provided by the MANUFACTURER;

c) the following information:

- the specification of the ME SYSTEM, including the use as intended by the MANUFACTURER and a listing of all of the items forming the ME SYSTEM;
- instructions for the installation, assembly and modification of the ME SYSTEM to ensure continued compliance with this standard;
- instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM (see 11.6.6 and 11.6.7);
- additional safety measures that should be applied, during installation of the ME SYSTEM;
- which parts of the ME SYSTEM are suitable for use within the PATIENT ENVIRONMENT;
- additional measures that should be applied during preventive maintenance;
- if a MULTIPLE SOCKET-OUTLET is present and it is a separate item, a warning that it shall not be placed on the floor;
- a warning that an additional MULTIPLE SOCKET-OUTLET or extension cord shall not be connected to the ME SYSTEM;
- a warning to connect only items that have been specified as part of the ME SYSTEM or that have been specified as being compatible with the ME SYSTEM;
- the maximum permitted load for any MULTIPLE SOCKET-OUTLET(S) used with the ME SYSTEM;
- an instruction that MULTIPLE SOCKET-OUTLETS provided with the ME SYSTEM shall only be used for supplying power to equipment that is intended to form part of the ME SYSTEM;
- an explanation of the RISKS of connecting non-ME EQUIPMENT that has been supplied as a part of the ME SYSTEM directly to the wall outlet when the non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer;
- an explanation of the RISKS of connecting any equipment that has not been supplied as a part of the ME SYSTEM to the MULTIPLE SOCKET-OUTLET;
- the permissible environmental conditions of use of the ME SYSTEM including conditions for transport and storage; and
- instructions to the OPERATOR not to touch parts referred to in 16.4 and the PATIENT simultaneously.

d) advice to the RESPONSIBLE ORGANIZATION:

- to carry out all adjustment cleaning, sterilization and disinfection PROCEDURES specified therein; and
- that the assembly of ME SYSTEMS and modifications during the actual service life require evaluation to the requirements of this standard.

Compliance is checked by inspection.

16.3 * Power supply

If ME EQUIPMENT is intended to receive its power from other equipment in an ME SYSTEM, the instructions for use shall specify the other equipment sufficiently to ensure compliance with the requirements of this standard (see 4.10.1, 5.5 f) and 7.9.2.3). See also Figure F.5.

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If an ME SYSTEM:

– is intended to receive its power from an isolated power supply (IPS) or an uninterruptible power supply (UPS), and

– the ME SYSTEM can draw large transient currents when being switching on or off or when operating,

the MANUFACTURER shall restrict such transient currents to the allowed level according to the specification of the IPS or the UPS from which the ME SYSTEM is intended to be supplied.

If an IPS or UPS is not specified, the actual transient current level shall be disclosed in the technical description and any installation instructions.

Compliance is checked by inspection.

16.4 ENCLOSURES

Parts of non-ME EQUIPMENT in the PATIENT ENVIRONMENT that can be contacted by the OPERATOR during routine maintenance, calibration, etc. after removal of covers, connectors, etc., without the use of a TOOL shall operate at a voltage not exceeding the voltage specified in 8.4.2 c) supplied from a source that is separated from the SUPPLY MAINS by two MEANS OF OPERATOR PROTECTION (see 8.5.1).

Compliance is checked by inspection.

16.5 * SEPARATION DEVICES

When FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of equipment of an ME SYSTEM or other systems can cause the allowable values of LEAKAGE CURRENT to be exceeded, then safety measures incorporating a SEPARATION DEVICE shall be applied.

The SEPARATION DEVICE shall have the dielectric strength, CREEPAGE DISTANCES and AIR CLEARANCES required for one MEANS OF OPERATOR PROTECTION appropriate for the highest voltage occurring across the SEPARATION DEVICE during a fault condition.

The WORKING VOLTAGE shall be the highest voltage across the SEPARATION DEVICE during a fault condition, but not less than the MAXIMUM MAINS VOLTAGE.

NOTE 1 For CLASS I equipment, potential differences can occur between the protective earth of the ME EQUIPMENT and the protective earth of other parts of the ME SYSTEM in the absence of a common protective earth.

NOTE 2 Situations that can require a SEPARATION DEVICE include FUNCTIONAL CONNECTIONS to an emergency calling system or a data processing system.

Compliance is checked by the tests in 8.8 and 8.9.

16.6 * LEAKAGE CURRENTS

16.6.1 TOUCH CURRENT

In NORMAL CONDITION, the TOUCH CURRENT from or between parts of the ME SYSTEM within the PATIENT ENVIRONMENT shall not exceed 100 μA.

In the event of the interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR, the TOUCH CURRENT from or between parts of an ME SYSTEM within the PATIENT ENVIRONMENT shall not exceed 500 μA.

NOTE For the purposes of this clause, the LEAKAGE CURRENT from accessible outer surfaces of equipment is also considered to be TOUCH CURRENT.

16.6.2 EARTH LEAKAGE CURRENT of MULTIPLE SOCKET-OUTLET

If the ME SYSTEM or part of the ME SYSTEM is supplied from a MULTIPLE SOCKET-OUTLET, then the current in the PROTECTIVE EARTH CONDUCTOR of the MULTIPLE SOCKET-OUTLET shall not exceed 5 mA.

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16.6.3 * PATIENT LEAKAGE CURRENT

The PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of an ME SYSTEM in NORMAL CONDITION shall not exceed the values specified for ME EQUIPMENT, as given in Table 3 and Table 4 (see also 8.7.3 and 16.1).

The total PATIENT LEAKAGE CURRENT may be measured at installation.

Compliance with the requirements of 16.6.1, 16.6.2 and 16.6.3 is checked by inspection and measurement using a measuring device as specified in 8.7.4.4.

16.6.4 Measurements

16.6.4.1 General conditions for ME SYSTEMS

a) *The TOUCH CURRENT, the PATIENT LEAKAGE CURRENT, the total PATIENT LEAKAGE CURRENT and the total EARTH LEAKAGE CURRENT are measured after the ME SYSTEM has been brought up to operating temperature as follows:*

The ME SYSTEM is operated:

– *For ME SYSTEMS intended for non-CONTINUOUS OPERATION;*

After operating in standby/quiescent mode until THERMAL STABILITY is reached, the ME SYSTEM is operated in NORMAL USE over consecutive cycles until THERMAL STABILITY is again achieved, or for seven hours, whichever is shorter. The "on" and "off" periods for each cycle are the RATED "on" and "off" periods;

– *For ME SYSTEMS intended for CONTINUOUS OPERATION;*

The ME SYSTEM is operated until THERMAL STABILITY is reached.

b) *The ME SYSTEM is connected to a supply with a voltage equal to the highest RATED MAINS VOLTAGE. When the characteristics of an ME SYSTEM can only be measured properly after it has been installed at the site of the RESPONSIBLE ORGANIZATION, prior to its clinical use, the ME SYSTEM is connected to the local SUPPLY MAINS.*

NOTE Where examination of the circuit arrangement and the arrangement of components and material of the ME SYSTEM shows no possibility of any HAZARD, the number of tests could be reduced.

16.6.4.2 Connection of the ME SYSTEM to the measuring supply circuit

a) The ME SYSTEM is tested after being assembled according to its ACCOMPANYING DOCUMENTS.

b) Measuring arrangement

If an isolating transformer is not used for LEAKAGE CURRENT measurements (e.g. when measuring LEAKAGE CURRENT for very high input power ME SYSTEMS), the reference earth of the measuring circuits is connected to the protective earth of the SUPPLY MAINS.

NOTE 1 It is recommended to position the measuring circuit as far as possible away from unscreened power supply leads and (unless specified otherwise in the following subclauses) to avoid placing the ME SYSTEM on or near a large earthed metal surface.

NOTE 2 However, APPLIED PARTS, including PATIENT cables (when present), should be placed on an insulating surface with a dielectric constant of approximately 1 (for example, expanded polystyrene) and approximately 200 mm above an earthed metal surface.

16.7 * Protection against MECHANICAL HAZARDS

If a MECHANICAL HAZARD exists, the ME SYSTEM shall comply with the applicable requirements of Clause 9.

Compliance is checked by inspection or applicable tests.

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16.8 Interruption of the power supply to parts of an ME SYSTEM

An ME SYSTEM shall be so designed that an interruption and restoration of the power to the ME SYSTEM as a whole, or any part of the ME SYSTEM, shall not result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE.

Compliance is checked by interruption and restoration of relevant power connections one at a time and all connections simultaneously.

16.9 ME SYSTEM connections and wiring

16.9.1 Connection terminals and connectors

Design and construction of electrical, hydraulic, pneumatic and gas connection terminals and connectors shall be such that incorrect connection of accessible connectors, removable without the use of a TOOL, shall be prevented unless it can be proven that no unacceptable RISK can result. In particular:

– Plugs for connection of PATIENT leads or PATIENT cables shall be so designed that they cannot be connected to other outlets of the same ME SYSTEM that are likely to be located in the PATIENT ENVIRONMENT unless it can be proved that no unacceptable RISK can result.

  Compliance is checked by inspection of PATIENT leads, PATIENT cables, connectors and outlets and, if interchange of the leads, cables, connectors or outlets is possible, by inspection of the RISK MANAGEMENT FILE.

– Medical gas connections on the ME SYSTEM for different gases to be operated in NORMAL USE shall not be interchangeable. See also ISO 407 [27].

  Compliance is checked by inspection of all medical gas connections.

16.9.2 MAINS PARTS, components and layout

16.9.2.1 * MULTIPLE SOCKET-OUTLET

a) A MULTIPLE SOCKET-OUTLET shall:
   – only allow connection by using a TOOL (see Figure I.1), or
   – be of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or
   – be supplied via a separating transformer (see 16.9.2.1 d) and Annex I).

   Compliance is checked by inspection.

b) A MULTIPLE SOCKET-OUTLET:
   – shall be marked with safety sign ISO 7010-W001 (see Table D.2, safety sign 2) such that it is visible in NORMAL USE; and:
     – shall be marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or
     – shall be marked to indicate which equipment or equipment parts may be safely attached.
   – may be a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT.

   NOTE Each outlet does not have to be marked.

   Compliance is checked by inspection.

c) The MULTIPLE SOCKET-OUTLET shall comply with IEC 60884-1 and the following requirements.
   – CREEPAGE DISTANCES and AIR CLEARANCES shall comply with 8.9.

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– It shall be of CLASS I construction and the PROTECTIVE EARTH CONDUCTOR shall be connected to the earthing contacts in the socket-outlets.

– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS shall comply with 8.6.

– ENCLOSURES shall comply with 8.4.2 d).

– MAINS TERMINAL DEVICES and wiring shall comply with 8.11.4, if applicable.

– RATINGS of components shall not conflict with the conditions of use (see 4.8).

– Design and construction of electrical connection terminals and connectors of MULTIPLE SOCKET-OUTLETS shall prevent the incorrect connection of accessible connectors that are removable without the use of a TOOL.

– Requirements for the POWER SUPPLY CORD as described in 8.11.3 shall be fulfilled.

d) * If the MULTIPLE SOCKET-OUTLET is combined with a separating transformer, the following additional requirements apply.

– The separating transformer shall comply with this standard. Alternatively the separating transformer may comply with the requirements of IEC 61558-2-1, except that the requirements of maximum RATED output power of 1 kVA and degree of protection IPX4 do not apply.

NOTE 1 As a separating transformer is not a MAINS SUPPLY TRANSFORMER, it does not require more than BASIC INSULATION.

NOTE 2 Limitation of output power is not explained in IEC 61558-2-1 and the RATED output power is defined by the fuse in the installation and by the allowable power supply cable used. However, the characteristics of the separating transformer need to be carefully selected, taking into account the variations in the load current of the ME SYSTEM to ensure that the voltage supplied to the various items of the ME SYSTEM remains within the limits specified for the equipment.

– The separating transformer assembly shall be of CLASS I construction.

– The degree of protection against ingress of water as given in IEC 60529 shall be specified.

– The separating transformer assembly shall be marked according to the requirements of 7.2 and 7.3.

– The MULTIPLE SOCKET-OUTLET shall be permanently connected to the separating transformer or the socket-outlet of the separating transformer assembly shall be of a type that cannot accept MAINS PLUGS of any of the kinds identified in IEC/TR 60083 (see Figure I.1 and Figure I.2).

Compliance is checked by inspection and as described in the relevant subclauses of this standard.

16.9.2.2 * PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS

For each part of an ME SYSTEM that shares a MAINS CONNECTION, the impedance and current carrying capability of the total protective earth path of an ME SYSTEM when tested as a unit shall comply with 8.6.4. The impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED shall not exceed 200 mΩ.

PROTECTIVE EARTH CONNECTIONS shall be made so that the removal of any single item of equipment in the ME SYSTEM will not interrupt the protective earthing of any other part of the ME SYSTEM, without at the same time disconnecting the electrical supply to that part.

Additional PROTECTIVE EARTH CONDUCTORS shall only be detachable by use of a TOOL.

Compliance is checked by inspection.

16.9.2.3 Protection of conductors

Conductors that connect different items of equipment within an ME SYSTEM shall be protected against mechanical damage.

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Compliance is checked by inspection.

17 * Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

The MANUFACTURER shall address In the RISK MANAGEMENT PROCESS the RISKS associated with:

– the electromagnetic phenomena existing at the locations where the ME EQUIPMENT or ME SYSTEM is intended to be used as indicated in the ACCOMPANYING DOCUMENTS; and

– the introduction by the ME EQUIPMENT or ME SYSTEM of electromagnetic phenomena into the environment that might degrade the performance of other devices, electrical equipment and systems.

See IEC 60601-1-2 and also see 1.3.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

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Annex A
(informative)

General guidance and rationale

A.1 General guidance

The requirements for ME EQUIPMENT and ME SYSTEMS differ from those for other kinds of electrical equipment because of the particular relationship of ME EQUIPMENT or ME SYSTEM to the PATIENT, the OPERATOR and the surroundings. The following aspects play an important role in this relationship:

a) the inability of the PATIENT or OPERATOR to detect the presence of certain HAZARDS, such as ionizing and non-ionizing radiation;

b) absence of normal reactions of the PATIENT who can be ill, unconscious, anaesthetized, immobilized, etc.;

c) absence of normal protection to currents provided by the PATIENT'S skin, if this is penetrated or treated to obtain a low skin-resistance;

d) support or replacement of vital body functions, which depends on the reliability of ME EQUIPMENT or ME SYSTEM;

e) the simultaneous connection to the PATIENT of more than one piece of ME EQUIPMENT;

f) combination of high-power ME EQUIPMENT and sensitive low-signal ME EQUIPMENT often in ad hoc combinations;

g) the application of electrical circuits directly to the human body, either through contacts to the skin or through the insertion of probes into internal organs;

h) conditions, particularly in operating theatres, that can present a combination of humidity, moisture or HAZARDS of fire or explosion caused by air, oxygen or nitrous oxide.

When ME EQUIPMENT is combined with another electrical equipment to form an ME SYSTEM, additional requirements apply. These are given in Clause 16. In some instances, reference to other parts of this standard is made. If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause could be applicable to ME SYSTEMS as well as to ME EQUIPMENT.

A.2 Safety of ME EQUIPMENT and ME SYSTEMS

BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS, as described in IEC/TR 60513 [12], are part of the total safety situation, comprising safety of ME EQUIPMENT, safety of the installation to which the ME EQUIPMENT or ME SYSTEM is connected and safety of application.

BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS are required for NORMAL USE and for reasonably foreseeable misuse and in NORMAL CONDITION and SINGLE FAULT CONDITIONS. Reliability of functioning is regarded as a safety aspect for life-supporting ME EQUIPMENT and where interruption of an examination or treatment is considered as a HAZARDOUS SITUATION for the PATIENT.

Adequate construction, lay-out and ACCOMPANYING DOCUMENTS that serve to prevent use errors are regarded as safety aspects.

Safety precautions are considered acceptable if they provide adequate protection without an undesirable restriction of normal function.

Generally, it is presumed that ME EQUIPMENT and ME SYSTEMS are operated under the jurisdiction of qualified or licensed persons and that the OPERATOR has the skill required for a particular medical application and acts according to the instructions for use.

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The total safety of ME EQUIPMENT can consist of:

– inherent safety by design;

– protective measures incorporated into the ME EQUIPMENT or additional protective measures, such as the use of shields or protective clothing; and

– information for safety, such as restrictions in the instructions for use concerning transport, mounting or positioning, connection, putting into service, operation and the position of the OPERATOR and his/her assistants in relation to the ME EQUIPMENT during use.

A.3 Guidance to the third edition

In this edition, a number of clauses and subclauses from the second edition have been deleted, e.g. when the clause or subclause was indicated as “Not used.” However, those clauses or subclauses from the second edition that stated “No general requirement” have been retained so that particular or collateral standards can refer to them. The statement, “No general requirement”, has been replaced with a reference to the RISK MANAGEMENT PROCESS because the “general requirement” is that, in the absence of a particular or collateral standard, these issues are dealt with through the application of RISK MANAGEMENT.

While preparing the third edition, basic safety standards and ISO/IEC guides have been taken into consideration to the extent possible consistent with the particular relationship of ME EQUIPMENT or ME SYSTEM to the PATIENT, the OPERATOR and the surroundings.

The format of the third edition has been aligned with the basic requirements of Part 2 of the ISO/IEC Directives. All the sections except Section 1 of the second edition have been converted into major clauses. This change was implemented because sections are no longer allowed under the drafting rules and the new numbering system will allow future changes to modify a clause without affecting the number of other parts of the standard.

The normative references have been moved from Appendix L of the second edition to Clause 2. Informative references are listed in the Bibliography.

The definitions in Clause 3 have been rearranged into a single alphabetical listing as organizing the definitions by category was becoming increasingly difficult and the result less intuitive. The index has been expanded to identify each page where a term is used in the body of the standard. A number of new defined terms have been introduced in support of new or expanded requirements.

A general requirement for a RISK MANAGEMENT PROCESS has been introduced in 4.2.

Clause 8 has been extensively restructured to bring together in one clause the requirements relating to electrical safety. The requirements in Clause 8 have been reviewed against the safety requirements for information technology (IT) equipment in IEC 60950-1 and harmonized where appropriate given the particular relationship of ME EQUIPMENT to the PATIENT, the OPERATOR and the surroundings.

Clause 9 on protection against MECHANICAL HAZARDS has been substantially revised to deal with a wide range of the HAZARDS that ME EQUIPMENT could pose to the OPERATOR or PATIENT. Requirements relating to the mechanical strength of the ME EQUIPMENT when subjected to the stresses caused by pushing, impact, dropping, and rough handling are in 15.3.

The standard now deals with USABILITY in 12.2 as opposed to “user or human errors.”

Section six of the second edition on protection against the HAZARDS of ignition of flammable anaesthetic mixtures has been moved to a normative annex. While this annex was originally intended to be informative because the use of such anaesthetics is rare, comments from National Committees indicated that some MANUFACTURERS might still want to offer ME EQUIPMENT for such applications.

The surface temperature limit in 11.1.2.2 for APPLIED PARTS that are in contact with the PATIENT for 10 min or more has been increased from 41 °C to 43 °C. However, the

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MANUFACTURER is to disclose in the ACCOMPANYING DOCUMENTS if the surface temperature of an APPLIED PART exceeds 41 °C.

The requirements of IEC 60601-1-4 [14] for PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS, as referred to in 52.1 of the second edition, have been incorporated into the body of this standard in a new Clause 14.

The requirements of IEC 60601-1-1 [13] for ME SYSTEMS have been incorporated into the body of this standard in a new Clause 16.

A.4 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclause in this standard, with clause and subclause numbers parallel to those in the body of the document.

Subclause 1.1 – Scope

The scope of this standard is established by the reference to the definitions of ME EQUIPMENT and ME SYSTEMS. This is to clearly define the scope of this standard as compared with requirements for other types of electrical equipment.

Laboratory equipment within the scope of IEC 61010-1 [22] is not covered by this standard except when a MANUFACTURER incorporates such laboratory equipment into an ME SYSTEM.

This standard does not apply to active implantable medical devices covered by the ISO 14708-1 [31] except where the ISO 14708-1 requires compliance with IEC 60601-1.

This standard does not apply to any other electrical equipment unless it falls under the definition of ME EQUIPMENT or ME SYSTEMS.

Subclause 1.3 – Collateral standards

Collateral standards are a vehicle developed by Technical Committee 62 as a way of extending the general standard. Collateral standards fall into two categories:

– standards that address additional BASIC SAFETY and ESSENTIAL PERFORMANCE requirements that are common to a subgroup of ME EQUIPMENT. For example, Subcommittee 62B developed IEC 60601-1-3 to provide general requirements for protection against ionizing radiation in medical diagnostic X-ray equipment in order that the dose equivalent to the PATIENT, the OPERATOR and other staff can be kept as low as reasonably achievable; or

– standards that address additional BASIC SAFETY or ESSENTIAL PERFORMANCE requirements that deal with characteristic of ME EQUIPMENT or ME SYSTEMS that are not fully covered by the general standard. At the time of publication, three collateral standards in this category have been published by Subcommittee 62A: EMC (IEC 60601-1-2), Usability (IEC 60601-1-6) and Alarm systems (IEC 60601-1-8).

The editions of IEC 60601-1-2, IEC 60601-1-3, IEC 60601-1-6 and IEC 60601-1-8 existing at the time of publication of this third edition of the general standard were all developed in relation to the second edition of the general standard (IEC 60601-1:1988). It is intended that revised editions of these collateral standards, relating specifically to this third edition, will be developed and published as soon as possible. As stated in 1.3, these will become normative at the date of their publication and shall apply together with this standard.

Until such new editions of these collateral standards are published, users of this standard should apply the existing editions as far as possible when they are relevant to the ME EQUIPMENT or ME SYSTEM concerned. However some requirements of these collateral standards might not be compatible with this standard.

The requirements from two of the collateral standards developed for the second edition of IEC 60601-1 have been incorporated into the body of this standard. They are:

– IEC 60601-1-1:2000, *Medical electrical equipment – General requirements for safety – Collateral standard: Safety requirements for medical electrical systems*

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– IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral standard: Programmable electrical medical systems* and its Amendment 1 (1999)[11].

While both standards will remain active until all the particular standards based on the second edition of IEC 60601-1 have been aligned with this standard, they are not applicable when applying this standard.

Additional collateral standards can be published from time to time as needs are identified. While those standards will not be mentioned in this standard, they still establish general requirements that need to be considered when applicable. Readers are encouraged to consult the registers of currently valid International Standards maintained by their national standards body to see what applicable collateral standards have been published.

Subclause 1.4 – Particular standards

A particular standard can specify:

– clauses or subclauses of this standard that apply without amendment;

– clauses or subclauses (or parts of them) of this standard that do not apply;

– clauses or subclauses (or parts of them) of this standard that are replaced by clauses or subclauses in the particular standard; or

– additional clauses or subclauses.

A particular standard can contain:

a) requirements that result in an increase of BASIC SAFETY or ESSENTIAL PERFORMANCE;

b) requirements that can be less stringent than the requirements in this standard, if the latter cannot be maintained because of, for example, the power output of ME EQUIPMENT;

c) requirements concerning performance, reliability, interfaces, etc.;

d) accuracy of working data; or

e) extension and limitation of environmental conditions.

Clause 2 – Normative references

This clause provides a list of the documents cited in other normative parts of this standard in such a way as to make them indispensable for the application of the document. However, conformance with the documents in this list is required only to the extent that they are referenced in a normative requirement in this standard. For example, if a reference is made to a specific clause, subclause, table or figure, then the user of this standard is only required to conform to the requirements in that clause, subclause, table or figure in order to satisfy the requirement in this standard.

Undated references are made only to a complete document or to a major part thereof and only if it is accepted that it will be possible to use all future changes of the referenced document for the purposes of this standard. For example, an undated reference is made to IEC 60529 because it is intended that the MANUFACTURER will always use the latest edition of that standard when assigning IP Codes to ENCLOSURES.

Undated references are understood to include all amendments to and revisions of the referenced document.

Dated references are made when the requirements of a particular edition are to be used to satisfy a requirement of this standard. Subsequent amendments to, or revisions of, dated references will need to be incorporated by amendment of this standard.

References to specific clauses, subclauses, tables and figures of another document are always dated.

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[11] There exists a consolidated edition 1.1 (2000) including IEC 60601-1-4 (1996) and its Amendment 1 (1999).

Clause 3 – Terminology and definitions

This clause contains definitions for terms that are necessary for the understanding of the requirements in this standard. Many of these terms are inherited from the second edition. However, a number of terms have been added during the course of developing new or modified requirements. Where possible, existing definitions in other standards have been copied or adapted.

Except when used to support other defined terms, a definition is only provided if the term is used more than once in the text of the standard.

Defined terms are printed in SMALL CAPITALS to assist the reader in identifying them in the body of the standard. When normal case is used, the words have their normal English meaning. The committee made an effort to avoid using the same word both as a defined term and in its normal English meaning. At times this has not been possible. For example, the word "procedure" is used as a defined term in Start-up PROCEDURE, specifically meaning a "specific way to perform an activity" of starting up the ME EQUIPMENT or ME SYSTEM. It is also used in the definition of PATIENT according to its general English meaning, i.e. "Living being (person or animal) undergoing a medical, surgical or dental procedure."

Subclause 3.8 – APPLIED PART

Parts that contact PATIENTS can present greater HAZARDS than other parts of the ENCLOSURE, and these APPLIED PARTS are therefore subject to more stringent requirements, for example, for temperature limits and (according to classification B/BF/CF) for LEAKAGE CURRENT.

NOTE Some other ACCESSIBLE PARTS of the ENCLOSURES of ME EQUIPMENT are subject to tests that are more demanding than those for ENCLOSURES of other kinds of equipment, because the PATIENT can touch them, or the OPERATOR can touch them and the PATIENT simultaneously.

In order to determine which requirements apply, it is necessary to distinguish between APPLIED PARTS and parts that are simply considered as the ENCLOSURE.

Thus, typically:

– an infrared therapy lamp does not have an APPLIED PART because it does not need to be brought into direct contact with the PATIENT;

– the only part of an X-ray table that is an APPLIED PART is the top on which the PATIENT lies;

– likewise, in an MRI scanner, the only APPLIED PART is the table supporting the PATIENT.

However, a part that unintentionally comes into contact with an unconscious, anaesthetized or incapacitated PATIENT can present the same RISKS as an APPLIED PART that necessarily has to contact the PATIENT. On the other hand, a part that an active PATIENT can reach out and touch might present no more RISK to that PATIENT than it presents to an OPERATOR.

The definition in the first and second editions of this standard failed to address this problem. The second amendment to the second edition extended the definition to include parts that can be brought into contact with the PATIENT, but the new definition continued to cause difficulties.

In this edition, subclause 4.6 requires the RISK MANAGEMENT PROCESS to identify which parts, other than APPLIED PARTS, are subject to the same requirements as APPLIED PARTS. These can include parts of non-ME EQUIPMENT in an ME SYSTEM.

Particular standards should specifically identify the APPLIED PART(S) in particular types of ME EQUIPMENT.

In order to assess which parts are APPLIED PARTS and what are the PATIENT CONNECTIONS, the following PROCESS is employed in the order shown.

a) Determine whether the ME EQUIPMENT has an APPLIED PART, and if it has, identify the extent of the APPLIED PART (these decisions being based on non-electrical considerations).

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b) If there is no APPLIED PART, there are no PATIENT CONNECTION(S).

c) If there is an APPLIED PART, there can be one or more PATIENT CONNECTION(S). Even if the APPLIED PART has no accessible conductive parts, foil applied in accordance with 8.7.4.7 is regarded as one PATIENT CONNECTION.

d) Where a conductive part of the APPLIED PART is not in direct contact with the PATIENT, but is not separated and current can flow through such a part to or from the PATIENT, it is to be treated as an individual PATIENT CONNECTION.

NOTE Relevant separation requirements are those that relate to MEANS OF PATIENT PROTECTION.

An APPLIED PART can include one or more functions. Each function can include one or more PATIENT CONNECTIONS. A PATIENT CONNECTION can be an electrode that is intended to carry current; or the electrical connection can be incidental to the purpose, for example with an intra-vascular fluid line or a PATIENT support.

See also the rationale for 3.78.

Figure A.1 to Figure A.7 (inclusive) provide examples of the way in which APPLIED PARTS and PATIENT CONNECTIONS are identified in order to apply the requirements for PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT in various ME EQUIPMENT and ME SYSTEMS.

Figure A.1 and Figure A.2 shows an ECG monitor that includes the ECG monitor, the PATIENT cable, PATIENT leads and the ECG electrodes. In Figure A.1 and Figure A.2:

– The APPLIED PART includes the electrodes and those parts of the PATIENT leads or PATIENT cable that need to physically contact the PATIENT in NORMAL USE.
– Application of RISK MANAGEMENT might identify other parts of the PATIENT lead or PATIENT cable that have to be treated as APPLIED PARTS because of the probability they will come in contact with the PATIENT.
– The PATIENT CONNECTIONS consist of the ECG electrodes, which are all part of the same function of the APPLIED PART.

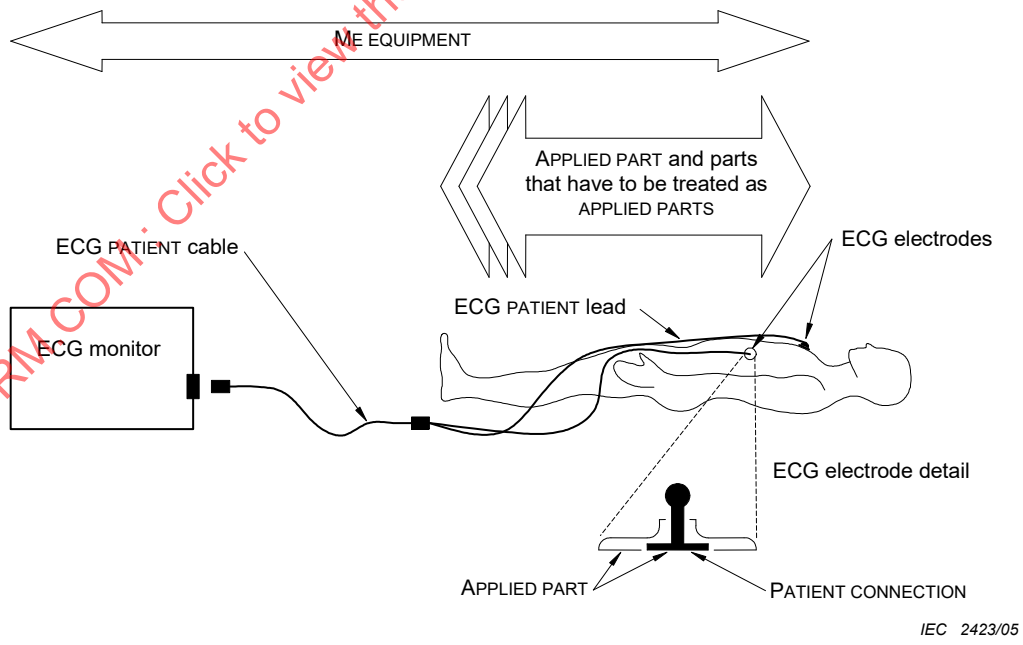


Figure A.1 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in an ECG monitor

Figure A.2 shows the required F-TYPE APPLIED PART insulation. The parts within the dotted line are the PATIENT circuit.

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In Figure A.2, the required APPLIED PART insulation is:

– one MEANS OF PATIENT PROTECTION between earth and parts within the dotted line based on the MAINS VOLTAGE;

– two MEANS OF PATIENT PROTECTION between earth and parts within the dotted line based on the voltage carried by these parts; and

– two MEANS OF PATIENT PROTECTION between live parts (including mains) and the parts within the dotted line.

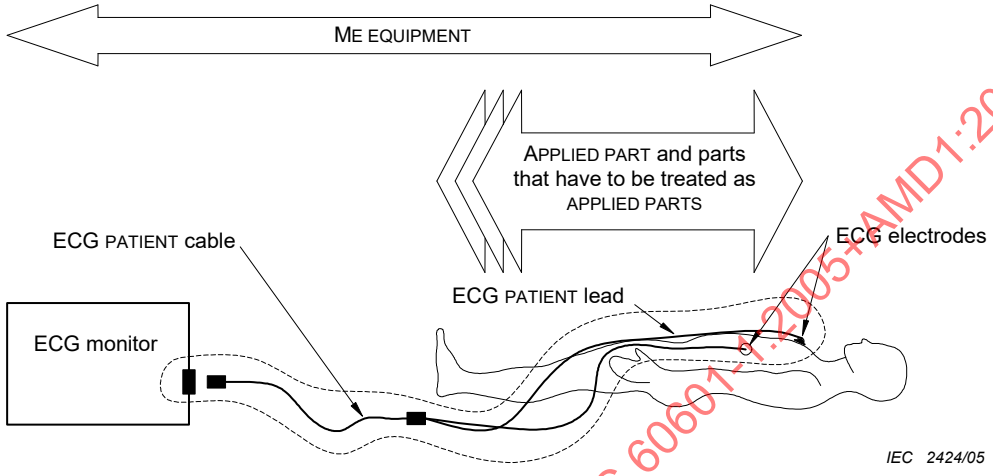


Figure A.2 – Example of the insulation of an F-TYPE APPLIED PART with the insulation incorporated in the ME EQUIPMENT

Figure A.3 shows an F-TYPE APPLIED PART with the insulation incorporated in a transducer. The parts within the dotted line are the PATIENT circuit. There are parts outside the dotted line that are subject to the requirements for APPLIED PARTS as determined through the RISK MANAGEMENT PROCESS.

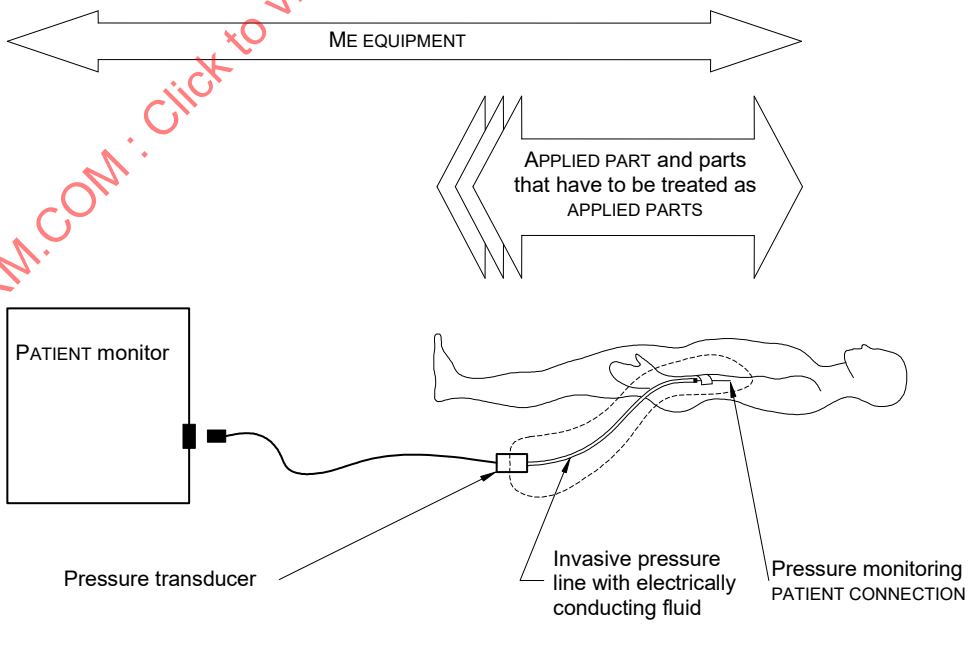


Figure A.3 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a PATIENT monitor with invasive pressure monitoring facility

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Figure A.4 shows a PATIENT monitor with ECG and invasive pressure monitoring facilities. In this example:

– The ME EQUIPMENT includes the ECG monitor; the ECG PATIENT cable, the PATIENT leads and their electrodes; and the pressure transducer and its fluid filled line.

– The APPLIED PART(s) include the ECG electrodes and those parts of the PATIENT cable and PATIENT leads that need to physically contact the PATIENT in NORMAL USE; and the fluid filled pressure monitoring line.

– Application of RISK MANAGEMENT might identify other parts of the ECG PATIENT cable, the PATIENT leads or the pressure transducer that have to be treated as APPLIED PARTS because of the probability they will come in contact with the PATIENT.

– The ECG PATIENT CONNECTIONS consist of the ECG electrodes.

– The pressure monitoring PATIENT CONNECTION consists of the electrically conducting fluid in the pressure line. For the measurement of PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT, an electrode is placed in the electrically conducting fluid and treated as a single PATIENT CONNECTION.

– If the PATIENT CONNECTIONS associated with the ECG function are not electrically separated from the PATIENT CONNECTION associated with the pressure monitoring function, these are treated as two functions of the same APPLIED PART.

– If the PATIENT CONNECTIONS associated with the ECG function are electrically separated from the PATIENT CONNECTION associated with the pressure monitoring function, these are treated as separate APPLIED PARTS.

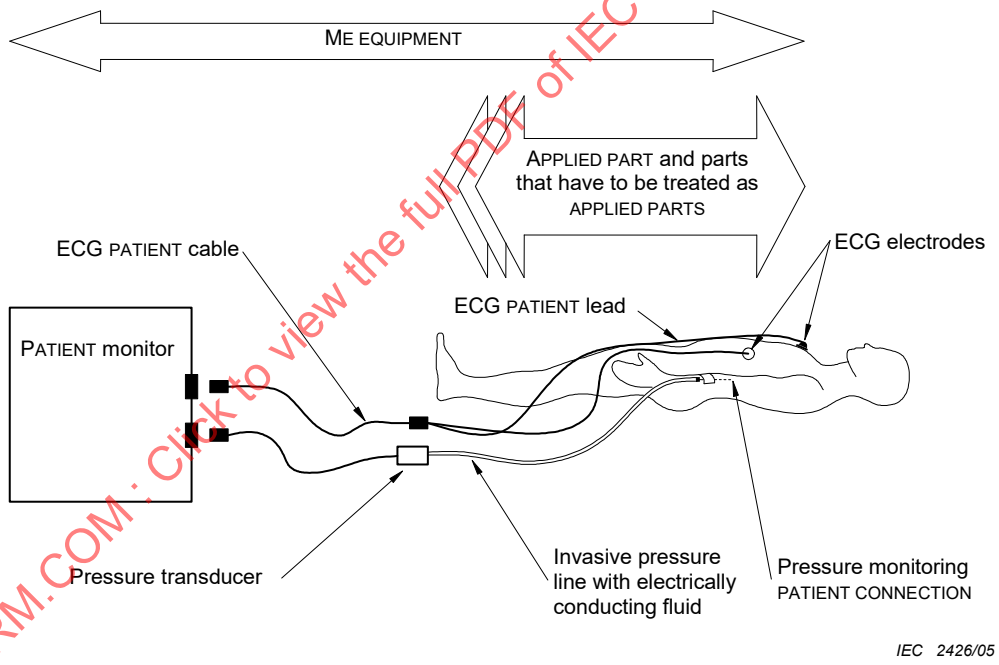


Figure A.4 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a multifunction PATIENT monitor with invasive pressure monitoring facilities

Figure A.5 shows an X-ray ME SYSTEM in which:

– The ME SYSTEM includes the X-ray source assembly, the X-ray table and the wall stand, which are all items of ME EQUIPMENT. Other parts of the ME SYSTEM such as the X-ray generator and OPERATOR console are not shown.

– The APPLIED PART(s) include the top of the table and the front of the wall stand, as these parts need to physically contact the PATIENT in NORMAL USE.

– The application of RISK MANAGEMENT might identify some parts of the tube assembly and some other parts of the table and the wall stand as having to be treated as APPLIED PARTS because of the probability they will come in contact with the PATIENT.

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– The PATIENT CONNECTIONS consist of the conductive parts of these APPLIED PARTS that electrically contact the PATIENT.

– The MANUFACTURER can specify that the table and the wall stand are different functions of the same APPLIED PART.

– Alternatively, the MANUFACTURER can specify that the table and the wall stand are different APPLIED PARTS.

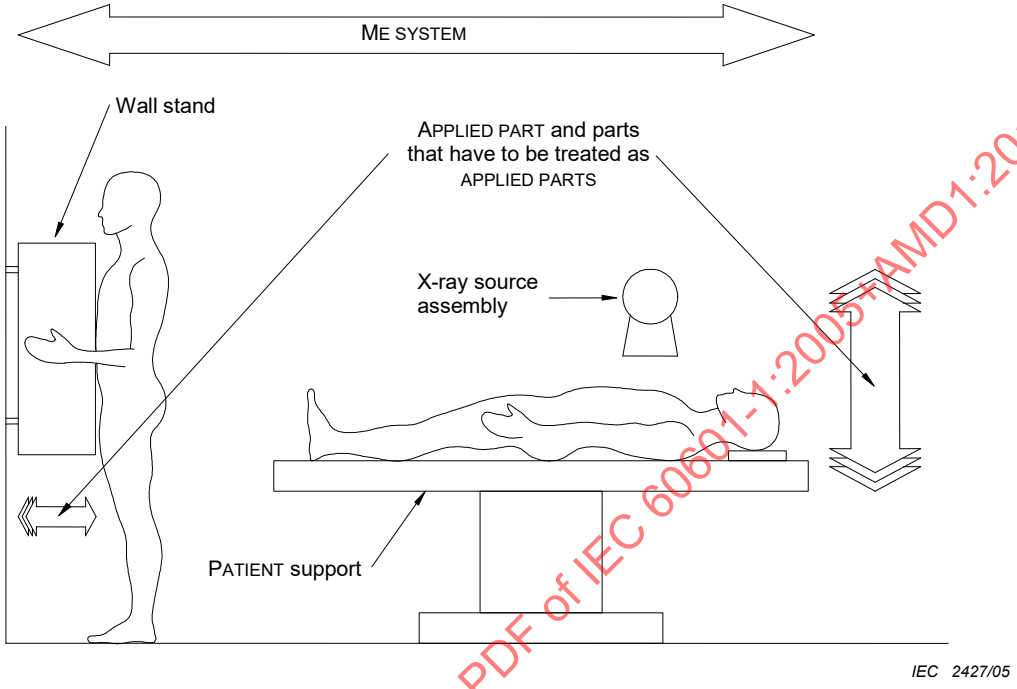


Figure A.5 – Identification of APPLIED PARTS and PATIENT CONNECTIONS in an X-ray ME SYSTEM

Figure A.6 shows a transcutaneous electronic nerve stimulator (TENS) that is intended to be worn on the PATIENT's belt and connected to electrodes applied to the PATIENT's upper arm. In this case:

– The ME EQUIPMENT includes the TENS stimulator, the electrode cable and the electrodes.

– The APPLIED PART includes the electrodes and those parts of the electrode leads that physically need to contact the PATIENT in NORMAL USE.

– The application of RISK MANAGEMENT might identify that the case of the stimulator and its belt clip also have to be treated as APPLIED PARTS because of the probability they will come in contact with the PATIENT.

– The PATIENT CONNECTIONS consist of the electrodes, which are all part of the same function of this APPLIED PART.

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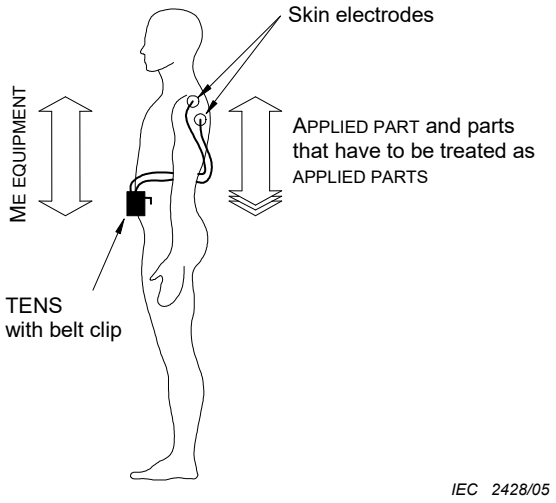


Figure A.6 – Identification of ME EQUIPMENT, APPLIED PARTS and PATIENT CONNECTIONS in a transcutaneous electronic nerve stimulator (TENS) intended to be worn on the PATIENT'S belt and connected to electrodes applied to the PATIENT'S upper arm

Figure A.7 shows an ECG processing ME EQUIPMENT / ME SYSTEM in which:

– The ME SYSTEM includes the ECG module, PATIENT cable, PATIENT leads and electrodes, and the personal computer and any of its ACCESSORIES (not shown).

– The MANUFACTURER can choose to specify one of the following situations:

  • The ECG module and its PATIENT cable, PATIENT leads and electrodes are an item of ME EQUIPMENT; and the personal computer is not an item of ME EQUIPMENT. This would be an ME SYSTEM.

  • The ECG module and its PATIENT cable, PATIENT leads and electrodes are one item of ME EQUIPMENT; and the personal computer is a separate item of ME EQUIPMENT. This would also be an ME SYSTEM.

  • The ECG module and its PATIENT cable, PATIENT leads and electrodes together with the personal computer is a single item of ME EQUIPMENT and not an ME SYSTEM.

– The APPLIED PART includes the electrodes and those parts of the PATIENT cable or, PATIENT leads that need to physically contact the PATIENT in NORMAL USE.

– Application of RISK MANAGEMENT might identify other parts of the PATIENT cable or, PATIENT leads have to be treated as APPLIED PARTS because of the probability they will come in contact with the PATIENT.

– The PATIENT CONNECTIONS consist of the ECG electrodes, which are all part of the same function of the APPLIED PART.

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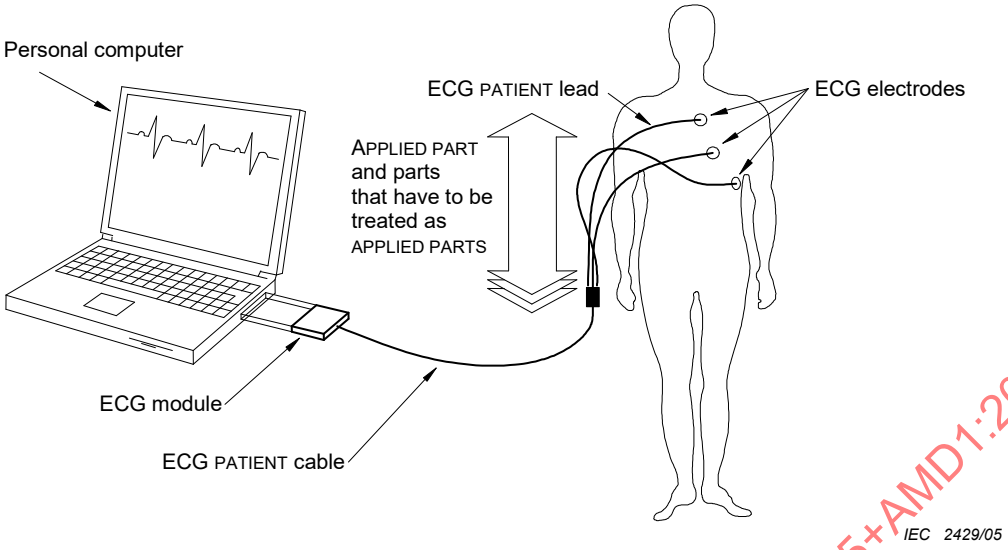


Figure A.7 – Identification of ME EQUIPMENT or ME SYSTEM, APPLIED PARTS and PATIENT CONNECTIONS in a personal computer with an ECG module

Subclause 4.6 would likely not apply to ACCESSIBLE PARTS of ME EQUIPMENT which are positioned according their INTENDED USE in such a way that the PATIENT could touch them only by a deliberate movement. This is based on the assumption that a PATIENT could react to a negative stimulus. Further, such PATIENTS are likely to have contact with non-ME EQUIPMENT such as bedside lights, personal computers, radios, etc.

Subclause 3.9 – BASIC INSULATION

This definition does not include insulation used exclusively for functional purposes.

Subclause 3.10 – BASIC SAFETY

BASIC SAFETY relates to a device not resulting in HARM incidental to its operation.

BASIC SAFETY is often a passive form of protection (such as radiation shielding or electrical grounding).

ESSENTIAL PERFORMANCE generally relates to ME EQUIPMENT or ME SYSTERMS operating as intended without creating a HAZARD. A failure of ESSENTIAL PERFORMANCE can be either a lack of performance (such as life supporting performance) or incorrect performance (such as delivering an incorrect dose to the PATIENT).

In general, BASIC SAFETY relates to product properties that are not device specific and ESSENTIAL PERFORMANCE relates to a class of products (such as a defibrillators being able to deliver the correct electrical shock).

While the terms BASIC SAFETY and ESSENTIAL PERFORMANCE are generally considered to be mutually exclusive, there are some HAZARDS that may relate to both BASIC SAFETY and ESSENTIAL PERFORMANCE concurrently.

Subclause 3.15 – CLEARLY LEGIBLE

Vision or visual acuity can be tested by reading a Snellen eye chart at a distance of 6 m. Near vision can be tested using a Jaeger test card. By examining a large number of people, doctors have decided what a “normal” human being should be able to see at various distances. That is the description of normal vision.

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Subclause 3.17 – COMPONENT WITH HIGH-INTEGRITY CHARACTERISITCS

The concept of high-integrity refers only to specific characteristics of the component. These characteristics are relied upon to ensure safety of the product. Such a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS should be identified in the ACCOMPANYING DOCUMENTS by the MANUFACTURER (e.g. for maintenance). See also the rationale for 4.9.

Subclause 3.18 – CONTINUOUS OPERATION

While the terms CONTINUOUS OPERATION or non-CONTINUOUS OPERATION are used with regard to the ME EQUIPMENT, parts of the ME EQUIPMENT can be RATED differently. For example, an electrosurgical generator might be RATED for CONTINUOUS OPERATION while the APPLIED PART is RATED for non-CONTINUOUS OPERATION.

Subclause 3.20 – DEFIBRILLATION-PROOF APPLIED PART

A DEFIBRILLATION-PROOF APPLIED PART is protected only against discharges of defibrillators complying with IEC 60601-2-4 [15]. Higher voltage defibrillators could damage DEFIBRILLATION-PROOF APPLIED PARTS.

Subclause 3.21 – DETACHABLE POWER SUPPLY CORD

Cord sets are covered by IEC 60320-1.

Subclause 3.22 – DIRECT CARDIAC APPLICATION

A distinction is made between use of APPLIED PARTS that might come in direct contact with the PATIENT'S heart and all other circumstances of contact with the PATIENT. Ventricular fibrillation can be caused by a much smaller current flowing through a small contact area where a wire or catheter makes direct contact with the heart than a current flowing through any other point of contact on or in the PATIENT'S body.

Subclause 3.23 – DOUBLE INSULATION

BASIC INSULATION and SUPPLEMENTARY INSULATION can, if required, be tested separately. Where multiple layers of insulation cannot be tested separately, the insulation system is considered as REINFORCED INSULATION.

Subclause 3.24 – DUTY CYCLE

The terms "on time" and "off time" are considered to include "bursts" of operation and deactivation as well as CONTINUOUS OPERATION.

Subclause 3.26 – ENCLOSURE

The ENCLOSURE of ME EQUIPMENT or ME EQUIPMENT parts includes all ACCESSIBLE PARTS, knobs, grips, cables, connectors and the like. This includes any ACCESSIBLE PARTS of external connections between other separate parts.

Subclause 3.27 – ESSENTIAL PERFORAMNCE

It has long been recognized that ME EQUIPMENT or an ME SYSTEM that does not perform properly could result in unacceptable RISK for PATIENTS, OPERATORS, or others. Hence the concept of "safety" has been broadened from the BASIC SAFETY considerations in the first and second editions of this standard to include ESSENTIAL PERFORMANCE matters.

In order to achieve its INTENDED USE, the ME EQUIPMENT or ME SYSTEM needs to perform within certain limits. These limits are usually specified by the MANUFACTURER but could be specified by this standard, a collateral standard or a particular standard in the IEC 60601 family.

Examples of ESSENTIAL PERFORMANCE are:

– correct administration of a drug by a syringe pump where inaccuracy/incorrect administration would cause an unacceptable RISK to the PATIENT;

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– the ability of an electrocardiograph/monitor to recover from the effects of the discharge of a defibrillator where the failure to recover could lead to an incorrect response by the medical staff that would present an unacceptable RISK to the PATIENT;

– correct operation of an ALARM SYSTEM in an intensive care or operating room monitoring system where an incorrect/missing ALARM SIGNAL could lead to an incorrect response by the medical staff that would present an unacceptable RISK to the PATIENT; or

– correct output of diagnostic information from ME EQUIPMENT that is likely to be relied upon to determine treatment, where incorrect information could lead to an inappropriate treatment that would present an unacceptable RISK to the PATIENT.

For purposes of this standard, performance related to BASIC SAFETY aspects of the ME EQUIPMENT, such as the performance of BASIC INSULATION, is not considered to be ESSENTIAL PERFORMANCE.

Particular and collateral standards in the IEC 60601 family are expected to identify specific ESSENTIAL PERFORMANCE.

Subclause 3.33 – FUNCTIONAL CONNECTION

The defined term FUNCTIONAL CONNECTION is used to facilitate the definition of an ME SYSTEM. The FUNCTIONAL CONNECTION is a coupling between items of an ME SYSTEM, including the possibility of supplying power.

The phrase “or otherwise” could include mechanical, optical or wireless connections for example.

Subclause 3.35 – FUNCTIONAL EARTH TERMINAL

In ME EQUIPMENT, functional earth connections can be made by means of a FUNCTIONAL EARTH TERMINAL that is accessible to the OPERATOR. Alternatively this standard also allows a functional earth connection for CLASS II ME EQUIPMENT via a green and yellow conductor in a POWER SUPPLY CORD. In this case the parts to which this conductor is connected cannot be ACCESSIBLE PARTS (see 8.6.9), and have to be insulated from ACCESSIBLE PARTS.

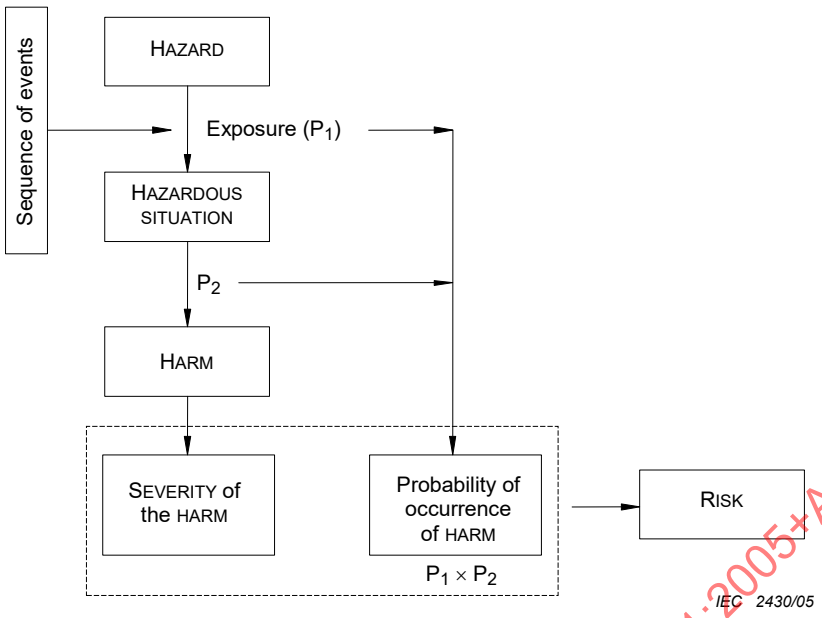
Subclause 3.38 – HARM

The definition of HARM is based on the definition in ISO 14971 modified to include animals. This change was made since the scope of the IEC 60601-1 includes the safety of animals.

Subclause 3.40 – HAZARDOUS SITUATION

As used in this standard, a HAZARD cannot result in HARM until such time as a sequence of events or other circumstances (including NORMAL USE) lead to a HAZARDOUS SITUATION. As a result of the RISK MANAGEMENT PROCESS, the related RISK acceptability can be assessed by estimating both SEVERITY and probability of occurrence of the HARM that could result from this HAZARDOUS SITUATION (see Figure A.8 adapted from the draft text of the 2nd edition of the ISO 14971).

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NOTE P_1 is the probability of a HAZARDOUS SITUATION occurring.
P_2 is the probability of a HAZARDOUS SITUATION leading to a HARM.

Figure A.8 – Pictorial representation of the relationship of HAZARD, sequence of events, HAZARDOUS SITUATION and HARM

Subclause 3.44 –

Subclause 3.49 – MAINS PART

A definition of MAINS PART is needed to identify the parts to which certain requirements apply. The definition given in the first and second editions of this standard depended on another defined term, "conductive connection." During the development of this edition, a difficulty with the definition of "conductive connection" became apparent and the requirements were revised so the defined term was no longer needed. This necessitated a new definition of MAINS PART focussing on the MEANS OF PROTECTION that separate the MAINS PART from other parts.

Subclause 3.50 – MAINS PLUG

A definition of MAINS PLUG is needed to identify the plug to which certain requirements apply. The words "mains plug" without a definition would also cover other connectors within ME EQUIPMENT that carry MAINS VOLTAGE.

Subclause 3.56 – MAXIMUM MAINS VOLTAGE

Several requirements and tests of this standard relate to the possibility that an unintended voltage originating from an external source becomes connected to the PATIENT or to certain parts of the ME EQUIPMENT. The actual magnitude of such a voltage is unknown but it is assumed to be related to the voltage of the SUPPLY MAINS in the location where the ME EQUIPMENT is used. See also the rationale for 8.5.3.

In the early stages of preparing this edition, a defined term "reference supply voltage" was introduced to avoid repetition of extensive wording. During the review of the National Committees' comments on an early draft, it became apparent that there was some confusion between the defined term "reference supply voltage" and the undefined term "reference voltage" which was used in relation to the requirements for dielectric strength, CREEPAGE DISTANCES and AIR CLEARANCES.

In order to clarify the requirements, the term "reference supply voltage" has been replaced by MAXIMUM MAINS VOLTAGE and "reference voltage" has been replaced by the defined terms WORKING VOLTAGE and PEAK WORKING VOLTAGE.

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Subclause 3.57 – MAXIMUM PERMISSIBLE WORKING PRESSURE

The MAXIMUM PERMISSIBLE WORKING PRESSURE is decided by a competent person, taking into account the original design specification, the manufacturer's rating, the current condition of the vessel and the circumstances of use.

In some countries, the figure could be reduced from time to time.

Subclause 3.58 – MEANS OF PROTECTION

One guiding principle in the development of the third edition of this standard was to make it less prescriptive than the second edition, especially Clauses 17 and 20 of the second edition. The concept of MEANS OF PROTECTION was conceived as a generic one that could cover a number of things such as PROTECTIVE EARTH CONNECTIONS, BASIC INSULATION, SUPPLEMENTARY INSULATION, impedances, etc; and that might also be expanded to include other things which serve in the same capacity but have not yet been envisaged or are not yet practical. This concept, with the general requirement for ME EQUIPMENT to have two MEANS OF PROTECTION, fitted in well with the single fault philosophy, which all agreed was to be retained in the third edition. It enables a consistent approach to carry through a design effort without getting bogged down in the wordy prescriptive subclauses.

The concept also fitted in well when it was decided to differentiate protection of PATIENTS from protection of OPERATORS.

Some National Committee comments during the development of this edition suggested that the concept could be extended to apply to protection against HAZARDS other than electric shock. However it was decided that such a change would not be justified by the benefits.

Subclause 3.59 – MEANS OF PATIENT PROTECTION

See the rationale for 8.5.1.

Subclause 3.60 – MEANS OF OPERATOR PROTECTION

See the rationale for 8.5.1.

Subclause 3.63 – MEDICAL ELECTRICAL EQUIPMENT

The present definition of ME EQUIPMENT excludes multiple connections to the same particular SUPPLY MAINS, but does not exclude different connectors to different particular SUPPLY MAINS. However, connection to more than one of different SUPPLY MAINS at the same time should be avoided. While it might be possible to design equipment with provision to be connected simultaneously to two different SUPPLY MAINS in an electrically safe manner, the particular HAZARDOUS SITUATIONS that might arise have not been identified in this standard.

This standard applies several terms to describe ME EQUIPMENT, ACCESSORIES and ME EQUIPMENT parts. They are FIXED (3.30), STATIONARY (3.118), TRANSPORTABLE (3.130), MOBILE (3.65), PORTABLE (3.85), HAND-HELD (3.37) and BODY-WORN (3.144). To help in understanding the relationship of these terms, the chart in Figure A.20 was developed.

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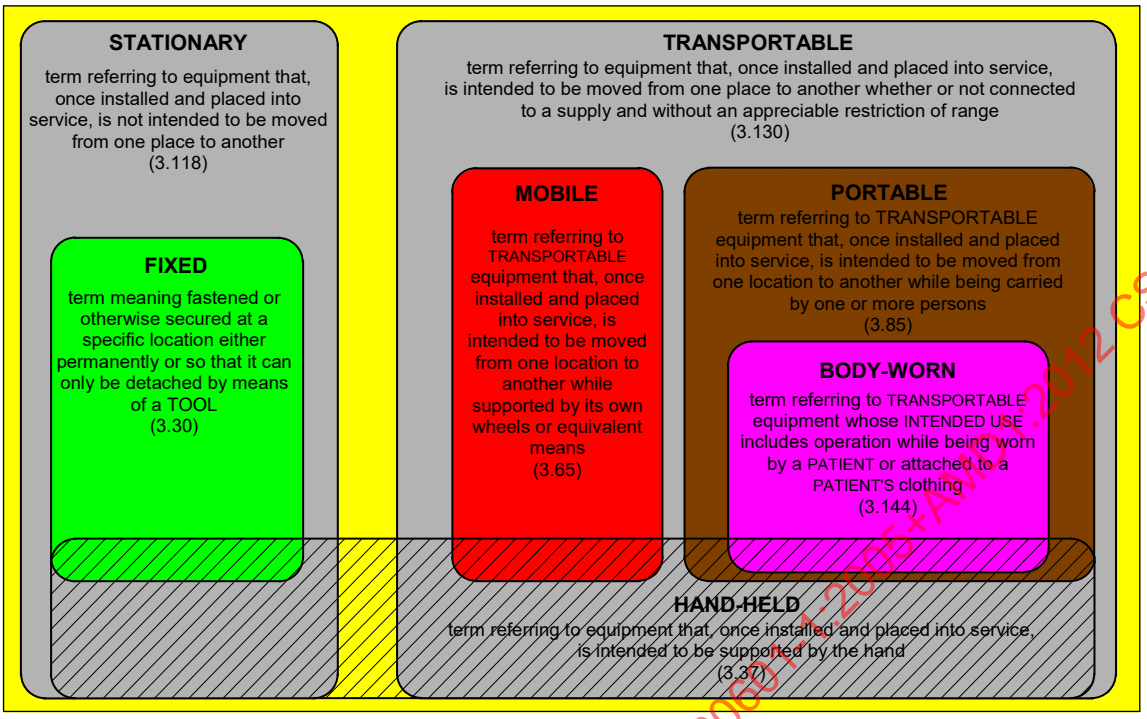


Figure A.20 – Relationship of the terms used to describe equipment, ACCESSORIES or equipment parts

Subclause 3.64 – MEDICAL ELECTRICAL SYSTEM

It is common practice for MANUFACTURERS, RESPONSIBLE ORGANISATIONS and OPERATORS to connect ME EQUIPMENT and other medical or non-medical equipment to MULTIPLE SOCKET-OUTLETS. The inclusion of such arrangements within the definition of ME SYSTEM brings them within the scope of this standard and thus allows appropriate requirements to be specified for BASIC SAFETY and ESSENTIAL PERFORMANCE.

To minimize the impairment of the safety level of this standard, the connection of a MULTIPLE SOCKET-OUTLET to the SUPPLY MAINS is subject to certain conditions. Subclause 16.9.2.1 requires that MULTIPLE SOCKET-OUTLETS are constructed to comply with the requirements from this standard applying to ME EQUIPMENT.

Subclause 3.66 – MODEL OR TYPE REFERENCE

The MODEL OR TYPE REFERENCE is intended to establish the relationship of the ME EQUIPMENT to commercial and technical publications, to ACCOMPANYING DOCUMENTS and between separable parts of ME EQUIPMENT. It is also important for identifying of ME EQUIPMENT or ACCESSORIES in case of a safety alert or other required field action.

Subclause 3.67 – MULTIPLE SOCKET-OUTLET

The definition is derived from IEC 60884-1.

In the second edition of IEC 60601-1-1 [13], there were definitions for multiple portable socket-outlet and auxiliary mains socket-outlet. In this edition, these definitions have been merged.

A single socket-outlet forming part of an equipment is also considered a MULTIPLE SOCKET-OUTLET.

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MULTIPLE SOCKET-OUTLETS are sometimes necessary and offer advantages and disadvantages, which have to be investigated in order to establish a balance. MULTIPLE SOCKET-OUTLETS might be necessary for the following reasons:

– to minimize the number of POWER SUPPLY CORDS lying on the floor;

– to allow all the equipment necessary for proper treatment or diagnosis to be used despite an insufficient number of FIXED mains socket-outlets;

– to improve mobility by having all equipment on one trolley;

– to reduce potential differences within the protective earth wiring to below those that occur in some FIXED installations.

The use of MULTIPLE SOCKET-OUTLETS should be avoided as far as possible for the following reasons:

– combined EARTH LEAKAGE CURRENTS could result in:

  • excessive EARTH LEAKAGE CURRENT in NORMAL CONDITION,

  • excessive TOUCH CURRENT in the SINGLE FAULT CONDITION of the broken PROTECTIVE EARTH CONDUCTOR of the MULTIPLE SOCKET-OUTLET supply cable;

– availability of the SUPPLY MAINS depends on the reliability of a single FIXED mains socket-outlet;

– a complete interruption of electrical supply is possible and might require a long set-up time to reactivate the complete ME SYSTEM;

– only one PROTECTIVE EARTH CONNECTION to the electrical installation is provided; this is less reliable than when each part of the ME SYSTEM is directly earthed;

– the protective earth resistance is increased.

The optimum solution includes installing an adequate number of FIXED mains socket-outlets according to appropriate installation rules.

Subclause 3.68 – NETWORK/DATA COUPLING

The definition of NETWORK/DATA COUPLING has been written so as not to be restricted to any particular technology, such as electronic transmission along wires. The definition allows for wireless electromagnetic transmission, infra-red, optical, etc., as well as any future technology.

Subclause 3.73 – OPERATOR

The OPERATOR is defined as the person who handles the equipment, which could be ME EQUIPMENT or any item of equipment in the context of an ME SYSTEM. This person could be:

– a health care professional using the equipment with a PATIENT,

– either a PATIENT or a layperson assisting a PATIENT in a home-care environment,

– a person who is using the equipment to compensate or alleviate the effects of disease, injury or disability, or

– the person that installs, assembles, maintains or repairs the equipment.

People who install, assemble, maintain or repair the equipment are also referred to in this standard as SERVICE PERSONNEL.

Many requirements in this standard are constructed so that SERVICE PERSONNEL experience the same RESIDUAL RISK as the person who uses the equipment for its INTENDED USE. However, SERVICE PERSONNEL, who are often engineers or engineering technicians, are expected to have certain competencies and to take account of the technical description. Other OPERATORS are expected to have different competencies and to follow the instructions for use. Therefore, this standard presumes in certain circumstances that the safety of SERVICE PERSONNEL depends partly on their knowledge and training to take appropriate precautions when gaining access to hazardous parts. The other OPERATORS are presumed to be competent to use the ME EQUIPMENT or ME SYSTEM but are not necessarily competent to avoid RISKS that can arise during servicing.

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Subclause 3.75 – OXYGEN RICH ENVIRONMENT

At a 25 % oxygen concentration, the increase in the burning rate of a paper strip is only moderate (30 %) (per NFPA 99 [42]). In NFPA 99, 23,5 % is defined to be oxygen-enriched atmosphere that requires protective measures, but it allows this value also for oxygen chambers at pressures of more than 200 kPa. NASA allows concentrations of 25,9 % in its space shuttles (NFPA 53 [41]). UL 2601-1 [44] uses 25 % as threshold value. A sample of epoxy circuit board material burns incompletely at 20,9 % and 25,9 % (burning length of 3 cm and 8,3 cm) but completely at 30 % according to Rimanosky, E.M. et al., ASTM STP 1267 [36].

When first considering the relationship between flame rate and the amount of oxygen, it would seem reasonable that the flame rate would be proportional to the total locally available amount of oxygen, which is given by the partial pressure. However, experience shows that this is only true to a degree. Figures C-1.2.2(a) and (b) in NFPA 53:1999 and Figure A.3.3.14.4 in NFPA 99:2002 show that for paper strips the increase of flame rate with oxygen concentration at a set absolute pressure is stronger than the increase of flame rate with absolute pressure at a set concentration. For the borderline “complete combustion” to “incomplete combustion” the oxygen concentration seems to come to the same number (14 %) at high pressures, independent of the absolute (and partial) pressure. Therefore, to be on the safe side, two numbers are given in the definition. The concentration limit makes sure that for smaller ambient pressures than one atmosphere the danger does not increase. The partial pressure limit makes sure that for higher pressures (e.g. in oxygen chambers) the situation is safe.

Subclause 3.77 – PATIENT AUXILIARY CURRENT

PATIENT AUXILIARY CURRENT is a current that is necessary for:

– the ME EQUIPMENT to perform its function, e.g. electrical impedance imaging, monitoring of respiration by impedance changes;

– monitoring the correct operation of the ME EQUIPMENT, e.g. contact impedance of electrodes with the PATIENT;

– the functioning of the ME EQUIPMENT;

or that is incidental to the functioning of the ME EQUIPMENT. An example is the bias current of an amplifier for physiological signals.

PATIENT AUXILIARY CURRENT could have a function, but not a physiological function, or it could have no function.

Subclause 3.78 – PATIENT CONNECTION

One of the HAZARDS associated with the application of PATIENT CONNECTIONS is the fact that LEAKAGE CURRENT can flow through the PATIENT via the PATIENT CONNECTIONS. Particular limits are placed on the magnitude of these currents, both in the NORMAL CONDITION and in various fault conditions.

NOTE The current that flows through the PATIENT between various PATIENT CONNECTIONS is known as PATIENT AUXILIARY CURRENT. The LEAKAGE CURRENT that flows through the PATIENT to earth is known as PATIENT LEAKAGE CURRENT.

The definition of PATIENT CONNECTION is intended to ensure the identification of each individual part of the APPLIED PART between which current could flow as PATIENT AUXILIARY CURRENT, and from which PATIENT LEAKAGE CURRENT could flow into an earthed PATIENT.

In some cases it will be necessary to carry out PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT measurements to determine which parts of the APPLIED PARTS are individual PATIENT CONNECTIONS.

PATIENT CONNECTIONS are not always accessible to touch. Any conductive parts of the APPLIED PART that come into electrical contact with the PATIENT, or which are prevented from doing so only by insulation or air gaps that do not comply with the relevant dielectric strength tests or

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AIR CLEARANCE and CREEPAGE DISTANCE requirements specified in this standard, are PATIENT CONNECTIONS. See also the rationale for 3.8.

Examples include the following.

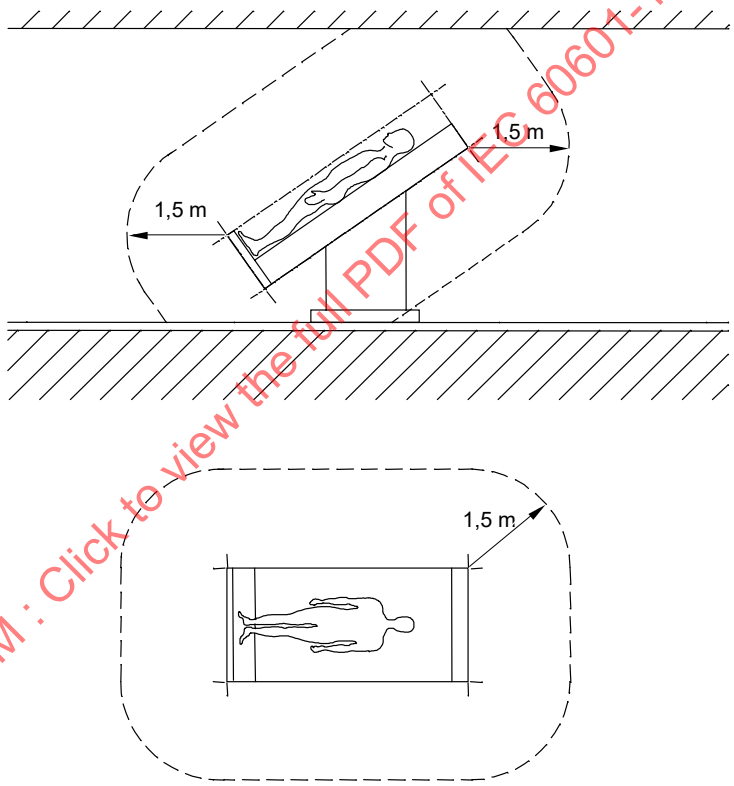
– A table top supporting a PATIENT is an APPLIED PART. Sheets do not provide adequate insulation and the conductive parts of the table top would therefore be classified as PATIENT CONNECTIONS.

– The administration set or needle of an infusion controller is an APPLIED PART. Conductive parts of the controller separated from the (potentially conducting) fluid column by inadequate insulation would be PATIENT CONNECTIONS.

Where an APPLIED PART has a surface of insulating material, 8.7.4.7 d) specifies that it is tested using foil or saline solution. This is then considered as a PATIENT CONNECTION.

Subclause 3.79 – PATIENT ENVIRONMENT

It is difficult for this standard to define dimensions for the volume in which diagnosis, monitoring or treatment occurs. The dimensions for the PATIENT ENVIRONMENT given in Figure A.9 have been justified in practice.



NOTE The dimensions in the figure show minimum extent of the PATIENT ENVIRONMENT in a free surrounding.

Figure A.9 – Example of PATIENT ENVIRONMENT

Subclause 3.81 – PEAK WORKING VOLTAGE

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This definition was taken from IEC 60950-1:2005, subclause 1.2.9.8. Use of this term along with the defined term WORKING VOLTAGE should make the INSULATION CO-ORDINATION requirements incorporated from IEC 60950-1 easier to understand for those already familiar with that standard. See also the rationale for 3.56.

Subclause 3.99 – REINFORCED INSULATION

The term "insulation system" does not imply that the insulation has to be one homogeneous piece. It could comprise several layers that cannot be tested separately as SUPPLEMENTARY or BASIC INSULATION.

Subclause 3.110 – SECONDARY CIRCUIT

This definition is based on the definition of the same term in IEC 60950-1:2005, subclause 1.2.8.5 and identifies circuits that are subject to lower transient overvoltages than the MAINS PART and therefore have lower values for dielectric strength test voltages and AIR CLEARANCES.

Subclause 3.112 – SEPARATION DEVICE

Assembly of equipment into an ME SYSTEM could involve connections that transfer power or signals. In both cases, the same separation requirements are needed.

Subclause 3.115 – SIGNAL INPUT/OUTPUT PART

If a SIGNAL INPUT/OUTPUT PART carries electrical signals, or if it carries non-electrical signals but nevertheless introduces a conductive connection to the other equipment (e.g. through an optical fibre cable with a metal sheath), appropriate separation from other circuits can be necessary to satisfy the requirements of this standard. Alternatively a SIGNAL INPUT/OUTPUT PART could have no conductive connections, in which case it will automatically satisfy the requirements for electrical BASIC SAFETY.

Subclause 3.120 – SUPPLY MAINS

An external d.c. power source (e.g. in an ambulance) is considered as a SUPPLY MAINS. ME EQUIPMENT specified for connection to such a power source has to satisfy all requirements for mains powered ME EQUIPMENT. In the past, some ME EQUIPMENT specified for such a power source has had a direct connection between the ENCLOSURE and one side of the supply, presumed to be at earth potential. In the event of interruption of the connection to this side of the supply, the ENCLOSURE of such ME EQUIPMENT assumes the supply potential and would therefore exceed the specified limit for TOUCH CURRENT. The first and second editions of this standard were intended to exclude such an arrangement, but this was not always understood by users of the standard. This rationale has been added to clarify the requirement.

Subclause 3.132 – TYPE B APPLIED PART

TYPE B APPLIED PARTS provide the lowest degree of PATIENT protection of all the types of APPLIED PART and are not suitable for DIRECT CARDIAC APPLICATION.

The PATIENT CONNECTION(S) of a TYPE B APPLIED PART could be:

– PROTECTIVELY EARTHED;
– connected to earth but not PROTECTIVELY EARTHED; or
– floating, but not isolated from earth to the degree that would be required for a TYPE BF APPLIED PART.

Subclause 3.133 – TYPE BF APPLIED PART

TYPE BF APPLIED PARTS provide a degree of PATIENT protection higher than provided by TYPE B APPLIED PARTS. This is achieved by isolating the PATIENT CONNECTIONS from earthed parts and other ACCESSIBLE PARTS of the ME EQUIPMENT, thus limiting the magnitude of current that would flow through the PATIENT in the event that an unintended voltage originating from an external source is connected to the PATIENT, and thereby applied between the PATIENT CONNECTIONS and earth. However, TYPE BF APPLIED PARTS are not suitable for DIRECT CARDIAC APPLICATION.

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Subclause 3.134 – TYPE CF APPLIED PART

TYPE CF APPLIED PARTS provide the highest degree of PATIENT protection. This is achieved by increased isolation of the PATIENT CONNECTION from earthed parts and other ACCESSIBLE PARTS of the ME EQUIPMENT, further limiting the magnitude of possible current flow through the PATIENT. TYPE CF APPLIED PARTS are suitable for DIRECT CARDIAC APPLICATION insofar as PATIENT LEAKAGE CURRENT is concerned, though they could be unsuitable in other respects, such as sterility or biocompatibility.

Subclause 3.139 – WORKING VOLTAGE

This definition is taken from IEC 60950-1:2005, subclause 1.2.9.6. Use of this term along with the defined term PEAK WORKING VOLTAGE should make the INSULATION CO-ORDINATION requirements incorporated from IEC 60950-1 easier to understand for those already familiar with that standard. See also the rationale for 3.56.

Subclause 4.1 –Conditions for application to ME EQUIPMENT or ME SYSTEMS

The condition for application of RISK MANAGEMENT to ME EQUIPMENT and ME SYSTEMS includes reasonably foreseeable misuse. The MANUFACTURER identifies foreseeable misuse as part of the RISK ANAYLSIS (see 4.2). This identification could include the results of a USABILITY ENGINEERING PROCESS.

Subclause 4.2 –RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

A change introduced in the third edition of this standard is that, in specifying minimum BASIC SAFETY and ESSENTIAL PERFORMANCE requirements, provision is made for assessing the adequacy of the design PROCESS where this provides an appropriate alternative to the application of laboratory testing with specific pass/fail criteria, (e.g. in assessing the safety of new technologies). Application of this principle leads to the introduction of a general requirement to carry out elements of a RISK MANAGEMENT PROCESS as part of demonstrating compliance with this standard.

The MANUFACTURER is responsible for ensuring that the design and construction of the ME EQUIPMENT renders it suitable for its INTENDED USE and that any RISKS that are associated with its use are acceptable when weighed against the benefits. ISO 14971 specifies a PROCEDURE for the MANUFACTURER to identify HAZARDS associated with the ME EQUIPMENT or ME SYSTEM and its ACCESSORIES, to estimate and evaluate the RISKS associated with those HAZARDS and to control those RISKS.

The scope of this standard is confined to type examination of ME EQUIPMENT and ME SYSTEMS; it does not extend to lifecycle monitoring. For this reason, the monitoring of production and post-production information and the planning thereof, as required by ISO 14971:2007, is excluded from the RISK MANAGEMENT PROCESS described in this standard. The requirement in ISO 14971:2007 for periodic review of the suitability of the RISK MANAGEMENT PROCESS is also excluded.

Compliance with the clauses of this standard that contains specific, verifiable requirements is presumed to reduce the associated RISK(S) to an acceptable level.

The MANUFACTURER of ME SYSTEMS should make this determination on a system level. The MANUFACTURER should assess RISKS resulting from the fact that individual system components have been integrated into one system. This assessment should include all aspects of the information exchanged between the system components. Even when these components are non-ME ELECTRICAL components, the potential RISK related to the integration of these components into the ME SYSTEM need to be considered. Further requirements for the integration of non-medical equipment into an ME SYSTEM are described in Clause 16. It gives the requirements for an ME SYSTEM and how RISKS associated with non-ME EQUIPMENT are addressed.

It should be noted that compliance with ISO 14971 does not require that the MANUFACTURER have a formal quality system in place.

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This RISK MANAGEMENT PROCESS results in a set of RECORDS and other documents: the RISK MANAGEMENT FILE. Compliance of the RISK MANAGEMENT PROCESS is checked by inspection of the RISK MANAGEMENT FILE.

In all cases, the MANUFACTURER is to be considered the expert on the device being developed and on the HAZARDS associated with its use.

Where compliance tests are by inspection or review of the RISK MANAGEMENT FILE, only the relevant parts of the RISK MANAGEMENT FILE need to be reviewed, e.g. MANUFACTURER'S calculations or test results, or the determination of RISK acceptability.

Some requirements of this standard use the term unacceptable RISK, other requirements use the term HAZARDOUS SITUATION. All unacceptable RISKS result from a HAZARDOUS SITUATION, not all HAZARDOUS SITUATIONS result in an unacceptable RISK.

In deciding which phrase to use in a requirement the following rule has been used.

– The phrase “no unacceptable RISK” is used when the MANUFACTURER has to, or is permitted to, make a judgement about the acceptability of the RISK. This judgement is to be supported by an appropriate rationale such as experience, historical data, etc.
– The phrase “no HAZARDOUS SITUATION” is used when the MANUFACTURER has to demonstrate (e.g. by technical drawing or technical description) that there is no exposure to a HAZARD or no possibility of HARM can develop. In these cases the only determination a MANUFACTURER has to make is whether or not a HAZARDOUS SITUATION exists; this determination is made regardless of the acceptability of the RISK that could develop from that HAZARDOUS SITUATION.
– The phrase “no HAZARD” is never used.

The following provides guidance on how to use several elements of the RISK MANAGEMENT PROCESS as defined in ISO 14971 within the context of IEC 60601-1.

– **INTENDED USE:** The INTENDED USE is determined at the highest level of the ME EQUIPMENT or ME SYSTEM and should be used in identifying HAZARDS or HAZARDOUS SITUATIONS related to the use of the ME EQUIPMENT or ME SYSTEM. The INTENDED USE is not (or very rarely) used in the evaluation of specific components. Further, the INTENDED USE is the primary input when determining what aspects of the clinical functions of the ME EQUIPMENT or ME SYSTEM constitute ESSENTIAL PERFORMANCE as required by 4.3.

– **HAZARD identification:** This standard and ISO 14971 require identification of all HAZARDS and HAZARDOUS SITUATIONS associated with the ME EQUIPMENT or ME SYSTEM, regardless of whether they are identified in an international safety standard or not (see 4.2.2, Note 1, and 4.2.3.2). This holds for NORMAL USE, reasonably foreseeable misuse and SINGLE FAULT CONDITIONS. However, when HAZARDS or HAZARDOUS SITUATIONS identified in this standard cannot occur for the specific ME EQUIPMENT or ME SYSTEM, the HAZARD identification would be performed only to document that the corresponding requirements of this standard do not apply. In this case, further RISK ASSESSMENT or VERIFICATION of compliance is not required. When a requirement does apply, no HAZARD identification is necessary (because the standard has already done so). For example, no HAZARD of electric shock arises in ME EQUIPMENT having no voltages capable of producing LEAKAGE CURRENTS that exceed the applicable limits as specified in 8.4.2 c).

– **RISK EVALUATION:** RISK is evaluated at two points in the RISK MANAGEMENT PROCESS—before and then again after implementation of RISK CONTROL measures. Evaluation before implementation of RISK CONTROL measures is applicable to the requirements of this standard only in order to demonstrate that the associated RISK is acceptable without applying a requirement. However, when this standard requires that RISKS related to a specific requirement remain acceptable or that no unacceptable RISK occurs in relation to a specific requirement, compliance is checked by inspection of the RISK MANAGEMENT FILE for the HAZARDS or HAZARDOUS SITUATIONS related to this requirement and for OBJECTIVE EVIDENCE (e.g. by MANUFACTURER’S calculations, analyses or test results) that the corresponding RISKS are judged to be acceptable based on the MANUFACTURER’S criteria

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for acceptability of RISK. The effectiveness of the RISK CONTROL measures is evaluated in accordance with subclause 6.3 of ISO 14971:2007.

– **RISK reduction:** When a requirement of this standard requires implementation of specific RISK CONTROL measures to assure that the associated RISK is acceptable, compliance is checked by either of the following:

  - by assuring that the specific measures have been implemented, in which case no RISK MANAGEMENT and no evaluation of RESIDUAL RISK are required because the RISKS are assumed to be reduced to an acceptable level by the presence of the specific measures (meeting the objective requirements of this standard), or
  - by inspection of the RISK MANAGEMENT FILE for the HAZARDS or HAZARDOUS SITUATIONS identified in the requirement in absence of the measures specified by the requirement and for OBJECTIVE EVIDENCE (e.g. by MANUFACTURER'S calculations, analyses or test results) that the corresponding RISKS are judged to be acceptable.

  Subclauses 7.2.2 for detachable components and 7.2.17 for protective packaging are examples where special markings are required unless no unacceptable RISKS occur. So, either the markings must be provided or the RISKS in absence of those markings must be evaluated and judged acceptable. Another example is 15.4.1 a) for the design and construction of connector plugs.

– **RISK/benefit analysis:** A RISK/benefit analysis according to subclause 6.5 of ISO 14971:2007 is only required when the RESIDUAL RISK associated with a specific HAZARD or HAZARDOUS SITUATION remains unacceptable using the criteria for RISK acceptability recorded in the RISK MANAGEMENT plan and further RISK CONTROL is not practicable. Such RISK/benefit analyses are not required when the RESIDUAL RISKS are judged acceptable or when the ME EQUIPMENT or ME SYSTEM complies with specific requirements of this standard. Subclause 11.1.2 is one of the few examples where a RISK/benefit analysis is required when temperature limits are exceeded to achieve a clinical purpose (see Table 24, footnote b).

Subclause 4.3 – ESSENTIAL PERFORMANCE

During the initial RISK ANALYSIS, the MANUFACTURER identifies the performance of the clinical fuction(s) of the ME EQUIPMENT or ME SYSTEM that is necessary for achieving the INTENDED USE. The MANUFACTURER also identifies other qualitative and quantitative characteristics that could affect the safety of the ME EQUIPMENT or ME SYSTEM.

The performance limits specified by the MANUFACTURER could be anywhere within the full range of intended performance in NORMAL CONDITION and SINGLE FAULT CONDITION, to no performance.

The MANUFACTURER then determines if the loss or failure to perform within specified limits would result in a RISK to the PATIENT. The estimate is often made with the assumption that the performance aspect in question has been lost or degraded beyond the specified limits (i.e. P_1 in Figure A.8 is 100 %). The MANUFACTURER takes into account the probability of a HAZARDOUS SITUATION leading to HARM (P_2 in Figure A.8) as well as the SEVERITY of that HARM. In some instances P_2 could also be 100 %, in which case the RISK estimate is based entirely on the SEVERITY of the HARM. When considering the RISK associated with a level of degraded performance, which might include full loss, the analysis should include expected measures as prescribed in the ACCOMPANYING DOCUMENTS, which might return some or all performance after a delay including service to the ME EQUIPMENT or ME SYSTEM, or a return of some or all of the PATIENT'S medical care with back-up medical care measures.

The MANUFACTURER then evaluates the RISK using their established RISK acceptance criteria. If the RISK is unacceptable, then the identified performance is ESSENTIAL PERFORMANCE because RISK reduction is required to achieve an acceptable level of RESIDUAL RISK.

Once the ESSENTIAL PERFORMANCE is identified, the MANUFACTURER puts in place RISK CONTROL measures that are appropriate to reduce the RISK to an acceptable level. When conducting the

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RISK CONTROL option analysis, the MANUFACTURER is to follow the priority order listed in ISO 14971, namely:

a) inherent safety by design;

b) protective measures;

c) information for safety.

The RISK CONTROL measures selected need to be reasonably practicable and consistent with the generally accepted technology. For example, it might be possible to build a critical care ventilator that will continue to function in the presence of a single component failure, but, given the generally accepted technology, this is not practicable. Therefore, the MANUFACTURER might rely on a protective measure, such as an ALARM SYSTEM, to alert the OPERATOR of the failure so the OPERATOR can take appropriate and timely action to prevent the onset of HARM. The ALARM SIGNAL coupled with required OPERATOR training might be adequate RISK CONTROL measures to reduce the RISK arising from the loss or degradation of the identified performance to an appropriate level, i.e. the RESIDUAL RISK is acceptable. These RISK CONTROL measures can be integral with the consideration of ESSENTIAL PERFORMANCE.

Of course, the RISK CONTROL measure has to be sufficiently independent such that the condition that causes the loss or degradation of the identified performance does not compromise the effectiveness of the RISK CONTROL measure. This is consistent with the two MEANS OF PROTECTION philosophy employed in the IEC 60601 series. For example, an ALARM SYSTEM intended to alert the OPERATOR that the SUPPLY MAINS has been interrupted could not depend on the SUPPLY MAINS as the sole source of its power. A back-up battery could be used to power the ALARM SYSTEM if the SUPPLY MAINS is interrupted.

In RISK CONTROL, timing is everything. If there is insufficient time from the onset of the event (interruption of the SUPPLY MAINS) for the OPERATOR to register that an ALARM CONDITION has occurred and take appropriate action to prevent the onset of HARM, then the ALARM SYSTEM alone would not be an effective RISK CONTROL measure. A back-up power source to keep the ME EQUIPMENT operating for a period of time sufficient for the OPERATOR to take the necessary corrective action could also be required.

As with all aspects of the RISK MANAGEMENT PROCESS, the identification of ESSENTIAL PERFORMANCE can be iterative. The MANUFACTURER might have to revisit the process of determining what the ESSENTIAL PERFORMANCE is during the lifecycle of the ME EQUIPMENT or ME SYSTEM.

See also the rationale for 3.27.

Subclause 4.4– EXPECTED SERVICE LIFE

The EXPECTED SERVICE LIFE is the time period during which the ME EQUIPMENT or ME SYSTEM is expected to remain suitable for its INTENDED USE. It is also the period when all RISK CONTROL measures need to remain effective to ensure that RISKS remain acceptable.

The EXPECTED SERVICE LIFE needs to be determined by the MANUFACTURER, as part of the RISK MANAGEMENT PROCESS, as a precondition for assessing compliance with many requirements of this standard, such as 4.5, 4.7, 7.1.3, 8.6.3, 9.8.2 and 11.6.6.

In the ACCOMPANYING DOCUMENTS, the MANUFACTURER should provide information to allow the RESPONSIBLE ORGANIZATION to assess when the ME EQUIPMENT is approaching the end of its life. Such information should include the EXPECTED SERVICE LIFE as determined by the MANUFACTURER (e.g. in terms of years of service or number of uses) but could also include tests to be performed as part of preventive maintenance, or other criteria to allow the RESPONSIBLE ORGANIZATION to make an appropriate determination. The need for such information and the appropriate way to present it should be addressed as part of the RISK MANAGEMENT PROCESS.

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In defining the EXPECTED SERVICE LIFE, the MANUFACTURER should assume that the RESPONSIBLE ORGANIZATION will follow the MANUFACTURER'S instructions for routine maintenance. See 7.9.2.13.

Subclause 4.5 – Alternative RISK CONTROL measures or test methods for ME EQUIPMENT or ME SYSTEMS

This subclause allows alternative means of achieving safety to those means specified in this standard. This is important as it permits a MANUFACTURER to use innovative solutions that are safe and can have other benefits, e.g. lower cost or better manufacturability.

Because it is often difficult to ascertain a sense of RISK acceptability for an individual RISK CONTROL measure or test method, the MANUFACTURER is permitted to use scientific data, clinical opinion, or comparative studies on a case-by-case basis to establish that the RESIDUAL RISK from applying an alternative remains acceptable.

Documentation in the RISK MANAGEMENT FILE should show that the RESIDUAL RISK achieved using the alternative means remains acceptable and is comparable to this standard. Comparative studies should take into account scientific studies referenced in this standard and applicable to the alternative means.

Subclause 4.6 – ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

A part that unintentionally comes into contact with an unconscious, anaesthetized or incapacitated PATIENT can present the same RISKS as an APPLIED PART that necessarily has to contact the PATIENT. On the other hand, a part that an active PATIENT could reach out and touch might present no more RISK to that PATIENT than it presents to an OPERATOR.

The definition of APPLIED PART in the first and second editions of this standard failed to address this problem. The second amendment to the second edition extended the definition to include parts that can be brought into contact with the PATIENT, but the new definition continued to cause difficulties.

Since this standard now requires a RISK MANAGEMENT PROCESS to be followed, it is appropriate to use this PROCESS to establish whether such parts should be subject to the requirements for APPLIED PARTS or not.

The exclusion of marking requirements reflects the majority view of the National Committees that responded to an enquiry on the subject during the development of this edition. It would be confusing to OPERATORS if parts that are not intended to be APPLIED PARTS were marked like APPLIED PARTS.

Parts identified as needing to be subject to the requirements for APPLIED PARTS (except for marking) will typically contact PATIENTS less frequently than APPLIED PARTS, so the benefits of electrical separation from earth would be less. However in some cases, these parts might need to satisfy the requirements for TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS in order to provide an appropriate level of safety.

Subclause 4.7 – SINGLE FAULT CONDTION for ME EQUIPMENT

The requirement that ME EQUIPMENT is SINGLE FAULT SAFE effectively puts a lower limit on the probability of occurrence of HARM from a HAZARD. If this probability is achieved then the RISK of the HAZARD is acceptable. In all cases where this discussion refers to the SEVERITY or probability of a particular HAZARD, it is intended to refer to the probability or SEVERITY of the HARM resulting from that HAZARD.

SINGLE FAULT SAFE is a concept that flows from the single fault philosophy described in IEC/TR 60513 [12]. SINGLE FAULT SAFE is a characteristic of ME EQUIPMENT that assures BASIC SAFETY during its EXPECTED SERVICE LIFE. For a high SEVERITY HARM, application of a RISK MANAGEMENT PROCESS can conclude that the single fault concept does not achieve an acceptable RISK.

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The probability of simultaneous occurrence of two single faults is considered small enough to be negligible, provided that:

a) a single fault causes operation of a protective device (e.g. a fuse, OVER-CURRENT RELEASE, safety catch, etc.) that prevents occurrence of a HAZARD, or

b) a single fault is discovered by an unmistakable and clearly discernible signal that becomes obvious to the OPERATOR, or

c) a single fault is discovered and remedied by periodic inspection and maintenance that is prescribed in the instructions for use. There is a finite probability that a second fault can arise before the next scheduled inspection and maintenance cycle. As with case a) above, for the probability of this double fault condition to be negligible, the probability of each fault has to be low. This means that the frequency of inspection and maintenance has to be high compared to the expected probability of occurrence of the fault. The longer the time that one SINGLE FAULT CONDITION remains present before being detected and rectified, the greater the probability that a second fault will arise. Therefore, the MANUFACTURER might need to explicitly consider the detection time in relation to the occurrence of a possible second fault as part of RISK ANALYSIS.

Non-exclusive examples of the categories a) to c) are:

– REINFORCED or DOUBLE INSULATION;

– CLASS I ME EQUIPMENT in case of a fault in BASIC INSULATION;

– abnormal indications of displays, defect in a redundant suspension cord causing excessive noise or friction;

– deterioration of a flexible PROTECTIVE EARTH CONDUCTOR that is moved in NORMAL USE.

Subclause 4.8 – Components of ME EQUIPMENT

Resistors bridging a MEANS OF PROTECTION

A resistor or group of series connected resistors (two or more), can bridge one or two MEANS OF PROTECTION (MOOP or MOPP), providing the following is observed:

– the resistor or group of resistors has a voltage rating twice the value of the WORKING VOLTAGE across the MEANS OF PROTECTION;

– the resistor or group of resistors can withstand dielectric strength tests according to 8.8.3 and considering the expected transient voltages that the component(s) will be subjected to during NORMAL USE over the EXPECTED SERVICE LIFE;

– the resistor or group of resistors has a power rating twice that expected in NORMAL USE;

– the resistor or group of resistors have a resistance value such that TOUCH CURRENT, PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT requirements are not exceeded;

– the resistor or group of resistors have a construction that maintains the MOP separation requirements for CREEPAGE DISTANCE and AIR CLEARANCE (For a series group, separation at each component is additive making up the required separation.);

– the resistor or group of resistors are constructed such that their inductance is low;

– the resistor or group of resistors have a construction that cannot fail short-circuit; and

– when using a group of resistors they all need have the same resistance value and the voltage and power doubling requirement applies also to each component based on the expected WORKING VOLTAGE across that resistor in NORMAL USE.

Subclause 4.9 – Use of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISITCS in ME EQUIPMENT

The first step to determine a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS is to conduct a RISK ANALYSIS to find those characteristics that are required to maintain BASIC SAFETY or ESSENTIAL PERFORMANCE. Having done this, the appropriate component can be selected. Reference can be made to IEC component standards as part of the determination of the characteristics required.

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TYPE TESTS of COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS are only part of the required determination of suitability. Since a particular COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS has to function as intended or a HAZARD is likely to occur, additional considerations include as appropriate:

– continuous surveillance as part of the manufacturing PROCESS and also after assembly into the end product;
– particular characteristics of the device concerned;
– lot testing;
– calibration;
– control of manufacturing defects;
– maintenance;
– EXPECTED SERVICE LIFE of equipment;
– use of relevant component standards;
– failure mode characteristics;
– environmental conditions;
– anticipated misuse of equipment;
– interaction with other equipment.

Subclause 4.10 – Power supply

An alternating voltage is considered in practice to be sinusoidal if any instantaneous value of the waveform concerned differs from the instantaneous value of the ideal waveform at the same moment by no more than ± 5 % of the peak value of the ideal waveform.

A polyphase voltage system is considered to be symmetrical if neither the magnitude of its negative sequence components nor the magnitude of its zero sequence components exceeds 2 % of the magnitude of its positive sequence components.

A polyphase supply system is considered to be symmetrical if, when supplied from a symmetrical voltage system, the resulting current system is symmetrical. That is, the magnitude of neither the negative sequence current components nor the zero sequence current components exceeds 5 % of the magnitude of the positive sequence current components.

Clause 5 – General requirements for testing ME EQUIPMENT

In ME EQUIPMENT there could be many pieces of insulation, components (electrical and mechanical) and constructional features in which a failure would not produce a HAZARD to PATIENT, OPERATOR or surroundings, even though causing a deterioration in or a failure of performance of ME EQUIPMENT.

Subclause 5.1 – TYPE TESTS

The RISK MANAGEMENT PROCESS identifies the RISK CONTROL measures that are necessary to ensure that the ME EQUIPMENT is safe.

Unless otherwise specified in this standard, tests should not be repeated. This applies particularly to the dielectric strength tests, which are performed only at the MANUFACTURER'S site or in test laboratories.

In order to ensure that every individually produced item of ME EQUIPMENT conforms to this standard, the MANUFACTURER or installer should carry out such measures during manufacture or installation assembly as to ensure that each item satisfies all requirements even if it is not completely tested individually during manufacture or installation.

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Such measures could take the form of:

a) production methods (to ensure good manufacturing output and constant quality) where such quality would be related to safety;

b) production tests (routine tests) performed on every produced item;

c) production tests performed on a production sample where results would justify a sufficient confidence level.

Production tests need not be identical with TYPE TESTS, but can be adapted to manufacturing conditions and possibly invoking less RISK for the quality of the insulation or other characteristics important for BASIC SAFETY and ESSENTIAL PERFORMANCE.

Production tests would, of course, be restricted to settings (possibly derived from TYPE TESTS) that would provoke the worst case situation.

Depending upon the nature of ME EQUIPMENT, production methods or tests could concern critical insulation of the MAINS PART, of the PATIENT CONNECTIONS and the insulation or the separation between these parts.

Suggested test parameters could be LEAKAGE CURRENT and dielectric strength.

When applicable, the continuity of protective earthing can be a major test parameter.

Guidance on general testing procedures that can be used with this standard is given in IEC/TR 62354 [66].

This standard uses several terms to describe fault conditions that could be encountered. They are:

SINGLE FAULT CONDITION

The SINGLE FAULT CONDITION is defined in 3.116 to describe those conditions where “a single means for reducing a RISK is defective” or “a single abnormal condition is present”. Possible SINGLE FAULT CONDITIONS are listed in this standard and can affect verifiable values like CREEPAGE DISTANCES, protective earth path impedances, LEAKAGE CURRENTS, etc.

Faults not leading to a SINGLE FAULT CONDITION

Compared with SINGLE FAULT CONDITIONS, this standard does not have verifiable requirements for faults not leading to a SINGLE FAULT CONDITION. This means this standard does not give guidance how reliable it is that faults can be prevented.

Combination of simultaneous independent faults

Because there are no reliable verifiable requirements defined in this standard for the prevention of faults, all possible simultaneous faults should be considered in accordance with 4.7.

Where a SINGLE FAULT CONDITION remains undetected (e.g. bridging of one MEANS OF OPERATOR PROTECTION), further simultaneous faults should be considered in accordance with 4.7.

NOTE For additional guidance, see IEC 60513:1994.

The worst cases of simultaneous faults are those which lead to most dangerous results. The wording of the standard is used to avoid conducting all possible simultaneous fault tests, because many of them could be covered by worst case testing.

Subclause 5.2 – Number of samples

The TYPE TEST sample or samples need to be representative of the units intended for the RESPONSIBLE ORGANIZATION.

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Subclause 5.7 – Humidity preconditioning treatment

According to IEC 60529, the ENCLOSURE of ME EQUIPMENT that is RATED IPX8 prevents, under stated conditions, the entry of an amount of water where its presence could result in a HAZARD.

The test condition as well as the acceptable amount and location of water are to be defined in particular standards. If no ingress of water is tolerated (sealed ENCLOSURES) the application of the humidity preconditioning treatment is inappropriate.

Parts sensitive to humidity, normally used in controlled environments and which do not influence BASIC SAFETY and ESSENTIAL PERFORMANCE, need not be subjected to this test. Examples are: high-density storage media in computer-based systems, disc and tape drives, etc.

To prevent condensation when ME EQUIPMENT is placed in the humidity cabinet, the temperature of such a cabinet should be equal to or slightly lower than the temperature of the ME EQUIPMENT when it is introduced. To avoid the need for a temperature stabilization system for the air in the room outside the cabinet, the cabinet air temperature during the treatment is adapted to that of the outside air within the limits of the range of +20 °C to +32 °C and then "stabilized" at the initial value. Although the effect of the cabinet temperature on the degree of absorption of humidity is recognized, it is felt that the reproducibility of test results is not impaired substantially and the cost-reducing effect is considerable.

Subclause 5.9 – Determination of APPLIED PARTS and ACCESSIBLE PARTS

Except in special cases, such as PATIENT supports and waterbeds, contact with ME EQUIPMENT is supposed to be made with:

– one hand, simulated for LEAKAGE CURRENT measurements by a metal foil of 10 cm x 20 cm (or less if the total ME EQUIPMENT is smaller);

– one finger, straight or bent in a natural position, simulated by a test finger provided with a stop plate;

– an edge or slit that can be pulled outwards allowing subsequent entry of a finger, simulated by a combination of test hook and test finger.

Subclause 5.9.2.1 – Test finger

An ACCESS COVER is a part of the ENCLOSURE that can be removed in order to allow access to parts of electrical equipment for purposes of adjustment, inspection, replacement or repair. It is presumed that parts that can be removed without the use of a TOOL are intended to be replaced by any OPERATOR, not only by SERVICE PERSONNEL, even if this is not described in the instructions for use. OPERATORS other than SERVICE PERSONNEL might not be as well trained or experienced in good safety practices as SERVICE PERSONNEL. Therefore, extra safety precautions are needed to prevent accidental contact with hazardous voltages. That is why parts such as lamps, fuses, and fuseholders that can be removed without the use of a TOOL are to be removed before determining which parts inside the ACCESS COVER are to be considered ACCESSIBLE PARTS.

Fuseholders where the fuselink is held in a cap that can be removed without use of a TOOL are a special concern. If the fuselink does not come out when the cap is removed, the OPERATOR could be inclined to try to remove it by gripping the end of the fuselink with the fingers. The OPERATOR could try to insert a new fuselink into the fuseholder without first inserting it in the cap. Both cases can be considered reasonably foreseeable misuse. This should be taken intoconsideration with assessing what parts are accessible.

The reader is referred to IEC 60127-6 [7] for more information on fuseholders.

Clause 6 – Classification of ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT can have a multiple classification.

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Subclause 6.2 – Protection against electric shock

The term “Class III equipment” is used in some other standards to identify equipment that is powered from a safety extra-low voltage (SELV) mains supply system. The term Class III equipment is not formally used in this standard. The BASIC SAFETY of Class III equipment is critically dependent on the installation and on other Class III equipment connected thereto. These factors are outside the control of the OPERATOR and this is considered to be unacceptable for ME EQUIPMENT. Additionally, limitation of voltage is not sufficient to ensure safety of the PATIENT. For these reasons, this standard does not recognize Class III construction.

Subclause 6.3 – Protection against harmful ingress of water or particulate matter

It should be noted that compliance with the requirements of this standard automatically allows MANUFACTURERS to rate ME EQUIPMENT as IP2X because the requirements of IEC 60529 for this rating are the same as the accessibility requirements (see 5.9).

Subclause 6.6 – Mode of operation

CONTINUOUS OPERATION and non-CONTINUOUS OPERATION cover the range of operating modes of virtually all equipment. ME EQUIPMENT that remains plugged into the SUPPLY MAINS continuously but is operated intermittently should be RATED for non-CONTINUOUS OPERATION, have the appropriate indication of on/off times in the ACCOMPANYING DOCUMENTS and markings on the ME EQUIPMENT (see 7.2.11).

Subclause 7.1.1 – USABILITY of the identification, marking and documents

For ME EQUIPMENT to be well designed, its markings and ACCOMPANYING DOCUMENTS should be clear, consistent, and help to reduce potential use error. Thus, markings and ACCOMPANYING DOCUMENTS should undergo the same rigorous evaluation as other OPERATOR-ME EQUIPMENT interface elements.

Subclause 7.1.2 – Legibility of markings

Markings on ME EQUIPMENT are expected to be CLEARLY LEGIBLE by an OPERATOR over the range of normal illumination levels where the ME EQUIPMENT is typically operated. The levels used in this test are derived from the following recommended illumination levels for use in interior lighting design [51]:

– 100 lx to 200 lx is recommended for working spaces where visual tasks are performed only occasionally;
– 500 lx to 1000 lx is recommended for visual tasks of small size or reading medium-pencil handwriting;
– 1 000 lx to 2 000 lx is recommended for visual tasks of low contrast or very small size: e.g. reading handwriting in hard-pencil on poor-quality paper.

If markings are not legible to the OPERATOR under the expected conditions of use, there would be an unacceptable RISK.

The Minimum Angle of Resolution (MAR) is a visual acuity measurement method developed as an improvement on the long-used Snellen scale. The values are express as a logarithm of the Minimum Angle of Resolution. Log MAR can be calculated from the Snellen scale, i.e. log MAR = log(6/6) = 0 for normal vision.

The Jaeger test card is used for determining near vision. N6 corresponds to reading at a distance of 0,87 m from the face.

An ambient light level of 500 lx is recommended for conducting the visual acuity examination.

If a recommended minimum font size is to be considered, then a readable font size is a function of reading distance and the resulting visual angle of the marking image presented to the retina of the eye. Calculations of visual angle in minutes of arc are found in

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ANSI/AAMI HE-75:2009 [71], subclause 6.2.2.6.5, Table 6.2. Using a minimal acceptable visual angle of 12 minutes of arc, a font size of 9 would be recommended for a reading distance of one meter and a font size of 6 for a typical reading distance of 0,7 m.

Subclause 7.1.3 – Durability of markings

The rubbing test is performed with distilled water, ethanol 96 % and isopropyl alcohol.

Ethanol 96% is defined in the European Pharmacopoeia as a reagent in the following terms: C_2H_6O (MW46.07).

Isopropyl alcohol is defined in the European Pharmacopoeia as a reagent in the following terms: C_3H_8O (MW60.1).

Subclause 7.2.2 – Identification

This subclause is intended to apply to any detachable component when misidentification could result in a HAZARDOUS SITUATION. For examples, normal consumables would probably need to be identified, but a cosmetic cover would not need to be identified.

Although a MODEL OR TYPE REFERENCE usually denotes a certain performance specification, it might not denote the exact construction, including the applied components and materials. The MODEL OR TYPE REFERENCE is supplemented by a serial number or lot or batch identifier. The serial number or lot or batch identifier can be used for other purposes such as providing traceability in case the MANUFACTURER needs to take a corrective action.

It is characteristic of software that different versions can run on a PEMS. The identification of the software will often be on the user interface, although this might not be possible e.g. where the software does not have a user interface. Identification of the software could need special tools. For this reason, the requirement permits the identification to be only available to designated people.

Subclause 7.2.3 – Consult ACCOMPANYING DOCUMENTS

It is not intended in every case when the instructions for use contain warnings, that the ME EQUIPMENT be marked with ISO 7010-M002 (see Table D.2, safety sign 10). Too many warnings and unnecessary warnings are counterproductive. Only when the MANUFACTURER, as a RISK CONTROL measure for a specific RISK, decides to mark the ME EQUIPMENT to instruct the OPERATOR to read the instructions for use, should safety sign ISO 7010-M002 be used.

Subclause 7.2.4 – ACCESSORIES

RESPONSIBLE ORGANIZATIONS and OPERATORS need to be able to identify ACCESSORIES in order to know which ones can be used without impairing BASIC SAFETY or ESSENTIAL PERFORMANCE. A MODEL OR TYPE REFERENCE alone is not sufficient, because different MANUFACTURERS might use the same number. The name marked on the ACCESSORY could be that of the ME EQUIPMENT MANUFACTURER or a different name.

Subclause 7.2.10 – APPLIED PARTS

According to the second edition of this standard, the marking could be either on the APPLIED PART itself or adjacent to the connection point. Neither location is satisfactory in all cases.

Where a conductor that is not separated from PATIENT CONNECTIONS extends up to the point inside ME EQUIPMENT where an isolation barrier exists, a TYPE BF or TYPE CF marking on the APPLIED PART itself could mislead the RESPONSIBLE ORGANIZATION or the OPERATOR into believing that isolation is built into the APPLIED PART itself. If, on the other hand, the classification depends on the particular APPLIED PART in use, a single marking on the connection point would be inaccurate and multiple marking would be confusing.

For DEFIBRILLATION-PROOF APPLIED PARTS, if protection against the effect of the discharge of a cardiac defibrillator is partly in the PATIENT cable, a warning to the OPERATOR is necessary because there can be non-obvious HAZARDOUS SITUATIONS if the wrong cable is used. These

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HAZARDOUS SITUATIONS can include decreasing the defibrillation energy delivered to the PATIENT, damage to the ME EQUIPMENT with consequent loss of ESSENTIAL PERFORMANCE, or electric shock to the OPERATOR or other persons.

Subclause 7.2.12 – Fuses

Examples of marking for fuses complying with IEC 60127-1 are:

– T 315L, 250V
– T 315mAL, 250V
– F 1,25H, 250V
– F 1,25AH, 250V

The operating speed can be marked by the letter or colour codes in IEC 60127-1, which are as follows:

– very quick acting: FF, or black
– quick acting: F, or red
– medium time lag: M, or yellow
– time lag: T, or blue
– long time lag: TT, or grey

Subclause 7.2.21 – Mass of MOBILE ME EQUIPMENT

MOBILE ME EQUIPMENT is intended to be transported from one location to another by its own wheels or equivalent means. For safety, it is important that the OPERATOR be aware of the total mass of the ME EQUIPMENT with its SAFE WORKING LOAD installed. This is important when moving the ME EQUIPMENT, and, for heavy ME EQUIPMENT, understanding any limitations on locations where the ME EQUIPMENT can be taken. The ME EQUIPMENT can have bins, shelves or drawers that might have their own maximum loading requirements. The marking on the ME EQUIPMENT needs to be sufficiently separate and distinct from any markings on the bins, shelves or draws to avoid confusing the OPERATOR as to what the marking applies.

Subclause 7.3.2 – HIGH VOLTAGE parts

HIGH VOLTAGE parts present a significant electric shock HAZARD to SERVICE PERSONNEL and others who could be required to work inside the ME EQUIPMENT while it is energized. Because the parts are inside the ENCLOSURE, the RISK is perceived to be substantially less than that for HIGH VOTAGE TERMINAL DEVICES located on the outside of the ME EQUIPMENT. Therefore, the "dangerous voltage" symbol (IEC 60417-5036) (2002-10) (see Table D.1, symbol 24) is permitted as a marking to alert SERVICE PERSONNEL and others to the potential presence of these dangerous voltages. The MANUFACTURER is permitted to use ISO 7010-W012 (see Table D.3, safety sign 3). The RISK MANAGEMENT PROCESS could determine that the safety sign is the most appropriate choice if the personnel exposed to the HAZARD have minimal training or might otherwise be unaware that HIGH VOLTAGE is present.

Subclause 7.3.4 – Fuses, THERMAL CUT-OUTS and OVER-CURRENT RELEASES

See the rationale for 7.2.12.

Subclause 7.3.5 – PROTECTIVE EARTH TERMINALS

This standard does not require marking of terminals for internal PROTECTIVE EARTH CONNECTIONS, but does not preclude it.

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Subclause 7.4.1 – Power switches

If a marking is used for a toggle-type switch, the symbols for "on" (|) and "off" (○) [symbols 12 and 13 from Table D.1] should be used to indicate its ON and OFF positions.

For a push-button type switch, the appropriate marking will depend on the type of switch. For a push button switch with bistable positions, the symbol (⏽) [symbol 14 from Table D.1] should be used to indicate that both the ON and OFF positions are stable.

For a push button switch with a momentary ON position, the symbol (⏾) [symbol 15 from Table D.1] should be used to indicate that mains power is applied for only as long as the push button is depressed. As soon as the button is released the switch returns to the stable OFF position.

Subclause 7.4.2 – Control devices

The different positions of switches that control the functionality of the ME EQUIPMENT or a part of the ME EQUIPMENT, but do not control mains power to the ME EQUIPMENT or a part of the ME EQUIPMENT should also be marked in such a way as to clearly indicate the state of the control function. Any appropriate means including figures, letters, indicator lights, etc. can be used. If the marking includes symbols, the symbols for "on" for part of the equipment (⊙) and "off" for part of the equipment (○) [symbols 16 and 17 from Table D.1] can be used to indicate its ON and OFF positions.

A switch or switch position by means of which the ME EQUIPMENT or part of the ME EQUIPMENT is switched on in order to bring it into the "stand-by" condition can be indicated by the stand-by symbol (⏻) [symbol 29 from Table D.1]. This symbol is required by IEC 60950-1 to indicate the stand-by mode of the information technology equipment covered by that standard.

Subclause 7.8 – Indicator lights and controls

For colours of indicator lights see also IEC 60073 [5].

Colour alone should not be used to convey important information. A redundant means of conveying information such as shape, location, sound or marking is recommended.

Subclause 7.9.1 – General

It is important that ME EQUIPMENT or an ME SYSTEM is not unintentionally used in an application for which it is not intended by its MANUFACTURER.

The USABILITY ENGINEERING PROCESS requires the MANUFACTURER to develop an applications specification that includes the intended environments of use. The MANUFACTURER is required to supply a summary of this specification in the ACCOMPANYING DOCUMENTS. See 12.2.

Subclause 7.9.2.1 – General

RESPONSIBLE ORGANIZATIONS and OPERATORS frequently deal with many different types of ME EQUIPMENT. Because of the complexity of modern ME EQUIPMENT, the instructions for use are an important part of the ME EQUIPMENT. Some commonality in the structure for the instructions for use could help OPERATORS to find needed material quickly and easily. However, because of the diversity of ME EQUIPMENT covered by this standard, no one format will be equally applicable to all ME EQUIPMENT.

When considering if the PATIENT can act as an OPERATOR, the MANUFACTURER needs to take into account that the level of protection provided by this standard for the OPERATOR can be different from that for the PATIENT. For example, acceptable LEAKAGE CURRENT levels and accessible voltages values are higher for the OPERATOR than they are for the PATIENT. Instead

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of PATIENT LEAKAGE CURRENT, TOUCH CURRENT could be applied. Additionally the OPERATOR can have access to voltages up to 42,4 V peak a.c. or 60 V d.c.

Other conditions to consider include:

– Is the ME EQUIPMENT to be used under medical supervision or guidance?
– What is the health condition of the PATIENT?
– What treatment is being provided to the PATIENT?
– Are there special USABILITY considerations (see IEC 60601-1-6)?
– Is the ME EQUIPMENT to be used in the professional healthcare environment, the home healthcare environment (see IEC 60601-1-11 [55]) or the emergency medical service environment (see IEC 60601-1-12 [58])?
– Does the PATIENT have access to the instructions for use?
– Is adequate training of the PATIENT as an OPERATOR available?

The problem of languages used in markings and in ACCOMPANYING DOCUMENTS cannot be solved by IEC. Even a requirement that identifications and ACCOMPANYING DOCUMENTS have to be in the national languages cannot be upheld world-wide.

Subclause 7.9.2.2 – Warning and safety notices

For CLASS I ME EQUIPMENT, where operation from either a SUPPLY MAINS or an INTERNAL ELECTRICAL POWER SOURCE is specified, the instructions for use should state that the INTERNAL ELECTRICAL POWER SOURCE is to be used if the integrity of the PROTECTIVE EARTH CONDUCTOR or the protective earthing system in the installation is in doubt.

Subclause 7.9.2.6 – Installation

The instructions for use can contain a statement saying that the MANUFACTURER, assembler, installer or importer considers himself responsible for the effect on BASIC SAFETY, reliability and performance of the ME EQUIPMENT or ME SYSTEM only if:

– appropriately trained personnel carry out assembly operations, extensions, readjustments, modifications or repairs;
– the electrical installation of the relevant room complies with the appropriate requirements; and
– the ME EQUIPMENT or ME SYSTEM is used in accordance with the instructions for use.

Subclause 7.9.2.7 – Isolation from the SUPPLY MAINS

A plug and socket provide suitable means for isolation from the SUPPLY MAINS to satisfy 8.11.1 a), but they would not be suitable if they were not readily accessible when needed.

Subclause 7.9.2.19 – Unique version identifier

MANUFACTURERS frequently issue multiple revisions of the instructions for use. RESPONSIBLE ORGANIZATIONS and OPERATORS need to be able to determine if the instructions for use they have are current. This is particularly important when dealing with PEMS software that can be updated in the environment of use. Providing a date of issuance is a widely accepted method for identifying versions of a document. The MANUFACTURER decides what level of detail is appropriate with month and year being common for printed material. However, greater granularity might be required, particularly for material distributed electronically. The MANUFACTURER could include a revision number when appropriate.

Subclause 7.9.3.1 – General

According to the INTENDED USE of ME EQUIPMENT, the MANUFACTURER should specify the permissible environmental conditions for which a HAZARD is not induced. Environmental conditions such as the following are expected to be considered:

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– the effect of humidity;
– the effect of temperature;
– the effect of atmospheric pressure;
– the effect of shock and vibration;
– the effect of ultra-violet radiation.
– the effect of the temperature of the water for water cooled ME EQUIPMENT;
– the effect of pollution.

Accuracy and precision are not possible to define in this standard. These concepts have to be addressed in particular standards.

The values listed below were used in the second edition of IEC 60601-1 to describe the range of environmental conditions over which ME EQUIPMENT was required to be safe.

a) an ambient temperature range of + 10 °C to + 40 °C;

b) a relative humidity range of 30 % to 75 %;

c) an atmospheric pressure range of 70,0 kPa to 106,0 kPa;

d) a temperature of the water at the inlet of water-cooled ME EQUIPMENT not higher than 25 °C.

These environmental conditions were based on the conditions in buildings without air-conditioning in climates where the ambient temperature occasionally reaches + 40 °C.

In the second edition of IEC 60601-1, the ME EQUIPMENT had to be safe when operated under the above conditions but it only needed to be fully operable under conditions specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

This edition specifies particular environmental conditions for some requirements and tests. Where this is not the case, ME EQUIPMENT has to remain safe and operate correctly over the range of environmental conditions specified by the MANUFACTURER in the ACCOMPANYING DOCUMENTS.

Attention is drawn to the fact that there was always a problem to apply a 40 °C environmental condition to a ME EQUIPMENT in cases where the APPLIED PART needed to operate at temperatures close to the 41 °C limit.

The second edition of IEC 60601-1 specified the following range of environmental conditions for transport and storage of ME EQUIPMENT unless otherwise specified by the MANUFACTURER:

– an ambient temperature range of - 40 °C to + 70 °C;
– a relative humidity range of 10 % to 100 %, including condensation;
– an atmospheric pressure range of 50 kPa to 106 kPa.

Amendment 2 to the second edition replaced the above list with a requirement that the MANUFACTURER state the permissible transport and storage conditions. However, in the absence of other information, the above list can serve as a useful starting point in determining the permissible limits.

Information on environmental parameters and a limited number of their severities within the range of conditions met by electrotechnical products when being transported, stored, installed and used can be found in the IEC 60721 series [18].

For PERMANENTLY INSTALLED high power ME EQUIPMENT, it might be necessary to control the voltage drop in the customer installation to prevent input voltage getting below the minimum normal voltage due to local conditions. Control can be done by specifying the required apparent impedance of the SUPPLY MAINS.

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Subclause 7.9.3.4 – Mains isolation

SERVICE PERSONNEL need to know how to isolate the ME EQUIPMENT from the SUPPLY MAINS. This is not always obvious, particularly if there is a switch in the MAINS PART that does not meet the requirements of 8.11.

Clause 8 – Protection against electrical HAZARDS from ME EQUIPMENT

The fundamental principle for protection against electric shock is that the voltage or current between any accessible surface and any other accessible surface or earth is low enough not to result in a HAZARDOUS SITUATION, in all relevant circumstances including NORMAL CONDITION and SINGLE FAULT CONDITION.

Requirements for achieving protection have been formulated in various ways in IEC basic safety standards, in previous editions of this standard, and in other IEC product standards.

In order for the fundamental principle to be satisfied:

a) parts that are "live" (as defined in the second edition of this standard) or "hazardous live" (as defined in some other standards, such as IEC 61140 [23] and IEC 61010-1 [22]) have to be inaccessible (but see below regarding problems in identifying what is "live") and

b) ACCESSIBLE PARTS including APPLIED PARTS have to be not "live" / "hazardous live."

NOTE The term "live" was defined in the second edition of this standard as, "State of a part which, when connection is made to that part, can cause a current exceeding the allowable LEAKAGE CURRENT (specified in Subclause 19.3) for the part concerned to flow from that part to earth or from that part to an ACCESSIBLE PART of the same EQUIPMENT.

These two requirements are in principle equivalent but some standards state both of them.

These requirements in turn imply that:

c) ACCESSIBLE PARTS including APPLIED PARTS have to be separated from certain internal live parts: in general two separate MEANS OF PROTECTION are necessary, one to provide separation in NORMAL CONDITION and a second to maintain BASIC SAFETY in SINGLE FAULT CONDITION, and

d) LEAKAGE CURRENTS (and possibly also voltages and energies) have to be below acceptable limits.

Most standards include explicit requirements covering each of these aspects of providing protection. For example the first and second editions of this standard dealt with a) in Clause 16, with b) and d) in Clause 19 and with c) in Clauses 17, 18 and 20.

Requirement a) has typically been formulated as a requirement for the provision of ENCLOSURES or barriers to prevent contact with internal hazardous live parts. However it can alternatively be formulated in terms of the determination of which parts are accessible. Anyway the adequacy of ENCLOSURES or barriers is determined by use of the relevant test fingers and probes.

Application of the above approach to ME EQUIPMENT has presented some difficulties. The limits for voltage and current depend on how, if at all, the part(s) concerned can be connected to a PATIENT, e.g. directly to the heart, directly to other parts of the body, or indirectly via the OPERATOR. This has led to difficulties in identifying which parts are "live" parts.

The definition of "live" in the second edition of this standard refers to the allowable LEAKAGE CURRENT. The definition is therefore difficult to apply to internal parts for which no particular LEAKAGE CURRENT limits are specified.

Certain parts could be regarded as "live" (within the definition of the second edition of this standard) for some purposes and at the same time as not "live" for other purposes. For example an internal part that can source a current of, say, 200 μA has to be separated from all ACCESSIBLE PARTS, including PATIENT CONNECTIONS in NORMAL CONDITION.

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The separation from PATIENT CONNECTIONS of TYPE CF APPLIED PARTS has to remain effective in SINGLE FAULT CONDITION, because a current of 200 μA from these is not permissible. The same part can however become connected to other ACCESSIBLE PARTS and PATIENT CONNECTIONS in SINGLE FAULT CONDITION.

Thus two MEANS OF PROTECTION (DOUBLE INSULATION or REINFORCED INSULATION) would be needed between such a part and the PATIENT CONNECTIONS of TYPE CF APPLIED PARTS, but a single MEANS OF PROTECTION (such as BASIC INSULATION alone) would be acceptable between such a part and other ACCESSIBLE PART.

Furthermore, requirements that specify the necessary separation between parts that are accessible and parts that are "live" do not easily take account of parts that are not "live" but can become "live," such as the parts of a floating circuit that become "live" when a connection is made to another part of the same circuit.

Consider, for example, the simple situation shown in Figure A.10.

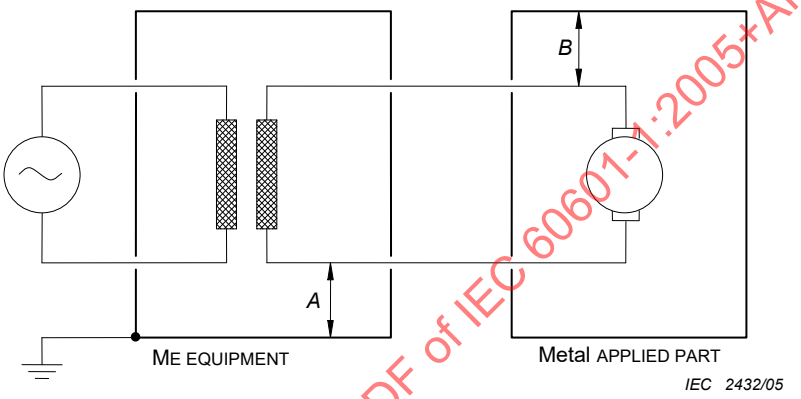


Figure A.10 – Floating circuit

The APPLIED PART has a metal ENCLOSURE that is not PROTECTIVELY EARTHED. If there is a direct connection at point A, then the other end of the SECONDARY CIRCUIT is "live," and even the first edition of this standard would have required DOUBLE INSULATION or REINFORCED INSULATION at point B.

If, instead, there is a direct connection at point B, the first edition would have required only BASIC INSULATION at point A; but this was dealt with in the second edition by adding Subclause 20.2 B-e, which requires DOUBLE INSULATION or REINFORCED INSULATION at point A.

If however there is some insulation at both points A and B, then no part of the SECONDARY CIRCUIT is "live" according to the definition in the second edition, so the second edition of this standard specifies no requirements for that insulation, which can therefore be minimal. The German National Committee of the IEC discovered this problem in 1993, unfortunately just too late for it to be dealt with in the second (and final) amendment to the second edition of this standard. The approach adopted in this edition is intended to overcome this problem.

The formulation proposed for the third edition of this standard is to specify:

1) how to determine which parts are to be regarded as ACCESSIBLE PARTS (by inspection and where necessary by the use of appropriate test probes and fingers);
2) the permissible limits for voltage/current/energy in NORMAL CONDITION and relevant SINGLE FAULT CONDITIONS; these limits depend on the possible circumstances of connection to a PATIENT or to an OPERATOR;
3) that NORMAL CONDITION includes short circuit of any insulation, AIR CLEARANCE or CREEPAGE DISTANCE or impedance which does not comply with specified requirements for the relevant WORKING VOLTAGE, and open circuit of any earth connection which does not comply with the requirements for PROTECTIVE EARTH CONNECTIONS; and

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4) that SINGLE FAULT CONDITIONS include short circuit of any insulation, AIR CLEARANCE or CREEPAGE DISTANCE which does comply with specified requirements for the relevant WORKING VOLTAGE, short circuit of any relevant component, and open circuit of any earth connection which does comply with the requirements for PROTECTIVE EARTH CONNECTIONS.

This approach avoids the need to include explicit separate requirements for particular protective means, as specified in existing IEC standards. Arguably it could avoid even a general requirement for two MEANS OF PROTECTION, as presently specified, but the working group considered that such a requirement is desirable.

Where requirements from the second edition that used the defined term “live” have been retained, they have been re-phrased so as not to use this term.

Generally, protection is obtained by a combination of:

– limitation of voltage or energy, or protective earthing (see 8.4 and 8.6);

– enclosing or guarding of energized circuits (see 5.9);

– insulation of adequate quality and construction (see 8.5).

The dielectric strength requirements are included to check the quality of the insulation material used at different places in the ME EQUIPMENT.

Subclause 8.1 – Fundamental rule of protection against electric shock

Subclause 8.1 a)

Insulation not complying with 8.8, spacing less than specified in 8.9, etc. are not MEANS OF PROTECTION, but they could influence the voltages or LEAKAGE CURRENTS appearing on ACCESSIBLE PARTS including APPLIED PARTS. Measurements might therefore need to be made with such parts intact or bypassed, whichever is the worse case.

As there are in general no integrity requirements for signal connections, interruption of a functional earth connection has to be considered as a NORMAL CONDITION.

Subclause 8.1 b)

LEAKAGE CURRENTS are not generally measured in the SINGLE FAULT CONDITION of breakdown of BASIC INSULATION in CLASS I EQUIPMENT because either the LEAKAGE CURRENTS in this case flow only during the time before a fuse or OVER-CURRENT RELEASE operates or the use of an isolated power supply limits the LEAKAGE CURRENTS to safe values. Exceptionally, LEAKAGE CURRENTS are measured during short circuiting of BASIC INSULATION in cases where there are doubts concerning the effectiveness of PROTECTIVE EARTH CONNECTIONS inside the ME EQUIPMENT (see 8.6.4 b)).

In certain instances the short-circuit condition is not necessarily the worst case. As an example, an overvoltage device, intended to prevent damage to insulation, could fail in the open-circuit condition thereby no longer rendering its safety function. This could lead to damaged insulation. It is recognized that in most cases in this subclause, the open-circuit condition is superfluous but for select components it was acknowledged that the open-circuit condition is a valid failure mode. Components of ME EQUIPMENT are also addressed in 4.8.

With regard to the presence of the MAXIMUM MAINS VOLTAGE on an unearthed ACCESSIBLE PART including APPLIED PARTS, see the rationales for 8.5.2.2 and 8.7.4.7 d).

If ME EQUIPMENT were configured as shown in Figure A.11, interruption of the connection would result in excessive TOUCH CURRENT. This situation is therefore one of the SINGLE FAULT CONDITIONS that should be investigated.

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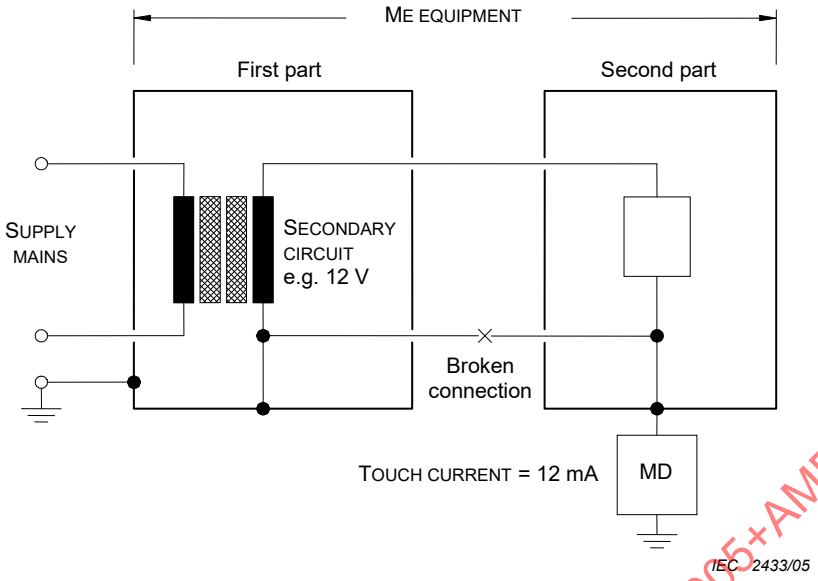


Figure A.11 – Interruption of a power-carrying conductor between ME EQUIPMENT parts in separate ENCLOSURES

Subclause 8.3 – Classification of APPLIED PARTS

Subclause 8.3 a)

ME EQUIPMENT intended for DIRECT CARDIAC APPLICATION having one or more TYPE CF APPLIED PARTS could have one or more additional TYPE B APPLIED PARTS or TYPE BF APPLIED PARTS that can be applied simultaneously (see also 7.2.10).

Similarly ME EQUIPMENT could have a mixture of TYPE B APPLIED PARTS and TYPE BF APPLIED PARTS.

Subclause 8.3 b)

Most particular standards developed for kinds of ME EQUIPMENT that have PATIENT electrodes require the APPLIED PARTS to be TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS. For similar kinds of ME EQUIPMENT for which no particular standards are available, it is better to include such a requirement in this standard than to allow such APPLIED PARTS to be TYPE B APPLIED PARTS. The TYPE B APPLIED PART classification is mainly used, in practice, for PATIENT supporting ME EQUIPMENT such as X-ray tables, not for PATIENT electrodes.

Subclause 8.4.1 – PATIENT CONNECTIONS intended to deliver current

This standard does not specify any limits for currents that are intended to produce a physiological effect in the PATIENT, but particular standards can do so. Any other currents flowing between PATIENT CONNECTIONS are subject to the specified limits for PATIENT AUXILIARY CURRENT.

Subclause 8.4.2 – ACCESSIBLE PARTS including APPLIED PARTS

Subclause 8.4.2 b)

It is presumed that TOUCH CURRENT can reach the PATIENT by chance contact through various paths, including a path via the OPERATOR. The limits for TOUCH CURRENT therefore apply to all ACCESSIBLE PARTS except PATIENT CONNECTIONS, which are covered by 8.4.2 a), and parts that satisfy the conditions specified in 8.4.2 c).

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Subclause 8.4.2 c)

There is little or no justification for the difference in the second edition between the cases where there is a cover that is removable without a TOOL and where there is no cover. The limit values have been harmonized with IEC 60950-1:2005 because Information Technology (IT) equipment is commonly used in ME SYSTEMS, and the values in IEC 60950-1 are not much different from those in the second edition of this standard. (60 V dc is the same, and 42,4 V peak is not much different from 25 V r.m.s.).

Essentially OPERATOR protection is now based on IEC 60950-1 and, therefore, we need to incorporate the protection requirements from that standard. Previously IEC 60601-1 did not have a requirement for protection against hazardous energy but there is a definite RISK from burn, fire and flying debris. This is now addressed using the requirement from IEC 60950-1:2005. The limit values have been established for many years in IEC 60950 and its predecessor standards. The maximum available energy is allowed to exceed 240 VA during the first 60 s after contact with the ACCESSIBLE PART (e.g. it takes time for the current limit circuit in a power supply to operate and during this time the hazardous energy level can be exceeded).

Subclause 8.4.2 d)

As well as parts that are determined to be ACCESSIBLE PARTS in accordance with 5.9, electrical contact with internal parts is supposed to be made with:

– a pencil or pen, held in a hand, simulated by a guided test pin;

– a necklace or similar pendant, simulated by a metal rod suspended over openings in a top cover;

– a screwdriver for adjustment of a preset control by the OPERATOR, simulated by an inserted metal rod.

Subclause 8.4.3 – ME EQUIPMENT intended to be connected to a power source by a plug

The 45 μC limit is the same as that specified in IEC 60335-1, which is based on the limits in IEC 60479-1 [11]. It is comparable (though not exactly equivalent) to the 100 nF limit specified in the second edition of this standard. With regard to BASIC SAFETY there is no reason to specify a more stringent limit between the line and earth pins, as in the second edition.

Subclause 8.4.4 – Internal capacitive circuits

The limit has been changed from the 2 mJ specified in the second edition of this standard to the same value as specified in the previous subclause, because whatever is safe for an OPERATOR, or even a PATIENT, who touches the pins of a MAINS PLUG is also safe for someone who opens an ACCESS COVER to gain access to the inside of ME EQUIPMENT.

Subclause 8.5.1 – MEANS OF PROTECTION

Two MEANS OF PROTECTION can be provided in several ways. The following are examples:

1) PATIENT CONNECTIONS and other ACCESSIBLE PARTS are separated from parts different from earth potential by BASIC INSULATION only, but PROTECTIVELY EARTHED and have such a low internal impedance to earth that LEAKAGE CURRENTS do not exceed the allowable values in NORMAL CONDITION and SINGLE FAULT CONDITION.

2) PATIENT CONNECTIONS and other ACCESSIBLE PARTS are separated from parts different from earth potential by BASIC INSULATION and an intermediate PROTECTIVELY EARTHED metal part, which could be a fully enclosing metal screen.

3) PATIENT CONNECTIONS and other ACCESSIBLE PARTS are separated from parts different from earth potential by DOUBLE or REINFORCED INSULATION.

4) Impedances of components prevent the flow to PATIENT CONNECTIONS and other ACCESSIBLE PARTS of LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS exceeding the allowable values.

A survey of insulation paths is found in Annex J.

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Previous editions of this standard also recognized the possibility of achieving separation by use of a PROTECTIVELY EARTHED intermediate circuit. However it is in general not possible for the whole of a circuit to be connected with very low impedance to the PROTECTIVE EARTH TERMINAL. Also, if one part of a circuit is earthed, other parts of the circuit are then different from earth potential, so have to be further separated from PATIENT CONNECTIONS and other ACCESSIBLE PARTS.

Air can form part or all of the BASIC INSULATION or SUPPLEMENTARY INSULATION.

In general DOUBLE INSULATION is preferable to REINFORCED INSULATION.

The first edition of this standard specified numerous pairs of parts between which separation was required, but the list was incomplete. It was expanded in the second edition but still remained incomplete, for example with regard to the situation illustrated in Figure A.10.

Discussion in the working group at an early stage of the development of this edition established that test houses actually have to identify the various circuits inside ME EQUIPMENT and the various points at which separation could be needed. This edition therefore specifies this PROCEDURE explicitly.

The distinction between MEANS OF OPERATOR PROTECTION and MEANS OF PATIENT PROTECTION was introduced in response to concerns that the requirements of previous editions of this standard for insulation testing, CREEPAGE DISTANCES and AIR CLEARANCES were too stringent.

Many ME SYSTEMS incorporate equipment complying with IEC 60950-1. Also many kinds of ME EQUIPMENT incorporate parts, such as power supplies, that have been primarily designed for use in equipment complying with IEC 60950-1. This led some experts and National Committees to propose that the requirements of this standard be harmonized with IEC 60950-1 as far as possible.

However the test voltages and the minimum values of CREEPAGE DISTANCES and AIR CLEARANCES specified in IEC 60950-1 are derived from IEC 60664-1 and are based on assumptions about possible overvoltages in mains and other circuits, particularly the frequency of occurrence of various levels of overvoltage. According to the understanding of the working group experts who revised the corresponding requirements of this standard, compliance with the requirements of IEC 60664-1 or IEC 60950-1 leaves a RISK that transient insulation breakdown could occur with a frequency up to about once per year.

The probability of occurrence of an OPERATOR coming in contact with a relevant part and with earth at the moment when breakdown occurs is low, so the RESIDUAL RISK is acceptable for ME EQUIPMENT, just as it is for IT equipment. However the probability of occurrence of a PATIENT being in contact with an APPLIED PART and with earth is significantly higher. The working group therefore decided that a larger margin of safety should be applied where PATIENT safety is concerned. However there was no reliable basis for deciding what additional margin might be applied to the values from IEC 60664-1, so the same values that were specified in the second edition of this standard have been retained for MEANS OF PATIENT PROTECTION.

For MEANS OF OPERATOR PROTECTION this revision of the standard allows the MANUFACTURER three options (see Figure A.12). One option is to apply the requirements of IEC 60950-1 and to identify the appropriate installation category and pollution degree. Alternatively, the MANUFACTURER can apply the values in the tables, which have been derived from IEC 60950-1 on the basis of reasonable assumptions about the installation category and pollution degree. The third option is to treat the MEANS OF OPERATOR PROTECTION as if it were a MEANS OF PATIENT PROTECTION.

Y capacitors are used to reduce radio frequency interference by providing a low impedance path to earth for high frequency a.c. They are also used for bridging DOUBLE or REINFORCED INSULATION as part of the interference suppression regime. There are four types: Y1, Y2, Y3 and Y4. Y1 capacitors are designed for use with three phase mains and have a WORKING VOLTAGE of up to 500 V a.c. and a withstand voltage of 4 000 V a.c. Y2 capacitors are designed for use with single phase mains and have a WORKING VOLTAGE up to 300 V a.c. and a withstand voltage of 1 500 V a.c. Y3 capacitors are similar to Y2 capacitors but have a

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WORKING VOLTAGE up to 250 V a.c. Y4 capacitors are designed for use with low voltage mainsand have a WORKING VOLTAGE up to 150 V a.c. and a withstand voltage of 1 000 V a.c. These capacitors are safety critical since they provide a leakage path to earth or across a barrier. So they must be certified and monitored by a recognised test house to IEC 60384-14, which serves to control their manufacture.

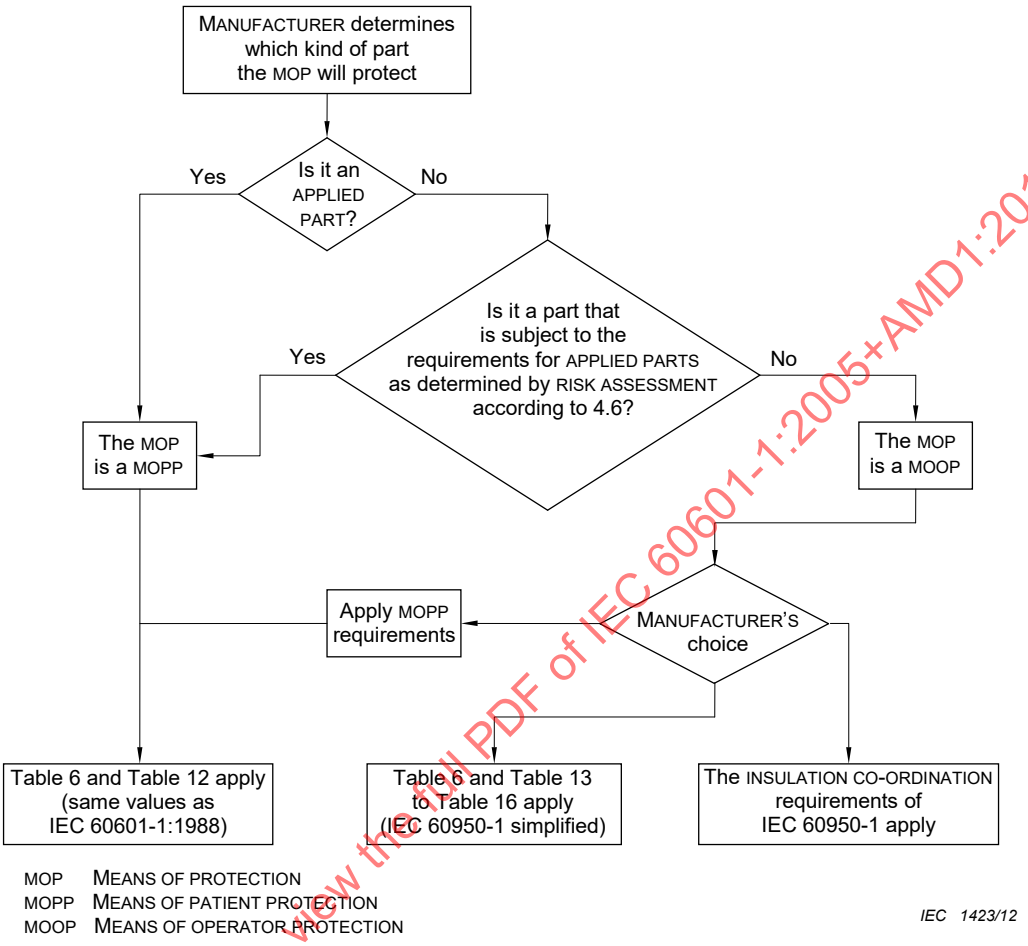


Figure A.12 – Identification of MEANS OF PATIENT PROTECTION and MEANS OF OPERATOR PROTECTION

Subclause 8.5.1.2 – MEANS OF PATIENT PROTECTION (MOPP)

When fitting Y capacitors across barriers, the dielectric strength requirement must be considered. For example, for voltages in the range of 212 V peak to 354 V peak, two MEANS OF PATIENT PROTECTION are required to be tested at 4 000 V a.c. This would then require the use of Y1 capacitors. Two Y2 capacitors in series would not withstand this voltage as they are rated at 1 500 V a.c. each. For voltages below 212 V peak, two Y2 capacitors would suffice as the dielectric strength requirement is 3 000 V a.c.

Subclause 8.5.2.1 – F-TYPE APPLIED PARTS

The essential feature of an F-TYPE APPLIED PART is its separation from other parts. This subclause specifies and quantifies the necessary degree of separation.

Multiple functions can be considered as multiple APPLIED PARTS (which have to be separated from each other by one MEANS OF PATIENT PROTECTION) or as one APPLIED PART. This is decided by the MANUFACTURER after assessing the RISK that earthing of one or more of the PATIENT CONNECTION(S) of one function could result in excessive LEAKAGE CURRENT through the

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PATIENT CONNECTION(S) of another function, in the condition in which an unintended voltage originating from an external source becomes connected to the PATIENT.

The 500 V r.m.s. limit for protective devices was already specified in the first edition of this standard. The original rationale is not known, but this voltage corresponds to the highest RATED voltage specified in 4.10.

Subclause 8.5.2.2 – TYPE B APPLIED PARTS

This requirement addresses the possibility that an unintended voltage originating from an external source becomes connected to a part of the ME EQUIPMENT. In the absence of appropriate separation between such a part and PATIENT CONNECTIONS, an excessive PATIENT LEAKAGE CURRENT could result.

According to Clause 17 c) of the second edition of this standard, this requirement applied to all APPLIED PARTS, but in many cases it no longer applies:

– For F-TYPE APPLIED PARTS, the isolation required by 8.5.2.1 also covers this situation (but TYPE BF APPLIED PARTS require an additional test, as explained in the rationale to 8.7.4.7 d)).

– A HAZARDOUS SITUATION cannot develop if either the ME EQUIPMENT part concerned or the PATIENT CONNECTIONS of a TYPE B APPLIED PART are PROTECTIVELY EARTHED. (Failure of the PROTECTIVE EARTH CONNECTION together with the appearance of the unintended voltage would be a double fault condition.)

– If the ME EQUIPMENT part concerned is physically contiguous with the APPLIED PART (for example a dental handpiece) the requirement does not apply if the RISK of contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low.

Subclause 8.5.2.3 – PATIENT leads or PATIENT cables

There are two sets of circumstances to guard against:

– firstly, for TYPE BF APPLIED PARTS and TYPE CF APPLIED PARTS, there should be no possibility of an accidental PATIENT-to-earth connection via any lead that can become detached from the ME EQUIPMENT; even for a TYPE B APPLIED PART an unwanted connection to earth can have an adverse effect on the operation of the ME EQUIPMENT;

– secondly, for all types of APPLIED PART, there should be no possibility of connecting the PATIENT accidentally to parts of ME EQUIPMENT or other conductive parts in the vicinity from which a current in excess of the allowable LEAKAGE CURRENT could flow.

An extreme case of the latter HAZARD would be a direct connection to the SUPPLY MAINS, resulting from insertion of the connector into a mains outlet or into the socket end of a DETACHABLE POWER SUPPLY CORD. It is essential to prevent this from occurring.

With certain combinations of PATIENT and MAINS CONNECTORS it will be possible to plug the PATIENT connector accidentally into the mains socket.

This possibility cannot reasonably be removed by dimensional requirements as to do so would make single-pole connectors excessively large. Such an incident is rendered safe by the requirement for the PATIENT connector to be protected by insulation having a CREEPAGE DISTANCE of at least 1,0 mm and a dielectric strength of at least 1 500 V. The latter on its own would not suffice as 1 500 V protection could easily be achieved by thin plastic foil that would not stand up to daily wear or to being pushed, possibly repeatedly, into a mains socket. For this reason also it can be seen that the insulation should be durable and rigid.

The wording of this requirement was modified from that in the second edition of this standard to avoid use of the phrases “conductive connection”, which was eliminated as a defined term. This change was a direct result of National Committee comments during the preparation of this edition.

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According to the rationale in the second edition of this standard, the test in which the test finger is applied with a force of 10 N was intended “to check the strength of the insulating material.” This has now been supplemented by an explicit cross reference to 8.8.4.1.

In response to an enquiry, one National Committee stated that this test is “a mechanical test of the protective cover over the pin;” suggesting that the test was intended to apply specifically to one particular kind of connector design, in which the contact is surrounded by a movable sheath designed to allow contact with the correct mating connector but not with other parts.

During the development of this edition of this standard, the question arose whether this test should be restricted to single-pole connectors, as in the second edition of this standard, or should apply to multi-pole connectors as well. Some multi-pole connectors are of similar shape to single-pole connectors and could similarly be inserted into a MAINS CONNECTOR, so the same considerations of adequacy of insulation apply equally. On the other hand, typical kinds of multi-pole connectors that are in common use cannot be inserted into a MAINS CONNECTOR, but would fail this test if they were subject to it, because the test finger can easily touch their contacts, even without the application of a 10 N force.

A further enquiry to the National Committees yielded a range of responses, with reasonable consensus on some questions but no consensus as to whether this test should apply to all connectors or should be restricted to single-pole connectors.

This test should certainly apply to a multi-pole connector that is of such shape and size that it could be inserted into a mains socket. In this case, the RISK is the same as with a single-pole connector.

Another reason for applying this test to some multi-pole connectors is that the test with the flat plate does not exhaustively assess the possibility of contact with conductive parts in the vicinity from which a current in excess of the allowable LEAKAGE CURRENT could flow. Almost any kind of connector, if detached from the ME EQUIPMENT or dropped, could possibly make contact with something besides the intended mating connector, but the RISK depends on the shape of the connector and the circumstances. In most cases the RISK is low. For example a typical “D” connector is likely to make contact with an earthed object only momentarily, whereas a straight pin could make contact for a prolonged period. However even prolonged contact with a metal object can result in a HAZARDOUS SITUATION only if it occurs in combination with a fault or abnormal situation that allows an excessive current to flow through the PATIENT. The RISK is in all cases much less than the RISK if the connector can make contact with a mains socket. The requirements of this standard should be formulated in relation to the RISK. The standard should minimise RISK to the PATIENT, while allowing MANUFACTURERS a reasonable range of choice of connectors.

“Any connector” should be understood to include multiple contact connectors, several connectors and connectors in series.

The dimension of 100 mm diameter is not in the least important and merely serves to indicate the scale of the flat surface. Any sheet of conductive material larger than this would be suitable.

Subclause 8.5.3 – MAXIMUM MAINS VOLTAGE

Several requirements and tests of this standard relate to the possibility that an unintended voltage originating from an external source becomes connected to the PATIENT or to certain parts of the ME EQUIPMENT. The actual magnitude of such a voltage is unknown; but according to the second edition of this standard it was taken to be the highest RATED MAINS VOLTAGE, or for polyphase equipment the phase to neutral supply voltage. These values reflected a reasonable worst-case assumption that the actual unintended external voltage is unlikely to exceed the voltage of the SUPPLY MAINS in the location where the ME EQUIPMENT is used, and that ME EQUIPMENT is unlikely to be used in a location where the SUPPLY MAINS has a voltage higher than its highest RATED MAINS VOLTAGE. For INTERNALLY POWERED ME EQUIPMENT the value specified was (and remains) 250 V, because this is the highest commonly encountered phase-to-neutral voltage in locations where ME EQUIPMENT is used.

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In early drafts of this edition, the corresponding wording only referred to a.c. SUPPLY MAINS. This mistake was pointed out during the comment period. Discussion of this comment confirmed that the requirements should not depend on whether the SUPPLY MAINS is a.c. or d.c., but revealed a further anomaly. If ME EQUIPMENT is specified for connection to an extra-low voltage (ELV) SUPPLY MAINS (for example 12 V in an ambulance) but not to any higher voltage SUPPLY MAINS, the external voltage assumed for test purposes would be only the ELV. Such ME EQUIPMENT could however be used in locations where a higher voltage SUPPLY MAINS is also installed. The wording has therefore been revised to remove this anomaly.

If ME EQUIPMENT has a highest RATED supply voltage less than 100 V, it will necessarily be used in a special location where that supply is available, and we do not know what other supplies could also be present. Therefore the external voltage assumed for relevant tests is 250 V, as for INTERNALLY POWERED ME EQUIPMENT.

However ME EQUIPMENT having a highest RATED MAINS VOLTAGE of around 115 V is unlikely to be used in locations having higher voltage SUPPLY MAINS, so the external voltage assumed for relevant tests is equal to the highest RATED MAINS VOLTAGE, as in the second edition of this standard.

Subclause 8.5.4 – WORKING VOLTAGE

The dielectric strength test voltages specified in Table 6 are appropriate for insulation that is normally subjected to a continuous WORKING VOLTAGE and to transient overvoltages.

The WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION is the voltage to which the DOUBLE INSULATION as a whole is subjected, because either MEANS OF PROTECTION can be subjected to this voltage if the other MEANS OF PROTECTION fails.

For insulation between two isolated parts or between an isolated part and an earthed part, the WORKING VOLTAGE could in some cases be equal to the arithmetic sum of the highest voltages between any two points within both parts.

For DEFIBRILLATION-PROOF APPLIED PARTS, a test voltage deduced on the basis of a WORKING VOLTAGE equal to the defibrillation peak voltage would be far too high for insulation that in NORMAL USE is exposed only occasionally to voltage impulses, normally shorter than 1 s and without additional overvoltage.

Subclause 8.5.5 – DEFIBRILLATION-PROOF APPLIED PARTS

The special test described in 8.5.5 is considered to ensure sufficient protection against exposure to defibrillation pulses, no separate dielectric strength test being necessary.

Subclause 8.5.5.1 – Defibrillation protection

One or the other of the defibrillation paddles could, by virtue of its clinical application, be connected to earth or at least referenced to earth.

When a defibrillator is used on the PATIENT, a HIGH VOLTAGE can thus be impressed either between one part of the ME EQUIPMENT and another, or between such parts collectively and earth. ACCESSIBLE PARTS should be adequately isolated from PATIENT CONNECTIONS or protected in some other way. The insulation of the PATIENT CONNECTIONS cannot be protected by voltage limiting devices relying on earthed connections.

The DEFIBRILLATION-PROOF APPLIED PART marking indicates that an APPLIED PART can safely remain attached to a PATIENT who is being defibrillated without any adverse effect on subsequent use of the ME EQUIPMENT.

The tests ensure:

a) that any ACCESSIBLE PARTS of ME EQUIPMENT, PATIENT cables, cable connectors, etc. that are not PROTECTIVELY EARTHED will not deliver a hazardous level of charge or energy due to flashover of defibrillation voltage; and

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b) that the ME EQUIPMENT will continue to function (at least with regard to BASIC SAFETY and ESSENTIAL PERFORMANCE) after exposure to defibrillation voltage.

The requirement and the test PROCEDURE refer to “any necessary time” stated in the ACCOMPANYING DOCUMENTS. There is no requirement for the ACCOMPANYING DOCUMENTS to include a statement of a recovery time, but if there is no statement the ME EQUIPMENT has to recover and deliver its BASIC SAFETY and ESSENTIAL PERFORMANCE immediately.

The tests are conducted with the ME EQUIPMENT connected to the SUPPLY MAINS and in operation according to the instructions for use because the tests deal not only with the effect of the defibrillation energy on BASIC SAFETY but also on the ability of the ME EQUIPMENT to deliver its ESSENTIAL PERFORMANCE after the stated recovery time.

NORMAL USE includes the situation that a PATIENT is defibrillated while connected to the ME EQUIPMENT and, at the same time, the OPERATOR or another person is in contact with the ENCLOSURE. The possibility of this occurring at the same time as the SINGLE FAULT CONDITION of a defective PROTECTIVE EARTH CONNECTION is very unlikely and is therefore disregarded. However, interruption of functional earth connections is more probable, and is therefore required for these tests.

The SEVERITY of electric shock that a person receives when touching ACCESSIBLE PARTS during the discharge of a defibrillator is limited to a value (corresponding to a charge of 100 μC) which can be felt and which could be unpleasant, but which is not dangerous.

SIGNAL INPUT/OUTPUT PARTS are included, as signal lines to remote ME EQUIPMENT could otherwise carry energies that might be hazardous.

The test circuits of Figure 9 and Figure 10 of this standard are designed to simplify the test by integrating the voltage appearing across the test resistance (R_1).

The value of the inductance L in the test circuits of Figure 9 and Figure 10 is chosen to provide a shorter than normal rise time in order to test adequately the incorporated protective means.

If ME EQUIPMENT would be designed according to 8.5.2.1 and 8.5.5.1, it might have two different functions on one common APPLIED PART circuit. Consider the example in Figure A.21. In this example, the ECG and an invasive blood pressure catheter (IBP) share one common APPLIED PART circuit. In real use in the hospital, sometimes only one function (ECG) is used while the other function (IBP) is not connected. If the PATIENT needs to be defibrillated, there is a potential that a second OPERATOR would get an electric shock at unused IBP outlets during selecting of proper adjustments at the ME EQUIPMENT (e.g. at a multi-parameter patient monitor). It should be pointed out that in principle, the 5 KV could occur at every disconnected connector, which does not have adequate recessed pins. However, in practice, the probability of occurrence of HARM is much higher at the unused APPLIED PART outlets on the ME EQUIPMENT compared to any connector of adapter cables. Adapter cables will normally not be touched by the OPERATOR during defibrillation, because before defibrillation the command “stand clear” will be given. Even in the case that a disconnected adapter cable would be touched by an OPERATOR during defibrillation, it will most probably be touched at the isolated plastic parts, but not at its internal pins.

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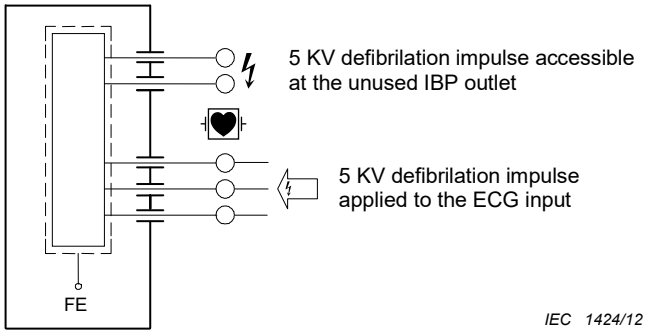


Figure A.21 – Example of ME EQUIPMENT having two different functions on one common APPLIED PART circuit

Rationale for impulse test voltage

When a defibrillation voltage is applied to the thorax of a PATIENT, via externally applied paddles (or defibrillation electrodes), the body tissue of the PATIENT in the vicinity of the paddles and between the paddles becomes a voltage dividing system.

The voltage distribution can be gauged roughly using three-dimensional field theory but is modified by local tissue conductivity that is far from uniform.

If the electrode of another item of ME EQUIPMENT is applied to the PATIENT, roughly within the compass of the defibrillator paddles, the voltage to which such an electrode is subjected depends on its position but will generally be less than the on-load defibrillation voltage.

Unfortunately it is not possible to say how much less as the electrode in question can be placed anywhere in this area, including immediately adjacent to one of the defibrillator paddles. In the absence of a relevant particular standard, it is required that such an electrode and the ME EQUIPMENT to which it is connected is able to withstand the full defibrillation voltage. This is the no-load voltage as one of the defibrillator paddles might not be making good contact with the PATIENT.

This standard therefore specifies 5 kV d.c. as the appropriate test voltage in the absence of a relevant particular standard.

Applying Subclause 4.5, a MANUFACTURER is allowed to use alternate means to address a RISK covered by this standard if the RESIDUAL RISK after applying the alternate means is equal or less than the RESIDUAL RISK after applying the requirements of this standard. It is possible for a MANUFACTURER to determine that a lower test voltage is appropriate depending on the INTENDED USE of the ME EQUIPMENT and the location of the APPLIED PARTS on the PAIENT if it can be demonstrated that the test voltage selected is the maximum voltage that can appear on the APPLIED PART with 5 kV applied to the chest. Such parts can be classified and marked as a DEFIBRILLATION-PROOF APPLIED PARTS.

Subclause 8.6 – Protective earthing, functional earthing and potential equalization of ME EQUIPMENT

Typically, metal ACCESSIBLE PARTS of CLASS I ME EQUIPMENT are PROTECTIVELY EARTHED. However, they could be separated by other MEANS OF PROTECTION, in accordance with 8.5. Also some metal ACCESSIBLE PARTS could be earthed incidentally, neither by a PROTECTIVE EARTH CONNECTION nor for functional purposes. For example, such a part could be in contact with another part that is PROTECTIVELY EARTHED but does not itself need to be PROTECTIVELY EARTHED.

Subclause 8.6.1 – Applicability of requirements

PROTECTIVE EARTH CONNECTIONS that are only relevant to the safety of OPERATORS are allowed to comply either with the requirements of this standard or with those of IEC 60950-1, but the

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latter alternative is not allowed for PROTECTIVE EARTH CONNECTIONS that are relevant to the safety of both OPERATORS and PATIENTS.

Subclause 8.6.2 – PROTECTIVE EARTH TERMINAL

These requirements are intended to ensure a reliable connection between the ME EQUIPMENT and the protective earthing system of the electrical installation.

Subclause 8.6.3 – Protective earthing of moving parts

Connections to moving parts, whether made by sliding contacts, by flexible wires or by any other means, could be more susceptible than ordinary FIXED connections to deterioration during the EXPECTED SERVICE LIFE of the ME EQUIPMENT. Therefore, they are not acceptable as PROTECTIVE EARTH CONNECTIONS unless their reliability is demonstrated.

Subclause 8.6.4 a)

PROTECTIVE EARTH CONNECTIONS can only perform their protective function if they are able to carry the fault current resulting from a failure in BASIC INSULATION.

Such a current is assumed to have sufficient amplitude to cause operation of protective devices in the electrical installation (fuses, circuit-breakers, earth leakage circuit-breakers and the like) in a reasonably short time.

It is therefore necessary to check both the impedance and the current-carrying capability of PROTECTIVE EARTH CONNECTIONS.

The minimum time required for the test current is intended to reveal any overheating of parts of the connection due to thin wiring or a bad contact. Such a “weak spot” might not be discovered by resistance measurement alone.

PROTECTIVE EARTH CONNECTIONS can have zones of higher impedance, for example due to oxidation of materials. Use of a current source with an unlimited voltage could prevent detection of such zones because of their ability to flash through. The impedance is therefore determined first, using a limited voltage.

If this voltage is sufficient to drive the specified test current through the total impedance, then this one test also serves to demonstrate the current-carrying capability of the connection. Otherwise an additional test is necessary, either using a higher voltage or by assessing the cross-sectional area of the connection by inspection.

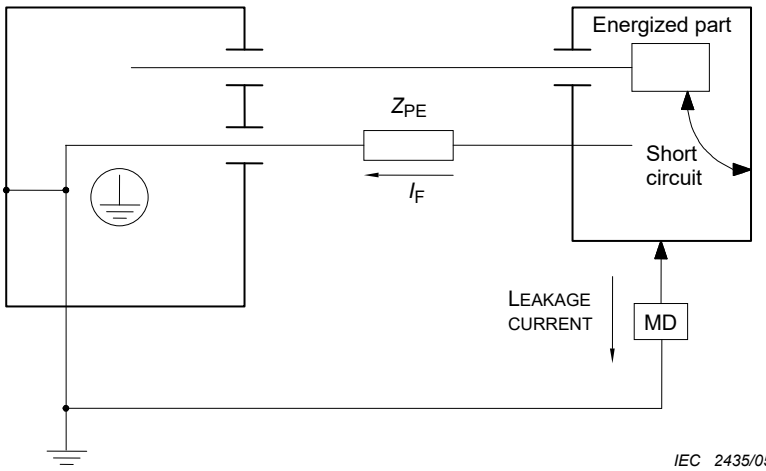
Where a long (> 3 m) DETACHABLE POWER SUPPLY CORD is supplied, specified or used, the 200 mΩ total protective earth pathway requirement still applies. Therefore, it might be necessary to use a DETACHABLE POWER SUPPLY CORD with conductors of a greater cross sectional area than the minimum required by 8.11.3.3.

Subclause 8.6.4 b)

The fault current could be limited to a relatively low value because of inherent impedance or the characteristic of the power source, for example where the power system is not connected to earth or connected to it via a high impedance (see Figure A.13).

In such cases, the cross-section of the PROTECTIVE EARTH CONNECTION can be determined primarily by mechanical considerations.

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Legend

Z_{PE} = Impedance of PROTECTIVE EARTH CONNECTION in ohms (exceeding the limit specified in 8.6.4 a))

I_F = Maximum continuous prospective fault current in amperes in the PROTECTIVE EARTH CONNECTION caused by a single failure of the insulation to earth

MD Measuring device (see Figure 12)

NOTE The figure shows ME EQUIPMENT having a main ENCLOSURE and a remote part in a separate ENCLOSURE, as an example of a situation where the impedance of a PROTECTIVE EARTH CONNECTION could exceed the limit specified in 8.6.4 a): however this situation could also exist in ME EQUIPMENT having a single ENCLOSURE.

Figure A.13 – Allowable protective earth impedance where the fault current is limited

Subclause 8.6.7 – POTENTIAL EQUALIZATION CONDUCTOR

Medically used rooms in most countries have no facilities for the use of detachable POTENTIAL EQUALIZATION CONDUCTORS. This standard therefore does not require any means to be provided for the connection of a POTENTIAL EQUALIZATION CONDUCTOR to the ME EQUIPMENT. If however the ME EQUIPMENT does have such means, for use in locations where POTENTIAL EQUALIZATION CONDUCTORS are used, the appropriate requirements have to be satisfied.

Subclause 8.6.9 – CLASS II ME EQUIPMENT

This requirement allows a CLASS II ME EQUIPMENT to have a connection to protective earth for functional reasons only. Green/yellow is required to avoid confusion in installation. The allowance does not degrade the degree of protection against electric shock.

The current flowing through the FUNCTIONAL EARTH CONDUCTOR has to be limited in the same way as current in the PROTECTIVE EARTH CONDUCTOR. To prevent the FUNCTIONAL EARTH CONDUCTOR from becoming a PROTECTIVE EARTH CONDUCTOR, the insulation between internal screens including internal wiring connected to them and ACCESSIBLE PARTS needs to provide two MEANS OF PROTECTION.

Subclause 8.7.2 – SINGLE FAULT CONDITIONS

Short circuiting of one part of DOUBLE INSULATION would be likely to increase LEAKAGE CURRENT by a factor of the order of 2. In some cases the test could be difficult to carry out and, as the allowable values for SINGLE FAULT CONDITION are five times those for NORMAL CONDITION, the test would not provide useful information.

Subclause 8.7.3 – Allowable values, Table 3 and Table 4

The value of electric current flowing in the human or animal body that can cause a certain degree of stimulation varies from individual to individual, according to the way in which the

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connection to the body is made and according to the frequency of the current applied and its duration.

Currents of low frequency flowing directly into or through the heart considerably increase the danger of ventricular fibrillation. For currents of medium or high frequency, the RISK of electric shock is less or negligible, but the RISK of burning remains.

The sensitivity of the human or animal body to electric currents, depending upon the degree and nature of contact with the ME EQUIPMENT, leads to a system of classification reflecting the degree and quality of protection provided by the APPLIED PARTS (classified as TYPE B APPLIED PARTS, TYPE BF APPLIED PARTS and TYPE CF APPLIED PARTS). TYPE B APPLIED PARTS and TYPE BF APPLIED PARTS are generally suitable for applications involving external or internal contact with the PATIENT, excluding the heart. TYPE CF APPLIED PARTS are suitable for DIRECT CARDIAC APPLICATIONS with regard to LEAKAGE CURRENT.

In conjunction with this classification, the requirements for allowable LEAKAGE CURRENT have been formulated. The absence of sufficient scientific data concerning the sensitivity of the human heart for currents causing ventricular fibrillation still presents a problem.

Nevertheless, the publication of the first edition of this standard in 1977 provided engineers with data enabling them to design ME EQUIPMENT; and these requirements have proved over the years since then to ensure a very low level of RISK without being too onerous for designers.

The requirements for LEAKAGE CURRENT were formulated taking into account:

– that the possibility of ventricular fibrillation is influenced by factors other than only electrical parameters;

– that the values for allowable LEAKAGE CURRENTS in SINGLE FAULT CONDITION should be as high as is considered safe, taking into account statistical considerations, in order not to present designers with unnecessary difficulties; and

– that values for NORMAL CONDITION are necessary to create a safe condition in all situations by providing a sufficiently high safety factor with respect to SINGLE FAULT CONDITIONS.

The measurement of LEAKAGE CURRENTS has been described in a way that enables the use of simple instruments, avoiding different interpretations of a given case and indicating possibilities for periodic checking by the RESPONSIBLE ORGANIZATION.

Allowable values of LEAKAGE and PATIENT AUXILIARY CURRENTS for a.c. and d.c. composite waveforms with frequencies up to and including 1 kHz take account of the following considerations.

a) In general the RISK of ventricular fibrillation or pump failure increases with the value or duration, up to a few seconds, of the current passing through the heart. Some areas of the heart are more sensitive than others. That is, a current that causes ventricular fibrillation when applied to one part of the heart could have no effect when applied to another part of the heart.

b) The RISK is highest and approximately equal for frequencies in the 10 Hz to 200 Hz range. It is lower, by a factor of nearly 5, at d.c. and by approximately 1,5 at 1 kHz. Beyond 1 kHz, the RISK decreases rapidly [45]. However lower limits are needed for d.c. to prevent tissue necrosis with long-term application.

The values in Table 3 and Table 4 apply to currents measured with the measuring device shown in Figure 12 a), which automatically allows for the reduced sensitivity at higher frequencies. SUPPLY MAINS frequencies of 50 Hz and 60 Hz are in the range of highest RISK.

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c) Although as a general rule requirements in a general standard are less restrictive than the requirements in particular standards, some of the allowable values in Table 3 and Table 4 have been set at such a value that:

– the majority of ME EQUIPMENT types can comply, and

– they can be applied to most ME EQUIPMENT types (existing or future) for which no particular standards exist.

EARTH LEAKAGE CURRENT

The EARTH LEAKAGE CURRENT flowing through the PROTECTIVE EARTH CONDUCTOR is not a HAZARD per se. The PATIENT and OPERATOR are protected by specifying appropriately low values for PATIENT LEAKAGE CURRENT and TOUCH CURRENT in NORMAL CONDITION and in relevant SINGLE FAULT CONDITIONS including interruption of the PROTECTIVE EARTH CONDUCTOR. However, an excessive EARTH LEAKAGE CURRENT could pose a possible problem for the installation's earthing system and any circuit breakers operated by current imbalance detectors.

See also IEC 60364-7-710 [10].

TOUCH CURRENT

The limits are based on the following considerations.

d) The TOUCH CURRENT of ME EQUIPMENT is subject to the same values regardless of the type(s) of APPLIED PARTS, if any, because even ME EQUIPMENT that does not itself have a TYPE CF APPLIED PART could be used in situations where intracardiac PROCEDURES are performed.

e) Although TOUCH CURRENT flows from parts other than PATIENT CONNECTIONS, it can reach the PATIENT by chance contact through various paths, including a path via the OPERATOR.

f) The current density created at the heart by current entering the chest is 50 μA/mm^2 per ampere [46]. The current density at the heart for 500 μA (maximum allowable value in SINGLE FAULT CONDITION) entering the chest is 0,025 μA/mm^2, well below the level of concern.

g) The probability of the TOUCH CURRENT flowing through the heart and causing ventricular fibrillation or pump failure.

TOUCH CURRENT could conceivably reach an intracardiac site if careless PROCEDURES are used in handling intracardiac conductors or fluid filled catheters. Such devices should always be handled with great care and always with dry rubber gloves. The following RISK ANALYSIS is based on pessimistic assumptions about the degree of care exercised.

The probability of a direct contact between an intracardiac device and an ME EQUIPMENT ENCLOSURE is considered to be very low, perhaps 1 in 100 medical procedures. The probability of an indirect contact via the medical staff is considered to be somewhat higher, say 1 in 10 medical procedures. The maximum allowable LEAKAGE CURRENT in NORMAL CONDITION is 100 μA, which itself has a probability of inducing ventricular fibrillation of 0,05. If the probability of indirect contact is 0,1 then the overall probability is 0,005. Although this probability would appear undesirably high, it should be recalled that with correct handling of the intracardiac device this probability can be reduced to that for mechanical stimulation alone, 0,001.

The probability of the TOUCH CURRENT rising to the maximum allowable level of 500 μA (SINGLE FAULT CONDITION) is considered to be 0,1 in departments with poor maintenance PROCEDURES. The probability of this current causing ventricular fibrillation is taken as 1.

The probability of accidental contact directly with the enclosure is, as above, considered as 0,01, giving an overall probability of 0,001, equal to the mechanical stimulation alone probability.

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The probability of TOUCH CURRENT at the maximum allowable level of 500 μA (SINGLE FAULT CONDITION) being conducted to an intracardiac device via the medical staff is 0,01 (0,1 for the SINGLE FAULT CONDITION, 0,1 for accidental contact). Since the probability of this current causing ventricular fibrillation is 1, the overall probability is also 0,01. Again this probability is high; however it can be brought down to the mechanical stimulation alone probability of 0,001 by adequate medical procedures.

h) The probability of the TOUCH CURRENT being perceptible to the PATIENT.

The probability of 500 μA being perceptible is 0,01 for men and 0,014 for women when using grip electrodes with intact skin [45] [48]. There is a higher perceptibility for current passing through mucous membranes or skin punctures [48]. Since distribution is normal, there will be a probability that some PATIENTS will perceive very small currents. One person is reported to have sensed 4 μA passing through a mucous membrane [48].

PATIENT LEAKAGE CURRENT

The allowable value of PATIENT LEAKAGE CURRENT for ME EQUIPMENT with TYPE CF APPLIED PARTS in NORMAL CONDITION is 10 μA, which has a probability of 0,002 for causing ventricular fibrillation or pump failure when applied through small areas to an intracardiac site.

Even with zero current, it has been observed that mechanical irritation can produce ventricular fibrillation [50]. A limit of 10 μA is readily achievable and does not significantly increase the RISK of ventricular fibrillation during intracardiac procedures.

The 50 μA maximum allowed in SINGLE FAULT CONDITION for ME EQUIPMENT with TYPE CF APPLIED PARTS is based on a value of current that has been found, under clinical conditions, to have a very low probability of causing ventricular fibrillation or interference with the pumping action of the heart.

For catheters 1,25 mm - 2 mm diameter likely to contact the myocardium, the probability of 50 μA causing ventricular fibrillation is near 0,01 (see Figure A.14 and its explanation). Small cross-section area (0,22 mm^2 and 0,93 mm^2) catheters used in angiography have higher probabilities of causing ventricular fibrillation or pump failure if placed directly on sensitive areas of the heart.

The overall probability of ventricular fibrillation being caused by PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION is 0,001 (0,1 for probability of SINGLE FAULT CONDITION, 0,01 probability of 50 μA causing ventricular fibrillation) equal to the probability for mechanical stimulation alone.

The 50 μA current allowed in SINGLE FAULT CONDITION is not likely to result in a current density sufficient to stimulate neuromuscular tissues nor, if d.c., cause necrosis.

For ME EQUIPMENT with TYPE B APPLIED PARTS and TYPE BF APPLIED PARTS where the maximum allowable PATIENT LEAKAGE CURRENT under SINGLE FAULT CONDITION is 500 μA, the same rationale applies as that for TOUCH CURRENT since this current will not flow directly to the heart.

As the existence of an earth connection to a PATIENT is a NORMAL CONDITION, not only PATIENT AUXILIARY CURRENT but also PATIENT LEAKAGE CURRENT can flow for a prolonged period. A very low value of direct current is therefore necessary to avoid tissue necrosis, regardless of the classification of the APPLIED PART.

The appearance of MAINS VOLTAGE, from a low-impedance source, on the PATIENT CONNECTIONS of an F-TYPE APPLIED PART would have to be caused by a double failure of protective means in other ME EQUIPMENT, simultaneously connected to the PATIENT and complying with this standard or another IEC standard, or by a single failure of protective means in equipment not complying with a standard. As such this condition is extremely unlikely in good medical practice.

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However the appearance of a lesser voltage, or of a LEAKAGE CURRENT from a source having an open-circuit voltage of the order of MAINS VOLTAGE, is possible.

Since the main safety feature of ME EQUIPMENT with an F-TYPE APPLIED PART is that the PATIENT is not earthed by the connection to the ME EQUIPMENT, the electrical separation of an F-TYPE APPLIED PART from earth is to have a minimum quality. This is assured by the requirement that, even if a hypothetical voltage of supply frequency and equal to the highest supply voltage to earth present in the location where the ME EQUIPMENT is used would appear on the PATIENT CONNECTIONS, the limit for the PATIENT LEAKAGE CURRENT would not be exceeded.

For TYPE CF APPLIED PARTS, the PATIENT LEAKAGE CURRENT will be limited to 50 μA, no worse than the previously discussed SINGLE FAULT CONDITION.

For TYPE BF APPLIED PARTS the maximum PATIENT LEAKAGE CURRENT under these conditions is 5 mA. Even this value entering the chest would produce only a current density at the heart of 0,25 μA/mm^2. This current would be very perceptible to the PATIENT, however the probability of its occurrence is very low. The RISK of harmful physiological effects is small and the MAXIMUM MAINS VOLTAGE used for this test represents a worst case, more severe than is likely to arise in practice.

Total PATIENT LEAKAGE CURRENT

The values of PATIENT LEAKAGE CURRENT in this standard are for a single function of a TYPE B APPLIED PART or TYPE BF APPLIED PART or a single PATIENT CONNECTION of a TYPE CF APPLIED PART. With multiple functions or multiple APPLIED PARTS the total PATIENT LEAKAGE CURRENT could be much higher. This total PATIENT LEAKAGE CURRENT is the vector sum of the individual PATIENT LEAKAGE CURRENTS. Therefore, it is necessary to specify limits for total PATIENT LEAKAGE CURRENT. These requirements are derived from IEC 60601-2-49:2001 [16].

This standard does not fix the number of APPLIED PARTS connected to a single PATIENT. It has been estimated that the number of APPLIED PARTS connected to a single PATIENT ranges from one to five.

Total PATIENT LEAKAGE CURRENT for TYPE CF APPLIED PARTS

For TYPE CF APPLIED PARTS the PATIENT LEAKAGE CURRENT for the NORMAL CONDITION is 10 μA. The following is to be considered for multiple PATIENT functions:

i) The current entering the heart is distributed over all of the PATIENT CONNECTIONS and is not applied to the same small sensitive area of the cardiac tissue.

j) The number of PATIENT CONNECTIONS connected directly to cardiac tissue is not likely to exceed three. Accordingly, the LEAKAGE CURRENT entering a single small area of the heart is less than 50 μA and is in the vicinity of 15 μA to 20 μA for an algebraic summation of the currents. The current would be less for a vector summation. The probability of ventricular fibrillation, according to the rationale for PATIENT LEAKAGE CURRENT, is in the range of 0,003 even if all the PATIENT CONNECTIONS are very close together. This is not much different from the probability of 0,002 that is accepted for a single APPLIED PART connected directly to the heart.

k) The LEAKAGE CURRENT from APPLIED PARTS on the surface of the body flows in a distributed manner through the body. According to the rationale for PATIENT LEAKAGE CURRENT, 5 mA entering the chest produces a current density at the heart of 0,025 μA/mm^2.

Therefore, 50 μA for NORMAL CONDITION for total PATIENT LEAKAGE CURRENT is considered acceptable.

For SINGLE FAULT CONDITION the LEAKAGE CURRENT for TYPE CF APPLIED PARTS has been increased to 0,1 mA. The rationale for PATIENT LEAKAGE CURRENT gives a probability of 0,07 of ventricular fibrillation for current directly entering the heart. The probability of a SINGLE FAULT CONDITION was given as 0,1. This was over a decade ago. Because of improvements in design, more reliable components, better materials, and the use of RISK MANAGEMENT in accordance with ISO 14971 and the consequent use of associated tools, such as HAZARD based RISK ANALYSIS, the probability of a SINGLE FAULT CONDITION should be much less. It is now felt to be

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in the vicinity of at least 0,02. The probability of ventricular fibrillation is 0,07 × 0,02, or 0,0014, close to that accepted for a single TYPE CF APPLIED PART.

Total PATIENT LEAKAGE CURRENT for TYPE BF APPLIED PARTS

The total PATIENT LEAKAGE CURRENT has been increased to 500 μA for NORMAL CONDITION and to 1 000 μA for SINGLE FAULT CONDITION. As explained in k) above, the current density at the heart for current of 5 000 μA is quite small. There should be no concern for either the NORMAL CONDITION or the SINGLE FAULT CONDITION.

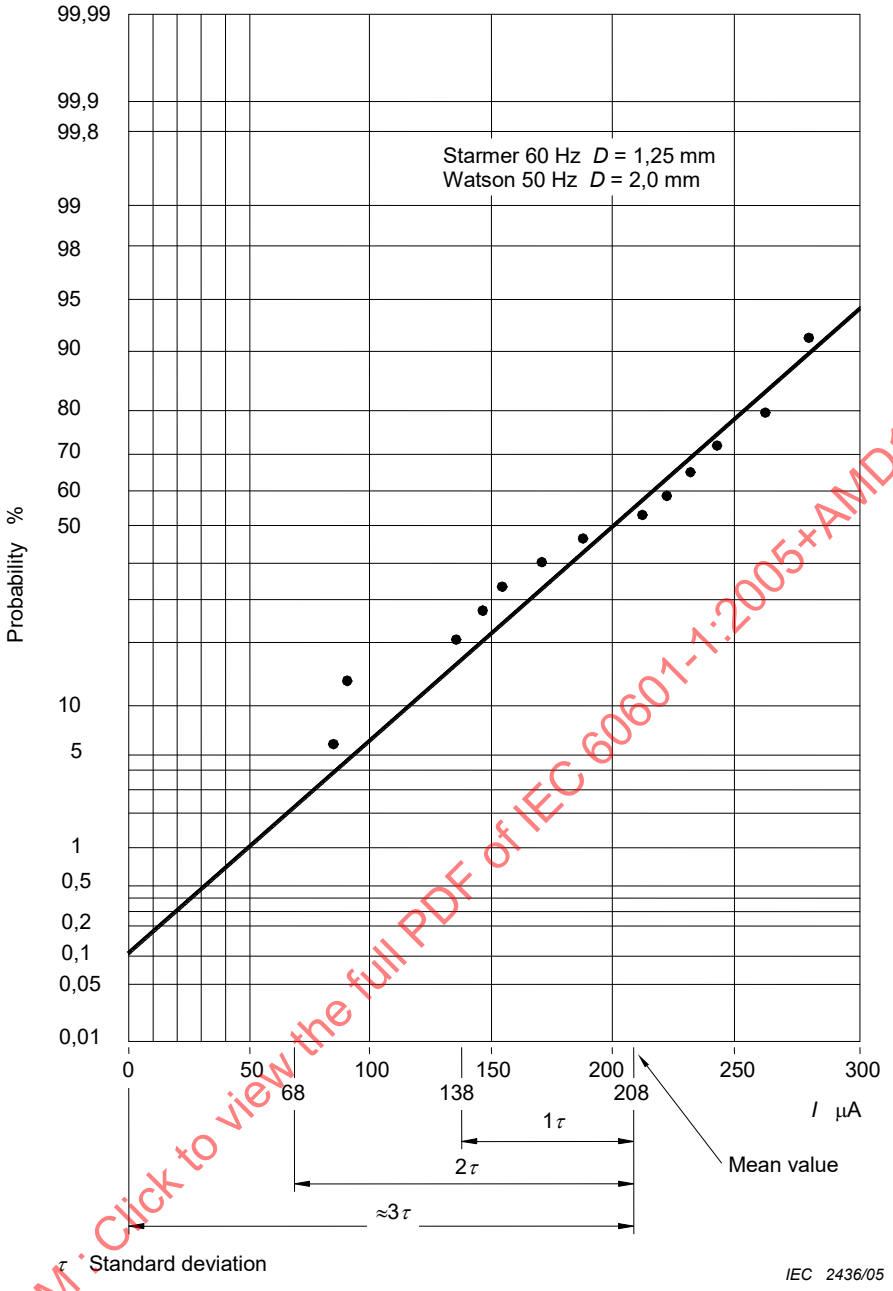
Total PATIENT LEAKAGE CURRENT caused by an external voltage on the PATIENT CONNECTION

For TYPE CF APPLIED PARTS, the limit has been increased to 100 μA. The rationale for PATIENT LEAKAGE CURRENT states that the probability of failure of protective earthing of CLASS I ME EQUIPMENT is 0,1 and that the probability of a fault in one MOP is less than 0,1. This was a decade ago. As explained earlier, these probabilities should be much lower today and are considered to be no worse than 0,02. The probability of MAINS VOLTAGE appearing on the PATIENT is 0,02 × 0,02, or 0,0004. This is below the probability of 0,001 accepted in the second edition of IEC 60601-1.

PATIENT AUXILIARY CURRENT

The allowable values for PATIENT AUXILIARY CURRENT are based on similar considerations to those for PATIENT LEAKAGE CURRENT. They apply regardless of whether the PATIENT AUXILIARY CURRENT is necessary for the functioning of the ME EQUIPMENT (e.g. impedance plethysmographs) or incidental to its functioning. Lower values are given for d.c. to prevent tissue necrosis with long-term application.

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NOTE Refer to original papers by Starmer [53] and Watson [54] for interpretation of data.

Figure A.14 – Probability of ventricular fibrillation

Explanation of Figure A.14

Articles by Starmer [53] and Watson [54] provide data on ventricular fibrillation caused by 50 Hz and 60 Hz currents applied directly to the hearts of human populations with cardiac disease. Fibrillation probability was obtained as a function of the electrode diameter and the magnitude of the current. For electrodes of 1,25 mm and 2 mm diameter and currents up to 0,3 mA, the distribution appears normal. Accordingly, it has been extrapolated to encompass the values commonly used in assessing PATIENT RISK (values noted on Figure A.14). From this extrapolation, it is seen that:

– any value of current, however small, has some probability of causing ventricular fibrillation, and

– the commonly used values have low probabilities, ranging from approximately 0,002 to 0,01.

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Since ventricular fibrillation is governed by many factors (PATIENT condition, probability of current entering a more sensitive area of the myocardium, probability of fibrillation as a function of current or current density, physiology, electric field, etc.), it is reasonable to use statistics in determining the possibility of RISK for the multiple conditions.

Heating effect of LEAKAGE CURRENTS

A current of 10 mA will produce no sensation of heating with a typical PATIENT CONNECTION with a contact area of the order of 1 cm^2, but a current a few times higher than this would produce a burn. The RISK of a burn depends on the magnitude of the current but not on its frequency, so the current has to be measured with a non-frequency-weighted device, such as a device similar to that shown in Figure 12 a) but without C_1 and R_1.

Subclause 8.7.3 f)

LEAKAGE CURRENTS can flow through a FUNCTIONAL EARTH CONDUCTOR. This can lead to an unexpected RISK if CLASS II equipment is combined with CLASS I equipment or with an earthed trolley, e.g. using an MSO. Although proper application of the 'rules' for assembling an ME SYSTEM would eliminate this RISK, the causal RISK can be mitigated by limiting the allowed LEAKAGE CURRENT in a FUNCTIONAL EARTH CONDUCTOR.

Subclause 8.7.4.2 – Measuring supply circuits

For correct results of LEAKAGE CURRENT measurements, it is essential to have a common reference point within the measuring circuit. The point also has to be electrically referenced to all parts of the circuit. Also the measured LEAKAGE CURRENT could be different according to the particular supply configuration. For example, if ME EQUIPMENT that is specified for connection to a supply having one side at earth potential is connected instead to a supply having two symmetrical phases (such as a 230 V supply in the USA) the measured LEAKAGE CURRENT will be much lower than the worst case. If the installed SUPPLY MAINS of the room where the measurements are made does not represent the worst case, a specific supply circuit has to be established. This can be done by using an isolating transformer with the appropriate point in the SECONDARY CIRCUIT connected to the reference point. Accurate and reproducible results when making LEAKAGE CURRENT measurements can also be obtained without an isolating transformer. However this would depend on the quality of the SUPPLY MAINS used for the measurements. Factors that need to be considered would include transients, interference signals and voltage differences between neutral and earth in the measuring circuit.

The earth symbols in the figures represent this common reference point, which is not connected to the protective earth of the SUPPLY MAINS. Such a separate reference point can provide additional protection for the person carrying out the measurements.

A variable-voltage transformer is necessary to provide 110 % of the RATED supply voltage to the ME EQUIPMENT. Although it would be possible to test with the MAINS VOLTAGE normally present in the test room and to multiply the measured LEAKAGE CURRENT values by the appropriate factor, this would not always produce the same result as testing with 110 % of the RATED supply voltage, particularly with ME EQUIPMENT that includes a switched-mode power supply.

The switches S_1 or $S_1 + S_2$ or $S_1 + S_2 + S_3$ in Figure F.1 to Figure F.4 (inclusive) can be omitted and the interruptions of the relevant leads can be obtained by other means.

Instead of the single or polyphase isolating transformers with adjustable output voltage(s), as shown in Figure F.1 to Figure F.5 (inclusive), a combination of an isolating transformer with set output voltage and an auto-transformer with adjustable output voltage can be used.

Subclause 8.7.4.3 – Connection to the measuring supply circuit

Although it is not unlikely that ME EQUIPMENT is used while placed on or in an earthed metal environment, such a position would be rather difficult to describe in a way that test results would become reproducible. The advice in the note in 8.7.4.3 d) 1) is therefore to be considered as a convention.

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The fact that PATIENT cables can have a significant capacitance to earth is usually important and of considerable influence on test results. A position providing reproducible results is therefore prescribed.

The isolation transformer in the measuring supply circuit provides additional protection for the person making the measurements and increases the accuracy of the LEAKAGE CURRENT measurements. However, it is not absolutely necessary to use an isolating transformer when making LEAKAGE CURRENT measurements. In some cases, such as high input power ME EQUIPMENT and ME SYSTEMS, use of an insolating transformer is not feasible. When making LEAKAGE CUURENT measurement without an isolating transformer, the MANUFACTURER needs to consider the following:

– is it possible to extrapolate the LEAKAGE CURRENTS at 110 % of the RATED supply voltage;
– the influence of currents that are driven by voltage differences between the protective earth and the mains supply neutral of ME EQUIPMENT or for ME SYSTEMS with multiple PROTECTIVE EARTH CONNECTIONS.

Measuring without an isolation transformer can produce LEAKAGE CURRENT readings that are greater than the LEAKAGE CURRENT measurement with an isolating transformer.

Subclause 8.7.4.5 – Measurement of EARTH LEAKAGE CURRENT and current in FUNCTIONAL EARTH CONNECTION

The measuring device represents a measuring method that takes into account the physiological effect of a current through the human body, including the heart, as well as the possibility of a low impedance contact between a PATIENT CONNECTION and the PATIENT. Although IEC 60990 [20] specifies some measuring devices for general use, none of these would be appropriate for measuring PATIENT LEAKAGE CURRENT. As the measuring device of the second edition is being retained for that purpose, it is most convenient to use the same device for all LEAKAGE CURRENT measurements, apart from the measurement of currents or current components with frequencies exceeding 1 kHz in relation to the 10 mA limit specified in 8.7.3 d).

Subclause 8.7.4.6 – Measurement of the TOUCH CURRENT

Where metal foil is to be applied to an ENCLOSURE made of insulating material, intimate contact can be achieved by pressing the foil against the insulating material with a pressure of approximately 5 kPa (0,5 N/cm^2).

Subclause 8.7.4.7 – Measurement of PATIENT LEAKAGE CURRENT

Subclause 8.7.4.7 b)

This test confirms that the separation between the PATIENT CONNECTIONS and other parts is adequate to limit the PATIENT LEAKAGE CURRENT to the allowed value when an external voltage is present.

If the APPLIED PART can be disconnected from the ME EQUIPMENT, it is possible that the contacts of its connector could touch an earthed object, but that situation is covered by thetests of 8.5.2.3, not by 8.7.4.7 b), which applies to the ME EQUIPMENT and the APPLIED PART together.

The 20 cm × 10 cm metal foil represents the size of a human hand. For some ME EQUIPMENT, the area of contact is greater then the size of the hand. In this case, the size of the foil can be increased.

Subclause 8.7.4.7 c)

Some of the tests specified in the second edition of this standard related to the possible presence of MAINS VOLTAGE on a SIGNAL INPUT PART or a SIGNAL OUTPUT PART (as defined in that edition, now covered by the combined term SIGNAL INPUT/OUTPUT PART). There were various exclusions, but if none of the exclusions applied this condition was regarded as a SINGLE FAULT CONDITION. The assumption made in this third edition is that, if the ACCOMPANYING DOCUMENTS place no restrictions on what other equipment is allowed to be

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connected to the SIGNAL INPUT/OUTPUT PART, the presence of the MAXIMUM MAINS VOLTAGE should be regarded as a NORMAL CONDITION.

Instead of an isolating transformer T_2 with an adjustable output voltage, a combination of an isolating transformer with a set output voltage and an auto-transformer with an adjustable output voltage can be used.

Subclause 8.7.4.7 d)

The test with an external voltage applied to unearthed metal ACCESSIBLE PARTS reflects the requirement in 8.5.2.2 for isolation between such parts and unearthed PATIENT CONNECTIONS of TYPE B APPLIED PARTS.

For TYPE BF APPLIED PARTS this test applies as well as the test of 8.7.4.7 b), even though both test the isolation between the PATIENT CONNECTIONS and other parts, because the PATIENT LEAKAGE CURRENT might not be the same in these two situations and different limit values apply.

Instead of an isolating transformer T_2 with an adjustable output voltage, a combination of an isolating transformer with a set output voltage and an auto-transformer with an adjustable output voltage can be used.

Care should be taken that the capacitance of the measuring device and its connecting leads to earth and to the body of the ME EQUIPMENT is kept as low as possible.

As explained in the rationale to 8.7.3, the presence of the MAXIMUM MAINS VOLTAGE on a PATIENT represents a worst case, this is more severe than is likely to arise in practice, and the allowable PATIENT LEAKAGE CURRENT for a TYPE BF APPLIED PART in this situation is 5 mA. It was pointed out that the application of MAINS VOLTAGE to an unearthed ACCESSIBLE PART could therefore cause a PATIENT LEAKAGE CURRENT of up to 5 mA to flow from the PATIENT CONNECTIONS of a TYPE BF APPLIED PART; whereas in the same situation a TYPE B APPLIED PART (which in general offers a lower level of safety) was allowed only 500 μA. In order to resolve this anomaly, the test of 8.7.4.7 d), with 110 % of the MAXIMUM MAINS VOLTAGE on unearthed ACCESSIBLE PARTS, also applies to TYPE BF APPLIED PARTS, and in this condition the allowable PATIENT LEAKAGE CURRENT is the general 500 μA value for SINGLE FAULT CONDITION.

There is no need to perform the test of 8.7.4.7 d) on TYPE CF APPLIED PARTS because for these the same allowable value of 50 μA would apply as in the test of 8.7.4.7 b).

Subclause 8.7.4.7 h)

The requirement represents a compromise between requiring extensive testing, which with most ME EQUIPMENT would yield no useful information, and having no specific requirement to address this RISK.

Most TYPE B APPLIED PARTS are earthed, so the measurement according to 8.7.4.7 g) (all PATIENT CONNECTIONS of a single function connected directly together) will give the same result as the measurement according to 8.7.4.7 h) (all PATIENT CONNECTIONS of all APPLIED PARTS of the same type connected together). If this is within the PATIENT LEAKAGE CURRENT limit it will certainly be within the total PATIENT LEAKAGE CURRENT limit. However it is possible to have TYPE B APPLIED PARTS that are not directly earthed, and in that case the measured values can be different.

Subclause 8.7.4.9 – ME EQUIPMENT with multiple PATIENT CONNECTIONS

This requirement was introduced in the second amendment to the second edition of this standard. It addresses a RISK that can arise, for example, with equipment for measuring physiological signals where an amplifier drives one electrode to reduce common-mode interference. If one of the sensing electrodes is disconnected from the PATIENT and picks up a large voltage at mains frequency, the amplifier could drive a large current into the PATIENT in a vain attempt to cancel the interference.

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The requirement represents a compromise between requiring extensive testing, which with most ME EQUIPMENT would yield no useful information, and having no specific requirement to address this RISK.

Subsequently IEC 60601-2-49:2001 [16] introduced a comprehensive set of tests, to be performed on all equipment within the scope of that standard. These include measurement of what is termed "PART LEAKAGE CURRENT" in that standard: this is the current flowing between the PATIENT CONNECTIONS of one function and the PATIENT CONNECTIONS of other function(s), which is covered in this edition of the general standard by the revised definition of PATIENT AUXILIARY CURRENT.

Consideration was given to incorporating these tests in this general standard, but it was decided that such specific testing should be left to particular standards. The scenarios to which they relate, such as having the PATIENT CONNECTIONS of one function in use and connected to the PATIENT while the PATIENT CONNECTIONS of another function are not in use and could make contact with earth or other objects, are likely to arise with multifunction PATIENT monitoring equipment but unlikely with most other kinds of ME EQUIPMENT.

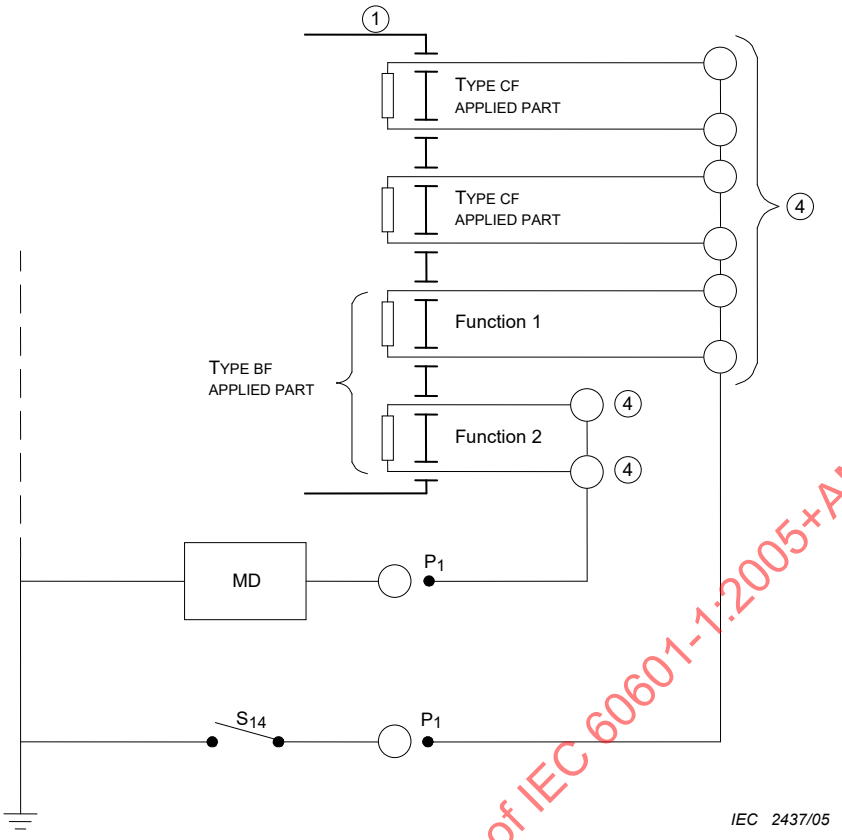
Figure A.15, based on Figure KK.101 of IEC 60601-2-49:2001 [16], shows an example of measuring the PATIENT LEAKAGE CURRENT from one function of a TYPE BF APPLIED PART while the PATIENT CONNECTIONS of another function of the same APPLIED PART and of two TYPE CF APPLIED PARTS are either floating or earthed.

Subclause 8.8.1 – General

Care should be taken that the voltage applied to a REINFORCED INSULATION does not overstress either of the MEANS OF PROTECTION in the ME EQUIPMENT. If there are multiple paths between the same points, these might need to be tested separately. There could, for example, be one path from the MAINS PART to a PATIENT CONNECTION that has BASIC INSULATION plus a PROTECTIVE EARTH CONNECTION plus PATIENT CONNECTIONS isolation as required by 8.5.2.1, and a parallel path having REINFORCED INSULATION. ME EQUIPMENT parts might need to be disconnected to allow the REINFORCED INSULATION to be tested without overstressing the separate insulation of the MAINS PART or the PATIENT CONNECTIONS.

This could be avoided, for example in the case of a transformer, by the use of a voltage divider with a tapping point connected to the core or some other suitable connecting point to ensure the correct voltage division over the actual insulations, or by the use of two test transformers, correctly phased.

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For legends, see Table 5.

Key

All measurements are made with S_{14} closed and again with S_{14} open.

Figure A.15 – Example of a measuring circuit for the PATIENT LEAKAGE CURRENT from a PATIENT CONNECTION to earth for ME EQUIPMENT with multiple PATIENT CONNECTIONS

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Subclause 8.8.2 – Distance through solid insulation or use of thin sheet material

The second edition of this standard placed no restrictions on the thickness of solid insulation, except as specified in 57.9.4 e) for transformers and for the need for all insulation covered by Clause 20 to be thick enough to pass the dielectric strength test. A very thin film of insulating material might pass that test but might not provide reliable insulation during the EXPECTED SERVICE LIFE of all production items.

Some National Committee comments during the development of this edition proposed introducing relevant requirements derived from IEC 60950-1 to address this omission. Both WG 14 (Testing) and WG 16 (Electrical hazards) recommended accepting these proposals.

These requirements have been included in IEC 60950-1 for many years without causing problems. They should not be onerous in practice for ME EQUIPMENT, and indeed most ME EQUIPMENT designed according to the previous editions of this standard would have satisfied them.

The requirements that have been introduced are intended to be technically equivalent to those of IEC 60950-1, but the editorial structure has been changed for clarity, as follows.

– IEC 60950-1 specifies a general requirement for distance through insulation, with an exception for voltages up to 71 V. This has been changed to state explicitly that the requirement applies above 71 V.

– IEC 60950-1 specifies an exception from the requirement for distance through insulation where the requirements for thin sheet material apply, as set out in another subclause, but

that subclause does not refer explicitly to the 71 V limit. This has been made explicit by stating the requirements for thin sheet material as an alternative to the thickness requirement, under the same introductory wording.

– IEC 60950-1 specifies that “Insulation in thin sheet materials is permitted . . provided that” certain conditions are satisfied. This has been changed to an explicit requirement that insulation in thin sheet materials needs to satisfy these conditions.

– IEC 60950-1 requires that insulation in thin sheet materials “is used within the equipment ENCLOSURE”. However the ENCLOSURE as defined in this standard includes all outer surfaces, including the surfaces of cables, APPLIED PARTS, etc. The requirement has therefore been rephrased.

Elsewhere in this standard the terms SUPPLEMENTARY INSULATION and REINFORCED INSULATION have mostly been replaced by references to MEANS OF PROTECTION, but they have been retained here because, as in IEC 60950-1, the requirements concerning distance through insulation and the use of thin sheet material apply to SUPPLEMENTARY INSULATION and to REINFORCED INSULATION, but not to BASIC INSULATION. Thus these requirements do not apply where BASIC INSULATION, as one MEANS OF PROTECTION, is used in conjunction with a PROTECTIVE EARTH CONNECTION as the other MEANS OF PROTECTION. Where DOUBLE INSULATION is used, these requirements apply to whichever constituent part thereof is regarded as the SUPPLEMENTARY INSULATION.

Subclause 8.8.3 – Dielectric strength

Components designed to limit the voltage might need to be removed in order to allow the full test voltage to be applied to the insulation being tested.

The purpose of this test is to check all solid insulation under the worst-case condition after having achieved operating temperature. For heating elements, the worst case is achieved with heaters remaining energized during measurement.

The test voltages specified are appropriate for solid insulation only. Spacings (CREEPAGE DISTANCES and CLEARANCES) are evaluated by 8.9. IEC 60664-1 gives details of electrical test methods for clearances using impulse voltage dielectric strength tests. These tests can be used under the IEC 60950-1 route for MOOPs, but are not specified for MOPPs. IEC 60664-1 states that the 2U + 1 000 V type of dielectric strength test “is not relevant for the testing of clearances”.

Since the dielectric strength test is applied immediately after the humidity preconditioning treatment, with the ME EQUIPMENT still in the humidity cabinet, adequate precautions for the protection of laboratory personnel could be necessary.

In Table 6, the values for OPERATOR protection are taken from IEC 60950-1 and the values for PATIENT protection are taken from the second edition of IEC 60601-1. In constructing the table, three principles were employed:

– MOPP are always at a higher value than MOOP.

– Mains circuits are effected by transient overvoltages as detailed in Table 10. In SECONDARY CIRCUITS, the transient overvoltage level is at least one level less than the mains circuits.

– The value of test voltage is primarily determined by the transient voltage on the SUPPLY MAINS which is usually orders of magnitude larger than the WORKING VOLTAGE.

In order to align with the second edition of IEC 60601-1 for the common WORKING VOLTAGE of 220 V r.m.s to 240 V r.m.s. the test voltage of 4 000 V r.m.s. was retained even though this value is more that twice the test voltage for one MOPP. However, each individual MOPP has to meet the 1 500 V r.m.s. minimum requirement.

Subclause 8.8.3 a)

The test voltage can be provided by a transformer, by a d.c. power source or by using the transformer(s) of the ME EQUIPMENT. In the last case, to prevent overheating, the test voltage can have a frequency that is higher than the RATED frequency of the ME EQUIPMENT.

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The PROCEDURE and duration of the test for WORKING VOLTAGE equal to or higher than 1 000 V a.c. or 1 500 V d.c. or peak values can be specified further by particular standards.

Subclause 8.8.4.1 – Mechanical strength and resistance to heat

Tests concerning flammability of materials will be found in IEC 60695-11-10.

Subclause 8.9 – CREEPAGE DISTANCES and AIR CLEARANCES

For ME EQUIPMENT intended to be supplied from the SUPPLY MAINS, AIR CLEARANCE and dielectric strength requirements are based on the expected overvoltage transients that could enter the equipment from the SUPPLY MAINS. According to IEC 60664-1, the magnitude of these transients is determined by the normal supply voltage and the supply arrangements. These transients are categorized according to IEC 60664-1 into four groups called overvoltage categories I to IV (also known as installation categories I to IV). Elsewhere in this standard overvoltage category II is assumed.

The design of solid insulation and AIR CLEARANCES should be co-ordinated in such a way that, if an incident overvoltage transient exceeds the limits of overvoltage category II, the solid insulation can withstand a higher voltage than the AIR CLEARANCES.

The values in Table 13 to Table 15 correspond to those of IEC 60950-1 for overvoltage category II for MAINS PARTS and overvoltage category I for SECONDARY CIRCUITS. If ME EQUIPMENT is intended to be used in locations where the SUPPLY MAINS is in overvoltage category III or IV, these values will be inadequate.

A SECONDARY CIRCUIT derived from a SUPPLY MAINS will normally be overvoltage category I if the SUPPLY MAINS is overvoltage category II; the maximum transients for various SUPPLY MAINS voltages in overvoltage category I are shown in the column headings of Table 13.

For insulation between the ENCLOSURE and the PATIENT CONNECTION of an F-TYPE APPLIED PART special rules apply:

1) In the case of an F-TYPE APPLIED PART containing no voltage difference, the insulation between the PATIENT CONNECTIONS and the ENCLOSURE will only be stressed to the MAINS VOLTAGE in the case of a fault in other equipment connected to the PATIENT.

   This condition rarely occurs, furthermore this insulation is not normally subject to the transient overvoltages found in the MAINS PART. In view of the above, the insulation necessary between the APPLIED PART and the ENCLOSURE for the case quoted, need only satisfy the requirements for BASIC INSULATION.

2) In the case of an F-TYPE APPLIED PART containing parts with voltage difference, the connection of a PATIENT CONNECTION to earth via an earthed PATIENT (NORMAL CONDITION) could subject the insulation between other parts and the ENCLOSURE to the whole of the voltage within the APPLIED PART.

   Since this voltage appears in NORMAL CONDITION, even though infrequently, the relevant insulation should satisfy the requirements for DOUBLE INSULATION or REINFORCED INSULATION.

3) The value to be applied is the highest of the values found according to Items 1) and 2) above.

In the absence of a theoretical background to refer to, it was decided that the values above 1 000 V would be drawn from Table 7 of IEC 61010-1:2001 [22] for CREEPAGE DISTANCES using the column for material group IIIa-b, pollution degree 3, which correlates with the existing values in the second edition of IEC 60601-1 or is slightly more onerous. For AIR CLEARANCES, the values have been estimated based on the relationship between creepage and clearance for values below 1 000 V r.m.s. from Table 12. These derived values are shown in Table A.1.

Table 16 of the second edition of IEC 60601-1 was split into two tables in this standard (Tables 9 and 10). To align it with tables derived from other standards such as IEC 60950-1,

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the factor between the a.c. voltages and the d.c. voltages was changed from 1,2 to about 1,4. This relaxation was accepted as it is a common approach in other standards and it prevents having different CREEPAGE DISTANCES or AIR CLEARANCES in circuits where there is a d.c. voltage rectified from an a.c. voltage.

Table A.1 – Values of AIR CLEARANCE and CREEPAGE DISTANCE derived from Table 7 of IEC 61010-1:2001 and Table 12

WORKING VOLTAGE V d.c. up to and including	WORKING VOLTAGE V r.m.s up to and including	Spacing providing one MEANS OF PATIENT PROTECTION		Spacing providing two MEANS OF PATIENT PROTECTION	
		AIR CLEARANCE mm	CREEPAGE DISTANCE mm	AIR CLEARANCE mm	CREEPAGE DISTANCE mm
1 500	1 250	11,5	20	23,0	40
1 920	1 600	14,5	25	29,0	50
2 400	2 000	18,5	32	37,0	64
3 000	2 500	23,0	40	46,0	80
3 840	3 200	29,0	50	58,0	100
4 800	4 000	36,0	63	72,0	126
6 000	5 000	46,0	80	92,0	160
7 560	6 300	57,0	100	114,0	200
9 600	8 000	71,5	125	143,0	250
12 000	10 000	91,5	160	183,0	320

Table A.2 contains CREEPAGE DISTANCES for WORKING VOLTAGE above 1 000 V derived from IEC 60664-1:2007, Table F.4.

Subclause 8.9.1 – Values

When using the values of CREEPAGE DISTANCE and AIR CLEARANCE, it should be noted that peak, d.c. and r.m.s. values are all used. It is important to read the tables carefully.

The tables for MOOPs use values from IEC 60950-1 representing the following basic principles, taken from IEC 60664-1:

– "The basis for the determination of a CREEPAGE DISTANCE is the long-term r.m.s. value of the voltage existing across it."

– "AIR CLEARANCES shall be dimensioned to withstand the required impulse withstand voltage". Impulse withstand voltage is the "highest peak value of withstand voltage …."

However, the tables for MOPPs are taken from the second edition of IEC 60601-1, where both creepages and clearances were related to r.m.s. or d.c. voltages.

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Table A.2 – CREEPAGE DISTANCES to avoid failure due to tracking from IEC 60664-1

WORKING VOLTAGE V r.m.s or d.c.	Spacing for one MEANS OF OPERATOR PROTECTION						
	Pollution degree 1	Pollution degree 2			Pollution degree 3		
	Material group	Material group			Material group		
	I, II, IIIa, IIIb	I	II	IIIa or IIIb	I	II	IIIa or IIIb
1 250	Use the AIR CLEARANCE from the appropriate table	6,3	9,0	12,5	16,0	18,0	20,0
1 600		8,0	11,0	16,0	20,0	22,0	25,0
2 000		10,0	14,0	20,0	25,0	28,0	32,0
2 500		12,5	18,0	25,0	32,0	36,0	40,0
3 200		16,0	22,0	32,0	40,0	45,0	50,0
4 000		20,0	28,0	40,0	50,0	56,0	63,0
5 000		25,0	36,0	50,0	63,0	71,0	80,0
6 300		32,0	45,0	63,0	80,0	90,0	100,0
8 000		40,0	56,0	80,0	100,0	110,0	125,0
10 000		50,0	71,0	100,0	125,0	140,0	160,0

Subclause 8.9.1.6 – Interpolation

Interpolation for CREEPAGE DISTANCES but not for AIR CLEARANCES is allowed, except where the WORKING VOLTAGE is above 2 kV r.m.s. or 2,8 kV d.c. This approach is generally consistent with IEC 60950-1 and IEC 61010-1 [22].

Subclause 8.9.1.15 – CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS

From IEC 60664-1:2007, Table F.2, a distance of 4 mm is adequate for pulses of 5 kV having a short duration of less than 10 ms, such voltages arising typically from the use of a defibrillator.

Subclause 8.9.2 – Application

Subclause 8.9.2 a)

Depending on the INTENDED USE of the ME EQUIPMENT, operation of the fuse or OVER-CURRENT RELEASE can be a HAZARD. The opening of a branch circuit breaker is not acceptable. Subclause 8.9.2 a) is based on the fact that there is an over-current device in the input of the ME EQUIPMENT before the part of the circuit where this subclause is applied. Before this over-current device, the spacings need to comply with the basic requirement for parts of opposite polarity within the MAINS PART.

Subclause 8.9.3 – Spaces filled by insulating compound

CREEPAGE DISTANCES are measured through the joint between two parts of an insulation barrier, except for cemented joints, i.e. those in which:

– either the two parts forming the joint are bonded by heat sealing or other similar means at the place where this is of importance;

– or the joint is completely filled with adhesive at the necessary places and the adhesive bonds to the surfaces of the insulating barrier so that humidity cannot be sucked into the joint.

In the second edition of this standard, the captions to Figures 43 to 45 referred to “uncemented joints.” Item 7 of the legends to these figures referred to 57.9.4 f), second dash, “for a description of cemented joints” but did not specify any test methods other than

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inspection. During the preparation of this edition, it was proposed to introduce relevant requirements derived from IEC 60950-1 to address the related subject of potting.

The requirements that have been introduced are closely based on those of IEC 60950-1 and cover potting, encapsulation, cemented joints, etc. The editorial structure has been somewhat revised from that of IEC 60950-1 for clarity. These requirements have been included in 8.9 rather than 8.8 because they specify circumstances that allow exemption from the requirements for CREEPAGE DISTANCES and AIR CLEARANCES, rather than additional requirements applying to solid insulation.

Subclause 8.9.4 – Measurement of CREEPAGE DISTANCES AND AIR CLEARANCES

Narrow gaps, running in the direction of a possible creepage path and being some tenths of 1 mm wide only, should be avoided as far as possible, for dirt and moisture can deposit there.

Subclauses 8.10.1 – Fixing of components

In many cases it will be obvious that components and wiring are adequately secured (e.g. small components soldered to a printed circuit board) without the need for specific justification in the RISK MANAGEMENT FILE; but if any relevant information is included in the RISK MANAGEMENT FILE, it should be taken into account in assessing compliance with these requirements.

Subclause 8.10.2 – Fixing of wiring

It is generally accepted that wiring connections are subject to the SINGLE FAULT CONDITION. That is those having only one means of being secured that would prevent a loosened/broken wire from resulting in a HAZARDOUS SITUATION, such as removing a PROTECTIVE EARTH CONNECTION or bridging a MEANS OF PROTECTION, are considered not in compliance.

Examples of connection that could comply with SINGLE FAULT CONDITION are:

– double crimping of both the wire and the wire insulation;
– mechanical security of the wire and soldering;
– mechanical security of the wire and wire movement restraints such as tie wraps, wire clamps, bundling straps, etc.;
– strain relief mechanisms and mechanical security.

Subclause 8.10.4 – Cord-connected HAND-HELD parts and cord-connected foot-operated control devices

HAND-HELD switches and footswitches are in practice exposed to severe conditions. This requirement ensures that even in the worst case, where the ENCLOSURE of such a switch is completely broken, only parts at voltages within the limits specified in 8.4.2 c), which are safe to touch, can become exposed.

Subclause 8.10.5 – Mechanical protection of wiring

There is no requirement for specific justification to be given in the RISK MANAGEMENT FILE, but if any relevant information is included in the RISK MANAGEMENT FILE it should be taken into account in assessing compliance with these requirements.

Subclause 8.10.7 – Insulation of internal wiring

Conductors can be routed in separated jacketed cords of adequate rating. Where conductors of different circuit categories have to be run through common cords, wiring channels, conduits or connecting devices, adequate separation is realized by sufficient rating of the conductor insulation and by arranging for sufficient AIR CLEARANCES and CREEPAGE DISTANCES, complying with the requirements of 8.9, between conductive parts in connecting devices.

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Subclause 8.11.1 – Isolation from the SUPPLY MAINS

Subclause 8.11.1 a)

Skilled persons, such as SERVICE PERSONNEL, who need to gain access to internal, possibly hazardous, ME EQUIPMENT parts, need a means by which the ME EQUIPMENT can be isolated from the SUPPLY MAINS.

A mains isolating switch, where provided, could also serve as a functional off switch for routine use or for disabling hazardous output in an emergency. However it does not necessarily serve these purposes, nor does this standard specify any general requirement for an emergency off switch.

Subclause 8.11.1 c)

In the second edition of this standard, the requirement for minimum contact spacing of switches used to provide isolation from the SUPPLY MAINS was specified in IEC Publication 328. IEC 61058-1 superseded IEC 328 in 1990. The first edition of IEC 61058-1 required 3 mm contact spacing for full disconnection from the SUPPLY MAINS. No mention of overvoltage category was made. The third edition of IEC 61058-1 introduced the concept of overvoltage category according to IEC 60664-1. For a 230 V SUPPLY MAINS in overvoltage category II, Table 22 of IEC 61058-1:2000 allows a minimum contact spacing of 1,5 mm. While the requirements in this standard generally relate to overvoltage category II (see 8.9.1.11), it was thought prudent to stay with the 3 mm requirement associated with a 230 V SUPPLY MAINS IN overvoltage category III for all switches intended to provide isolation from the SUPPLY MAINS. Not only is this consistent with the requirement of the second edition of IEC 60601-1 but it is also harmonious with the requirements of IEC 60065 and IEC 60950-1, which both require a minimum contact separation of 3 mm for switches intended to provide isolation from the SUPPLY MAINS.

Subclause 8.11.1 h)

Such a protective device whether or not it caused the operation of an over-current protection device built into the ME EQUIPMENT, would be likely also to cause a fuse or circuit breaker in the installation to operate, thus removing the supply of power to other ME EQUIPMENT, possibly including life-support ME EQUIPMENT. Such a device might also cause undesirable thermal effects inside the ME EQUIPMENT and might anyway not be a reliable method of protecting against the relevant HAZARDS.

Subclause 8.11.1 i)

Parts that cannot be disconnected from the supply might include, for example, a circuit for room lighting or a circuit for remote control of the mains switch. Such parts could become accessible when a cover is opened, for example for the purpose of maintenance.

A spatially separated arrangement is one where parts that need to be accessible for servicing are located such that the SERVICE PERSONNEL are unlikely to come in contact with parts energized at voltages exceeding those specified in this standard while performing the required service. In this case, a warning is deemed to provide adequate safety for the SERVICE PERSONNEL.

Subclause 8.11.2 – MULTIPLE SOCKET-OUTLETS

This requirement reduces the probability that other equipment is connected that might lead to excessive LEAKAGE CURRENT.

Subclause 8.11.3.4 – APPLIANCE COUPLERS

A POWER SUPPLY CORD connected to a MAINS CONNECTOR is subject to similar stresses to a non-DETACHABLE POWER SUPPLY CORD. If it is not adequately protected from excessive bending, a HAZARDOUS SITUATION could result.

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Subclause 8.11.3.5 – Cord anchorage

If a power cord were not adequately protected against strain and abrasion, there would be a high probability of damage to insulation providing MEANS OF PROTECTION and, with CLASS I ME EQUIPMENT, a high probability of breakage or disconnection of the PROTECTIVE EARTH CONDUCTOR.

Subclause 8.11.3.6 – Cord guards

If a power cord were not adequately protected against excessive bending, there would be a high probability of breakage of power-carrying conductors, giving a RISK of fire, and with CLASS I ME EQUIPMENT, a high probability of breakage of the PROTECTIVE EARTH CONDUCTOR.

The bending test described is identical to that specified in IEC 60950-1:2005, subclause 3.2.8. The second edition of IEC 60601-1 included the wording “Guards which fail the above dimensional test shall have to pass the test described in IEC 60335-1, Amendment 6. 1988, subclause 25.10.” This alternative has been retained, but the reference is now to a later edition of IEC 60335-1. Also the requirement to perform one test in all cases, and then to perform the other test if the ME EQUIPMENT fails the first test, has been changed to allow either test to be performed first, because this makes no difference to whether the ME EQUIPMENT complies.

Subclause 8.11.4.1 – General requirements for MAINS TERMINAL DEVICES

Mains terminals should ensure connections of sufficiently low resistance to avoid overheating and should minimise the RISK of disconnection. Reliable connection can be made by means of screws, nuts, soldering, clamping, crimping of conductors or equally effective methods.

Use of terminals of components other than terminal blocks as terminals intended for external conductors is allowed in special cases where the terminal arrangement is adequate (accessible and clearly marked) and complying with this standard. The wiring terminals of certain types of components are often rated for field wiring purposes. These include fuse holders, EMC filters, circuit breakers, contactors, wiring strips, motor controllers and phase detectors. Each of these can be one of the first connected components thereby putting them in a good position to accept the first wiring connections.

Subclause 8.11.4.2 – Arrangement of MAINS TERMINAL DEVICES

Subclause 8.11.4.2 a)

One naturally expects to see all the terminals for connection of external cords or POWER SUPPLY CORDS grouped together. The possibility of an incorrect connection can increase if the terminals are not grouped together.

Subclause 8.11.4.4 – Connections to mains terminals

The term “special preparation of the conductor” covers soldering of the strands, use of cord lugs, attachment of eyelets, etc., by SERVICE PERSONNEL (i.e. in the field), but not the reshaping of the conductor before its introduction into the terminal or the twisting of a stranded conductor to consolidate the end. When preparation of the conductor is performed by the MANUFACTURER and the flexible cord is provided as the only acceptable replacement part, such part is considered to comply with this requirement.

Subclause 8.11.5 – Mains fuses and OVER-CURRENT RELEASES

Provision of fuses or OVER-CURRENT RELEASES in ME EQUIPMENT reduces the RISK that a fault in the ME EQUIPMENT will cause a protective device in the installation to operate, thus removing the supply of power to other ME EQUIPMENT, possibly including life-support ME EQUIPMENT.

It is obvious that fusing in a PROTECTIVE EARTH CONNECTION would be inappropriate.

Fusing of the neutral conductor of PERMANENTLY INSTALLED ME EQUIPMENT would serve no purpose and, with 3-phase equipment, might lead to overstressing of insulation in the event that such a fuse were to operate while the line connections remained intact. However an

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OVER-CURRENT RELEASE that interrupts all poles, including the neutral, simultaneously is acceptable.

The exemption for the case where DOUBLE INSULATION or REINFORCED INSULATION is present between all parts of opposite polarity within the MAINS PART was supported by the National Committees' responses to an inquiry during the preparation of this edition. It could apply where provision of a fuse or OVER-CURRENT RELEASE would be inconvenient, for example in a small plug-in power supply.

Clause 9 – Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Requirements in Clause 9 describe HAZARDS of a mechanical nature caused by ME EQUIPMENT (HARM caused by moving parts, by rough surfaces, by sharp edges and corners, by instability, by expelled parts, by vibration and noise and by breakdown of PATIENT supports and of suspension means for ME EQUIPMENT parts). Requirements describing HAZARDS caused by damage or deterioration of ME EQUIPMENT (mechanical strength) have been collected into 15.3.

ME EQUIPMENT can become unsafe because of parts damaged or deteriorated by mechanical stresses such as blows, pressures, shocks, vibration, by ingress of solid particles, dust, fluids and moisture and aggressive gases, by thermal and dynamic stresses, by corrosion, by loosening of fastenings of a moving part or a suspended mass, and by radiation.

Effects of mechanical overloads, material failure or wear can be avoided by:

– means that interrupt or render non-hazardous the operation or the energy supply (for example, fuses, pressure-relief valves) as soon as overloading occurs; or

– means that guard against or catch flying or falling parts (caused by material failures, wear or overload) that could constitute a MECHANICAL HAZARD.

Protection against breakdown of PATIENT supports and suspensions can be provided by redundancy or the provision of safety catches.

ME EQUIPMENT parts that are intended to be held in the hand or positioned on a bed need to be sufficiently robust to withstand a fall. They can be subject to vibration and shocks, not only when transported but also when used in vehicles.

Subclause 9.2 – MECHANICAL HAZARDS associated with moving parts

OPERATORS, PATIENTS and other people need to be protected from MECHANICAL HAZARDS. This can be achieved in a number of ways, for example:

– by providing sufficient distance between people and MECHANICAL HAZARDS;

– by restricting access to areas that present MECHANICAL HAZARDS;

– by providing a barrier, whether mechanical or non-mechanical, between people and MECHANICAL HAZARDS;

– by reducing the RISK associated with MECHANICAL HAZARDS;

– by ensuring adequate OPERATOR control over the movements causing a MECHANICAL HAZARD; or

– by providing back-up systems so that an acceptable RESIDUAL RISK is achieved when the initial control system fails.

When reference is made, in this subclause, to the RISK to persons, rather than to the PATIENT or OPERATOR, it should be noted, that there can be other people, in addition to the PATIENT or OPERATOR in the vicinity of ME EQUIPMENT. Depending upon the ME EQUIPMENT, visitors, family members and other non-qualified personnel could be in the vicinity.

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Subclause 9.2.1 – General

Requirements concerning moving parts have been based on those in other standards applying to non-medical equipment and machinery, but have been modified to take account of the necessity for ME EQUIPMENT to be in contact with or very close to the PATIENT.

Due to the diversity of situations, it is not possible in this standard to dictate where the warnings to address RESIDUAL RISK should be placed. Depending on the application, and the level of RESIDUAL RISK, it could be important to place a warning on the product. It might, however, be acceptable to place the warning only in the ACCOMPANYING DOCUMENTS.

Subclause 9.2.2.4 – GUARDS and other RISK CONTROL measures

The degree of protection required for ENCLOSURES or GUARDS protecting moving parts depends upon the general design and INTENDED USE of the ME EQUIPMENT. Factors to be taken into consideration in judging the acceptability of exposed moving parts include the degree of exposure, the shape of the moving parts, the probability of occurrence of accidental contact, the speed of movement and the probability of occurrence that fingers, arms or clothing will be drawn into moving parts (for example where gears mesh, where belts travel on to a pulley or where moving parts close in a pinching or shearing action).

These factors can be considered with respect to both NORMAL USE and the setting of any adjustments, or the replacement of any ACCESSORY or attachment, possibly including the installation, because GUARDS can be provided at installation and might not be part of a single item of STATIONARY equipment.

Features of GUARDS that can be considered include:

– removable with the use of TOOLS only;
– removable for servicing and replacement;
– strength and rigidity;
– completeness;
– creation of additional HAZARDS such as pinch points, and the necessity for additional handling because of the increased need for servicing such as for cleaning.

Subclause 9.2.2.5 – Continuous activation

Motion control systems with the OPERATOR in the feedback loop need to employ continuous activation (e.g. momentary contact, dead-man switch). Such factors as speed of motion and visible feedback to the OPERATOR also need to be adequate.

In some circumstances, OPERATOR training and other qualifications are necessary in order to have adequate OPERATOR control. In such cases, it could be desirable to utilize “lock out controls” that require intentional action to allow movement. Examples of such controls include:

– a key switch with an “enable” function;
– a finger print switch with an “enable” function;
– a password card.

In other circumstances, accidental control can be a concern. In this case, controls could employ such construction techniques as:

– control with an “enable” function, before any motions are possible;
– controls with recessed actuators; this could prevent movement if a hand or leg hits actuator unintentionally.

If the OPERATOR could have access to hazardous moving parts, controls could be designed which would prevent access to the TRAPPING ZONE by location of the OPERATOR controls. An example is a control system that needs two-hand activation.

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For OPERATOR control systems without continuous activation, there can be an acceptable mitigation of RISKS, however it is necessary to evaluate the system to the other options in 9.2.2.1.

This clause deals with electronic motion control systems. For manually driven motion systems see other options in 9.2.2.1.

Subclause 9.2.2.6 – Speed of movement(s)

For some medical equipment there will be unavoidable HAZARDS due to moving parts.

Subclause 9.2.3 – Other MECHANICAL HAZARDS associated with moving parts

Subclause 9.2.2.1 deals with MECHANICAL HAZARDS caused by TRAPPING ZONES. Movement could result in other MECHANICAL HAZARDS, such as impact, puncture, etc.

Subclause 9.2.4 – Emergency stopping devices

Emergency stopping devices are designed to prevent accidental damage by preventing or stopping movements of ME EQUIPMENT parts. There could be more than one emergency stopping device on ME EQUIPMENT. ME EQUIPMENT can also include emergency off devices that are intended to disconnect all power to the installation. Emergency off devices are not subject to the requirements of this subclause unless they are also intended to provide the emergency stopping function. Emergency stopping devices could be only one part of the emergency switching function.

Subclause 9.2.5 – Release of PATIENT

This requirement takes account of the possible effect of a power interruption causing unwanted movements, and the likely need in that situation, for the removal of compression forces or the removal of PATIENTS from a hazardous position.

Subclause 9.3 – MECHANICAL HAZARD associated with surfaces, corners and edges

The RISK associated with a sharp edge depends upon the position of the sharp edge and the application of the ME EQUIPMENT. For this reason, compliance with this subclause is checked by inspection. In cases of doubt, the test for sharp edges described in UL 1439 [43], can be used as guidance.

This subclause applies for surfaces accessible during NORMAL USE. Care should be given to protecting SERVICE PERSONNEL, or other internal systems where damage could result in an unacceptable RISK (e.g. fluid systems).

Subclause 9.4 – Instability HAZARDS

In NORMAL USE, many types of ME EQUIPMENT are exposed to a variety of conditions during transport (movement from room to room during NORMAL USE). While the requirements of this standard attempt to represent those that might be encountered, the RISK MANAGEMENT PROCESS should evaluate the conditions under which the ME EQUIPMENT is intended to be used and how those conditions might impact BASIC SAFETY or ESSENTIAL PERFORMANCE.

Where failure to remain stable during the performance of these tests could cause HARM to the OPERATOR, PATIENT and other persons (e.g. from crushing or falling); or result in the ME EQUIPMENT failing to meet the applicable BASIC SAFETY requirements of this standard (such as: exposing hazardous voltages, reducing CREEPAGE DISTANCES or AIR CLEARANCES or creating breaches in fire proof ENCLOSURES which are not clearly obvious) or causing a loss of ESSENTIAL PERFORMANCE, instability should be considered to result in an unacceptable RISK.

All ME EQUIPMENT is tested for overbalance with 5° tip, 10° tip, and push in 9.4.2.1, 9.4.2.2, 9.4.2.3 a) and b). In 9.4.3.1 a), b) and c) and 9.4.3.2 a) and b), only MOBILE ME EQUIPMENT is tested as these are requirements for wheels and their brakes.

Subclause 9.4.2 – Instability – overbalance

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As an aid to understanding, Table A.3 and Figure A.16 illustrate the logic behind the stability test requirements.

Table A.3 – Instability test conditions

Transport warning	Test plane angle	
	10° plane	5° plane
Transport warning not provided	Must pass in all positions	Not applicable (represented by 10° test)
Transport warning provided	Must pass in transport position (only)	Must pass in all positions except transport

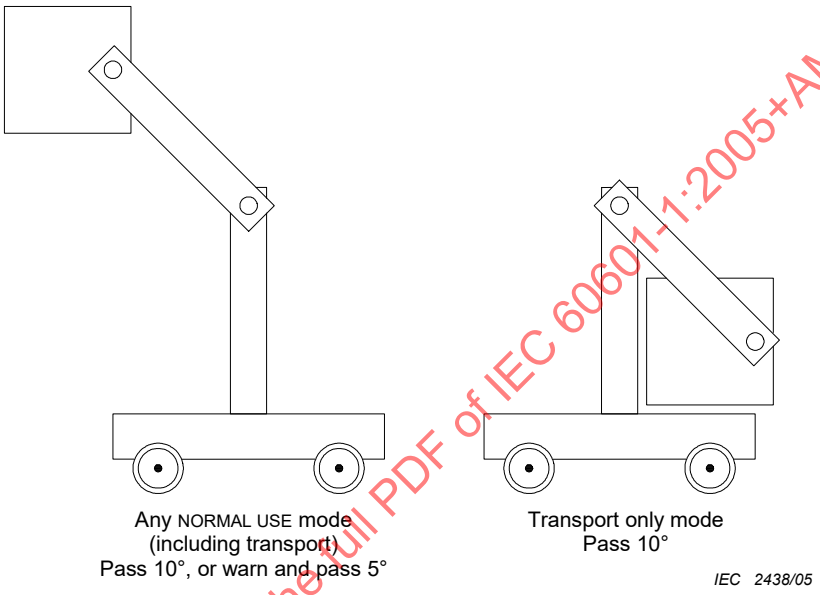


Figure A.16 – Instability test conditions

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Subclause 9.4.2.3 a)

The push force of 15 % of the ME EQUIPMENT'S weight or a maximum of 150 N was selected in order to represent foreseeable misuse for typical ME EQUIPMENT, based on input from ME EQUIPMENT MANUFACTURERS. The marking option for ME EQUIPMENT that overbalances with this push force is considered something that provides medical care benefit, and with the no-pushing marking the committee presumes that the RISK would be acceptable, but the MANUFACTURER needs to make this determination based on their own analysis, which might include usability studies, including the location of the marking.

Subclause 9.4.2.4 – Castors and wheels

Compliance with this subclause is required not only to avoid obvious unacceptable RISK but also to ensure the substantially operative movement as an ESSENTIAL PERFORMANCE. MOBILE ME EQUIPMENT is defined as equipment intended to be moved from one location to another.

Subclause 9.4.2.4.3 – Movement over a threshold

The 10 mm threshold height came from the thought that cables are represented by an 8 mm to 10 mm height. The committee felt that elevator alignment is now closer to 10 mm (e.g. 4 mm) rather than 20 mm. Normally, hospitals would not have door threshold.

The manual speed of 0,8 m/s was selected from an anticipated range of 0,4 m/s to 1,5 m/s during NORMAL USE, based on input from ME EQUIPMENT MANUFACTURERS. A speed of 0,8 m/s was felt to be the most representative of NORMAL USE and normal walking speed. There's a balance between too slow a speed such that the ME EQUIPMENT won't go over the threshold and too fast a speed causing the ME EQUIPMENT to become unstable. A single speed was selected for the test as this was felt to be necessary for reproducibility among testers.

Some MOBILE ME EQUIPMENT is provided with castors for convenience but not as means to be wheeled across thresholds or similar obstacles. When the MANUFACTURER clearly indicates this use is not intended there should be no need for the threshold test. Examples of equipment that might not require a threshold test include trolleys and treatment tables that are fitted with castors to enable them to be moved easily aside for cleaning the floor or making space.

Subclause 9.4.3 – Instability from unwanted lateral movement (including sliding)

The braking functional verification tests allow the braking system to be assessed with compliance giving the presumption of acceptable RISK. The test criteria assume that generally any initial elastic movement and subsequent movement up to 50 mm are acceptable. In accordance with 4.2, if these movements for a specific piece of ME EQUIPMENT and its INTENDED USE seem inappropriate, the RISK should be lowered with additional RISK CONTROL measures.

The braking push force of 15 % or the maximum of 150 N was selected in order to represent reasonably foreseeable misuse for typical ME EQUIPMENT based on input from ME EQUIPMENT MANUFACTURERS.

The intent of braking requirements is to provide a generic test for general ME EQUIPMENT. Thus compliance criteria are black and white. It is acknowledged that some slow unwanted movement of low weight carts (low momentum), could be considered an acceptable RISK.

It is accepted that for many carts with 4 wheels, providing 2 brakes is a reasonable RISK CONTROL measure to mitigate unwanted movement due to inadequate braking. Placing 4 brakes on many carts will not result in greater usage of the brakes, as some of the wheels will typically be pivoted out of reach.

Subclause 4.5 is always applicable and allows the MANUFACTURER to use alternative RISK CONTROL measures, or variations to test method, or test compliance criteria, with justification.

Subclause 9.4.3.1 c) – Instability in transport

The hard flat surface used in this test should reflect the worst case of INTENDED USE. Slippage of wheels against the hard flat surface is a secondary concern. If slippage is detected, it should be determined whether a more appropriate surface should be chosen for the test or the wheel material is inappropriate.

Subclause 9.5 – Expelled parts HAZARD

Expelled parts are ME EQUIPMENT parts or fragments of ME EQUIPMENT parts, such as parts of a damaged vacuum display, a mechanical spring, a gas pressure cylinder, a rotating flywheel or an exploded lithium battery that could be expelled by collision, expansion etc.

The degree of protection against "expelled parts" depends upon the probability of occurrence of HARM and the SEVERITY of HARM. Protective measures can include an ENCLOSURE, barrier, or electronic means (e.g. redundant means to prevent lithium battery charging current).

Subclause 9.6.1 – General

Excessive noise can cause fatigue, interference with speech and acoustic signals, or even damage to hearing. Limits to prevent hearing damage are described in ISO standards.

In medically used rooms, much lower limits are needed for the comfort of PATIENTS and medical personnel. The actual effect of ME EQUIPMENT noise is strongly influenced by the

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acoustical properties of the room, the insulation between rooms and interaction of ME EQUIPMENT parts.

Excessive vibration will cause discomfort to the PATIENT, OPERATOR, and other persons. Prolonged exposure can cause vascular, neurological, or osteo-articular disorders. Excessive vibration can also cause damage to ME EQUIPMENT or a shift in calibration.

Most ME EQUIPMENT covered by this standard exposes the PATIENT and OPERATOR or other persons to negligible levels of noise and vibration. The RISK MANAGEMENT PROCESS should be able to clearly identify those cases where measurements are required.

Subclause 9.6.2 – Acoustic energy

These values are based on the potential for long term hearing impairment. The value usually used for regulatory purposes worldwide is currently 90 dBA with an offset of 5 dBA. However the latest research indicates a value of 85 dBA for 8 h over a 24 h period with an offset of 3 dBA when the time doubles or halves [34].

Although the criteria for judging whether a noise is considered impact noise is intentionally not provided, judgement should be used referring to the situation. Examples of impact noise include: the gradient noise of MRI equipment, and lithotripsy impulses.

Subclause 9.6.3 – Hand-transmitted vibration

Threshold values for vibration are much less clear than those for acoustic energy (noise). The value used here is from the *Directive of the European Parliament and of the Council on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (vibration)* (sixteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC). It corresponds to about a 10 % incidence of blanching (indicative of neurological damage) after 8 years of regular exposure according to ISO 5349-1. It is more difficult to establish limit values for whole body vibration. Therefore this standard does not specify such limits. The end points such as back pain and other adverse health effects are not easily quantifiable, and so no agreed-upon exposure standards have been developed. Relevant information of this subject can be found in standards such as ISO 5805 [28], and ISO 8041 [29].

When a person is exposed to various levels of acceleration over a 24 h period, allowable cumulative exposure can be determined as follows. Consider first Table A.4 of allowable time of exposure over a 24 h period for each level of acceleration.

Table A.4 – Allowable time exposure for level of acceleration

Allowable time of exposure over a 24 h period h	**Acceleration** m/s^2
1	7,07
2	5,00
3	4,08
4	3,54
5	3,16
6	2,89
7	2,67
8	2,50
9	2,36
12	2,04
16	1,77
24	1,44

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Some examples of allowable cumulative exposure are provided below.

If a person were exposed to a 5 m/s^2 acceleration for 1 h (which represents 1/2 daily allowable exposure time for this acceleration), followed by an exposure to a 1,44 m/s^2 acceleration for 12 h (which represents 1/2 daily allowable exposure time for this acceleration), this would be an acceptable cumulative exposure over a 24 h period.

If a person were exposed to a 4,08 m/s^2 acceleration for 1 h (which represents 1/3 the allowable daily exposure time for this acceleration), followed by exposure to a 2,36 m/s^2 acceleration for 3 h (which represents 1/3 allowable daily exposure time for this acceleration), followed by exposure to a 1,44 m/s^2 acceleration for 8 h (which represents 1/3 allowable daily exposure time for this acceleration), this would be an acceptable cumulative exposure over a 24 h period.

If a person were exposed to a 5 m/s^2 acceleration for 1 h (which represents 1/2 the allowable daily exposure time for this acceleration), followed by exposure to a 4,08 m/s^2 acceleration for 1 h (which represents 1/3 allowable daily exposure time for this acceleration), followed by exposure to a 2,04 m/s^2 acceleration for 2 h (which represents 1/6 allowable daily exposure time for this acceleration), this would be an acceptable cumulative exposure over a 24 h period.

To summarize, for each acceleration determine the fractional value of allowable daily exposure by dividing the actual exposure time for a given acceleration by the allowable daily exposure time for that acceleration. The sum of the fractional values for each acceleration is not to be greater than 1.

Subclause 9.7 – Pressure vessels and parts subject to pneumatic and hydraulic pressure

The requirements of this subclause do not represent the most stringent combination of national regulations or standards.

In some countries such regulations or standards apply.

Type of systems considered include pneumatic pressure systems, hydraulic pressure systems, steam pressure systems and combinations thereof. These systems might or might not include pressure vessels.

HAZARDS

a) Mechanical rupture or breakage (HARM: lacerations, puncture wounds)

The requirements from Clause 45 of the second edition dealing with this HAZARD, have been moved to this subclause, and remain unchanged.

Requirements have been clarified to indicate that all parts have a MAXIMUM PERMISSIBLE WORKING PRESSURE not less than the pressure in NORMAL CONDITION or SINGLE FAULT CONDITION. In principal there should be a suitable safety factor between the MAXIMUM PERMISSIBLE WORKING PRESSURE and the bursting pressure, where the bursting pressure is the pressure at which a part suffers from permanent (plastic) deformation or leakage. Industry standards for pressure parts vary, but suitable safety factors are 3 ×, 4 ×, and sometimes 5 × (ISO, ASME, SAE). As a suitable safety factor can vary, depending on factors associated with the end-use application and RISK, it was considered inappropriate to specify a minimum safety factor in the definition of MAXIMUM PERMISSIBLE WORKING PRESSURE, but instead leave this to the declaration of the MANUFACTURER of such part. It is assumed that MAXIMUM PERMISSIBLE WORKING PRESSURE declarations will be based on recognized international or national standards, and therefore below bursting pressures at least in line with the multiplication factor shown in Figure 32, (3 ×, derated after 1 MPa to as low as 1,3 × after 30 MPa).

For pressure vessels exceeding both an energy limit (pressure × volume) and a maximum pressure limit, the requirement is to conduct a hydrostatic overpressure test based on the MAXIMUM PERMISSIBLE WORKING PRESSURE declaration and the multiplication factor shown in Figure 32, (3 ×, derated after 1 MPa to as low as 1,3 × after 30 MPa).

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b) Mechanical loss of support (HARM: crush, puncture wounds)

Requirements have been clarified to specify that components in a pressure system, such as those in a hydraulic lift system whose integrity is relied on to reduce the RISK from loss of support need to comply with the NORMAL CONDITION TENSILE SAFETY FACTORS specified in 9.8. The TENSILE SAFETY FACTOR is typically 4 × for parts not impaired by wear, and 8 × for parts impaired by wear (Case B). Thus parts subject to pressure whose failure could result in mechanical rupture and loss in support need to have a MAXIMUM PERMISSIBLE WORKING PRESSURE based on the higher of the SINGLE FAULT CONDITION pressure and the MANUFACTURER's declaration for each system component as specified in 9.7, or the NORMAL CONDITION pressure and the TENSILE SAFETY FACTOR as specified in 9.8.

c) Leakage of toxic gas or liquid (HARM: chemical or biological cell damage)

The requirements from Clause 45 of the second edition dealing with this HAZARD have been moved to this clause, and remain unchanged.

Requirements have been clarified to indicate that all pressure system components need to have a MAXIMUM PERMISSIBLE WORKING PRESSURE based on the SINGLE FAULT CONDITION pressure and the MANUFACTURER's declaration for each system component.

d) Leakage of flammable gas or liquid (HARM: fire causing burns or property damage)

The requirements from Clause 45 of the second edition dealing with this HAZARD, have been moved to this clause, and remain unchanged.

Requirements have been clarified to indicate that all pressure system components need to have a MAXIMUM PERMISSIBLE WORKING PRESSURE based on the SINGLE FAULT CONDITION pressure and MANUFACTURER'S declaration each system component.

Subclause 9.7.5 – Pressure vessels

The Oxford dictionary defines a pressure vessel as "a container designed to hold material at high pressures." This is the usage intended by this standard.

It is assumed that a hydraulic test is not necessary if the pressure is less than or equal to 50 kPa or the product of the pressure and volume is less than or equal to 200 kPa · l.

The safety factors implied by Figure 32 are higher than those generally applied in testing pressure vessels. However, whereas hydraulic testing is normally used to verify that a pressure vessel is free from production faults or serious deterioration, the adequacy of the design being determined in other ways, the present hydraulic test is intended to verify the adequacy of a design where this cannot be established in other ways.

The deletion of national references in the amended text avoids subordinating the requirements of the standard to those of local regulations. The ME EQUIPMENT will sometimes have to satisfy both, or the more demanding, assuming that there are no local regulations that conflict with this standard.

A hydraulic test is specified even for pneumatic vessels, as this is safer for the tester. In achieving the test pressure with a gas, the gas will compress, resulting in more stored energy in the test vessel than would a hydraulic test method. Both methods result in the same test pressure, which is the objective of the test.

Subclause 9.8 – MECHANICAL HAZARDS associated with support systems

The term "support" is taken to include "suspension" and loads can include PATIENTS, OPERATORS and other masses.

Support systems can broadly be categorized as follows.

– A suspension system is one that contains flexing or rigid elements that are designed to suspend masses, including PATIENTS and OPERATORS during NORMAL USE.

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– Flexing elements include ropes, cables, chains, belts, bands and springs. Additionally a jack screw nut is considered impaired by wear to the extent needing a higher TENSILE SAFETY FACTOR.

– An actuating system is one that contains elements such as electric, pneumatic or hydraulic actuators, motors, gearboxes, shafts, bearings, pulleys, sheaves, band wheels and guides.

– A support structure is generally a rigid device that can be static or moving and which supports ME EQUIPMENT, external loads and, where necessary, PATIENTS and OPERATORS.

Subclause 9.8.2 – TENSILE SAFETY FACTOR

TENSILE SAFETY FACTORS are applied to provide a margin of safety to the design after all reasonable allowances for operating conditions, material and manufacturing variables, etc., have been made.

In determining whether case A or B is to be used from Table 21, certainty of material strength is required in order to apply case A values. Additionally there needs to be confidence in the determination of TOTAL LOAD in order to apply case A values. TOTAL LOAD is constituted from "static force" and "dynamic force" components. The static force is normally clear. But the dynamic force/loading is sometimes uncertain. When the dynamic forces are known as well as static forces, the TENSILE SAFETY FACTOR is determined with case A. When the dynamic forces are not clear, and the static forces are known, the TENSILE SAFETY FACTOR is determined with case B.

External forces for PATIENT supports can include those generated by application of CPR, etc.

Elongation at break of 5 % is based on historical experience with metallic materials, in particular steel and cast iron. Materials with elongation at break less than 5 % are considered brittle and their failure is likely catastrophic, and therefore a higher safety factor is considered appropriate.

For non-metallic materials:

– Where no other experience exists, and where failure mode is likely catastrophic, this elongation factor is considered appropriate, and therefore a higher TENSILE SAFETY FACTOR is considered appropriate.

– Where experience and testing show otherwise, an elongation at break of less than 5 % can be appropriate before a higher TENSILE SAFETY FACTOR is justified.

For example, PATIENT tables of X-ray/CT/MR systems are often designed with plastic materials laminated or reinforced by carbon fibres/cloths or glass fibres/cloths, since these PATIENT tables must be optimised for low absorption of X-ray radiation (aluminium equivalence), MR compatibility (low proton signal), as well as structural stability. Although these plastic materials reinforced by carbon fibres/cloths can have elongation at break of less than 5 %, many years knowledge, acquired expertise, and post-market surveillance can provide sufficient evidence that suitable structural stability of PATIENT tables is achieved by applying a TENSILE SAFETY FACTOR from Table 21, Situation 1 (rather than Situation 2).

At end of life or periodic maintenance cycle, ME EQUIPMENT needs to maintain structural integrity. Line 1 of Table 21 is normally appropriate for end of life or the end of the periodic maintenance cycle since wear is no longer considered.

Suspension and actuating systems have TENSILE SAFETY FACTORS that are necessarily high to reduce the effects of deterioration through wear and fatigue.

Particular attention should be given to the fixing of structures to floors, ceilings, etc. that are subject to variable TENSILE SAFETY FACTORS.

A hidden defect is one that is not revealed during manufacture, service or normal operation of the ME EQUIPMENT but that could cause failure of a part that could result in a HAZARD. Examples are high internal stresses in heat-treated parts such as springs, broken strands of wire inside cables and porosity inside castings.

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Figure A.17 contains an example of determining the appropriate TENSILE SAFETY FACTOR using Table 21. Figure A.18 contains an example of determining design and test loads. These examples are not intended to cover all possible cases. For a particular design, these TENSILE SAFETY FACTORS and design/test loads can vary according to the materials used, their wear characteristics, loading conditions, etc.

This subclause focuses on safety factors as the suggested approach to have confidence that the equipment will maintain structural integrity during its EXPECTED SERVICE LIFE. In some cases the specified safety factors are more than needed, and in some cases even larger factors could be considered appropriate. The compliance criteria can be satisfied by RISK MANAGEMENT rather than by the use of the safety factor route. For new materials or for structures with sophisticated monitoring of stresses, the safety factors might not be necessary.

If it is deemed that the failure mode of the part does not result in an unacceptable RISK, the TENSILE SAFETY FACTORS specified in Table 21 do not apply. For example, for proprietary components such as bearings it is acceptable to rely on the component MANUFACTURER'S data for load and life expectancy without applying a TENSILE SAFETY FACTOR.

A jack screw nut considered impaired by wear is usually intentionally constructed from a material softer than the jack screw. The intent is to have generic requirement provided for general ME EQUIPMENT.

Newer jack screw designs can have less friction than traditional designs, and, for example, can include multiple ball bearings. Such designs can be considered as less “impaired by wear” as dictated by vendor declarations and a MANUFACTURER’S RISK ASSESSMENT.

Subclause 4.5 is always applicable and allows the MANUFACTURER to use alternative RISK CONTROL measures, or variations to a test method or test compliance criteria, with justification.

Subclause 9.8.3 – Strength of PATIENT or OPERATOR support or suspension systems

This subclause deals with forces applied on support or suspension parts of ME EQUIPMENT, intended to support or suspend the mass of a human body or part of the mass of a human body, and to ACCESSORIES used on such support or suspension parts. For adult PATIENTS or OPERATORS the 135 kg mass represent the 99 percentile of the population. For specific populations, higher mass or lower mass can be used (e.g. heavy person or paediatric application).

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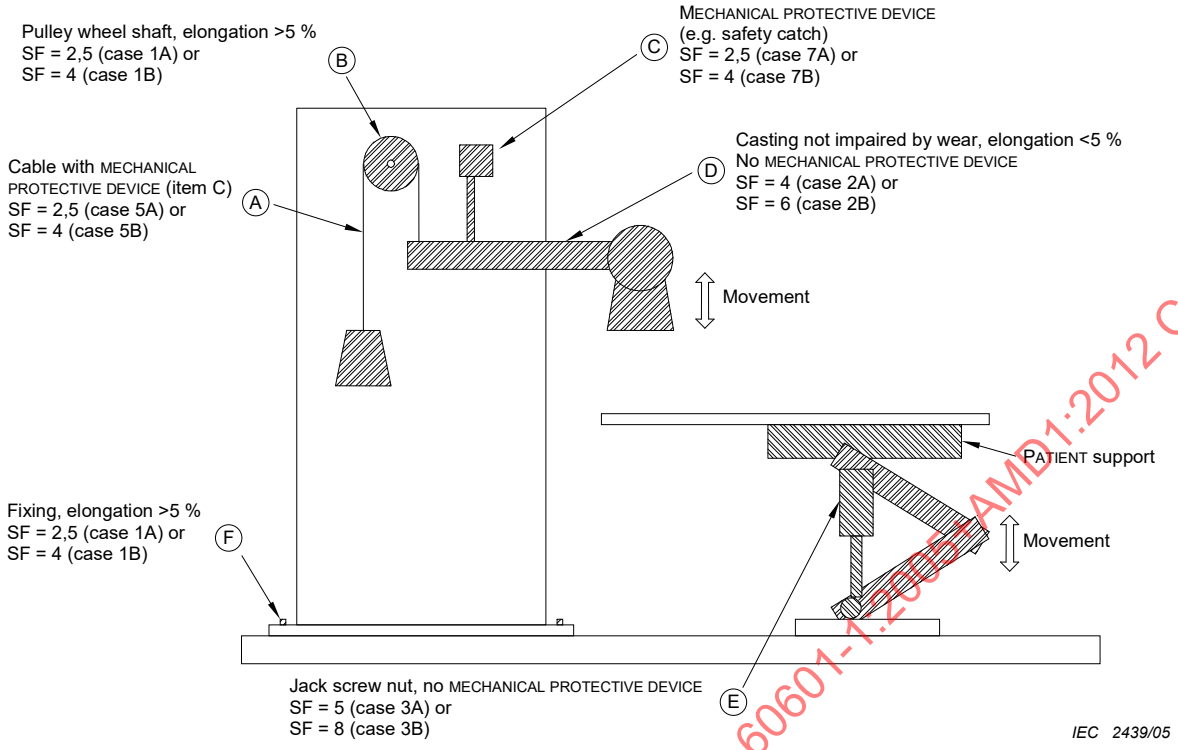
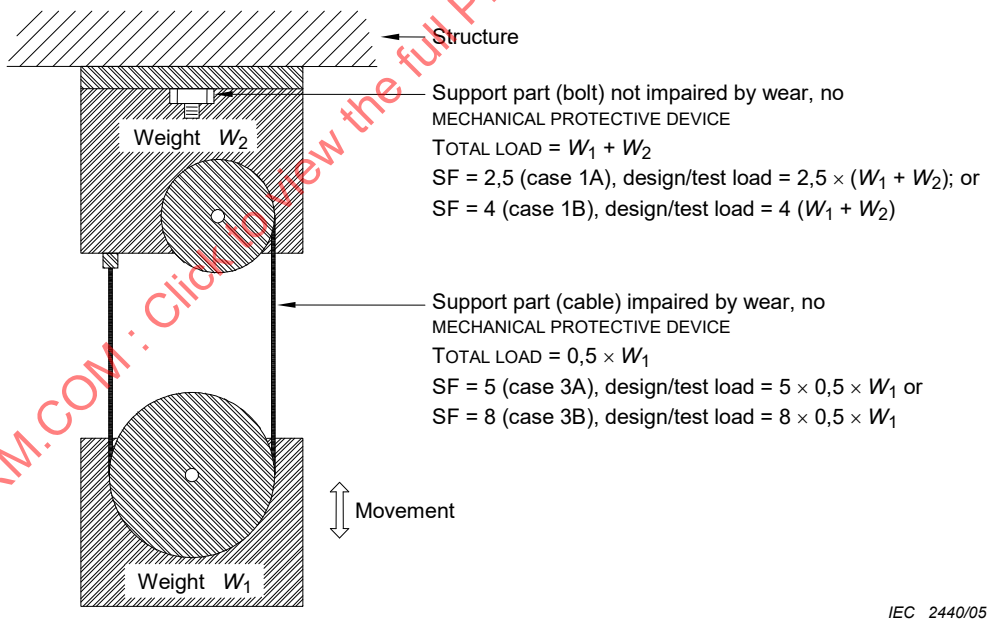


Figure A.17 – Example of determining TENSILE SAFETY FACTOR using Table 21



NOTE TOTAL LOAD is shown based on only static forces to obtain actual total loads, dynamic forces also need to be included.

Figure A.18 – Example of determining design and test loads

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Subclause 9.8.3.2 – Static forces due to loading from persons

Figure A.19 contains an example of human body mass distribution for PATIENT support surfaces.

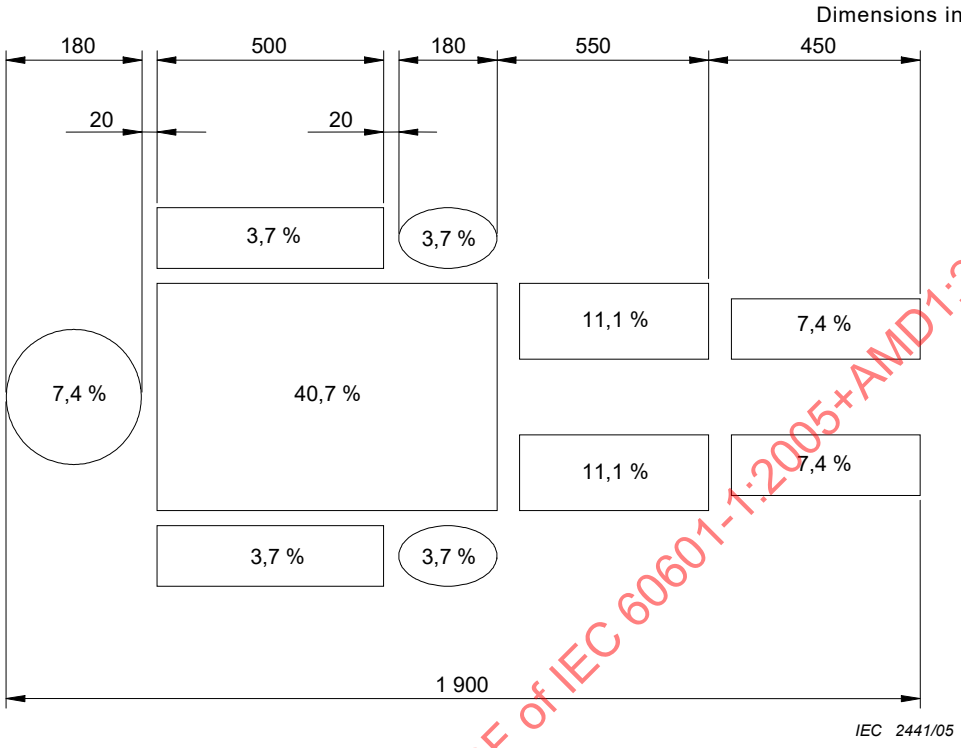


Figure A.19 – Example of human body mass distribution

The distribution mass of a body diagram is an average distribution based on anthropometrical data. Due to the variety of population or specific categories of age, it can vary. For sedentary people not having a physical activity the mass of the upper part of the body can represent a more important percentage.

The variety of ME EQUIPMENT does not allow more precision to be given in this general standard. It is up to the particular standard to define more adequately the distribution area or the worst-case position, rather than dynamic tests.

A foot rest is tested for twice its normal load, rather than a load based on a TENSILE SAFETY FACTOR value from Table 21, as it is intended to support a PATIENT'S weight for only a short duration of time.

The test with a mass of 80 kg placed 60 mm from the outer edge is intended to simulate the centre of gravity of a PATIENT sitting or leaning on the edge of a support surface.

During the static loading tests, it's intended that any temporary elastic deflection (during the test), and permanent plastic deflection (after the test) are checked for any adverse effect on BASIC SAFETY or ESSENTIAL PERFORMANCE.

For the step loading test, the committee felt that a 5° deflection would provide a measurable quantity that would represent a reasonable limit for acceptance. The 2X loading factor is a precedent from the 2nd edition of IEC 60601-1, and seems to recognize the temporary loading that steps represent during their life.

For the sitting surface loading test, no specific linear or arc limits are specified. The intent is to evaluate any temporary elastic or permanent plastic deflections for any adverse effect on BASIC SAFETY or ESSENTIAL PERFORMANCE. The 60 % sitting loading factor was considered representative of actual sitting load, when legs are dangling off the edge of the sitting surface. Loss of function is not considered unacceptable unless associated with ESSENTIAL

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PERFORMANCE. The intent is damage should not result in injury to persons, or loss of RISK CONTROL measures. Surfaces that are intended to support sitting and at other times full patient loads are also evaluated for compliance with the appropriate loading factor(s) in 9.8.2.

Subclause 9.8.3.3 – Dynamic forces due to loading from persons

A general dynamic test is defined which represents common situations represented by a person sitting down or standing up.

The requirement of this subclause is intended to apply to the chairs for dental surgical procedures, X-ray tables, and many other similar types of ME EQUIPMENT. The ME EQUIPMENT should be in all operating modes and positions where dynamic loads from PATIENTS can be reasonably expected. For example, when a PATIENT table is positioned in an area of a CAT or magnet structure, the dynamic test is not applicable as the dynamic loading caused by a PATIENT is negligible.

ME EQUIPMENT should be designed to bear a repeating force, by considering appropriate TENSILE SAFETY FACTORS and the results of fatigue calculations. TENSILE SAFETY FACTORS exist to show the reliability of the equipment without real testing.

The bottom portion of the human body test mass apparatus shown in Figure 33 is foam, and should simulate contact by the relevant PATIENT part.

Subclause 9.8.4 – Systems with MECHANICAL PROTECTIVE DEVICES

The intent of a MECHANICAL PROTECTIVE DEVICE is to act to prevent HARM in the event of the failure of the primary support means that is subject to wear. The failure of the primary support means subject to wear is considered a SINGLE FAULT CONDITION if it has a TENSILE SAFETY FACTOR in accordance with Table 21, rows 5 and 6. To protect against HARM in this SINGLE FAULT CONDITION, the MECHANICAL PROTECTIVE DEVICE acts as a backup, and needs to have the TENSILE SAFETY FACTOR indicated in Table 21, Row 7. It is considered good engineering practice to construct a MECHANICAL PROTECTIVE DEVICE from non-brittle materials, and therefore Row 7 does not include an elongation column.

To test a MECHANICAL PROTECTIVE DEVICE, the primary support means subject to wear needs to be defeated. For example if the primary support system is a cable, the cable would be cut.

Clause 10 – Protection against unwanted and excessive radiation HAZARDS

Radiation from ME EQUIPMENT can occur in all forms known in physics. BASIC SAFETY requirements are concerned with unwanted radiation. Protective measures are necessary for ME EQUIPMENT and for the environment and methods for determining levels of radiation need to be standardized.

This clause is intended to deal with stray radiation (such as scattered radiation from radiological equipment) and incidental radiation (such as X-ray emitted by CRTs). A requirement for unintended or excessive output of radiation that ME EQUIPMENT is intended to deliver to the PATIENT is covered in 12.4.5.

For ionizing radiation IEC requirements generally comply with the International Commission for Radiation Protection (ICRP) Recommendations. Their purpose is to provide data that are immediately usable by designer and RESPONSIBLE ORGANIZATION.

Their evaluation is possible only by adequate study of operating methods and duration of operation of ME EQUIPMENT and positioning of OPERATOR and assistants, because application of worst case conditions would give rise to situations that might hamper proper diagnosis or treatment.

Recent ICRP publications also instruct the OPERATOR in methods for the restriction of intentional irradiation.

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Subclause 10.1.1 – ME EQUIPMENT not intended to produce diagnostic or therapeutic X-radiation

Spurious X-radiation from components such as Video Display Units (VDU) is a potential source of concern for ME EQUIPMENT, many of which contain VDUs. Annex H of IEC 60950-1:2001 contains a well-accepted PROCEDURE for measuring such spurious emissions for information technology equipment. The limits in that annex are based on ICRP 60 [39]. The requirements from Annex H of IEC 60950-1:2001 were incorporated into the body of this standard because this was the only normative reference that required the use of IEC 60950-1.

Other normative references to IEC 60950-1 are alternative means of addressing items such as CREEPAGE DISTANCE and AIR CLEARANCE. A user of this standard does not have to reference 60950-1 unless they wish to use the insulation coordination methods contain in that document.

Subclause 10.3 – Microwave radiation

This subclause specifies a microwave power density limit to mitigate thermal harm to whole body tissue. The intention is that compliance might be appropriately determined with engineering judgement, in lieu of testing, when it's obvious that emissions are nowhere near the 10 W/m^2 power density limit. Knowledge about equipment transmission specifications and engineering judgement might be used to determine compliance. The safety threshold of 10 W/m^2 greatly exceeds that allowed for wireless communication uses, where SAR (W/kg) limits are applicable. For example, equipment with microprocessor clock oscillators or intentional transmission radios such as Wi-Fi™, Bluetooth®, GPS, or cellular would comply with this threshold since these meet more stringent limits for their applicable bandwidth. When this confidence does not exist, appropriate power density measurements should be conducted.

Subclause 10.4 – Lasers

IEC 60825-1 is applicable to safety of laser products emitting laser radiation in the wavelength range 180 nm to 1 mm. A laser product can consist of a single laser with or without a separate power supply or it can incorporate one or more lasers in a complex optical, electrical, or mechanical system.

Any laser product is exempt from all further requirements of IEC 60825-1 if classification by the manufacturer of that product according to Clauses 3, 8 and 9 of IEC 60825-1 shows that the emission level does not exceed the AEL (Accessible Emission Limit) of Class 1 under all conditions of operation, maintenance, service and failure.

In previous editions of IEC 60825-1, LEDs were included in the scope of that standard, and they can be still included in other parts of the IEC 60825 series. However, with the development of lamp safety standards, optical radiation safety of LEDs in general can be more appropriately addressed by lamp safety standards. The removal of LEDs from the scope of IEC 60825-1 does not preclude other standards from including LEDs whenever they refer to lasers. IEC 62471 [67] can be applied to determine the risk group class of an LED or product incorporating one or more LEDs.

IEC 62471 gives guidance for evaluating the photobiological safety of lamps and lamp systems including luminaires. Specifically, it specifies the exposure limits, reference measurement technique and classification scheme for the evaluation and control of photobiological hazards from all electrically powered incoherent broadband sources of optical radiation, including LEDs but excluding lasers, in the wavelength range from 200 nm through 3 000 nm. IEC 62471 was originally prepared as Standard CIE S 009:2002 by the International Commission on Illumination.

Subclause 11.1 – Excessive temperatures in ME EQUIPMENT

Temperature limits are required to prevent HAZARDOUS SITUATIONS for almost all types of ME EQUIPMENT with the purpose of preventing rapid ageing of insulation and discomfort where

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ME EQUIPMENT is touched or manipulated, or injuries where PATIENTS could contact ME EQUIPMENT parts.

ME EQUIPMENT parts might be inserted into body cavities, usually temporarily but sometimes permanently.

For PATIENT contact, special temperature limits have been set.

Subclause 11.1.1 – Maximum temperature during NORMAL USE

Table 22 addresses limits for parts that could affect compliance of the ME EQUIPMENT with this standard in general (e.g. electrical BASIC SAFETY).

It is not intended that the ME EQUIPMENT parts be tested in every possible configuration of NORMAL USE as long as the MANUFACTURER can determine the worst-case conditions. The "worst case" will almost always include the highest allowable ambient temperature and operation of the ME EQUIPMENT at the maximum DUTY CYCLE, but other specific aspects of the configuration of the ME EQUIPMENT (such as attachment of ACCESSORIES) should be determined by the MANUFACTURER based on a thorough understanding of the ME EQUIPMENT'S design.

Subclause 11.1.2 – Temperature of APPLIED PARTS

Table 23 and Table 24 addresses HAZARDS that could arise from human contact with higher temperatures. Human contact temperatures were based on clinical expertise, clinical literature [52] and experimentation. In addition, the values agree with those of the European Norm EN 563 [38].

Although the maximum surface temperature for an APPLIED PART was raised from 41 °C to 43 °C in response to the clinical input mentioned above, input from some clinicians pointed out that infants as well as some other (thermally) high risk groups could be more prone to HARM from heated surfaces at 43 °C.

Ideally, particular standards for ME EQUIPMENT used for these PATIENT groups would have requirements for (where necessary) lower contact temperatures. In order to address those cases where such particular standards do not exist, the working group felt that notification of the RESPONSIBLE ORGANIZATION when temperatures exceed the second edition limit of 41 °C was adequate. However, the new 43 °C limit is to be considered an absolute maximum.

When measuring APPLIED PART temperatures, the method used should simulate the worst-case configuration when possible using real or simulated human skin. Determination of the worst-case configuration should consider aspects such as the likely body temperature and whether or not the part of the body or APPLIED PART itself is covered (such as with a blanket). Simulated human skin for these purposes could include materials such as silicon rubber.

Subclause 11.1.2.2 – APPLIED PARTS not intended to supply heat to a PATIENT

Table A.5 is provided as guidance for ME EQUIPMENT that creates low temperatures (cools) for therapeutic purposes or as part of its operation. Normative requirements have not been included in this standard because such ME EQUIPMENT is uncommon.

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Table A.5 – Guidance on surface temperatures for ME EQUIPMENT that creates low temperatures (cools) for therapeutic purposes or as part of its operation

ME EQUIPMENT and its parts		Minimum Temperature [a] °C	
		Aluminium	Steel
External surface of ME EQUIPMENT and its parts that are likely to be touched for a time "*t*".[b]	*t* < 1 s	–20	–20
	1 s ≤ *t* < 10 s	–10	–15
	10 s ≤ *t* < 60 s	–2	–7

[a] The allowable minimum temperature limit values for external surfaces that are likely to be touched by the PATIENT, OPERATOR and other persons are based on freezing threshold values of a finger touching different materials (frostbite threshold).

[b] The probability of occurrence of contact and the duration of contact should be determined and documented in the RISK MANAGEMENT FILE.

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Subclause 11.1.3 – Measurements

The proper use of thermocouples is recognized in other standards as a valid test technique. The temperature limits are lowered to compensate for errors that could occur in the construction and placing of the thermocouple.

During development of the requirements of 11.1.3, the working group discussed whether it would be appropriate to reduce the maximum allowable temperature for surfaces and APPLIED PARTS at higher altitudes. In response to this question, a thorough evaluation was performed by Dr. Joachim Kohl, an expert member of the group. The following summarizes the results of that evaluation (see Figure A.22).

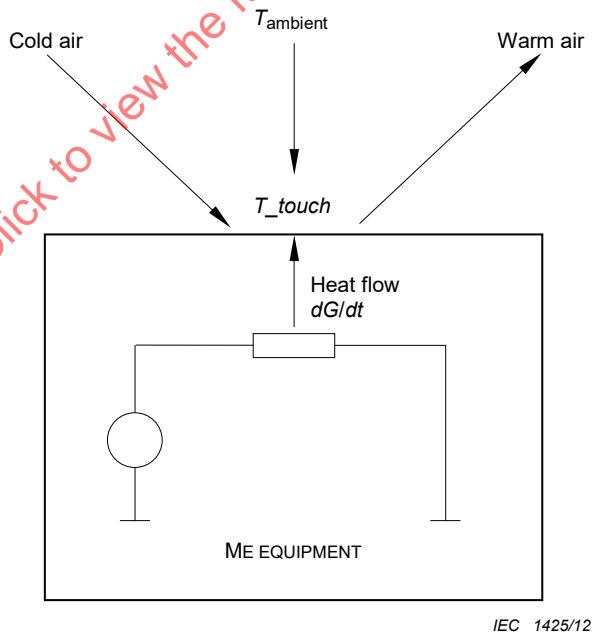


Figure A.22 – Maximum allowable temperature for surfaces and APPLIED PARTS at higher altitudes

The following variables and symbols are used in the evaluation:

T_touch touch temperature at the surface of the ME EQUIPMENT

DeltaT	temperature difference of the touched area to ambient
R_thermal	thermal resistance of the ME EQUIPMENT area under test to ambient
Q	heat
dQ/dt	heat flow
Pambient	ambient air pressure
alpha	heat transfer coefficient = *dQ/dt* / (*DeltaT* * *area*)
L	characteristic length of the heat transfer area
area	cooling area of the device
lambda	heat conductance
eta	dynamic viscosity
rho	density of gas
Nu	Nusselt number
Re	Reynold number
Gr	Grashof number
sqrt	square root
~	proportional

Evaluation of the effects of altitude on thermal transfer:

The standard heat transfer equation is:

$$DeltaT = R_thermal * dQ/dt$$

For *R_thermal*, one can estimate:

$$R_thermal \sim 1 / Pambient^{m}$$

with the exponent *m* = 0,6 … 0,8, we will assume 1.

Equations about the proportionality to 1 / *Pambient*^{m}:

Therefore,

$$R_thermal \sim 1 / alpha$$

where the proportionality factor contains geometric data.

Definition of *Nu*:

$$Nu = alpha * L / lambda$$

Results of theoretical investigations:

$$Nu \sim Re^{m}$$

The proportionality factor depends on geometry and on the kind of gas and the way of air flow, but not on temperature, pressure, density.

The exponent m is determined by geometry and the way of air flow. For free convection due to a temperature gradient *Re* is given by:

$$Re = sqrt\ (\ 0{,}4 * Gr)$$

The definition of *Gr* leads to:

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$$Gr \sim (rho \ / \ eta)^2$$

so that:

$$Re \sim rho \ / \ eta.$$

This last relationship also holds true for forced convection.

From the general gas equation we can see:

$$rho \sim Pambient$$

Lambda and *eta* do not depend on pressure (according to standard physics textbooks). Putting it all together leads to the above stated proportionality between *R_thermal* and *Pambient*.

Subclause 11.2 – Fire prevention

Within most environments where ME EQUIPMENT is used, other sources of "fuel" for combustion are typically far more significant than that provided by the ME EQUIPMENT itself. The requirements addressing fire in this standard focus on preventing the ME EQUIPMENT from being the source of combustion. For this reason, these requirements focus on ME EQUIPMENT that contains or is used in the presence of OXYGEN RICH ENVIRONMENTS. These requirements attempt to ensure that any potential source of ignition remains isolated from the OXYGEN RICH ENVIRONMENTS under NORMAL USE and SINGLE FAULT CONDITIONS.

Where ME EQUIPMENT is not used in such environments, assuring that the limits for operating temperatures and requirements for overload protection are met should be considered adequate.

For ME EQUIPMENT that could provide a significant source of fuel (in comparison to the normal operating environments) additional requirements should be provided by particular standards. Where no particular standard exists, such issues should be specifically addressed in applying the RISK MANAGEMENT PROCESS as required in 4.2.

Subclause 11.2.1 –Strength and rigidity required to prevent fire in ME EQUIPMENT.

At least all electrical parts that could result in a HAZARDOUS SITUATION, with the exception of POWER SUPPLY CORDS and other necessary interconnecting cords, should be enclosed in material that will not support combustion.

This does not preclude the use of an outer cover of other material covering an inner cover complying with the above recommendation.

For guidance on assessing fire HAZARDS, see IEC 60695-1-10 [17].

Subclause 11.2.2 – ME EQUIPMENT and ME SYSTEMS used in conjunction with OXYGEN RICH ENVIRONMENTS

While not a flammable mixture, the presence of an OXYGEN RICH ENVIRONMENT increases the flammability of many substances. Reports of fires in OXYGEN RICH ENVIRONMENTS in ME EQUIPMENT are unusual. However, when such fires do occur in the hospital environment they can have tragic consequences.

ME EQUIPMENT intended to operate in conjunction with an OXYGEN RICH ENVIRONMENT should be designed to minimize the probability or occurrence of ignition of flammable materials.

Where appropriate, particular standards should specify the corresponding requirements.

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Subclause 11.2.2.1 a)

Cotton is regarded to be the material with the lowest ignition temperature and energy in comparison with electronic circuits and it is assumed that it can be found in the interior of a device as dust.

The maximum surface temperature limit is based on the minimum hotplate ignition temperature for fire retardant cotton in 100 % oxygen that is given in NFPA 53 [41] as 310 °C. The assumption was therefore made that 300 °C was an acceptable temperature limit in ME EQUIPMENT with OXYGEN RICH ENVIRONMENTS.

The worst case conditions described in the text make it possible to provide simple numbers as limitations.

The values for sparking are taken from Kohl, H.-J. *et al.*, ASTM STP 1395 [37].

This subclause allows the use of electronic circuits in OXYGEN RICH ENVIRONMENTS only when their power supply is limited. The resistive limitation of the power input is necessary for the SINGLE FAULT CONDITION of an open solder joint that might spark. The same reason applies to the limitation of energy in capacitances and inductances. In most cases the limitation in item 4) to 300 °C is more restrictive than these. For most small components like decoupling capacitors, or where the failure of a component causes the maximum possible power to be drawn from the source, it is necessary to limit the power to about 1 W. The PROCEDURE to find the necessary value to limit the power so that the 300 °C limit is not exceeded can be as follows:

– look for the smallest component that can match to the power source in a SINGLE FAULT CONDITION;
– estimate its thermal resistance;
– calculate the power limitation = 200 °C / thermal resistance.

Subclause 11.2.2.1 b) 2)

This item addresses the condition of an undetected oxygen leak. In accordance with the definition of SINGLE FAULT SAFE, such a leak (because it is undetected) is considered a NORMAL CONDITION (see 4.7). Similarly, only the failure of the ventilation, which is undetected, needs to be considered a NORMAL CONDITION. Where a ventilation system's design makes it unlikely that it will be completely blocked in NORMAL USE, such blockages should not be considered. The only way to find the maximum leak rate that needs to be considered is to find the minimum leak rate that can safely be detected by the RESPONSIBLE ORGANIZATION.

Subclause 11.2.2.1 b) 3)

The cause of the HAZARDOUS SITUATION is: a leak occurs and is not detected; some time later an electrical failure occurs that starts an ignition. The time interval t_c for checking the seals can be calculated as follows:

– estimate the probability per time p_e of an electrical failure that exceeds the values given in 11.2.2.1 a);
– estimate the probability per time of the oxygen leak p_o ;
– determine the accepted probability of dangerous failures per time r ;
– calculate: $t_c = r / (0{,}5 \times p_e \times p_o)$.

Subclause 11.2.2.2 – External exhaust outlets for OXYGEN RICH ENVIRONMENT

Serious oxygen fires have been reported where the ignition source has been a faulty electrical connector close to an oxygen outlet.

Subclause 11.3 – Constructional requirement for fire ENCLOSURES of ME EQUIPMENT

The requirements for fire ENCLOSURES from IEC 61010-1 [22] have been included primarily as an alternate to the tests related to SINGLE FAULT CONDITIONS (associated with combustion and

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its consequences listed in Clause 13). By requiring flame resistance for the ENCLOSURE and materials contained within it, the probability of occurrence of fire escaping such ENCLOSURES is considered minimal. Where the fire ENCLOSURE constitutes only a part of the ME EQUIPMENT, careful analysis should be performed to assure that a reliable barrier to the propagation of fire exists.

IEC 60950-1:2005 components (i.e. power supplies, modems, network routers, etc.) are allowed to be integrated into ME EQUIPMENT when MOOP insulation has been determined to be adequate and TOUCH CURRENT limits have been satisfied.

The flame resistance requirements for wire insulation, when used inside a fire ENCLOSURE, in accordance with IEC 60950-1:2005, subclause 4.7.3.4, are:

– Minimum of FV-2 when tested in accordance with IEC 60695-11-10, or
– insulated with PVC, TFE, PTFE, FEP, polychloroprene or polyimide.

While the ME EQUIPMENT flame resistance requirement of FV-1 for wire insulation when used inside a flame enclosure is slightly more stringent than the IEC 60950-1:2005, subclause 4.7.3.4 requirement, it would seem reasonable to conclude an equivalent level of risk should IEC 60950-1 compliant wire be integrated into the ME EQUIPMENT or ME SYSTEM either:

– indirectly when IEC 60950-1 components have been integrated into the ME EQUIPMENT or ME SYSTEM, or
– directly as part of a wire selection decision for the ME EQUIPMENT or ME SYSTEM.

IEC 61010-1:2010 [22], subclause 9.3.2, requires wire insulation when used inside a fire enclosure to have a UL 2556 [72] rating of VW-1, or comply with the applicable requirements of IEC 60332-1-2 [55] or IEC 60332-2-2 [56]. These wire flame resistance requirements are considered acceptable for ME EQUIPMENT and ME SYSTEMS.

Subclause 11.4 – ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics

While the use of flammable anaesthetics is uncommon, it was determined during the writing of this edition that some MANUFACTURERS might still want to rate their ME EQUIPMENT as CATEGORY AP or CATEGORY APG. In order to make this edition more usable (by removing the rarely used section on this topic) while maintaining the availability of the CATEGORY AP and CATEGORY APG RATINGS, the material has been moved to an annex and only this clause's brief reference to it remains in the body of the standard.

The final determination of whether ME EQUIPMENT should be RATED CATEGORY AP or CATEGORY APG should be determined by the MANUFACTURER based on the INTENDED USE. Requirements related to CATEGORY AP and CATEGORY APG are found in Annex G (see also the rationale for Annex G).

Subclause 11.5 – ME EQUIPMENT and ME SYSTEMS intended for use with flammable agents

While it was necessary to address cases where ME EQUIPMENT is used with flammable agents (such as some disinfectants) or in areas where they are commonly used and where the MANUFACTURER of the ME EQUIPMENT has given no special handling instructions or precautions, the variety of such agents, their volatility as well as many other determinant factors precludes giving specific instructions. The only reasonable solution in such cases is to assure that the MANUFACTURER evaluates and addresses the associated RISK.

A mixture of the vapour of a flammable disinfection or cleaning agent with air can be treated as a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR subject to national or local regulations.

Subclause 11.6.2 – Overflow in ME EQUIPMENT

The purpose of this test is to assess not only whether the liquid actually wets any parts in a way that would adversely affect a MEANS OF PROTECTION or result in a HAZARD; but also

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whether a similar amount of liquid that could overflow on another occasion and reach the same parts of the ME EQUIPMENT, but possibly not land in exactly the same way, could adversely affect a MEANS OF PROTECTION or result in a HAZARD. The results of the test should be evaluated to assure they realistically represent conditions that will be experienced when the ME EQUIPMENT is used.

Subclause 11.6.3 – Spillage on ME EQUIPMENT and ME SYSTEMS

In addition to ME EQUIPMENT that requires the use of fluids some ME EQUIPMENT is exposed to fluid spills as part of REASONABLY FORESEEABLE MISUSES. In such cases spillage is considered NORMAL USE and the associated RISKS are addressed by the requirements of this subclause. Furthermore, as described in 9.4.2, tilting of TRANSPORTABLE ME EQUIPMENT to an angle of 10º is considered NORMAL USE. In such cases (as well as for ME EQUIPMENT requiring fluids) the amount and location where spills can occur vary greatly. Only a proper evaluation of the ME EQUIPMENT being tested can determine an appropriate application of the requirement. Doing such an evaluation is the responsibility of the MANUFACTURER and the results are to be provided to those performing the test (typically in the RISK MANAGEMENT FILE). This requirement would be an appropriate area for evaluation by writers of particular standards.

In accord with the principles outlined in IEC 62366, where explicit warnings or safety notices (validated as described in IEC 62366) are given, failure to heed such warnings or safety notices is considered abuse of the ME EQUIPMENT that is beyond the responsibility of the MANUFACTURER. Therefore where such warnings or safety notices are given, the liquid reservoir is filled only to the intended fill level before being tilted to 10º. Where they are not given, the liquid reservoir is filled 15% above the intended level.

Examination of the NORMAL USE of ME EQUIPMENT should provide an adequate estimate of the amount of fluid that is likely to be spilled on it.

Spillage for equipment that does not require the use of fluids is considered to be a SINGLE FAULT CONDITION.

Subclause 11.6.4 – Leakage

Leakage is considered to be a SINGLE FAULT CONDITION.

Subclause 11.6.5 – Ingress of water and particulate matter into ME EQUIPMENT and ME SYSTEMS

Although it is unlikely that ME EQUIPMENT would be RATED for protection against particulate matter, IEC 60529 does address the possibility and it should be considered a valid option. The presence of any water or particulate matter inside the ENCLOSURE after testing in accordance with its IEC 60529 classification is regarded as a NORMAL CONDITION. The requirement is therefore to assess the possibility of a HAZARDOUS SITUATION due to such ingress in combination with a possible SINGLE FAULT CONDITION (such as an interrupted PROTECTIVE EARTH CONNECTION).

Subclause 11.6.8 – Compatibility with substances used with the ME EQUIPMENT

ME EQUIPMENT, ACCESSORIES and parts thereof should be designed to be used safely with the substances with which they are intended to come into contact in NORMAL USE.

Where appropriate, particular standards should specify the corresponding requirements.

Subclause 11.8 – * Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Interruption of the power supply could result in a HAZARDOUS SITUATION due to loss of functionality. This HAZARDOUS SITUATION is dealt with in 7.9.2.4. Restoration of the power source can also result in HAZARDOUS SITUATIONS. Examples could include unintended activation of moving parts or resumption of dangerous outputs. These potentially HAZARDOUS SITUATION and the duration of the power interruption that could result in the HAZARDOUS SITUATIONS need to be considered as part of the RISK MANAGEMENT PROCESS.

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IEC 61000-4-11 [21] defines general and reproducible conditions for the operation of electrical and electronic equipment if they undergo voltage dips, short interruptions and voltage variations. The voltage level and duration of short interruptions are defined in Tables 210 and 211 of IEC 60601-1-2:2001. IEC 60601-1-2 treats these short interruptions as a NORMAL CONDITION.

For ME EQUIPMENT in which the safety of the PATIENT depends on the continuity of the power, particular standards should include requirements regarding power failure alarms or other precautions.

Clause 12 – Accuracy of controls and instruments and protection against hazardous outputs

IEC 60601-1 is the guideline for all particular standards and, therefore, contain some requirements of a more general character in order to serve this purpose. For this reason, it is necessary to have some generally formulated requirements in Clause 12.

Standardization bodies, including those outside IEC, have adopted the system of this IEC publication in order to have a single uniform system of standards. In such cases it is most important to give a guideline in this clause.

This clause introduces the concept of USABILITY. The term was chosen over the commonly used terms of “user error” or “human error” because not all errors are the result of oversight or carelessness on the part of the OPERATOR of the ME EQUIPMENT. All too frequently, use errors are the direct result of poor human interface design that seduces the OPERATOR into an incorrect decision. Use errors caused by inadequate USABILITY have become an increasing cause for concern. The USABILITY ENGINEERING PROCESS described in IEC 60601-1-6 is intended to achieve reasonable USABILITY, which in turn is intended to minimise use errors and to minimise use associated RISKS.

Subclause 12.4.1 – Intentional exceeding of safety limits

If the control range of ME EQUIPMENT is such that the delivered output in a part of the range considerably differs from the output that is regarded as non-hazardous, means should be provided that prevent such a setting or that indicate to the OPERATOR (for example by means of an apparent additional resistance when the control is set or the bypassing of an interlock) that the selected setting is in excess of a safety limit.

Where appropriate, particular standards should specify safe output levels.

Subclause 12.4.3 – Accidental selection of excessive output values

Protection for the accidental selection of excessive output values can be obtained by appropriate steps to minimise the possibility to accidentally select excessive output, e.g. by interlocks in order to achieve deliberate action or by separated output terminals. In considering the measures for protection, the standard on human factors could be taken into account.

Clause 13 – HAZARDOUS SITUATIONS and fault conditions

ME EQUIPMENT or its parts could result in HAZARDOUS SITUATIONS due to abnormal operation or fault conditions, which, therefore, needs to be investigated. While this clause identifies specific fault conditions, 4.7 requires that the RISK ANALYSIS be used to identify other failures which should be investigated.

Subclause 13.1.1 – General

While separation requirements (CREEPAGE DISTANCES and AIR CLEARNACES) and insulation requirements are detailed in Clause 8, these requirements should not be viewed as applying only to RISKS associated with electrical HAZARDS. In addition to the potential for electric

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currents to cause fibrillation (due to electric shock), these currents can also be the root cause of injuries not directly related to electric shock.

Examples of these other HAZARDS (related to inadequate or faulty insulation or short circuits across physical spacing used as insulation) could include sparks that could become a source of ignition of flammable materials (as discussed in Clause 11) or functional failures that could cause a loss of ESENTIAL PERFORMANCE. In these cases, compliance with the insulation requirements of Clause 8 should always be considered evidence that RISKS arising from the failure of insulation or spacing have been adequately addressed when evaluating the safety of ME EQUIPMENT.

Finally, it should be noted that the requirements for CREEPAGE DISTANCES and AIR CLEARNACES are not intended to be required at the circuit board level where there is no significant RISK that spacings will be compromised (shorted) by contaminates (from NORMAL USE or the manufacturing PROCESS) such as fluids or particulate matter (see also IEC 60529). In most applications, spacing between (for example) circuit board traces and component leads are not considered likely to fail. In cases where there is doubt as to whether spacing could fail (wherethe CREEPAGE DISTANCE and AIR CLEARNACE requirements of 8.9 are not met), the MANUFACTURER'S RISK ANALYSIS should evaluate the likelihood of shorting across such gaps, but only where such short-circuiting could directly result in unacceptable RIRKS. Where shorting across spacing or insulation failures are clearly not likely to result in unacceptable RISKS, such analysis should not be required.

Subclause 13.1.2 – Emissions, deformation of ENCLOSURE or exceeding maximum temperature

The delivery of unintended hazardous quantities of energy or substances to a PATIENT or into the natural environment could be addressed by particular standards.

Hazardous quantities of poisonous or ignitable gas depend on the type of gas, concentration, place of emission etc.

SINGLE FAULT CONDITIONS that might result in a small fire, but where the fire would remain contained within a fire ENCLOSURE, are acceptable because the containment will limit the effects to the area inside of the fire ENCLOSURE.

The power level (15 Watts) cited in the original publication of this standard as the threshold below which ignition will not occur in normal ambient concentrations of oxygen was found to be significantly below the level used in IEC 61010-1 [22]. The original 15 W value was not based on any scientific test or research but came from "common practice" at some certification bodies (an anecdotal value only).

However, IEC 60950-1 provides a variety of energy levels based on voltage ranging from 100 VA to 150 VA. For purposes of simplicity, the lowest of these values (100 VA) with minimal restrictions on construction were used as an alternative to the 15 W limit (without construction restrictions) originally used in this standard for ME EQUIPMENT in general.

Direct application of the requirements for limited energy circuits in IEC 60950-1 can also be considered to assure that the RISK of fire has been reduced to acceptable levels at higher energies to demonstrate equivalent safety as well.

Since facilities where ME EQUIPMENT compliant with this standard is used will also contain information technology equipment (compliant with IEC 60950-1) and such equipment can be part of ME EQUIPMENT or ME SYSTEMS, it would be unreasonable to require the ME EQUIPMENT to offer a higher level of protection against ignition than does the other equipment used in the same environment.

It is felt that limiting the maximum temperatures for APPLIED PARTS to the NORMAL CONDITION values is appropriate because exceeding them is known to result in HARM and the PATIENT is frequently unable to pull away.

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The restrictions of this subclause are regarded to be sufficient to avoid an enduring fire. A fire is not only dangerous by itself but has side effects such as destroying isolation barriers or destroying mechanical stability. These cannot be taken into account by the above limitations. Therefore, the MANUFACTURER needs to consider the following when coming to a conclusion:

– Obviously a limitation of 100 VA cannot guarantee 'no ignition'. Smaller components such as resistors, semiconductors etc. can be exposed to levels of power that could cause ignition. However, standards such as IEC 60950-1 and IEC 61010-1 and experience demonstrate that when such situations arise if the components are mounted on FV1 rated material an enduring fire is very unlikely to occur.

– Ignition could destroy isolation barriers exposing hazardous voltages. A device which is designed according to the requirements of this subclause should still be checked to determine whether such barriers would be affected and whether additional appropriate precautions independent of the requirements of this subclause.

  Since no enduring fire will occur, the mechanical stability is regarded as maintained.

Subclause 13.2.9 – Interruption and short circuiting of motor capacitors

The effect of functioning centrifugal switches can be taken into account. A locked rotor condition is specified because some capacitor motors might or might not start, causing variable results. Capacitor voltage is checked to assure that its dielectric will not be stressed causing the accumulation of hazardous gases including hydrogen.

While the short circuit or open circuit of the capacitor is a SINGLE FAULT CONDITION and locking of the rotor is also a SINGLE FAULT CONDITION (see 13.2.8) this is regarded as an instance of the situation referred to in 4.7, where one SINGLE FAULT CONDITION can result unavoidably in another SINGLE FAULT CONDITION and the two failures are considered as one SINGLE FAULT CONDITION.

Subclause 13.2.10 – Additional test criteria for motor operated ME EQUIPMENT and Table 26, last line

Temperature limits of motor windings in ME EQUIPMENT are determined after the first hour as an arithmetic average because experience of test houses has shown that ME EQUIPMENT for non-CONTINUOUS OPERATION reaches variable values that could temporarily differ from the maximum values. Therefore, lower temperature limits are required. The values in Table 26 are based on the requirements of IEC 60950-1:2005.

Subclause 13.2.13.1 – General overload test conditions

The ball pressure test is not intended to represent the exact conditions experienced in use. The test is performed at elevated temperatures to test the robustness (adequate safety factor) of the mechanical properties of the insulation. The principle is not unlike dielectric withstand testing which subjects insulation to voltages far in excess of those seen in use.

Subclause 13.2.13.4 – ME EQUIPMENT RATED for non-CONTINUOUS OPERATION

Where ME EQUIPMENT or parts thereof are RATED for non-CONTINUOUS OPERATION but controls allow OPERATORS to leave it in operation (should a medical or other emergency occur), the CONTINUOUS OPERATION of the ME EQUIPMENT is considered reasonably foreseeable misuse. Where safety is dependent on switching the ME EQUIPMENT or parts thereof off after a prescribed period, steps should be taken to assure that intentional action is not required to do so.

Clause 14 – PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Computers are increasingly used in ME EQUIPMENT, often in safety-critical roles. The use of computing technologies increases the level of complexity in ME EQUIPMENT. This complexity means that systematic failures can escape the practical limits of testing. Accordingly, this clause goes beyond traditional test and measurement of the finished ME EQUIPMENT and includes requirements for the PROCESSES by which it is developed. Testing of the finished

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product is not, by itself, adequate to address the safety of PROGRAMMABLE MEDICAL ELECTRICAL SYSTEMS.

For these reasons, this clause requires that a PROCESS with specific elements be established and followed. The intention is to establish these specific PROCESS elements, leaving the user of this clause to determine in detail how to accomplish them. This is similar to the approach taken in the ISO 9000 series. Because users of this clause are expected to be qualified to perform the identified activities, detail has been kept to a minimum.

While iteration of some elements of the PROCESS is expected, no specific requirements to do so have been included. These requirements were omitted because the need to repeat PROCESSES or portions of them is unique to each particular device. In addition, the need for such iteration will arise from the more detailed understanding that emerges during the design PROCESS.

Because users of this standard are required to establish, maintain and apply a RISK MANAGEMENT PROCESS as part of compliance, this clause establishes those characteristics unique to programmable systems that should be considered as part of that PROCESS. Requirements for development and modification of medical device software have been specified in IEC 62304. The requirements from IEC 62304 that apply to development prior to placing a product in service are included by reference for the PEMS software.

There are some requirements in IEC 62304 that apply to software maintenance after a product has been placed into service. These requirements have not been included in the reference.

The effective application of Clause 14 will require, subject to the task in hand, competence in the following:

– application of the specific ME EQUIPMENT with emphasis on safety considerations;
– ME EQUIPMENT development PROCESS;
– methods by which safety is assured;
– techniques of RISK ANALYSIS and RISK CONTROL.

Requirements have been minimized to those that are essential to assuring BASIC SAFETY and ESSENTIAL PERFORMANCE. This has been done in recognition of the extensive and growing literature in the fields of software assurance and RISK ASSESSMENT techniques as well as the rapid evolution of this discipline.

Subclause 14.1 – General

This standard requires the application of a RISK MANAGEMENT PROCESS in accordance with ISO 14971. This is particularly relevant to PEMS, because of the difficulty of showing the correctness of software or complex hardware. Therefore the design of a PEMS has to be performed within a RISK MANAGEMENT PROCESS, in which RISK CONTROL measures are related to the RISKS being controlled. For a software PESS, the software safety requirements from subclause 4.3 of IEC 62304:2006 and the software RISK MANAGEMENT requirements from Clause 7 of IEC 62304:2006 are included. If the application of RISK MANAGEMENT shows that a PESS has the potential to contribute to a HAZARDOUS SITUATION, and non-software RISK CONTROL measures external to the PESS have not reduced the RISK to an acceptable level, Clause 14 adds extra RISK MANAGEMENT and life-cycle PROCESSES for the PEMS.

Compliance VERIFICATION requires the MANUFACTURER'S internal assessment to cover not only the requirements of this clause but also those of IEC 62304 that have been included by reference.

Compliance with the requirements of Clause 14 is judged by examining the documentation produced by the PROCESSES required in the various subclauses.

The concept of assessment has been introduced in the compliance statement to allow for methods other than inspection where necessary, such as audit. Thus, although there is no

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general requirement for the MANUFACTURER to operate a quality management system in accordance with ISO 13485 [30], certain features of such a system are necessary. One feature that is commonly regarded as essential for a quality management system to be effective is a PROCESS of audit and review performed within the organisation to confirm that it is actually following its own PROCEDURES; this is separate from any external assessment that could be performed to demonstrate compliance with standards or regulatory requirements. This standard, therefore, requires that the MANUFACTURER not only document certain aspects of the design PROCESS but also carry out an assessment to confirm that the requirements of this clause have been followed.

Subclause 14.2 – Documentation

The expected way by which compliance with PROCESS requirements can be determined is by assuring that the documentation required for each PROCESS step has been generated. While most of the requirements of 4.2 are crucial components of an adequate software life-cycle, Clause 14 contains many additional PROCESS steps not required by 4.2. Therefore, the documentation that these additional PROCESS steps (in Clause 14) require is necessary for a certification body to determine that the PROCESS steps have been performed.

Because Clause 14 addresses those RISKS associated with PEMS, this documentation is part of the RISK MANAGEMENT FILE.

Since compliance with Clause 14 is determined by inspection and assessment to assure that the required documentation has been generated, the quality and accuracy of these documents is important. Because demonstration of the safety of a PEMS depends on documentation, an effective system is needed to ensure the integrity of the documentation and, if different versions of a document exist, to identify the applicability of each version. Therefore it is required that the documents be generated, revised and maintained under a formal document control system. MANUFACTURERS should assure that this documentation is clear and comprehensive to assist in the assessment PROCESS.

Subclause 14.3 – RISK MANAGEMENT plan

Subclause 4.2.2 requires that a RISK MANAGEMENT plan be prepared and maintained in the RISK MANAGEMENT FILE.

In addition to elements of the RISK MANAGEMENT plan required by 4.2.2, a PEMS VALIDATION plan is required because validation is seen as a necessary activity when developing a PEMS.

Subclause 14.4 – PEMS DEVELOPMENT LIFE-CYCLE

A documented life-cycle helps ensure that safety issues are considered throughout a product's development. This is important for all products and it is vital for PEMS. Safety cannot be added to a PEMS after it has been developed. Two reasons for this are as follows.

a) The actual PROCESSES used in the development of a PEMS, and the quality and rigour of those PROCESSES, are decided as a result of RISK ASSESSMENT. If it is discovered later on that inappropriate PROCESSES were used or that inadequate quality and rigour were applied, then the development will have to be repeated with correct PROCESSES.

b) Changes made at a late stage in the PEMS DEVELOPMENT LIFE-CYCLE are likely to be expensive (both in time and money). This is particularly true if a system requirement is incorrect or missing. System architecture can also be vulnerable to late changes. Often, the architecture is part of the safety case. Late changes can require significant rework in order to maintain the integrity of an architectural solution.

Framework

A life-cycle for the development of a product provides a framework that allows the necessary safety activities to take place in a timely and systematic manner. It should not impose unnecessary restrictions and it should ensure that all the required safety activities take place. The life-cycle needs to be decided early. Different life-cycle models are acceptable.

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Clause H.2 explains PEMS DEVELOPMENT LIFE-CYCLES in more detail. Clauses 5, 7, 8 and 9 of IEC 62304:2006 describe the PROCESSES to be included in the software development life-cycle for the development of safe medical device software.

Milestones and activities

The requirement for milestones, and activities with inputs and outputs for each, ensures that due consideration is given to:

– the activities,

– what needs to be done before the activity can start, and

– what the activity needs to provide,

so that VERIFICATION of the results can be performed.

The sequence of activities in the life-cycle is required to be defined in terms of milestones because this offers the greatest flexibility to the MANUFACTURER. No requirement is made concerning the number or nature of the milestones, nor is there any implication that all project activities have to pass through the milestones simultaneously. This standard has not used the term “phases” although this term was used in IEC 60601-1-4 [14]. The term has been avoided because it is difficult to express concurrency and overlap in a phase model.

In a good life-cycle:

– the necessary activities are defined in advance of their performance;

– the PROCESSES used in development activities could be specified as an outcome of RISK MANAGEMENT;

– the sequence of activities is defined so as to ensure that necessary inputs to an activity are available before the activity starts;

– criteria are defined for deciding whether the activity has been satisfactorily completed; and

– accountability is facilitated.

Activities are defined in terms of inputs and outputs because it is simple to measure whether those inputs and outputs exist. The MANUFACTURER is responsible for deciding how the milestones are achieved and how the required documentation is produced.

In order to determine whether each activity has been satisfactorily completed, it is required that the criteria for VERIFICATION of each activity be defined. VERIFICATION examines whether the inputs have been transformed into the outputs completely, correctly and according to the required PROCESS. No requirement is made concerning the type or extent of VERIFICATION, except for VERIFICATION of RISK CONTROL measures and ESSENTIAL PERFORMANCE (see 14.10).

Subclause 14.5 – Problem resolution

Where appropriate, a documented system for problem resolution is required by this standard.

Problems can arise:

– with the product;

– within a PROCESS;

– between PROCESSES.

Examples of problems are:

– inconsistent requirements;

– ambiguous requirements;

– missing specifications;

– coding errors;

– incorrect operation of the PEMS.

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A system for problem resolution is needed to ensure that when a problem arises, its impact on HAZARDS and their consequent RISK is managed. Ad hoc methods for resolving problems can undermine the benefits obtained by using a systematic life-cycle approach. An appropriate place to document the system for problem resolution is as part of the PEMS DEVELOPMENT LIFE-CYCLE.

Subclause 14.6.1 – Identification of known and foreseeable HAZARDS

PEMS have extra initiating causes for HAZARDS.

Subclause 14.6.2 – RISK CONTROL

As the choice of the PROCEDURES and tools used by a MANUFACTURER for the development of a PEMS will be influenced by many factors, this subclause requires that one of the factors for the choice is the RISK reduction required for the RISK CONTROL measure. A RISK CONTROL measure that is developed using PROCEDURES and tools that are known to be good is more likely to carry out its intended functions than one developed using PROCEDURES and tools that are of unknown quality.

Subclause 14.7 – Requirement specification

RISK CONTROL measures are used to control the RISK of identified HAZARDS. The requirements for these measures are documented in requirement specifications. The requirement should both specify what the measure does and how well it does it. Subclause 4.2 does not demand a requirements specification.

Verifiable requirements

Requirements should be verifiable. This applies to both the function of the RISK CONTROL measure and how likely it is to perform correctly. Quantitative VERIFICATION of failure rates is, generally, impractical for software. VERIFICATION of a qualitative approach would be by verifying that the appropriate PROCESSES were used.

Identifiable safety requirements

The requirement to distinguish the RISK CONTROL measures and ESSENTIAL PERFORMANCE is needed to ensure that they are implemented and to ensure that if there is a need to change the ESSENTIAL PERFORMANCE or a RISK CONTROL measure, the impact of the change on the RESIDUAL RISK can be assessed.

Decomposition

Examples of a PEMS structure are shown in Annex H. Requirements to implement the RISK CONTROL measures should be specified for the PEMS and for any PESS that implements or partially implements one or more RISK CONTROL measure. This can be in a single document or in several documents.

Subclause 14.8 – Architecture

An architecture specification is not required by 4.2. It is an additional requirement for PEMS because:

– often the architecture chosen will be part of a RISK CONTROL measure. RISK CONTROL measures need to be explicit for complex systems such as a PEMS;

– architecture specifications are recognized as a necessary part of a good software development PROCESS such as is required for a PEMS.

There is a list of architecture features for inclusion in the specification where appropriate. This list has been selected because in particular circumstances one or more of the features could be used to control the RISK of a HAZARD. For example, the use of a COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS will effectively remove any RISK that would result from the failure of that component.

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Subclause 14.8 e)

Partitioning of functionality can be useful when there is a significant need for rigorous safety validation of PEMS.

The software (firmware and application layers) is distinctly divided into critical, non-critical and supervisory sections. Partitioning is used so that the instructions and data of the critical, non-critical and supervisory sections do not interfere with each other and that there is separation of duties among the sections of the software. If there is no separation of duties among the sections of the software, all software should be defined as critical, to make sure that the analysis has taken into consideration the critical section of the software.

Requirements for separating critical code from non-critical code include RISK ASSESSMENT of the entire system, RISK CONTROL strategies employed, analysis of physical resources and an analysis of logical properties (e.g., control and data coupling). In general, partitioning should separate and isolate the safety-related functionality from the non-safety-related functionality in the design and implementation. This PROCESS can minimize, or at least reduce, the VERIFICATION necessary to assure that data shared by or passed to the critical section does not affect the specified operation of the safety critical code.

Partitioning includes the following steps:

a) identification of critical, non-critical and supervisory sections. The means of identification depends upon the modularity of the code, the programming language, the code design and other specification attributes;

b) description of the interfaces between the critical and non-critical sections:

   1) identification of data or variables global to the critical and non-critical sections, modules, etc., identified in step a);

   2) identification of any parameters that are passed between critical and non-critical sections, modules, etc., identified in step a);

   3) description of the flow of the data, variables or parameters identified in steps b) 1) and b) 2);

   4) description of the mechanism which is used to prevent data corruption, overwriting or other errors of the above identified data, variables or parameters which would affect safety critical performance;

c) validation of the integrity of the partition. This can be accomplished by functional testing and stress testing techniques.

Subclause 14.8 g) to n)

There is a list of items to be taken into consideration in the architecture specification. This list has been selected because each of these items could influence the choice of architecture.

Subclause 14.9 – Design and implementation

The technical solutions chosen need to be defined. It is often appropriate to decompose a PEMS into subsystems. Figure H.1 shows examples of PEMS/ PESS structures with different amounts of decomposition. Reasons for decomposing a PEMS could include the following.

Keeping the complexity of subsystems manageable

The less complex the system the easier it is to understand and consequently easier to design and then maintain. The resulting design is more likely to be correct and easier to test. Coding standards should specify limits for complexity.

Architecture

The system architecture could make it logical to separate systems e.g. if diverse systems are needed they should be implemented as distinct subsystems.

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Modularity

Modularity can facilitate the provision of different system options, reuse of an existing proven subsystem and the extension of system functionality.

Physical components

A sensible division of physical subsystems will help the diagnosis and repair of hardware faults.

Different technologies

Often different engineers will implement the hardware and the software design. In this case specifying each as a separate subsystem will enable each to be implemented independently.

The overall system will only function correctly if each of its constituent subsystems has been adequately specified. This leads to the requirement for a design specification for each subsystem. A design specification for a subsystem would typically include a detailed interface specification, and could include implementation details, e.g. algorithms.

Each subsystem should be tested to show that the design specification has been correctly implemented. This leads to the requirement for a test specification for each subsystem.

The design and test specifications can be documented in whatever form is practicable, e.g. they can be separate documents or they can be combined in a larger document. The design specification and the test specification for each subsystem should be identifiable.

Examples of the elements of the design environment are given in H.4 a). Such elements will have an influence on the quality and correctness of the design. Some elements will have been identified as the suitably validated tools and PROCEDURES (see 14.6.2). The descriptive data regarding the design environment facilitates VERIFICATION that the suitably validated tools and PROCEDURES have been used.

Subclause 14.10 – VERIFICATION

Subclause 4.2 requires VERIFICATION of RISK CONTROL measures. There are additional requirements for PEMS. These are that:

– the ESSENTIAL PERFORMANCE is verified; and

– there is a VERIFICATION plan.

ESSENTIAL PERFORMANCE is significant for PEMS because the PEMS uses a PESS to control its functions. ESSENTIAL PERFORMANCE will often depend on the PEMS functions being carried out correctly.

A VERIFICATION plan leaves it up to the MANUFACTURER how to achieve the requirements of this clause. This is a better and more flexible approach than specifying how to verify a PEMS in this clause. The MANUFACTURER is responsible for planning the VERIFICATION so that it is adequately thorough and then to implement the plan.

The requirement lists activities that affect the thoroughness of the VERIFICATION and which need to be planned.

Subclause 14.11 – PEMS VALIDATION

The final phase of any PEMS DEVELOPMENT LIFE-CYCLE model is PEMS VALIDATION. PEMS VALIDATION is intended to assure that the right product is built. Validation is important for PEMS because unexpected interactions between functions might occur that can only be discovered by validation.

PEMS VALIDATION can include tests for a high volume of data, heavy loads or stresses, human factors, security, performance, configuration compatibility, fault testing, documentation and safety.

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Independence is needed to avoid conflicts of interest and because the assumptions of the designer should not influence or limit the extent of the PEMS VALIDATION. Examples of level of independence include:

– separate person;

– separate management;

– separate organization.

Subclause 14.12 – Modification

Typically the design of a PEMS is not completely new but is partly or even largely derived from earlier design(s). Nevertheless, it might be possible to treat the design as if it were completely new and to establish the RISK MANAGEMENT report and demonstrate compliance with the requirements of this standard without reference to previous documentation. If however the RISK MANAGEMENT report does need to include some information from the documentation of the previous design(s), it is then necessary to confirm that all such information remains valid despite the changes introduced in the new design.

Subclause 14.13 – PEMS intended to be incorporated into an IT-NETWORK

Many hospitals are operating ME EQUIPMENT in a networked environment today. Originally, these IT-NETWORKS were installed to optimize business economic and technical area. For this, a fast electronic data interchange is required. Today, these IT-NETWORKS are used for medical applications within the hospital, between hospitals, and from home.

Initially, the use was only the exchange of laboratory data. Now there are large amounts of data transported over the IT-NETWORKS, such as medical image data. There are further requests from the user to get “real time” solutions (e.g. control of operation robots via an IT-NETWORK).

Additional guidance on incorporation of a PEMS into an IT-NETWORK is found in Annex H.

Subclause 15.1– Arrangements of controls and indicators of ME EQUIPMENT

Controls, instruments, indicating lamps, etc. that are associated with a specific function of the ME EQUIPMENT should be grouped together.

Subclause 15.2 – Serviceability

The exchange of such parts is expected to be easy to perform, preferably without special TOOLS. In addition, the disassembly of the worn out part or of the part exchanged preventively and the assembly of the spare one should not result in a HAZARDOUS SITUATION. To ensure this, the instructions for performing such activities have to be easy to understand and to follow, without introducing any RISK of mix-up.

Subclause 15.3.2 – Push test

ENCLOSURES need to have adequate rigidity if they are to maintain a level of protection from internal live parts. This requirement is harmonized with the force test of IEC 60950-1. The force is dependent on the person handling the ME EQUIPMENT, not the weight of the ME EQUIPMENT. In most cases, the application of a force of 250 N is considered reasonably foreseeable. However there can be cases where a RISK ASSESSMENT finds that the 45 N force applied over an area of 625 mm^2, as required by the second edition of this standard, would continue to be an acceptable VERIFICATION method for determining an acceptable level of RISK. For example, ultrasound transducers and similar small HAND-HELD APPLIED PARTS, which balance the needs of robustness with other needs relating to efficacy and biocompatibility,have established track RECORDS of safety and effectiveness over many years, and therefore could continue to use the older VERIFICATION test.

Internal components are not subjected to the force test of IEC 60950-1 because their robustness is verified per the tests of 15.3.4 and 15.3.5.

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Subclause 15.3.3 – Impact test

An ENCLOSURE'S resistance to impact is required to prevent unacceptable RISK during reasonably foreseeable misuse. The energy of the test impact approximates ME EQUIPMENT being accidentally struck by an object in the hand of a passer-by or by a broomstick or mop handle during cleaning of the floor. The test equipment has been simplified and harmonized with other standards containing ENCLOSURE impact requirements, including IEC 60950-1.

Where a MANUFACTURER feels the requirements of this subclause are not necessary to mitigate an unacceptable RISK, justification is documented in the RISK MANAGEMENT FILE per 4.5, along with an identification of alternate requirements met. For example, FIXED ME EQUIPMENT can have one side of the ENCLOSURE protected by the floor, wall or ceiling. The MANUFACTURER documents the evaluation of the probability that the ME EQUIPMENT could be moved or installed incorrectly. The MANUFACTURER also evaluates and identifies, through the RISK MANAGEMENT PROCESS, what resistance to impact the protected side of the ENCLOSURE needs to have to ensure no unacceptable RISKS are generated by failure to comply with the original requirements of this subclause.

Subclause 15.3.4 – Drop test

The tests for HAND-HELD ME EQUIPMENT or its parts that are hand held are different from the test for PORTABLE and MOBILE ME EQUIPMENT because of the difference in practical application.

A drop surface of wood of density > 600 kg/m^3 allows selection of most common hardwoods. Oak, beech, birch, ash and maple are acceptable. These varieties have similar hardness while hardwoods of density < 600 kg/m^3 (e.g. mahogany, elm, sweet gum, cherry) and softwoods have greatly decreased hardness in comparison.

Subclause 15.3.4.2 – PORTABLE ME EQUIPMENT

This test represents NORMAL USE, as explained in the rationale for 15.3.5. This test is not intended to represent reasonably foreseeable misuse. There is not currently a test that directly addresses free fall type reasonably foreseeable misuse, however it is felt the ball impact test in 15.3.3 represents foreseeable misuse, albeit indirectly. As stated in 4.2, if the RISK MANAGEMENT PROCESS concludes that a more severe test is appropriate, this should be done.

Subclause 15.3.5 – Rough handling test

Contrary to what is often assumed, ME EQUIPMENT can be used in a hostile environment. In case of emergency, ME EQUIPMENT is carried or wheeled on trolleys over doorsteps and into elevators and subjected to bumps and vibration. Such conditions can in fact typify NORMAL USE for some ME EQUIPMENT. Encountering obstacles is considered commonplace and quite reasonably foreseeable misuse. Not all obstacles are clearly marked and the OPERATOR cannot always stop the ME EQUIPMENT in time after having become aware of the obstacle

The 0,8 m/s speed together with the severity of the obstacles chosen, are considered to represent worst case reasonably foreseeable misuse levels of stress/shock energies. The intent of tis test is to ascertain the risks from damage caused by rough handling shock/stress. Instability is evaluated in 9.4.

The meaning of "in its normal direction of travel" is the direction(s) the ME EQUIPMENT is likely to travel at the maximum normal speed. For most cases, this would be the forward direction. Some ME EQUIPMENT, such as a bed, is likely to travel in a forward or backward direction, at normal speed, and therefore each test should be considered for each direction.

Subclause 15.3.6 – Mould stress relief test

Many thermoforming PROCESSES can leave residual stresses in plastics. Because polymer chains are held together by weak van der Waals bonds, these residual stresses can result in viscous flow (deformation). Elevated temperature results in weakening of van der Waals bonds and an increase in the rate of viscous flow. Thermoplastics with low melting temperatures, such as polyethylene and polypropylene, are more susceptible to stress relief

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deformation than polymers with higher melting temperatures, such as polycarbonate and polyetheramide.

Compliance should be verified by analysis of the polymer properties, when possible. This VERIFICATION should consist of a documented comparison of the maximum temperature the polymer will be exposed to in NORMAL USE and the polymer manufacturer's recommended temperature use range.

Subclause 15.3.7 – Environmental influences

a) ME EQUIPMENT is often used or stored in environmental conditions that are within the INTENDED USE as declared by the MANUFACTER. In such cases no HAZARD is expected. However the environmental conditions could differ from those declared and still the ME EQUIPMENT is expected to remain safe. To ensure this, the RESPONSIBLE ORGANISATION has to perform the periodic inspection and maintenance prescribed by the MANUFACTURER. These activities are expected to prevent any deterioration of the safety level and also detect signs of commencing of any such deterioration. To ensure this, the instructions for preventive maintenance have to be easy to understand and to follow, without introducing any RISK for mix-ups or for overlooking of safety-relevant symptoms.

b) The exchange of such parts is expected to be easy to perform, preferably without special TOOLS. In addition, the disassembly of the worn out part or of the part exchanged preventively and the assembly of the spare one should not create a HAZARD. To ensure this, the instructions for performing such activities have to be easy to understand and to follow, without introducing any RISK of mix-up.

c) Corrosion of metal to metal interfaces should be taken into account.

Subclause 15.4.3 – Batteries

If a HAZARDOUS SITUATION might develop as a result of exhaustion of the battery, means should be provided to forewarn of this condition.

Where appropriate, particular standards should specify the corresponding requirement.

Subclause 15.4.3.5 – Excessive current and voltage protection

Subclause 4.7 requires the ME EQUIPMENT to be SINGLE FAULT SAFE. One possible fault could be the bridging of a CREEPAGE DISTANCE between the positive and negative terminals of an INTERNAL ELECTRICAL POWER SOURCE in the area between the INTERNAL ELECTRICAL POWER SOURCE and any protective device (see Figure A.23).

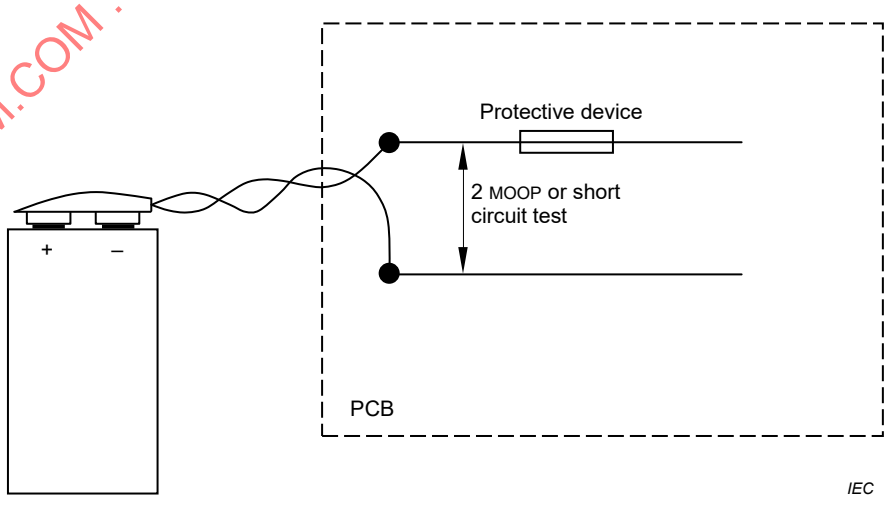


Figure A.23 – Example of the needed MEANS OF OPERATOR PROTECTION between the terminals of an INTERNAL ELECTRICAL POWER SOURCE and a subsequent protective device

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A short circuit test would be required to demonstrate that this area is SINGLE FAULT SAFE unless two MEANS OF OPERATOR PROTECTION are present. In that case, the test can be omitted.

Subclause 15.4.4 – Indicators

It is important for an OPERATOR and SERVICE PERSONNEL to be able to determine the functional status of ME EQUIPMENT. In NORMAL USE, the OPERATOR needs to be able to distinguish between ME EQUIPMENT in stand-by and ME EQUIPMENT in a fully functional state. Some ME EQUIPMENT has an extended warm-up period. Other ME EQUIPMENT has standby or battery charging modes.

It can be hazardous for ME EQUIPMENT to be left unattended in the wrong state. SERVICE PERSONNEL need to be able to determine when ME EQUIPMENT is energized to avoid HAZARDS.

Subclause 15.4.7.3 – Entry of liquids

The former IPX8 rating requirement for foot switches amounts to no more than "greater protection than IPX7." By making this requirement IPX6 minimum, the requirement sets a defined level of protection while allowing higher levels where appropriate.

For equipment used on the floor in areas where liquids are usually not found, the IPX1 requirement is included because it is considered extremely likely that some wetting will occur.

Subclause 15.5 – MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5

The addition of "and transformers providing separation in accordance with 8.5" to the original title that only identified "Mains transformers" is intentional. The tests for transformers should be utilized any time that the transformer is used to establish separation between OPERATORS, PATIENTS, etc. and a HAZARD.

Revisions to 15.5 do not change significantly current methods (including those of the second edition of this standard) of testing. The methods and requirements were simplified and now include all different types of protectors like: PTCs, feedback control (switch mode power supplies), primary or secondary over-current devices, etc. Those transformers that have not been tested in accordance with the 5X frequency and 5X voltage tests of 15.5.2 to establish the adequacy of insulation between the turns of a winding that are shorted at the terminals (rather than external to the transformer) to assure that failure of that insulation will not cause maximum allowable temperatures to be exceeded.

Because of the difficulties that would be encountered when trying to test transformers that are RATED for high frequencies (such as those used in switch mode power supplies), the 2X frequency and voltage tests are specified in those cases as well. The second edition only applied this test where the voltage exceeded 500 V.

Subclause 15.5.1.1 – Transformers

Output windings are required to be "tested in turn" because under overload conditions, testing all windings simultaneously can cause over temperature devices to operate which would not operate if only one winding was being overloaded. A single output winding being overloaded is actually quite likely. Therefore this combination of conditions is considered the likely worst case scenario.

The intent of the requirement is to test under the worst-case condition (nearly always with either a full load or no-load). Such a worst case can be determined through evaluation of the transformer design or by performing a few spot tests. Generally, testing all possible conditions to determine worst case is unnecessary.

The limits of Table 31 are applied at a 25 °C ambient because of the impracticality of performing the overload and short tests inside of a thermal chamber.

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Subclause 15.5.2 – Dielectric strength

It is necessary to raise the frequency of the test voltage in proportion to the voltage to prevent saturation of the magnetic core and consequent very high current.

The electrical insulation between the primary winding and other windings, screens and the core of a MAINS SUPPLY TRANSFORMER is presumed to have been investigated by the dielectric strength tests performed on the assembled ME EQUIPMENT as described in 8.8.3. The dielectric strength tests of 8.8.3 need not be repeated.

Subclause 15.5.3 – Construction of transformers used to provide separation as required by 8.5

The original citation of subclause 5.12 of IEC 61558-1 was made incorrect by modifications to the 61558 series. In reviewing the revised IEC 61558 standards, it was determined that citation of the standard would not reduce the cost of transformers or provide any other benefits since the spacing and dielectric requirements of IEC 60601-1 would be required to be applied to provide MEANS OF PATIENT PROTECTION. For this reason, the citation was deleted, and the principles of the second edition of IEC 60601-1 were employed with reference to spacing and dielectric requirements of the third edition. Where only MEANS OF OPERATOR PROTECTION is required, transformers constructed for use in IEC 60950-1 equipment should be considered acceptable.

Additionally, Annex U of IEC 60950-1:2005 includes requirements relating to the use of triple-insulated winding wire in transformers instead of a separate layer of insulation between windings (as would be traditionally be provided by bobbins for example). Transformers which use this method of separation between windings and which comply with all other requirements of this standard should generally be considered to provide an adequate level of BASIC SAFETY.

Clause 16 – ME SYSTEMS

Increasingly, ME EQUIPMENT is being combined with other pieces of equipment that might not have originally been intended for medical application to create systems where one or more of the elements of the system come into contact with the PATIENT. Clause 16 provides requirements to ensure the safety of the PATIENT who could come into contact with ME SYSTEMS.

Clause 16 on ME SYSTEMS is intended to be used by MANUFACTURERS of combinations of electrical equipment that include one or more items of ME EQUIPMENT. The equipment can be separate items or can be in a single ENCLOSURE or a combination of these cases.

Clause 16 is also intended to be used by personnel from institutions for medical practice who assemble or adapt ME SYSTEMS, as they can become the MANUFACTURER by that action. In this case, engineering expertise in the application of the electrical equipment design standards is required to ensure that the ME SYSTEM complies with all requirements of Clause 16.

More and more, such ME SYSTEMS comprise equipment originally manufactured for use in different specific application fields, not necessarily medical, that are connected with each other in a direct or indirect way. ME EQUIPMENT complying with this standard can be connected with other, non-ME EQUIPMENT. The latter equipment might fully meet the requirements in the safety standards applicable in their specific application field. However, they do not always comply with the safety requirements for ME EQUIPMENT and, thereby, influence the safety of the whole ME SYSTEM. It is for this reason that the MANUFACTURER is required to apply RISK MANAGEMENT to the whole ME SYSTEM. One example of an additional HAZARD is the ignition of fire when an ME SYSTEM containing non-ME EQUIPMENT is used in an OXYGEN RICH ENVIRONMENT, possibly accidentally.

The electrical equipment can be situated either in a medically used room that is intended for diagnosis, treatment or monitoring of PATIENTS, or in a non-medically used room where no medical practice is performed. Within a medically used room, electrical equipment might be placed inside or outside a volume that is defined as PATIENT ENVIRONMENT.

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There are two situations possible in medical practice.

a) Where Clause 16 does not apply

Simultaneously operated ME EQUIPMENT, i.e. different ME EQUIPMENT connected at the same time to a PATIENT but not connected to each other. Such ME EQUIPMENT can influence each other. For example, high-frequency surgical equipment in the operating theatre can influence PATIENT monitoring.

NOTE Assistance can be available from the instructions for use for each ME EQUIPMENT.

b) Where Clause 16 applies

ME SYSTEMS, consisting of ME EQUIPMENT and possibly also non-ME EQUIPMENT, interconnected permanently or temporarily for a certain purpose such as diagnosis or treatment of a PATIENT. Examples: ME SYSTEMS for diagnostic X-ray examination, endoscopes with video camera, PATIENT monitoring, ultrasound equipment with a personal computer, computed tomography or magnetic resonance imaging.

The various parts of such an ME SYSTEM could be situated within the PATIENT ENVIRONMENT or outside it but still within a medically used room, or parts of the ME SYSTEM could be located in a non-medically used room containing, for example, electrical power distribution or data processing equipment.

Subclause 16.1 – General requirements for the ME SYSTEMS

The basic requirement for the safety of ME SYSTEMS is that, after installation or subsequent modification, an ME SYSTEM does not result in an unacceptable RISK. Compliance with the requirements imposed on ME SYSTEMS in this standard will imply that the RESIDUAL RISK is presumed to be acceptable, unless there is OBJECTIVE EVIDENCE to the contrary.

The MANUFACTURER of ME SYSTEMS that can be reconfigured by the OPERATOR or the RESPONSIBLE ORGANIZATION could be challenged to provide information on all possible combinations of the equipment, which could represent an unreasonable burden. RISK MANAGEMENT methods provide a very adequate means of determining which combination of items constitutes the largest RISKS, and which measures need to be taken to provide for the adequate level of safety. Ultimately, compliance testing can be done after assembly of the complete ME SYSTEM.

Appropriate documentation concerning the standards compliance can be a declaration of conformity by the MANUFACTURER or a certificate from a test house.

ME SYSTEMS, by their nature, can be frequently modified; Clause 16 does not apply to the modification of individual items in an ME SYSTEM

Subclause 16.2 – ACCOMPANYING DOCUMENTS of an ME SYSTEM

The documents that accompany an ME SYSTEM intended for DIRECT CARDIAC APPLICATION should provide data on such items as:

– use of rubber gloves;
– use of stop-cocks made of insulating material;
– minimum distances between PATIENT and equipment being part of the ME SYSTEM (PATIENT ENVIRONMENT);
– instructions about how to use the ME EQUIPMENT in the typical medical application, for example, use of a catheter.

For safety reasons, particular attention should be paid to the different levels of RISK when, within the PATIENT ENVIRONMENT, electrodes or other body sensors are used on the PATIENT, externally and internally, including direct connections to the heart.

Possible connections to the heart of a PATIENT should be kept isolated from the equipment.

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The warning not to place MULTIPLE SOCKET-OUTLETS on the floor is to prevent the ingress of liquids and to prevent mechanical damage.

Furthermore, measures should be taken to ensure that, when assembling or modifying an ME SYSTEM incorporating MULTIPLE SOCKET-OUTLETS, these are mounted in such a way as to prevent ingress of liquids and to avoid mechanical damage during NORMAL USE and transportation.

Relevant safety standards for non-ME EQUIPMENT could specify or require disclosure of permissible environmental conditions. Accordingly, the environmental conditions permitted for various items in an ME SYSTEM can be different. The permissible environmental conditions for the ME SYSTEM is to be specified so that no HAZARDOUS SITUATION will arise when operating it within these specified limits.

Subclause 16.3 – Power supply

This requirement is to ensure the safety according to IEC 60601-1 at the ME SYSTEM level.

BASIC SAFETY after assembly is maintained, for example, by one or more of the following measures:

– measures that are built-in within the ME EQUIPMENT, for example, separation of relevant circuits;

– SEPARATION DEVICES provided as ACCESSORIES to the ME EQUIPMENT (see 16.5);

– SEPARATION DEVICES provided as ACCESSORIES to the ME SYSTEM;

– separating transformer;

– additional PROTECTIVE EARTH CONDUCTORS.

Non-ME EQUIPMENT can provide the specified power supply for ME EQUIPMENT in accordance with 5.5 f), 7.9.2.14 and 8.2.1.

Subclause 16.5 – SEPARATION DEVICES

The BASIC SAFETY of some ME EQUIPMENT depends on the precondition that any SIGNAL INPUT/OUTPUT PARTS are connected only to equipment that is specified for this purpose, otherwise LEAKAGE CURRENTS could be increased by unwanted currents flowing through signal cables.

HAZARDOUS SITUATIONS could occur if the SIGNAL INPUT/OUTPUT PART of ME EQUIPMENT is connected to equipment outside the medically used room, possibly in another building and therefore connected to another mains supply branch circuit.

A SEPARATION DEVICE prevents a HAZARDOUS SITUATION to the PATIENT or OPERATOR. Additionally, the inclusion of the SEPARATION DEVICE helps to avoid HAZARDOUS SITUATIONS through malfunction of equipment caused by unwanted currents flowing through cables.

The need for a SEPARATION DEVICE depends on the configuration of the ME SYSTEM.

Subclause 16.6 – LEAKAGE CURRENTS

Relevant standards for some non-ME EQUIPMENT can have limits for TOUCH CURRENTS that are higher than required by Clause 16; these higher limits are acceptable only outside the PATIENT ENVIRONMENT. It is essential to reduce TOUCH CURRENTS when non-ME EQUIPMENT is to be used within the PATIENT ENVIRONMENT. LEAKAGE CURRENT reduction measures can include:

– additional PROTECTIVELY EARTHED parts;

– a separating transformer;

– an additional non-conductive ENCLOSURE.

Interconnecting cables and their connector housings are parts of the ENCLOSURE and therefore the LEAKAGE CURRENT limits within the PATIENT ENVIRONMENT, as required in 16.6.1, are applicable.

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If a MULTIPLE SOCKET-OUTLET without a separating transformer is used, the interruption of its protective earthing could result in TOUCH CURRENTS equal to the sum of the individual EARTH LEAKAGE CURRENTS.

Subclause 16.6.3 – PATIENT LEAKAGE CURRENT

For ME EQUIPMENT, the maximum allowed values for PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT (applicable with several APPLIED PARTS connected to the ME EQUIPMENT) are given in Table 3 and Table 4; see also 8.7.3. An ME SYSTEM is to provide the equivalent level of safety as provided by ME EQUIPMENT within the PATIENT ENVIRONMENT (see 16.1). Therefore, the same maximum values for PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT apply, regardless whether the APPLIED PARTS are connected to the same element of the ME SYSTEM or not. This holds for the operation of the ME SYSTEM in NORMAL CONDITION, as the single fault concept is not applicable to an ME SYSTEM.

It should be noted that combinations of equipment or of APPLIED PARTS, made by the RESPONSIBLE ORGANIZATION or OPERATOR, that are outside the range of combinations indicated by the MANUFACTURER, could lead to HAZARDOUS SITUATIONS. This warning holds in particular when combinations of equipment are used for medical purposes on the same PATIENT, which have not been intended by their MANUFACTURER(S) to be used in such combinations.

Subclause 16.7 – Protection against MECHANICAL HAZARDS

Attention should be paid to the effects of interruptions causing unplanned movements, removal of compression forces, and the safe removal of PATIENTS from the PATIENT ENVIRONMENT when a HAZARDOUS SITUATION occurs.

Subclause 16.9.2.1 – MULTIPLE SOCKET-OUTLET

The second edition of this standard used the defined term “auxiliary mains socket-outlet (AMSO)” to describe a socket-outlet intended for provision of mains supply to other ME EQUIPMENT or to other separate parts of the ME EQUIPMENT. The systems collateral standard, IEC 60601-1-1 [13], defined a term “multiple portable socket-outlet (MPSO)”. The two terms have been combined into a new term, “MULTIPLE SOCKET-OUTLET (MSO).” Subclause 57.2 e) of the second edition required that an AMSO be designed so that it could not accept a MAINS PLUG. An exception for emergency trolleys was allowed. With the combination of the two definitions and the change to 8.11.2 to require any MSO on ME EQUIPMENT to comply with 16.9.2.1, the need for rapid exchange in an emergency situation is reconciled with the need to restrict LEAKAGE CURRENT.

Reassignment of the mains connection for the ME SYSTEM is a dangerous practice and beyond the scope of this clause. See 16.2 for disclosure requirements.

Excessive TOUCH CURRENTS can occur unless casual access for additional equipment connections is impeded or prevented.

Subclause 16.9.2.1 d)

The TOUCH CURRENT of the ME SYSTEM must be less than 500 µA in SINGLE FAULT CONDITION. A separating transformer can be used as a measure to reduce that TOUCH CURRENT. Therefore a separating transformer with BASIC INSULATION is sufficient. The DOUBLE or REINFORCED INSULATION as required for isolating transformers is not needed.

Transformers providing a greater degree of safety e.g. ones constructed to IEC 60601-1 requirements or to the isolating transformer requirements in other parts of the IEC 61558 series, e.g. IEC 61558-2-4 [63] or IEC 61558-2-23 [64], are also acceptable.

The CLASS I requirement for the transformer assembly is necessary to provide connected equipment with a PROTECTIVE EARTH CONNECTION.

Isolation monitoring of the separating transformer is not necessary. SINGLE FAULT CONDITION can be detected during routine maintenance and the occurrence of two independent SINGLE

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FAULT CONDITIONS is of no concern. The transformer construction can be of a type with or without a PROTECTIVELY EARTHED centre tapped secondary winding.

Subclause 16.9.2.2 – PROTECTIVE EARTH CONNECTIONS in ME SYSTEMS

All PROTECTIVE EARTH CONDUCTORS and POWER SUPPLY CORDS should be routed together.

When a MULTIPLE SOCKET-OUTLET is used to construct an ME SYSTEM, each individual item of equipment plugged in to the MULTIPLE SOCKET-OUTLET needs to meet the relevant ME EQUIPMENT or non-ME EQUIPMENT requirements. The total protective earth impedance when tested as a complete system according to 8.6.4 needs to meet the highest impedance requirement from 8.6.4. a) (i.e. shall not exceed 200 mΩ). This might require measures such as using short power supply cords within the ME SYSTEM and using a system POWER SUPPLY CORD of greater cross sectional area than is necessary for current carrying purposes to reduce its protective earth impedance. It is unacceptable practice to connect MULTIPLE SOCKET-OUTLETS in series.

Within the PATIENT ENVIRONMENT it is important to limit potential differences between different parts of an ME SYSTEM, and an adequate connection with a protective earthing system plays an important role in limiting that potential difference. It is therefore important to prevent interruption of that protective means to any part of the ME SYSTEM.

– The additional protective earthing could be used when the TOUCH CURRENT in SINGLE FAULT CONDITION exceeds the allowable limits.
– The additional protective earthing is not necessary for ME EQUIPMENT complying with this standard. However, in the case of non-ME EQUIPMENT this will prevent TOUCH CURRENTS exceeding allowable limits.
– The use of a TOOL is not required to disconnect the MAINS PLUG because the MAINS PLUG will disconnect both the mains and the protective earth.

Clause 17 – Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1-2 specifies electromagnetic immunity test levels to minimize the effect of the electromagnetic environment on the ME EQUIPMENT and ME SYSTEMS covered by this standard. It specifies electromagnetic emissions limits to minimize the effect on other equipment of electromagnetic disturbances that could be emitted, intentionally or unintentionally, by ME EQUIPMENT and ME SYSTEMS. It also specifies requirements for identification, marking and documents so that the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM provides information to the RESPONSIBLE ORGANIZATION that is essential in determining the suitability of the ME EQUIPMENT or ME SYSTEM for the electromagnetic environment of use, and in managing the electromagnetic environment of use to permit the ME EQUIPMENT or ME SYSTEM to maintain BASIC SAFETY and provide its ESSENTIAL PERFORMANCE without disturbing other equipment.

Electromagnetic emission requirements are necessary for the protection of:

– safety services (e.g. police, fire and ambulance communications);
– other ME EQUIPMENT and ME SYSTEMS;
– non-ME EQUIPMENT (e.g. computers);
– telecommunications (e.g. radio/TV, telephone, radio-navigation).

More importantly, electromagnetic immunity requirements are necessary to assure that ME EQUIPMENT and ME SYSTEMS maintain BASIC SAFETY and continue to provide their ESSENTIAL PERFORMANCE in the presence of the electromagnetic disturbances to which they can be expected to be exposed during NORMAL USE.

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Annex G – Protection against HAZARDS of ignition of flammable anaesthetic mixtures (see also the rationale for 11.4)

Section six of the second edition of this standard has been moved to a normative annex. This was done in recognition of the fact that flammable anaesthetics are rarely used and their use is expected to cease entirely within a short period. However, it is also recognized that the practice of medicine changes frequently and that even now some MANUFACTURERS might still want to offer ME EQUIPMENT for such applications. In order to assure that the material contained in Section six along with the associated CATEGORY AP and CATEGORY APG RATINGS remain available while improving the readability of the standard for most users, the material has been moved to Annex G.

Subclause G.1.3 – Requirements for ME EQUIPMENT

The most devastating accidents with flammable anaesthetic agents occur when the mixture of the agent with oxygen normally used is that which will cause the most rapid combustion, a state that sometimes is described as “detonation optimum.” The worst example of such an agent is cyclopropane, while the oxygen/ether mixture normally used is far below that point.

Subclause G.5.3 – Low-energy circuits

The graphs of Figure G.1, Figure G.2 and Figure G.3 are given to assist in the design of circuits that fulfil the requirements for allowable limits stated for CATEGORY AP ME EQUIPMENT without performing the ignition test.

Extrapolation for higher voltages is not valid because the ignition condition of gases changes at higher voltages. The limit for inductances is introduced because high inductance values generally produce higher voltages.

Subclause G.5.4 – External ventilation with internal overpressure

The amount of air or inert gas escaping from the ME EQUIPMENT by leakage is assumed to be limited so that hygienic conditions in the medically used room are not disturbed appreciably.

For the purposes of G.5.4 and G.5.5 the term “enclosure” can represent either the ENCLOSURE as defined in 3.26 or a distinct compartment or housing.

Subclause G.5.5 – ENCLOSURES with restricted breathing

Subclause G.5.5 a)

This requirement is regarded as sufficient to prevent ignition in NORMAL USE during an operational period of several hours since average conditions in NORMAL USE are less stringent.

Subclause G.6.2 – Power supply

This requirement prevents the introduction of voltages higher than those permitted by G.6.3. Such voltages can exist on earth wiring.

Subclause G.6.3 – Temperatures and low-energy circuits

The graphs of Figure G.4, Figure G.5 and Figure G.6 are given to assist in the design of circuits that fulfil the requirements for allowable limits stated for CATEGORY APG ME EQUIPMENT, without performing the ignition test.

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Annex B
(informative)

Sequence of testing

B.1 General

Tests should, if applicable, be performed in the sequence indicated below, unless otherwise stated by particular standards. See also 5.8.

However, this does not preclude the possibility of conducting a test that preliminary inspection suggests might cause failure.

The tests for radiation HAZARDS in Clause 10, biocompatibility in 11.7, USABILITY in 12.2, ALARM SYSTEMS in 12.3, PEMS in Clause 14 and electromagnetic compatibility in Clause 17 can be performed independently from the tests in the following sequence.

The tests specified for ME SYSTEMS in Clause 16 should be performed in the same sequence as the tests for ME EQUIPMENT.

B.2 RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS and ESSENTIAL PERFORMANCE

See 4.2 and 4.3.

B.3 General requirements

See 4.1, 4.5 to 4.10 (inclusive) and 5.1 to 5.7(inclusive).

B.4 Classification of ME EQUIPMENT and ME SYSTEMS

See Clause 6.

B.5 Determination of APPLIED PARTS and ACCESSIBLE PARTS

See 5.9.

B.6 ME EQUIPMENT identification, marking and documents

See 7.2 to 7.8.2 (inclusive), Annex C.

B.7 Energy consumption (power input)

See 4.11.

B.8 Limitation of voltage, current or energy

See 8.4.

B.9 Separation of parts

See 8.5.1 to 8.5.4 (inclusive).

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B.10 CREEPAGE DISTANCES and AIR CLEARANCES

See 8.9.

B.11 HAZARDS associated with moving parts

See 9.2 except 9.2.2.4.1.

B.12 HAZARD associated with surfaces, corners and edges

See 9.3.

B.13 Serviceability

See 15.2.

B.14 Accuracy of controls and instruments and protection against hazardous outputs

See 12.1 and 12.4.

B.15 Instability HAZARDS

See 9.4.

B.16 Noise, vibration and acoustic energy

See 9.6.

B.17 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

See 11.8.

B.18 Protective earthing, functional earthing and potential equalization of ME EQUIPMENT

See 8.6.

B.19 Excessive temperatures in ME EQUIPMENT

See 11.1.

B.20 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS and dielectric strength at steady-state operating temperature

See 8.4.2 and 8.7 and 8.8.3.

B.21 Humidity preconditioning treatment

See 5.7.

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B.22 LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS and dielectric strength after humidity preconditioning at ambient temperature in the laboratory

See 8.4.2 and 8.7 and 8.8.3.

B.23 Defibrillation protection

See 8.5.5.

B.24 Expelled parts HAZARD

See 9.5.

B.25 Pressure vessels and parts subject to pneumatic and hydraulic pressure

See 9.7.

B.26 HAZARDS associated with support systems

See 9.8.

B.27 Mechanical strength

See 15.3 and 9.2.2.4.1.

B.28 HAZARDOUS SITUATIONS and fault conditions

See Clause 13.

B.29 MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5

See 15.5.

B.30 ME EQUIPMENT components and general assembly

See 15.4 and 8.10.

B.31 MAINS PARTS, components and layout

See 8.11.

B.32 Insulation other than wire insulation

See 8.8.4.

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B.33 Fire prevention and constructional requirements for fire ENCLOSURES of ME EQUIPMENT

See 11.2 and 11.3.

B.34 Overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT

See 11.6.

B.35 CATEGORY AP and CATEGORY APG ME EQUIPMENT

See 11.4 and Annex G.

B.36 VERIFICATION of markings

See 7.2 to 7.8.2 (inclusive), Annex C and 7.1.

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Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

The requirements for marking on the outside of ME EQUIPMENT and its parts are found in 7.2. Additional requirements for marking on the outside of ME EQUIPMENT, ME SYSTEMS and their parts are found in the subclauses listed in Table C.1. Symbols and safety signs used in marking on the outside of ME EQUIPMENT are found in Annex D.

Table C.1– Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts [12)]

Description of marking	Subclause
CATEGORY APG ME EQUIPMENT: marking of	G.3.1
CATEGORY AP ME EQUIPMENT: marking of	G.3.2
CATEGORY AP and APG: marking of major parts	G.3.3
CATEGORY AP and APG ME EQUIPMENT: marking of parts	G.3.5
Depressurizing pressure system elements: warning about	9.7.2
Emergency stop device actuator: marking of	9.2.4
Hazardous voltage: warning of	8.11.1 i)
Mass of PATIENT, if designed for less than 135 kg: marking of	9.8.3.1
Moving parts: warning of	9.2.1
MULTIPLE SOCKET-OUTLET: marking of	16.9.2.1 b)
Overbalancing during transport: warning about	9.4.2.2
POTENTIAL EQUALIZATION CONDUCTOR terminal: marking of	8.6.7
Prohibition against pushing, leaning, resting: warning of	9.4.2.3 a)
Prohibition against sitting or stepping: warning of	9.4.2.3 b)
Reservoir or liquid storage chamber: marking of overflow HAZARD	11.6.2
MECHANICAL PROTECTIVE DEVICE intended to function only once: marking of	9.8.4.3
Separating transformer assembly: marking of	16.9.2.1 d)
Surfaces where application of force results in a RISK of overbalancing: marking of	9.4.2.3
Transport conditions: warning for	9.4.2.2

C.2 Marking on the inside of ME EQUIPMENT, ME SYSTEMS or their parts

The requirements for marking on the inside of ME EQUIPMENT and its parts are found in 7.3. Additional requirements for marking on the inside of ME EQUIPMENT, ME SYSTEMS and their parts are found in the subclauses listed in Table C.2. Symbols used in marking on the inside of ME EQUIPMENT are found in Annex D.

12) See 7.2.1 for the minimum requirements for marking on ME EQUIPMENT and on interchangeable parts.

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Table C.2 – Marking on the inside of ME EQUIPMENT, ME SYSTEMS or their parts

Description of marking	Subclause
Hazardous energies: marking of capacitors or the connected circuit parts	8.4.4
Hazardous voltage: marking of parts	8.11.1 i)
MAINS TERMINAL DEVICES: marking of terminals other than terminal blocks	8.11.4.1
Marking of pressure vessels and pipes: national certification mark	9.7.5
Separating transformer assembly: marking of	16.9.2.1 d)

C.3 Marking of controls and instruments

The requirements for marking of controls and instruments are found in 7.4. Additional requirements for marking of controls and instruments are found in the subclauses listed in Table C.3.

Table C.3 – Marking of controls and instruments

Description of marking	Subclause
Controls: scale marking of	15.4.6.1 b)
Varying the temperature setting of THERMOSTATS: clear indication of	15.4.2.2

C.4 ACCOMPANYING DOCUMENTS, general

The requirements for general information to be included in the ACCOMPANYING DOCUMENTS are found in 7.9.1. Additional requirements for general information to be included in the ACCOMPANYING DOCUMENTS are found in the subclauses listed in Table C.4.

Table C.4 – ACCOMPANYING DOCUMENTS, general

Description of requirement	Clause
CATEGORY AP and CATEGORY APG ME EQUIPMENT and parts	G.3.4
CLASS II ME EQUIPMENT with isolated internal screens: explanation of	8.6.9
Defibrillation voltage, any necessary recovery time	8.5.5.1 b)
Fixing of structures to floor, wall, ceiling, etc.	9.8.1
Instability excluding transport: placement and loading of doors, drawers and shelves	9.4.2.2 e)
IT-NETWORK: instructions for connecting ME EQUIPMENT	14.13
Isolation device: requirements for	8.11.4.4
Lifting points: indication of	9.4.4 a)
Mass of PATIENT, if support systems designed for less than 135 kg	9.8.3.1
Mass of PATIENT, if support systems designed for more than 135 kg	9.8.3.1
MECHANICAL PROTECTIVE DEVICE intended to function only once: instruction to call SERVICE PERSONNEL	9.8.4.3
ME EQUIPMENT: placement of SAFE WORKING LOAD	9.4.2.4.3
ME SYSTEMS: addition requirements	16.2
Noise: protective means	9.6.2.1 b)
Passing over an obstruction: instructions for	9.4.2.4.3
Working conditions	5.4 a)

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C.5 ACCOMPANYING DOCUMENTS, Instructions for use

The requirements for information to be included in the instructions for use are found in 7.9.2. Additional requirements for information to be included in the instructions for use are found in the subclauses listed in Table C.5.

Table C.5 – ACCOMPANYING DOCUMENTS, instructions for use

Description of requirement	Subclause
ACCESSIBLE PARTS: instruction not to touch them and the PATIENT simultaneously	8.4.2 c)
ACCESSIBLE PARTS: instructions to the OPERATOR to open ACCCESS COVERS	8.4.2 c)
APPLIED PARTS (hot or cold): temperatures and clinical effects of	11.1.2.1
APPLIED PARTS not intended to deliver heat: temperature exceeding 41 °C	11.1.2.2
Cleaning or disinfection PROCESSES: specification of	11.6.6
Effect of multiple cleanings/disinfections	11.6.6
Foot-operated controls: intended for use in areas where liquids are likely to be found	15.4.7.3 b)
Mass of ACCESSORIES	9.8.3.1
ME SYSTEMS: other equipment intended to provide power to ME EQUIPMENT	16.3
MOBILE ME EQUIPMENT: requirement that more than one person is needed to move	9.4.2.4.2
Moving parts: warning of	9.2.1
POTENTIAL EQUALIZATION CONDUCTOR terminal: information on the function and use of	8.6.7
Reservoir or liquid storage chamber: information on overflow HAZARD	11.6.2
Transport conditions: warning for	9.4.2.2

C.6 ACCOMPANYING DOCUMENTS, technical description

The requirements for information to be included in the technical description are found in 7.9.3. Additional requirements for information to be included in the technical description are found in the subclauses listed in Table C.6.

Table C.6 – ACCOMPANYING DOCUMENTS, technical description

Description of requirement	Clause
External means of isolation: description of	8.11.1 b)
ME SYSTEM large transient currents: disclosure of	16.3
Non-automatic discharging device for internal capacitors: specification of	8.4.4

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Annex D
(informative)

Symbols on marking
(see Clause 7)

Symbols are frequently used on ME EQUIPMENT in preference to words with the intention of obviating language differences and permitting easier comprehension of a marking or indication, sometimes in a restricted space. New and improved symbols and safety signs have been introduced since the publication of the second edition of IEC 60601-1 which necessitates changes in the list of approved symbols and safety signs for use on ME EQUIPMENT.

Chief among these changes is the revision of the usage of symbol 24 in Table D.1. This symbol was formally used to indicate a warning as well as an informative marking (e.g. this is where the HIGH VOLTAGE is connected). A new safety sign (3) in Table D.2 has been added to indicate, “Warning: Dangerous Voltage.” In this edition of the standard, the safety signs of Table D.2 are required where a warning is intended while the symbols in Table D.1 are used when the intention is solely to inform.

Similarly is the revision of the usage of symbol 10 in Table D.1, which was formerly used to indicate “attention: consult ACCOMPANYING DOCUMENTS”. That symbol is now used to indicate caution. A new symbol (11) in Table D.1 has been added to indicate, “follow operating instructions”. Additionally, a new safety sign (10) in Table D.2 has been added to mark ME EQUIPMENT where failure to follow operating instructions could place the PATIENT or OPERATOR at RISK.

Consistent use of these symbols and safety signs in all fields of use (e.g., medical, consumer products, and general transportation) will help ME EQUIPMENT OPERATORS to become familiar with their meaning. Conversely, any inconsistent use will lead to confusion and mistakes and jeopardize safety.

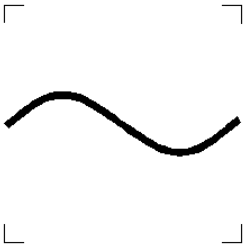
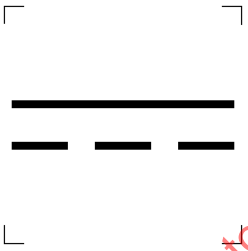
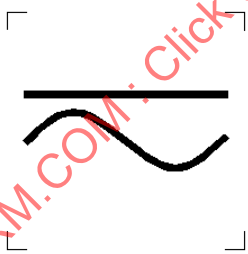
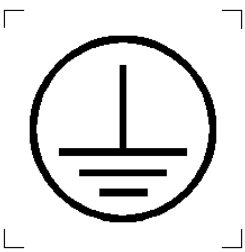
IEC 60878 [60] provides a useful compendium of graphical symbols and safety sign used on electrical equipment in medical practice that were complied from relevant ISO and IEC standards. See also 7.5 and 7.6.

For symbol requirements not met by the symbols in IEC 60878, refer in the first instance to published IEC or ISO symbols, noting that, where necessary, two or more symbols can be grouped together to convey a particular meaning and that, provided the essential communicative characteristics of the basic symbol are maintained, some latitude in graphic design is permissible. The colours of symbols are not specified, except for the background of the AP and APG symbols (see Clause G.3). The colours of safety signs are specified in ISO 3864-1.

In the following tables, the symbol graphic and title are provided for information.

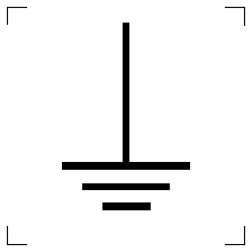
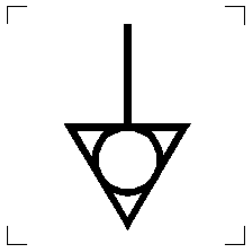
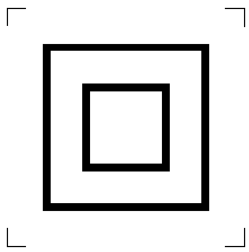
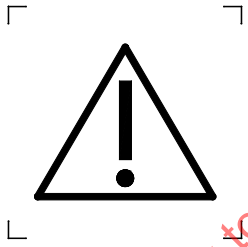
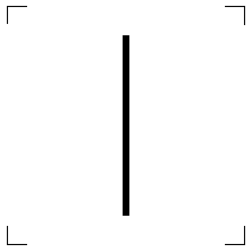
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Table D.1 – General symbols

No.	Symbol	Reference	Title
1		IEC 60417-5032	Alternating current
2		IEC 60417-5032-1	Three-phase alternating current
3		IEC 60417-5032-2	Three-phase alternating current with neutral conductor
4		IEC 60417-5031	Direct current
5		IEC 60417-5033	Both direct and alternating current
6		IEC 60417-5019	Protective earth (ground)

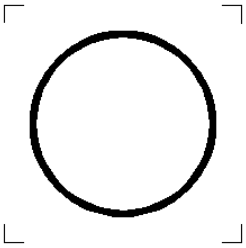
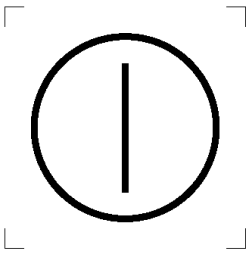
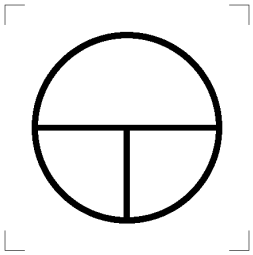
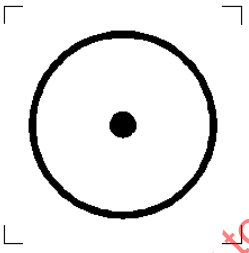
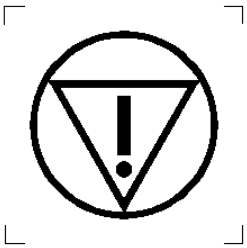
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Table D.1 *(continued)*

No.	Symbol	Reference	Title
7		IEC 60417-5017	Earth (ground)
8		IEC 60417-5021	Equipotentiality
9		IEC 60417-5172	CLASS II equipment
10		ISO 7000-0434A	Caution In case of application as a safety sign, the rules according to ISO 3864-1 are to be adhered to. See safety sign ISO 7010-W001 (Table D.2, safety sign 2).
11		ISO 7000-1641	Operating instructions
12		IEC 60417-5007	“ON” (power)

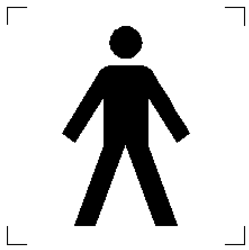
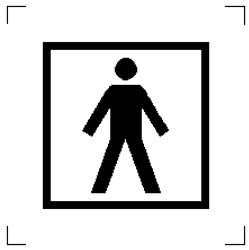
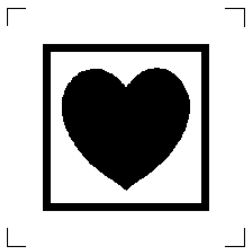
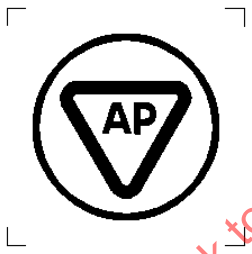
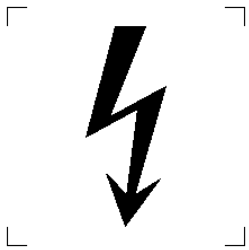
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Table D.1 *(continued)*

No.	Symbol	Reference	Title
13		IEC 60417-5008	“OFF” (power)
14		IEC 60417-5010	“ON” / “OFF” (push-push) NOTE Each position, "ON" or "OFF", is a stable position.
15		IEC 60417-5011	“ON” / “OFF” (push button) NOTE "OFF" is a stable position, whilst the "ON" position only remains during the time the button is depressed.
16		IEC 60417-5264	“ON” for part of equipment
17		IEC 60417-5265	“OFF” for part of the equipment
18		IEC 60417-5638	Emergency stop

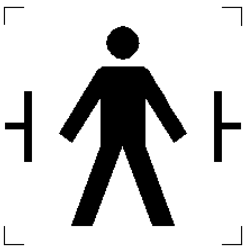
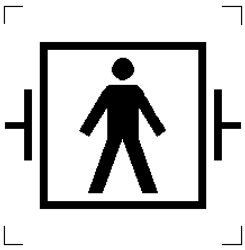
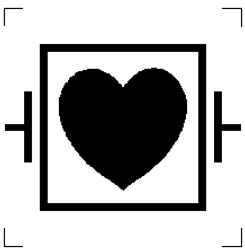
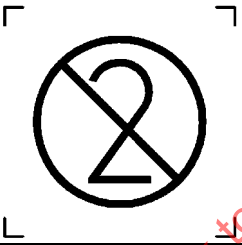
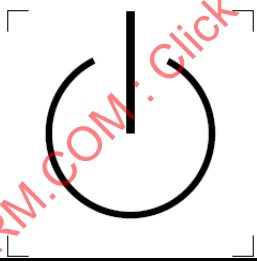
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Table D.1 *(continued)*

No.	Symbol	Reference	Title
19		IEC 60417-5840	TYPE B APPLIED PART NOTE Subclause 7.2.10 requires that, for clear differentiation with symbol 20, symbol 19 is not to be applied in such a way as to give the impression of being inscribed within a square.
20		IEC 60417-5333	TYPE BF APPLIED PART
21		IEC 60417-5335	TYPE CF APPLIED PART
22		IEC 60417-5331	CATEGORY AP equipment
23		IEC 60417-5332	CATEGORY APG equipment
24		IEC 60417-5036	Dangerous voltage

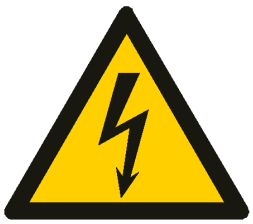
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Table D.1 *(continued)*

No.	Symbol	Reference	Title
25		IEC 60417-5841	DEFIBRILLATION-PROOF TYPE B APPLIED PART
26		IEC 60417-5334	DEFIBRILLATION-PROOF TYPE BF APPLIED PART
27		IEC 60417-5336	DEFIBRILLATION-PROOF TYPE CF APPLIED PART
28		ISO 7000-1051	Do not reuse
29		IEC 60417-5009	Stand-by

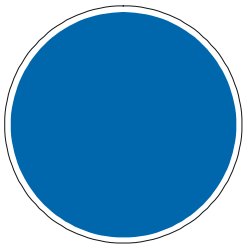
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Table D.2 – Safety signs

No.	Safety sign	Reference	Title
1		ISO 3864-1, Figure 3	Template for constructing a warning sign NOTE Background colour: yellow Triangular band: Black Symbol or text: Black
2		ISO 7010-W001	General warning sign
3		ISO 7010-W012	Warning, electricity
4		ISO 7010-P001 and ISO 3864-1, Figure 1	General prohibition sign and Template for constructing a prohibition sign NOTE Background colour: white Circular band and slash: red Symbol or text: black
5		ISO 7010-P017	No pushing
6		ISO 7010-P018	No sitting

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Table D.2 *(continued)*

No.	Safety sign	Reference	Title
7		ISO 7010-P019	No stepping on surface
8		ISO 3864-1 Figure 2	Template for constructing a mandatory action sign NOTE Background colour: blue Symbol or text: white
9		ISO 7010-M001	General mandatory action sign
10		ISO 7010-M002	Refer to instruction manual/ booklet NOTE On ME EQUIPMENT "Follow instructions for use"

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Table D.3 – General codes

1	**N**	IEC 60445	Connection point for the neutral conductor on PERMANENTLY INSTALLED equipment
2	**IPN_1N_2**	IEC 60529	N_1 = 0 Non-protected 1 Protected against solid foreign objects of 50 mm ∅ and greater 2 Protected against solid foreign objects of 12,5 mm ∅ and greater 3 Protected against solid foreign objects of 2,5 mm ∅ and greater 4 Protected against solid foreign objects of 1,0 mm ∅ and greater 5 Dust-protected 6 Dust-tight N_2 = 0 Non-protected 1 Protection against vertically falling water drops 2 Protection against vertically falling water drops when ENCLOSURE tilted up to 15° 3 Protected against spraying water 4 Protected against splashing water 5 Protected against water jets 6 Protected against powerful water jets 7 Protected against the effects of temporary immersion in water 8 Protected against the effects of continuous immersion in water NOTE When a characteristic numeral is not required to be specified, it is replaced by the letter “X” (“XX” if both numerals are omitted).

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Annex E
(informative)

Examples of the connection of the measuring device (MD) for measurement of the PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT
(see 8.7)

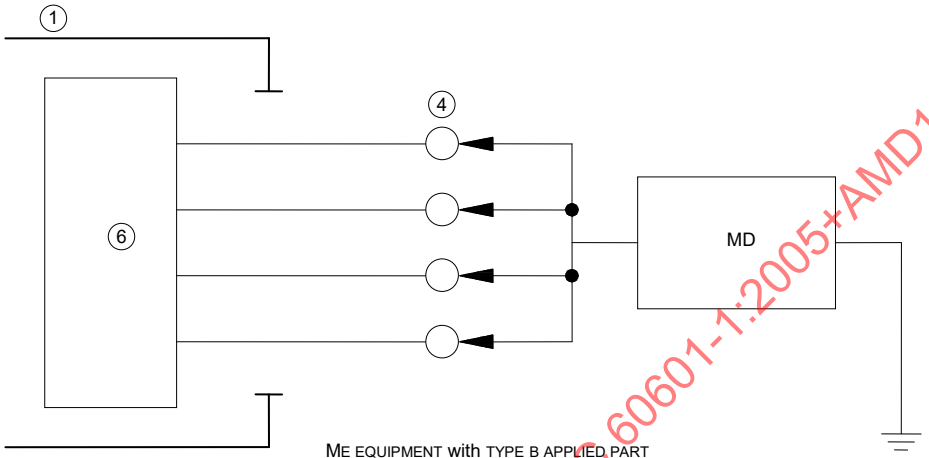


Figure E.1 – TYPE B APPLIED PART

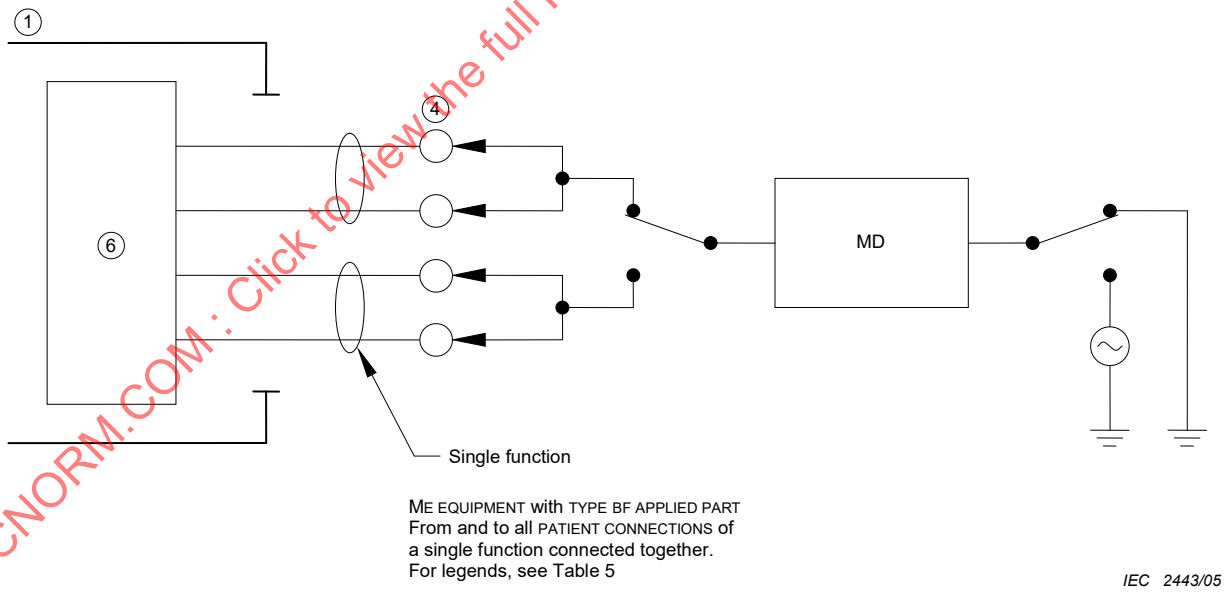


Figure E.2 – TYPE BF APPLIED PART

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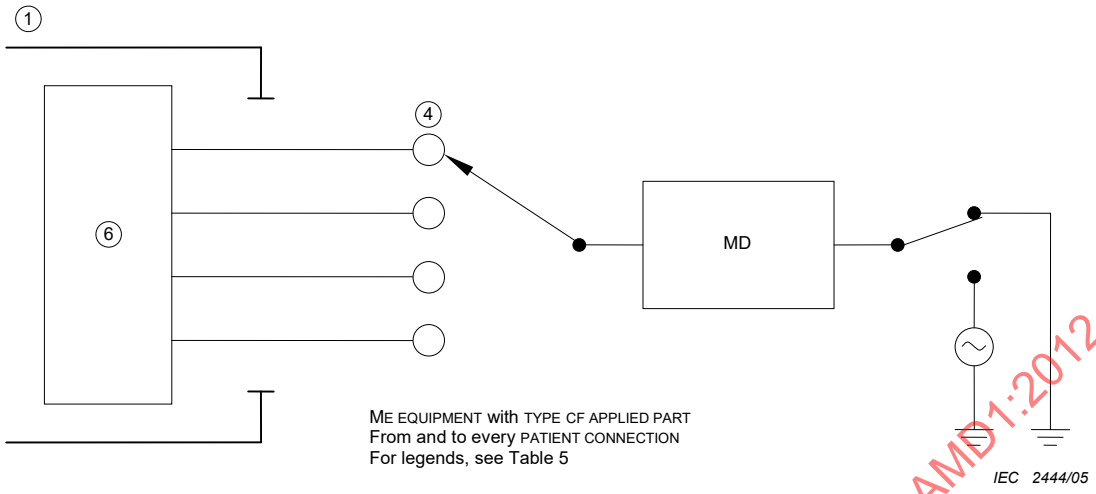


Figure E.3 – TYPE CF APPLIED PART

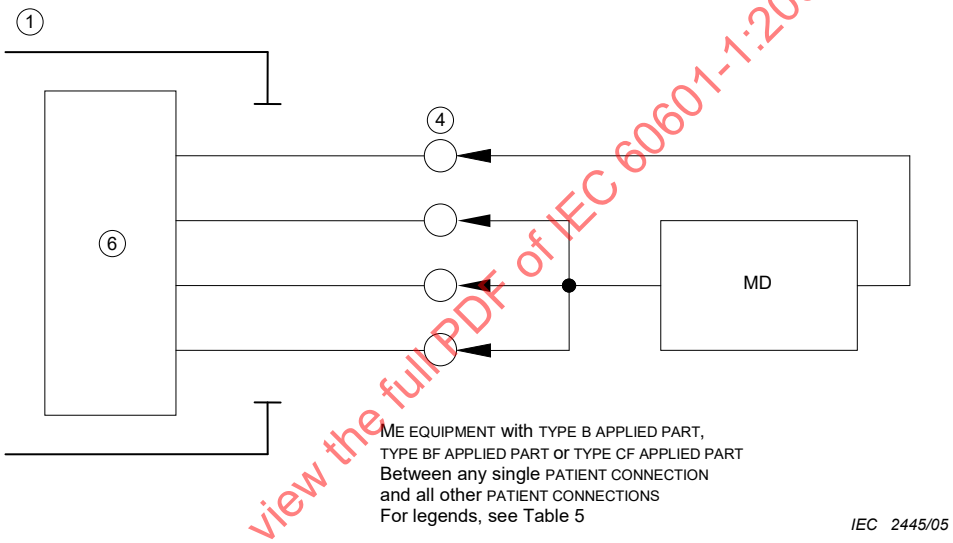


Figure E.4 – PATIENT AUXILIARY CURRENT

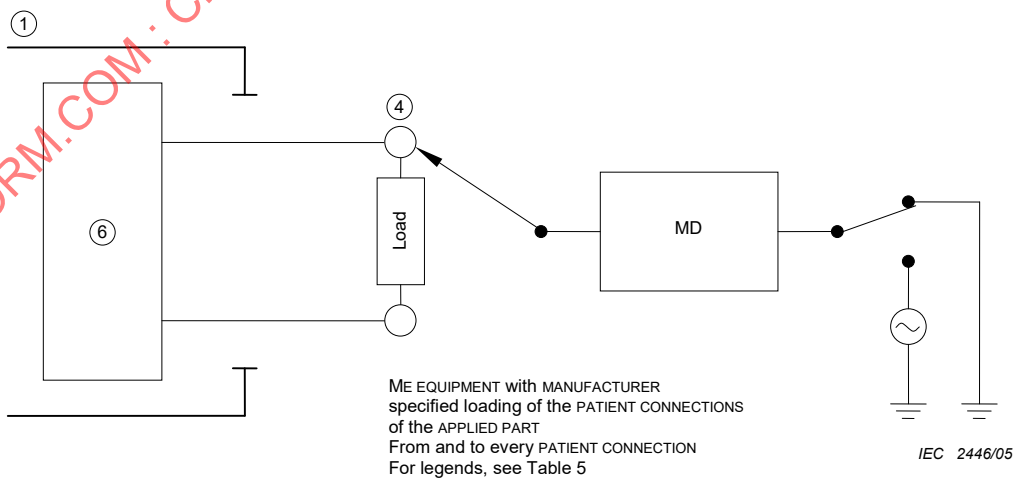
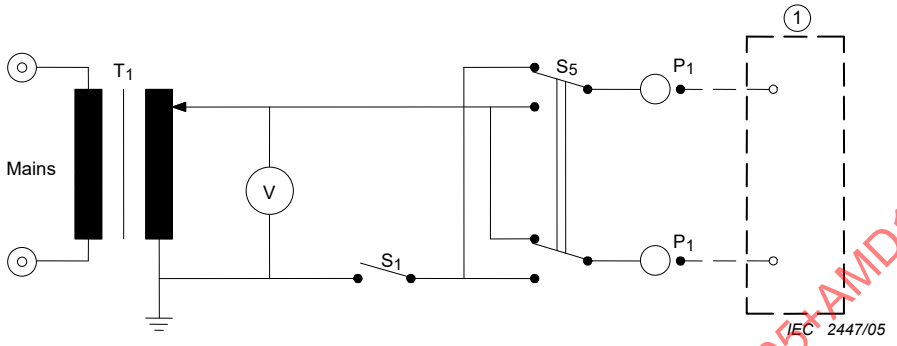


Figure E.5 – Loading of the PATIENT CONNECTIONS if specified by the MANUFACTURER

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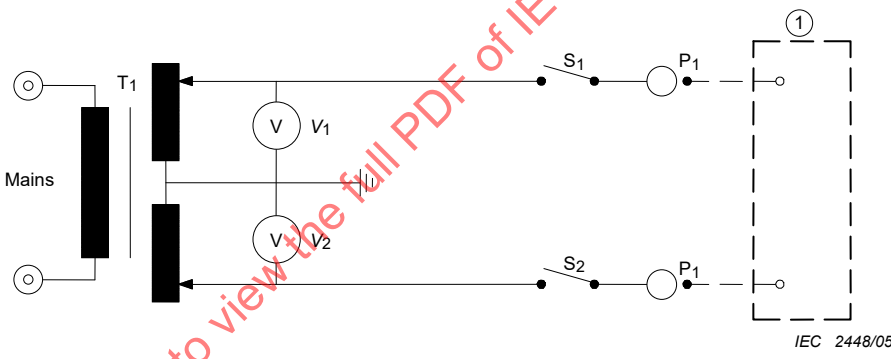
Annex F
(informative)

Suitable measuring supply circuits



For legends, see Table 5.

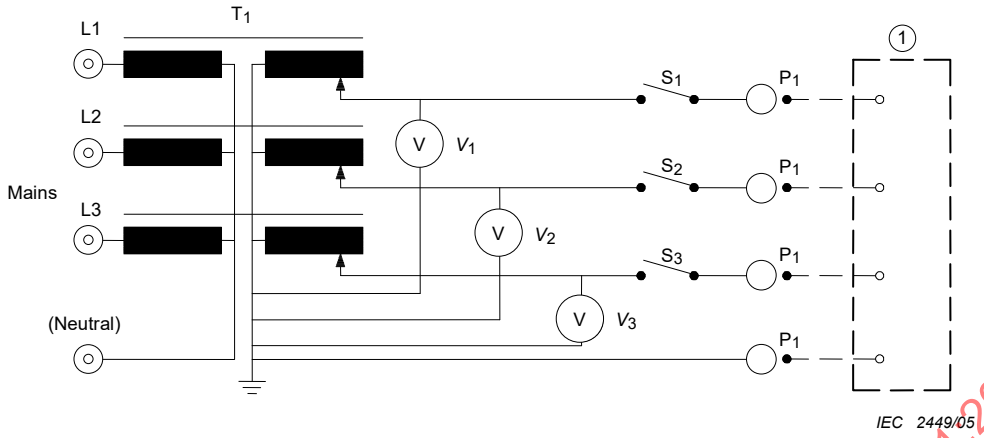
Figure F.1 – Measuring supply circuit with one side of the SUPPLY MAINS at approximately earth potential
(see 8.7.4.2)



For legends, see Table 5.

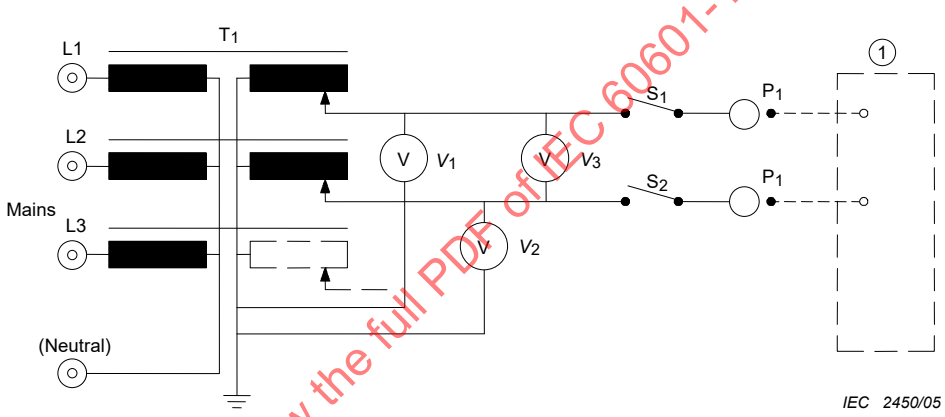
Figure F.2 – Measuring supply circuit with SUPPLY MAINS approximately symmetrical to earth potential
(see 8.7.4.2)

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For legends, see Table 5.

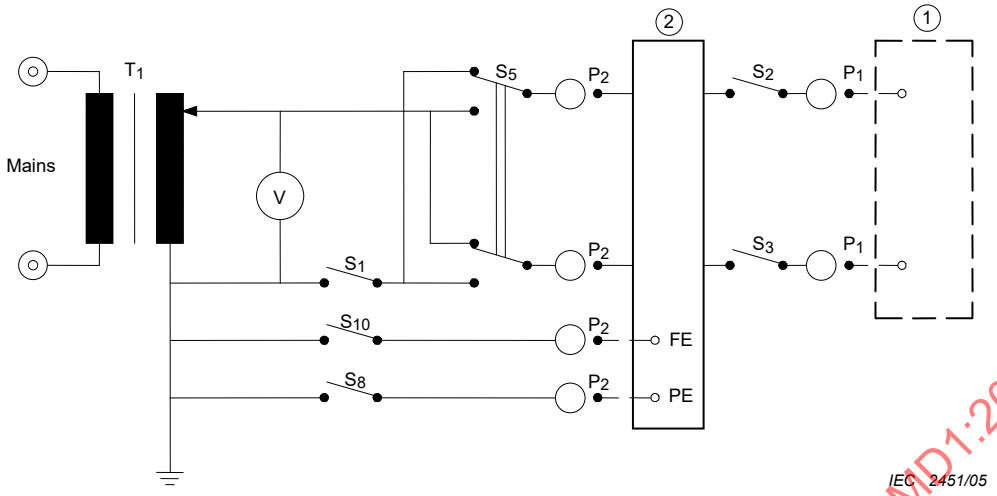
Figure F.3 – Measuring supply circuit for polyphase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS
(see 8.7.4.2)



For legends, see Table 5.

Figure F.4 – Measuring supply circuit for single-phase ME EQUIPMENT specified for connection to a polyphase SUPPLY MAINS
(see 8.7.4.2)

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For legends, see Table 5.

Figure F.5 – Measuring supply circuit for ME EQUIPMENT having a separate power supply unit or intended to receive its power from another equipment in an ME SYSTEM
(see 8.7.4.2)

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Annex G
(normative)

Protection against HAZARDS of ignition of flammable anaesthetic mixtures

NOTE This annex replaces the former Section Six: "Protection against HAZARDS of ignition of flammable anaesthetic mixtures" of the second edition.

G.1 Introduction

G.1.1 Applicability

Where ME EQUIPMENT is used in areas in which flammable anaesthetics or flammable agents for disinfection or skin cleaning are applied, an explosion RISK can exist if such anaesthetics or agents are mixed with air, or with oxygen or nitrous oxide.

Ignition of such a mixture can be caused by sparks or by contact with parts having a high surface temperature.

Sparks can be caused where electrical circuits are opened or closed by operation of switches, connectors, fuses or OVER-CURRENT RELEASES and the like.

In HIGH VOLTAGE parts, sparks can be caused by corona. Static discharges can cause sparks.

The probability of occurrence of the ignition of such anaesthetic mixtures depends on their concentration, the appropriate minimum ignition energy, the presence of high surface temperatures and the energy of sparking.

G.1.2 Industrial equipment and components

The constructional requirements of IEC 60079-0 are generally not appropriate for ME EQUIPMENT for several reasons:

a) they lead to constructions of a size, weight or design that are not applicable for medical reasons or that cannot be sterilizable;

b) some constructions allow an explosion inside an ENCLOSURE, but prevent propagation outside it. Such a construction, which might be inherently safe, would be unacceptable in an operating theatre where continuity of operation of ME EQUIPMENT is essential;

c) industrial requirements were made for flammable agents mixed with air. They cannot be applied to mixtures with oxygen or nitrous oxide used in medical practice;

d) in medical practice flammable anaesthetic mixtures occur only in relatively small quantities.

However some of the constructions described in IEC 60079-0 are acceptable for CATEGORY AP ME EQUIPMENT (see G.5.1).

G.1.3 * Requirements for ME EQUIPMENT

In this annex, the location of flammable anaesthetic mixtures is described:

– as much as necessary for the construction of ME EQUIPMENT, as minimum for specified conditions of exhaust and absorption;

– as much as necessary for the allocation of ME EQUIPMENT and the construction of the electrical installation in the IEC 60364 series.

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The recommendations, limits and tests of this annex are based on the results of statistical considerations obtained from experiments with the most readily flammable mixtures of ether vapour with air and with oxygen, using the test apparatus described in Clause G.7. This is justified because combinations with ether have the lowest ignition temperatures and the lowest ignition energies of commonly used agents.

Where temperatures or circuit parameters of ME EQUIPMENT used in a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR exceed allowable limits and sparking cannot be avoided the relevant parts and circuits can be enclosed in ENCLOSURES with pressurized inert gas or clean air or in ENCLOSURES with restricted breathing.

ENCLOSURES with restricted breathing delay the build-up of an ignitable concentration. They are recognized because it is assumed that a period in which ME EQUIPMENT is used in a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR is followed by a period of ventilation during which such a concentration will disappear.

For ME EQUIPMENT containing or used in a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE, requirements, limits and tests are far more stringent.

These recommendations apply not only to NORMAL CONDITION but, additionally, in the SINGLE FAULT CONDITION, as indicated in 4.7. Only two exemptions from an actual ignition test are recognized, these being either the absence of sparks and limited temperature or limited temperature and restricted circuit parameters.

G.2 Locations and basic requirements

G.2.1 Parts of CATEGORY APG ME EQUIPMENT

Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs shall be CATEGORY AP or APG ME EQUIPMENT and shall comply with the requirements of Clause G.3, G.4 and G.5.

G.2.2 FLAMMABLE ANAESTHETIC MIXTURE WITH AIR

Where a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs because of a leakage or discharge of a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE from an ENCLOSURE, it is considered to propagate to a volume surrounding the leakage or discharge point at a distance from 5 cm to 25 cm from such a point.

G.2.3 FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE

A FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE may be contained in a completely or partly enclosed ME EQUIPMENT part and in the PATIENT'S respiratory tract. Such a mixture is considered to propagate to a distance of 5 cm from an ENCLOSURE part where leakage or discharge occurs.

G.2.4 ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH AIR

ME EQUIPMENT or parts thereof specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH AIR (in a location defined in G.2.2) shall be CATEGORY AP or APG ME EQUIPMENT and shall comply with the requirements of Clause G.4 and G.5.

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G.2.5 ME EQUIPMENT specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE

ME EQUIPMENT or parts thereof specified for use with FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE (in a location defined in G.2.2) shall be CATEGORY APG ME EQUIPMENT and shall comply with the requirements of G.4 and G.6.

Compliance with the requirements of G.2.4 and G.2.5 is checked by inspection and by the appropriate tests of Clause G.3, G.4 and G.5.

These tests shall be performed after applicable tests according to 11.6.6 and 11.6.7.

G.3 Marking, ACCOMPANYING DOCUMENTS

G.3.1 CATEGORY APG marking

CATEGORY APG ME EQUIPMENT shall be marked on a prominent location with a green-coloured band at least 2 cm wide imprinted with the characters "APG" (see symbol IEC 60417-5332 (2002-10) (Table D.1, symbol 23)). The length of the green-coloured band should be at least 4 cm. The size of the marking should be as large as possible for the particular case. If this marking is impossible, the relevant information shall be given in the instructions for use.

Compliance is checked by inspection and by application of the tests and criteria in 7.1.2 and 7.1.3.

G.3.2 CATEGORY AP marking

CATEGORY AP ME EQUIPMENT shall be marked on a prominent location with a green-coloured circle of at least 2 cm diameter, imprinted with the characters "AP" (see symbol IEC 60417-5331 (2002-10) (Table D.1, symbol 22)).

The size of the marking should be as large as possible for the particular case. If this marking is impossible, the relevant information shall be given in the instructions for use.

Compliance is checked by inspection and by application of the tests and criteria in 7.1.2 and 7.1.3.

G.3.3 Placement of markings

The marking according to G.3.1 and G.3.2 shall be present on the major part of the ME EQUIPMENT if this part is CATEGORY AP or CATEGORY APG. It need not be repeated on detachable parts that can only be used together with the marked ME EQUIPMENT.

Compliance is checked by inspection.

G.3.4 ACCOMPANYING DOCUMENTS

ACCOMPANYING DOCUMENTS shall contain an indication to enable the RESPONSIBLE ORGANIZATION to distinguish the parts of ME EQUIPMENT (see G.3.5) that are CATEGORY AP and CATEGORY APG.

Compliance is checked by inspection.

G.3.5 Marking when parts of ME EQUIPMENT are CATEGORY AP or CATEGORY APG

On ME EQUIPMENT in which only certain ME EQUIPMENT parts are CATEGORY AP or CATEGORY APG, the marking shall clearly indicate which parts are CATEGORY AP or CATEGORY APG.

Compliance is checked by inspection.

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G.4 Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT

G.4.1 Electrical connections

a) CREEPAGE DISTANCES and AIR CLEARANCES between the connection points of POWER SUPPLY CORD shall be according to THE Table 12 values for one MEANS OF PATIENT PROTECTION.

b) Connections, except those in the circuits described in G.5.3 and G.6.3, shall be protected against accidental disconnection in NORMAL USE or shall be so designed that connection or disconnection can be performed only with the use of a TOOL.

c) CATEGORY AP and CATEGORY APG ME EQUIPMENT shall not be provided with a DETACHABLE POWER SUPPLY CORD unless the circuit complies with the requirements of G.5.3 and G.6.3.

Compliance is checked by inspection or measurement.

G.4.2 Construction details

a) Opening of an ENCLOSURE providing protection against the penetration of gases or vapours into the ME EQUIPMENT or into parts thereof shall be possible only with the aid of a TOOL.

Compliance is checked by inspection.

b) To minimize arcing and sparking due to foreign objects penetrating the ENCLOSURE:

- top covers of ENCLOSURES shall have no openings; openings for controls are permitted if these openings are covered by the control knob;
- openings in side-covers shall have such dimensions that penetration by a solid cylindrical object of more than 4 mm diameter is prevented;
- openings in base plates shall have such dimensions that penetration by a solid cylindrical object of more than 12 mm diameter is prevented.

Compliance is checked by means of a cylindrical test rod of 4 mm diameter for side-covers and 12 mm diameter for base plates. The test rod is not to enter the ENCLOSURE when applied in all possible directions without appreciable force.

c) Where insulation of electrical conductors equal to one MEANS OF PATIENT PROTECTION may contact a part containing a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE or ignitable gases alone or oxygen, a short circuit of these conductors or a short circuit of one conductor to a conductive part containing the gas or mixture shall not result in loss of integrity of such a part or result in an inadmissible temperature in such a part (see G.6.3 a)) or in any HAZARDOUS SITUATION.

Compliance is checked by inspection. In case of doubt, a short-circuit test (without explosive gases) should be performed and the temperature in the relevant part should be measured if possible. The short-circuit test need not be performed if the product of the open-circuit voltage in volts and the short-circuit current in amperes does not exceed 10.

G.4.3 Prevention of electrostatic charges

a) Electrostatic charges shall be prevented on CATEGORY AP and CATEGORY APG ME EQUIPMENT by a combination of appropriate measures such as:

- the use of antistatic materials with a limited electrical resistance as specified in G.4.3 b), and

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– provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor or to the protective earth system or the potential equalization system or via wheels to an antistatic floor of the medically used room.

b) The electrical resistance limits of anaesthetic tubing, mattresses and pads, castor tyres and other antistatic material shall comply with ISO 2882.

Compliance with the allowable resistance limits given in ISO 2882 is checked by measurements according to ISO 1853, ISO 2878 and ISO 23529.

G.4.4 Corona

Parts and components of ME EQUIPMENT operating at more than 2 000 V a.c. or more than 2 400 V d.c. that are not included in ENCLOSURES in compliance with G.5.4 or G.5.5 shall be so designed that corona cannot be produced.

Compliance is checked by inspection and measurement.

G.5 Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components thereof

G.5.1 General

ME EQUIPMENT, its parts or components shall not ignite FLAMMABLE ANAESTHETIC MIXTURES WITH AIR in NORMAL USE and NORMAL CONDITION.

ME EQUIPMENT, its parts or components complying with one of Subclauses G.5.2 to G.5.5 (inclusive) are considered to comply with the requirement of this subclause.

ME EQUIPMENT, its parts or components complying with the requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2), for sand-filled ENCLOSURES (IEC 60079-5) or for oil-immersed equipment (IEC 60079-6) as well as with the requirements of this standard (excluding those of G.5.2 to G.5.5), are considered to comply with the requirements for CATEGORY AP ME EQUIPMENT.

G.5.2 Temperature limits

ME EQUIPMENT, its parts or components not producing sparks and not producing operating temperatures of surfaces in contact with gas mixtures in NORMAL USE and NORMAL CONDITION, exceeding 150 °C in case of restricted vertical air circulation by convection, or exceeding 200 °C in case of unrestricted vertical air circulation, if measured at an ambient temperature of 25 °C, are considered to comply with the requirements of G.5.1.

The operating temperatures are measured during the tests mentioned in 11.1.

G.5.3 * Low-energy circuits

ME EQUIPMENT, its parts or components that may produce sparks in NORMAL USE and NORMAL CONDITION of the ME EQUIPMENT (for example, switches, relays, plug connections that can be detached without the use of a TOOL, including connections inside ME EQUIPMENT that are not sufficiently locked or secured, and brush motors) shall comply with the temperature requirements of G.5.2 and additionally the voltage U_{max} and the current I_{max}, which can occur in their circuits, taking into account the capacitance C_{max} and the inductance L_{max} shall comply with the following:

$U_{max} \leq U_{zR}$ with a given current I_{zR}, see Figure G.1,

$U_{max} \leq U_c$ with a given capacitance C_{max}, see Figure G.2,

$I_{max} \leq I_{zR}$ with a given voltage U_{zR}, see Figure G.1, and

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$I_{max} \leq I_{zL}$ with a given inductance L_{max} and a $U_{max} \leq 24$ V, see Figure G.3.

– The graphs of Figure G.1, Figure G.2 and Figure G.3 have been obtained with the test apparatus according to Figure G.7 with the most readily flammable mixtures of ether vapour with air (ether volume percentage 4,3 ± 0,2 %) for an ignition probability (without safety factor) of 10^{-3}.

– Extrapolation of the graph of Figure G.1 is allowed for combinations of currents and corresponding voltages within the limitations $I_{zR} \cdot U_{zR} \leq 50$ W.

Extrapolation for voltages of more than 42 V is not valid.

– Extrapolation of the graph of Figure G.2 is allowed for combinations of capacitances and corresponding voltages within the limitations:

$$\frac{C}{2} U^2 \leq 1{,}2 \text{ mJ}$$

Extrapolation for voltages of more than 242 V is not valid.

If the equivalent resistance R is less than 8 000 Ω, U_{max} is additionally determined with the actual resistance R.

– Extrapolation of the graph of Figure G.3 is allowed for combinations of currents and corresponding inductances within the limitations

$$\frac{L}{2} I^2 \leq 0{,}3 \text{ mJ}$$

Extrapolation for inductances larger than 900 mH is not valid.

– Voltage U_{max} is taken as the highest supply voltage occurring in the circuit under investigation with the sparking contact open, taking into account the MAINS VOLTAGE variations required in 4.10.

– Current I_{max} is taken as the highest current flowing in the circuit under investigation with the sparking contact closed, taking into account the MAINS VOLTAGE variations required in 4.10.

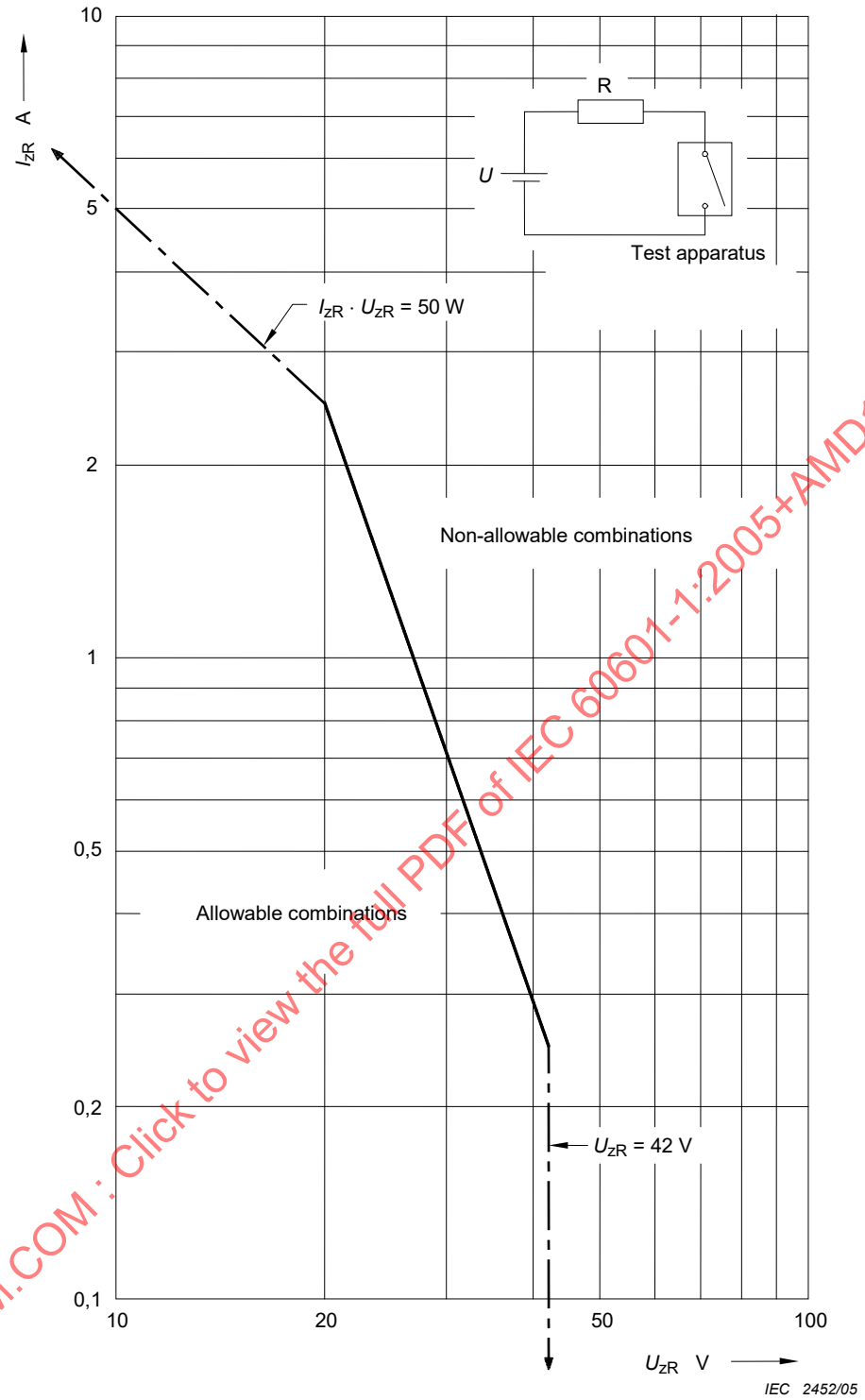
– Capacitance C_{max} and inductance L_{max}, are taken as the values that occur at the component under investigation that produces sparks in the ME EQUIPMENT.

– If the circuit is supplied with a.c., the peak value is taken into account.

– If the circuit is complicated and consists of more than one capacitance, inductance and resistance, or a combination thereof, an equivalent circuit is calculated to determine the equivalent maximum capacitance, the equivalent maximum inductance and additionally the equivalent U_{max} and I_{max}, either as d.c. values or as a.c. peak values.

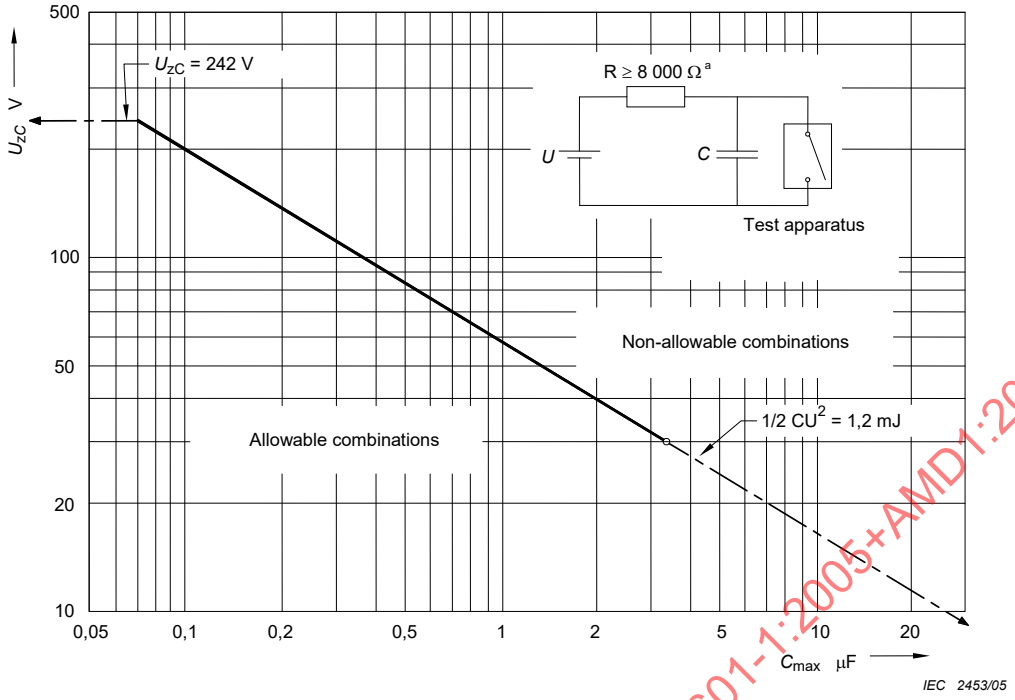
Compliance is checked either by temperature measurement and determination of U_{max}, I_{max}, R, L_{max} and C_{max} and application of Figure G.1, Figure G.2 and Figure G.3, or by examination of the design data.

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Figure G.1– Maximum allowable current I_{zR} as a function of the maximum allowable voltage U_{zR} measured in a purely resistive circuit with the most flammable mixture of ether vapour with air



[a] 8 000 Ω or the actual resistance, if R is less than 8 000 Ω

Figure G.2 – Maximum allowable voltage U_{zC} as a function of the capacitance C_{max} measured in a capacitive circuit with the most flammable mixture of ether vapour with air

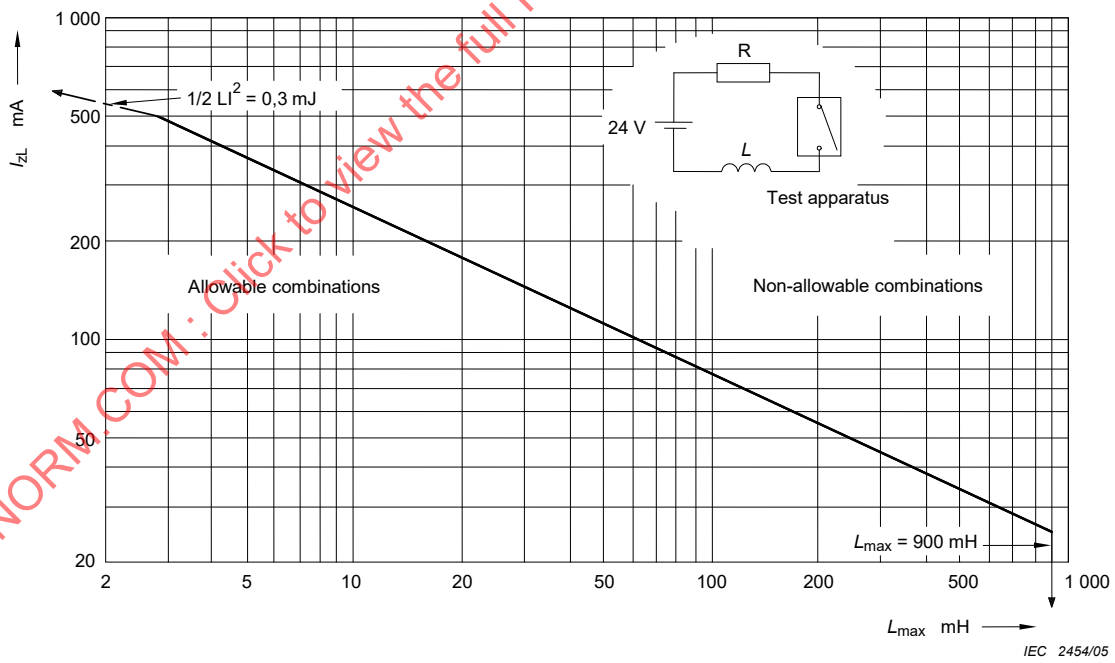


Figure G.3 – Maximum allowable current I_{zL} as a function of the inductance L_{max} measured in an inductive circuit with the most flammable mixture of ether vapour with air

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G.5.4 * External ventilation with internal overpressure

Where ME EQUIPMENT, its parts or components are enclosed in an ENCLOSURE with external ventilation by means of internal overpressure the following requirements shall apply.

a) FLAMMABLE ANAESTHETIC MIXTURES WITH AIR that might have penetrated into the ENCLOSURE of ME EQUIPMENT or of an ME EQUIPMENT part shall be removed by ventilation before the ME EQUIPMENT or the ME EQUIPMENT part can be energized, and subsequently the penetration of such mixtures during operation shall be prevented by maintenance of overpressure within the ME EQUIPMENT or the ME EQUIPMENT part by means of air not containing flammable gases or vapours or by means of a physiologically acceptable inert gas (for example nitrogen).

b) The overpressure inside the ENCLOSURE shall be at least 75 Pa in NORMAL CONDITION. The overpressure shall be maintained at the site of potential ignition even if the air or inert gas can escape through openings in the ENCLOSURE that are necessary for the normal operation of ME EQUIPMENT or its parts.

Energizing ME EQUIPMENT shall only be possible after the required minimum overpressure has been present for a time sufficient to ventilate the relevant ENCLOSURE so that the displaced volume of air or of inert gas is at least five times the volume of the ENCLOSURE. (However, ME EQUIPMENT may be energized at any time or repeatedly if the overpressure is continuously present.)

c) If the overpressure drops below 50 Pa during operation, ignition sources shall be de-energized automatically by means that either shall be located in a place where the requirements and tests of Clause G.4 do not apply, or comply with the requirements of Clause G.5.

d) The external surface of the ENCLOSURE in which the internal overpressure is maintained shall not attain in NORMAL CONDITION and NORMAL USE an operating temperature exceeding 150 °C, measured in an ambient temperature of 25 °C.

Compliance with the requirements of G.5.4 a) to G.5.4 d) is checked by temperature, pressure and flow measurements and inspection of the pressure monitoring device.

G.5.5 ENCLOSURES with restricted breathing

Where ME EQUIPMENT, its parts or components are enclosed in an ENCLOSURE with restricted breathing the following requirements shall apply:

a) * ENCLOSURES with restricted breathing shall be so designed that the formation of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR inside the ENCLOSURE does not occur whilst the ENCLOSURE is surrounded by a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR of a high concentration for a period of at least 30 min but without any pressure difference to the space inside the ENCLOSURE.

b) If the required tightness is obtained by gaskets or sealing, the material used shall therefore be resistant to ageing.

Compliance is checked by application of test B-b of IEC 60068-2-2, Clause 15, temperature 70 °C ± 2 °C, duration 96 h.

c) If the ENCLOSURE contains inlets for flexible cords, their gas-tightness shall be maintained when the cords are stressed by bending or pulling. The cords shall be fitted with adequate anchorages to limit these stresses (see 8.11.3.5).

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Compliance with the requirements of G.5.5 a), G.5.5 b) and G.5.5 c) is checked by application of the following tests:

After completion of the test of G.5.4 b) if relevant, an internal overpressure of 400 Pa is created and 30 pulls of the value shown in Table G.1 are applied to each flexible cord alternately, in the axial direction of the cord inlet and in the least favourable perpendicular direction, each pull without jerks and of 1 s duration. At the end of the test the overpressure is not be reduced to less than 200 Pa.

Table G.1 – Gas-tightness of cord inlets

Mass (*m*) of ME EQUIPMENT kg	**Pull** N
$m \leq 1$	30
$1 < m \leq 4$	60
$m > 4$	100

When the ENCLOSURE of ME EQUIPMENT parts or components is sealed or gas-tight and no doubt exists that the ENCLOSURE complies with the aforementioned requirement, the ENCLOSURE is tested by inspection only.

The operating temperature of the external surface of the ENCLOSURE shall not exceed 150 °C measured at an ambient temperature of 25 °C. The steady state operating temperature of the ENCLOSURE is also measured.

G.6 Requirements and tests for CATEGORY APG ME EQUIPMENT, parts and components thereof

G.6.1 General

ME EQUIPMENT, its parts or components shall not ignite FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE. This requirement applies both in NORMAL USE and in the event of any applicable SINGLE FAULT CONDITION, as described in 4.7.

ME EQUIPMENT, its parts or components that do not comply with the requirements of G.6.3 are tested by a CONTINUOUS OPERATION test over a period of 10 min in an ether/oxygen mixture (ether volume percentage 12,2 % ± 0,4 %) after the thermal steady state condition has been attained, but not longer than 3 h after switching on.

G.6.2 * Power supply

Parts or components of CATEGORY APG ME EQUIPMENT that operate in a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE shall be supplied from a source that is isolated from earth by at least insulation equal to one MEANS OF PATIENT PROTECTION and from electrical parts by insulation equal to two MEANS OF PATIENT PROTECTION.

Compliance is checked by inspection of circuit diagrams and measurement.

G.6.3 * Temperatures and low-energy circuits

ME EQUIPMENT, and its parts or components are considered to comply with the requirements of G.6.1 without being tested according to G.6.1 if, in NORMAL USE, NORMAL CONDITION and SINGLE FAULT CONDITIONS (see 4.7):

a) no sparks are produced and no temperatures exceeding 90 °C occur, or

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b) a temperature limit of 90 °C is not exceeded, ME EQUIPMENT or its parts contain components that may produce sparks in NORMAL USE, NORMAL CONDITION and applicable SINGLE FAULT CONDITIONS, but the voltage U_{max} and the current I_{max} that can occur in their circuits, taking into account the capacitance C_{max} and the inductance Lmax, comply with the following:

$U_{max} \leq U_{zR}$ with a given I_{zR}, see Figure G.4, and

$U_{max} \leq U_{zC}$ with given C_{max}, see Figure G.5, as well as

$I_{max} \leq I_{zR}$ with a given voltage U_{zR}, see Figure G.4, and

$I_{max} \leq I_{zL}$ with a given inductance L_{max} and $U_{max} \leq 24$ V, see Figure G.6.

– The graphs in Figure G.4, Figure G.5 and Figure G.6 have been obtained with the test apparatus according to Figure G.7 with the most readily flammable mixture of ether vapour with oxygen (ether volume percentage 4,3 ± 0,2 %) for an ignition probability of 10^{-3}. The maximum allowable values of I_{zR} (Figure G.4), U_{zC} (Figure G.5) and I_{zL} (Figure G.6) include a safety factor of 1,5.

– Extrapolation of the curves of Figure G.4, Figure G.5 and Figure G.6 is limited to the areas indicated.

– Voltage U_{max} is taken as the highest no-load voltage occurring in the circuit under investigation, taking into account MAINS VOLTAGE variations as required in 4.10.

– Current I_{max} is taken as the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as required in 4.10.

– Capacitance C_{max} and inductance L_{max} are taken as values that occur in the relevant circuit.

– If the equivalent resistance R in Figure G.5 is less than 8 000 Ω, U_{max} is additionally determined with the actual resistance R.

– If the circuit is supplied with a.c., the peak value is taken into account.

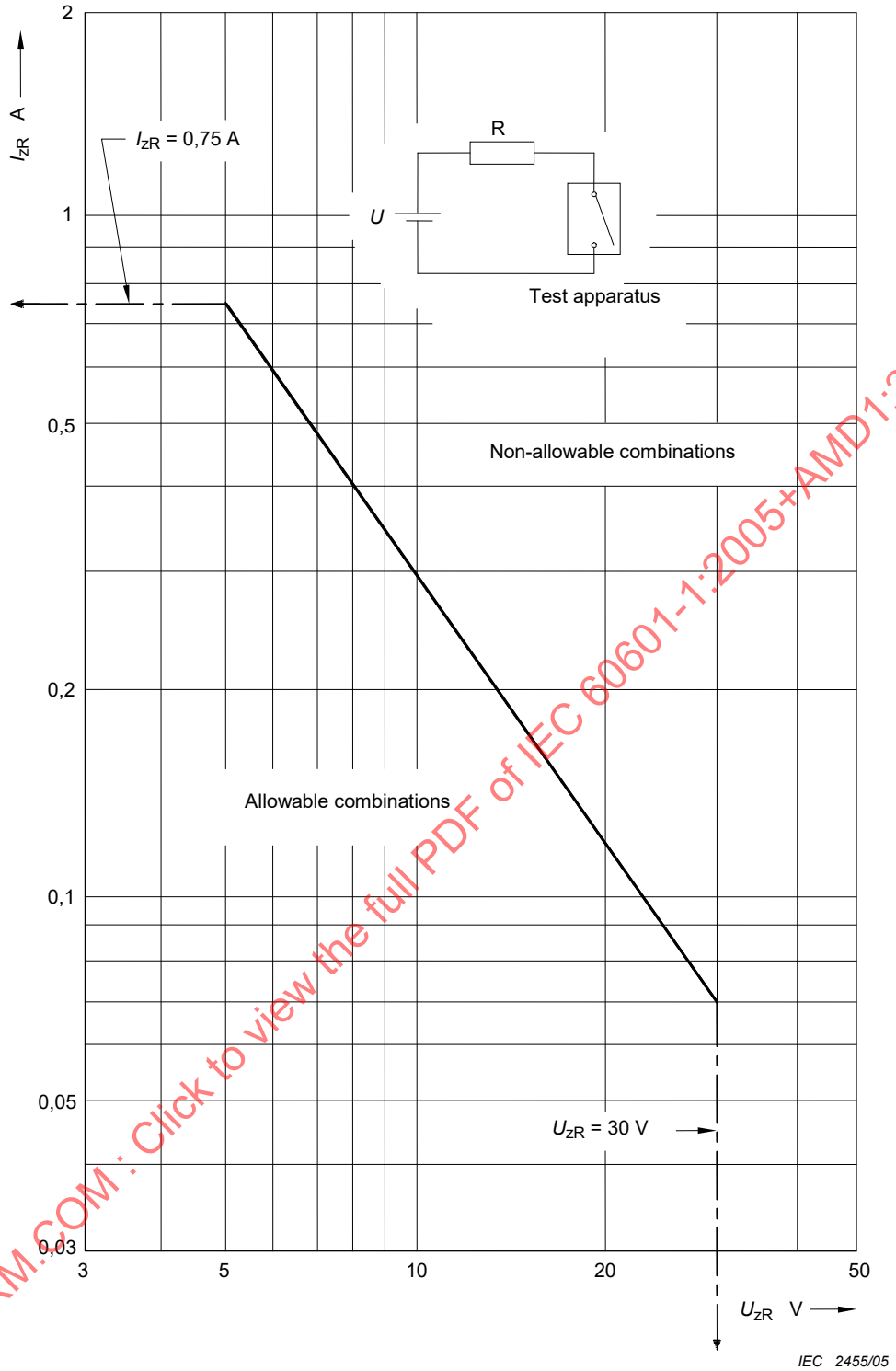
– If the circuit is complicated and consists of more than one capacitance, inductance and resistance or a combination thereof an equivalent circuit is calculated to determine the equivalent maximum capacitance, the equivalent maximum inductance and, additionally, the equivalent U_{max} and I_{max} either as d.c. values or a.c. peak values.

– If the energy produced in an inductance or capacitance in a circuit is limited by voltage-limiting or current-limiting devices preventing the limits of Figure G.4, Figure G.5 and Figure G.6 being exceeded, two independent components shall be applied, so that the required limitation of voltage or current is obtained even in the case of a first fault (short circuit or open circuit) in one of these components.

This requirement does not apply to transformers designed and made according to this standard and to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in the event of rupture.

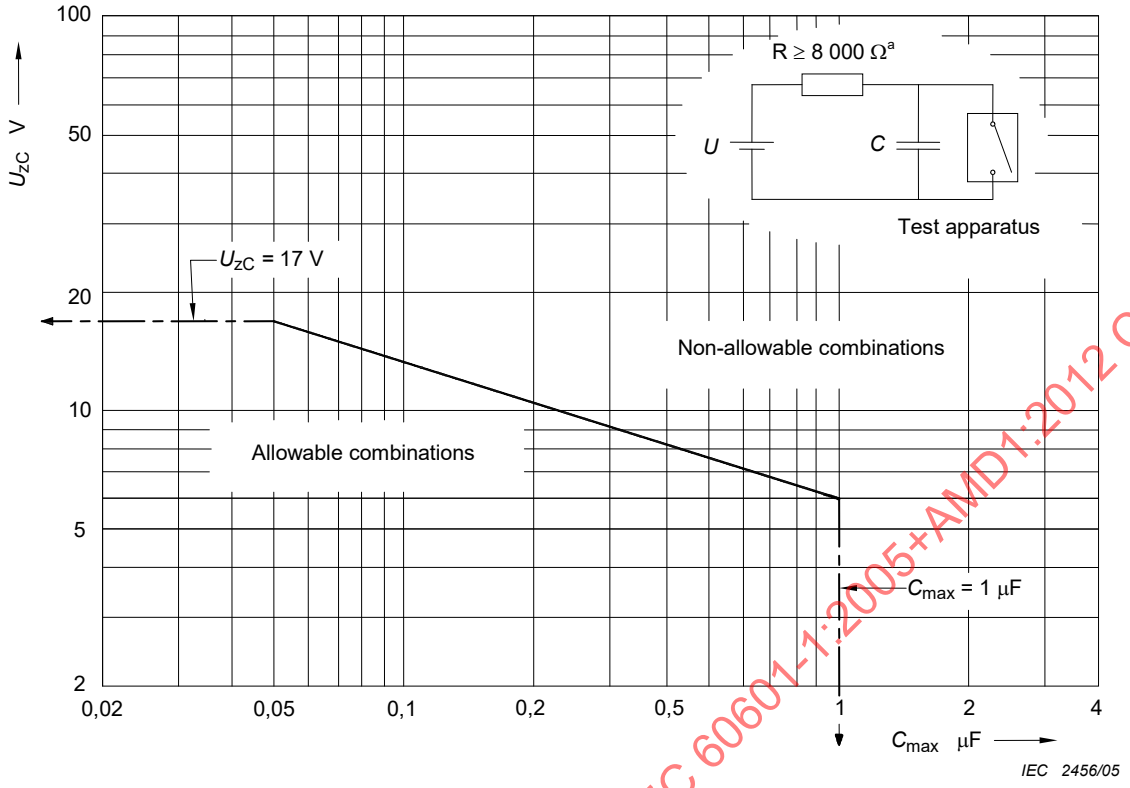
Compliance is checked by inspection, temperature measurements, comparison with design data or by measurement of U_{max}, I_{max}, R, L_{max} and C_{max} and using Figure G.4, Figure G.5 and Figure G.6.

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Figure G.4 – Maximum allowable current I_{zR} as a function of the maximum allowable voltage U_{zR} measured in a purely resistive circuit with the most flammable mixture of ether vapour with oxygen



[a] 8 000 Ω or the actual resistance, if *R* is less than 8 000 Ω

Figure G.5 – Maximum allowable voltage U_{zc} as a function of the capacitance C_{max} measured in a capacitive circuit with the most flammable mixture of ether vapour with oxygen

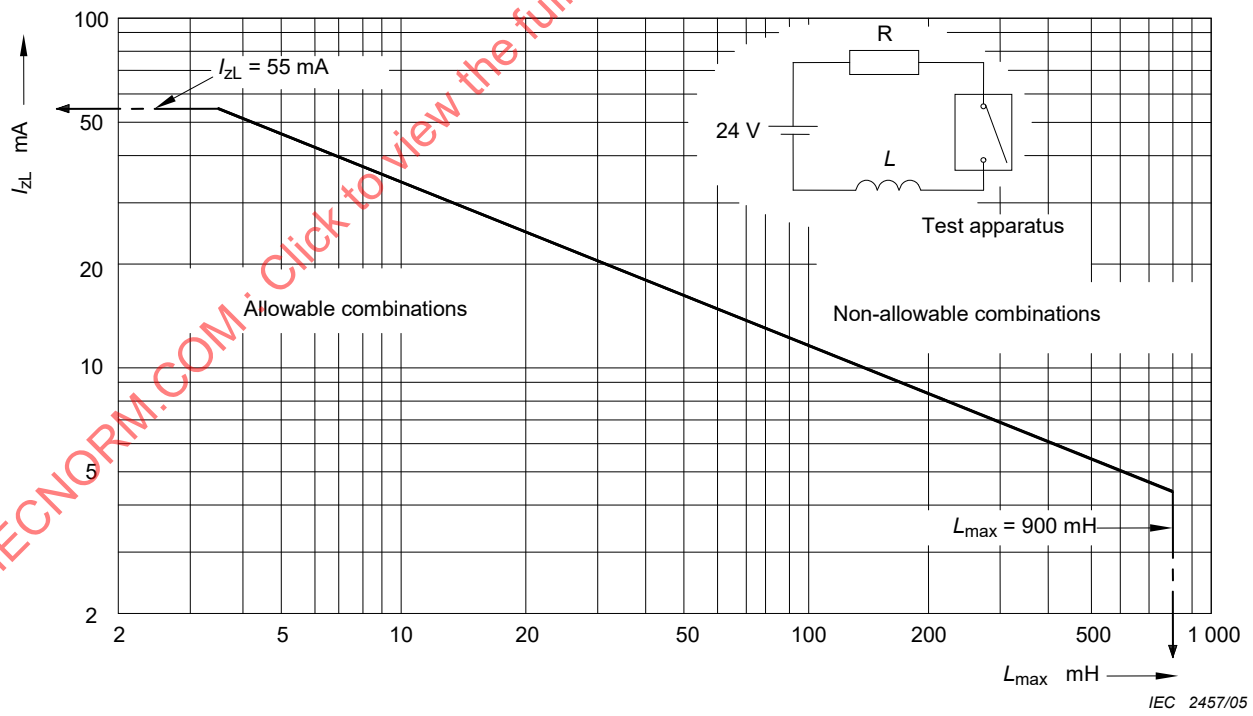


Figure G.6 – Maximum allowable current I_{zL} as a function of the inductance L_{max} measured in an inductive circuit with the most flammable mixture of ether vapour with oxygen

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G.6.4 Heating elements

ME EQUIPMENT, its parts and components that heat a FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE shall be provided with a non-SELF-RESETTING THERMAL CUT-OUT, as an additional protection against overheating.

Compliance is checked by the corresponding test of 15.4.2.1.

The current-carrying part of the heating element shall not be in direct contact with the FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE.

Compliance is checked by inspection.

G.7 Test apparatus for flammable mixtures

NOTE Formally Appendix F of the second edition.

The test apparatus comprises an ignition space with a volume of at least 250 cm^3, which contains the prescribed atmosphere or mixture and a contact arrangement (see Figure G.7) providing sparks by opening and closing.

The contact arrangement consists of a cadmium disk with two groves and a second disk with four tungsten wires having a diameter of 0,2 mm that slides over the first disk. The free length of the tungsten wires is 11 mm. The shaft to which the tungsten wires are connected rotates with a speed of 80 r/min. The shaft connected to the cadmium disk turns in opposite direction to the shaft connected to the disk with wires.

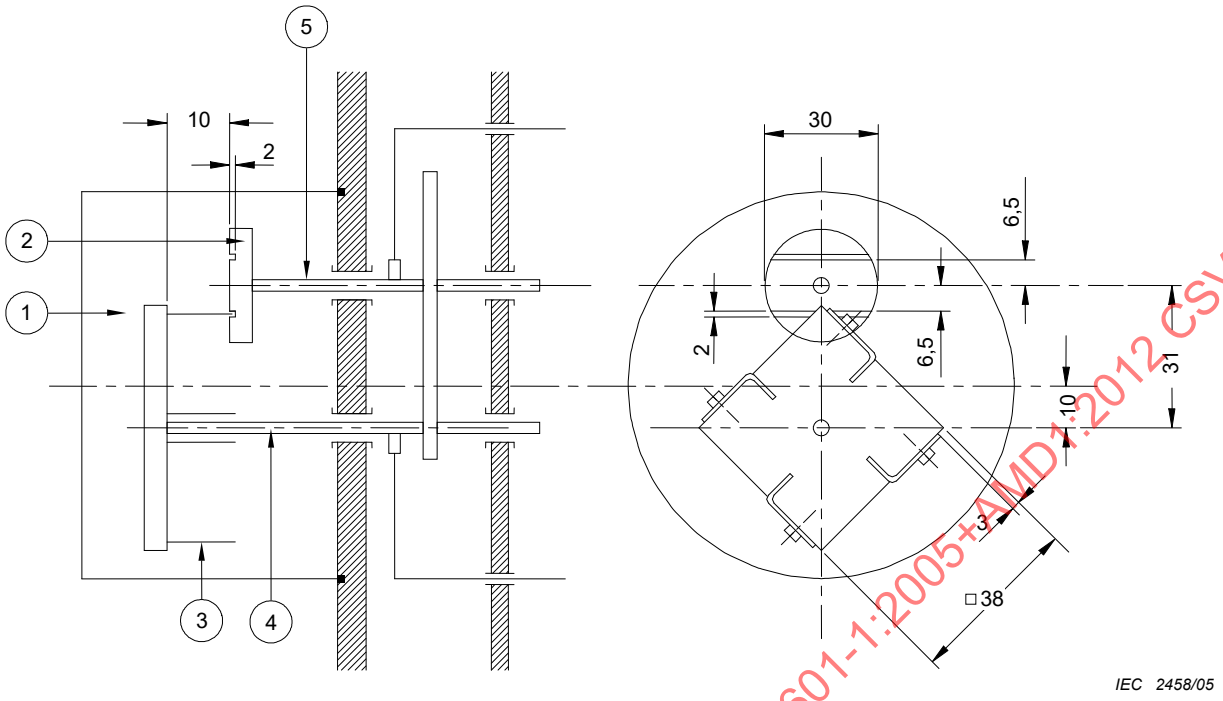
The ratio of the rotation speed of the shaft connected to the wires and the other shaft is 50:12.

Both shafts are isolated from each other and from the frame.

The ignition space must be able to support an internal overpressure of 1,5 MPa.

With the contact arrangement, the circuit to be tested is closed or opened and it is checked if the sparks will ignite the atmosphere or mixture under test.

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Dimensions in millimetres

Legend

1 Ignition space
2 Cadmium disk
3 Tungsten wire
4 Shaft of wire disk
5 Shaft of disk with grooves

Figure G.7 – Test apparatus

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Annex H
(informative)

PEMS structure, PEMS DEVELOPMENT LIFE-CYCLE and documentation

H.1 Examples for PEMS/PESS structures

A PEMS can be a very simple piece of ME EQUIPMENT or a complex ME SYSTEM or anything in between.

Figure H.1 shows some possible examples of a PEMS.

Figure H.1 a) shows a complex system. The PEMS breaks down into a number of major subsystems, which in turn are made up of subsystems, which include a PESS.

Figure H.1 b) shows a simpler implementation. In this case the intermediate major subsystem level is missing and the PESS is a subsystem of the PEMS itself.

Figure H.1 c) illustrates the simplest implementation of a PEMS. In this case the PEMS and the PESS are the same.

The structure of the PEMS is extremely important for implementing safety requirements. An architecture should be documented for the PEMS that describes the structure of the PEMS and the relationship between each PESS and the PEMS as a whole. The architecture should indicate:

– the division of the PEMS into components, especially those implemented in each PESS and including software components;
– the functions to be performed by each PESS and its components (including where appropriate safety-related functions);
– the interfaces between software components;
– the interfaces between software components and components external to the software.

H.2 PEMS DEVELOPMENT LIFE-CYCLE model

Compliance with the PEMS clause of this standard (Clause 14) requires that a PEMS DEVELOPMENT LIFE-CYCLE be specified and then followed; it does not require that any particular PEMS DEVELOPMENT LIFE-CYCLE is used, but it does require that the PEMS DEVELOPMENT LIFE-CYCLE has certain attributes. These requirements can be found in 14.4.

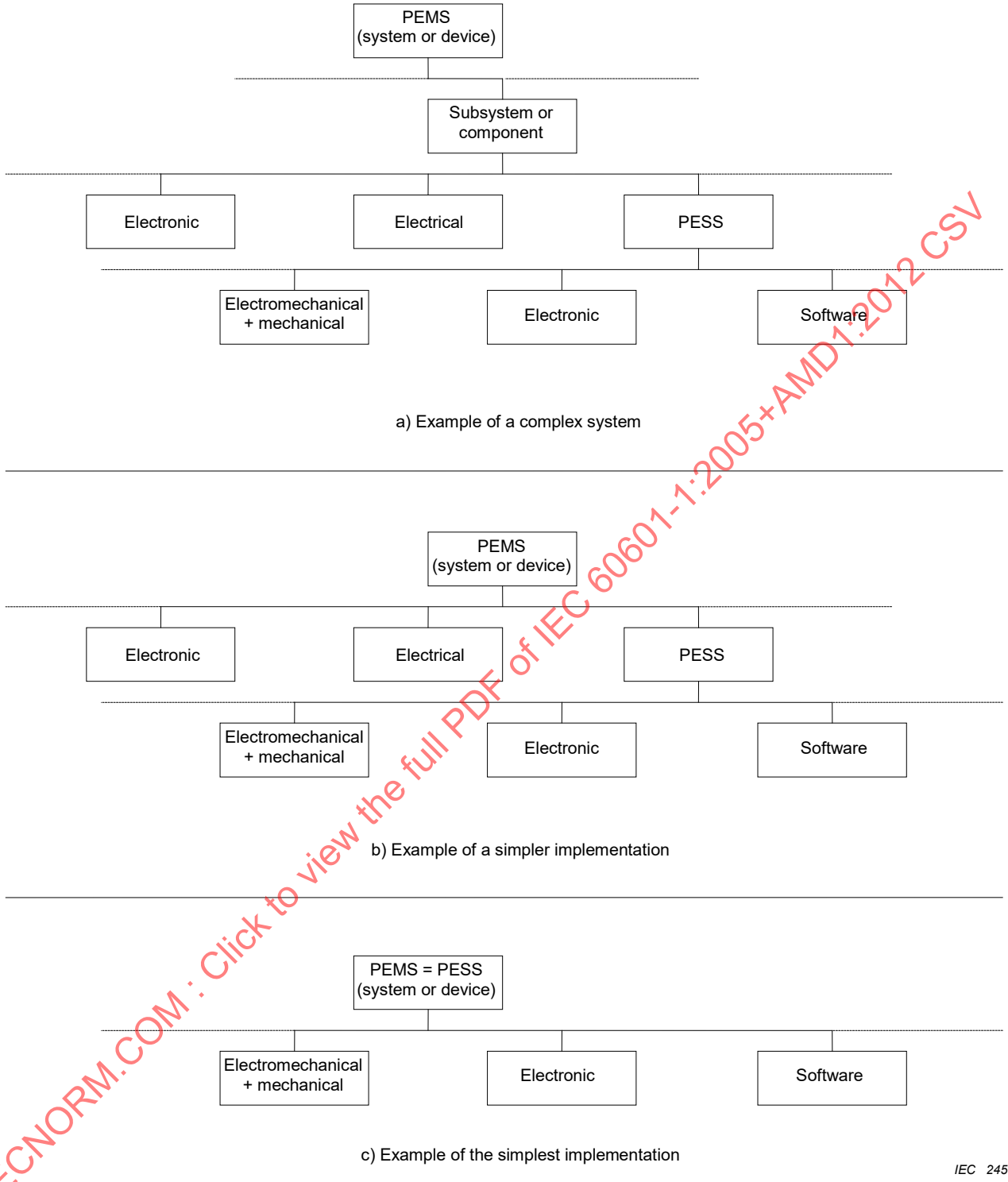
The PEMS DEVELOPMENT LIFE-CYCLE is a part of the overall product life-cycle.

Figure H.2 is a view of the PEMS DEVELOPMENT LIFE-CYCLE which shows activities grouped into two main PROCESSES. On the left is decomposition PROCESS and on the right is the integration PROCESS.

Figure H.2 illustrates:

– layered design activities;
– for each layer of design, a corresponding layer of integration and VERIFICATION;
– verified parts are integrated to assemble the next higher layer;
– problem resolution PROCESS interactions.

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Figure H.1 – Examples of PEMS/ PESS structures

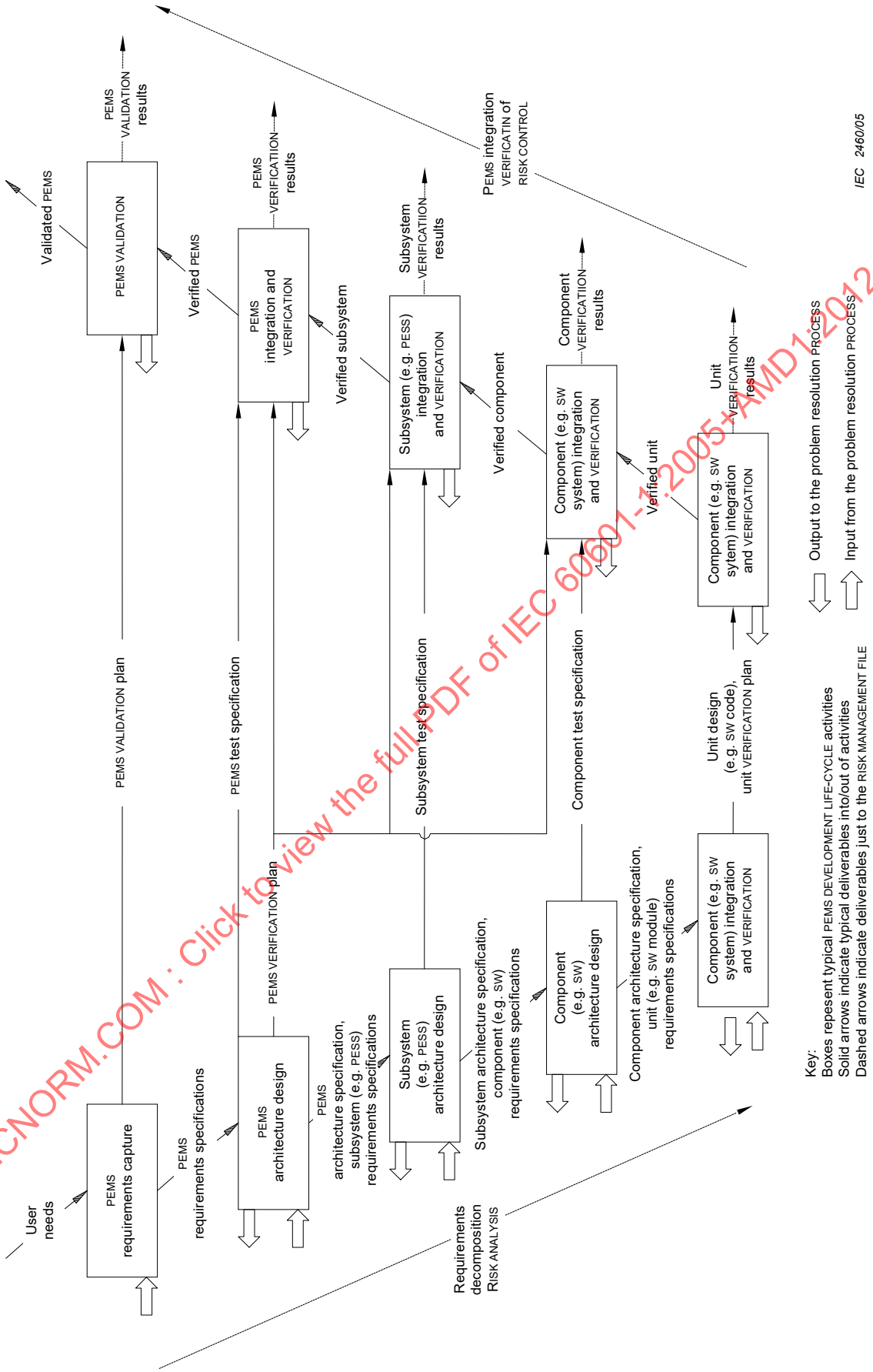


Figure H.2 – A PEMS DEVELOPMENT LIFE-CYCLE model

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As the design is decomposed from the requirements, the functional building blocks, architecture and technology are decided. The decomposition PROCESS concludes when the design information enables the components of the PEMS to be built (examples of such design information are circuit diagrams and software code). The decomposition components are integrated together. VERIFICATION is performed as the components are integrated to determine whether or not the implementation satisfies the requirements. At the conclusion of the integration PROCESS, a PEMS VALIDATION is performed to determine whether or not the PEMS works as intended.

H.3 Software PROCESSES

IEC 62304 describes the processes to be included in the software development life-cycle for the development of safe medical device software.

H.4 Design and implementation

During application of the PEMS DEVELOPMENT LIFE-CYCLE model, design and implementation will include the selection of:

a) the design environment, for example:
   - software development methods;
   - computer aided software engineering (CASE) tools;
   - programming language;
   - hardware and software development platforms;
   - simulation tools;
   - design and coding standards;

b) electronic components;

c) redundant hardware;

d) human-PEMS interface;

e) energy sources;

f) environmental conditions;

g) third-party software;

h) networking options.

These elements of the design environment can be characterized in general and in the specific manner of their use in the design and implementation PROCESS.

H.5 Documentation

Not used.

Figure H.3 – Not used

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H.6 PEMS intended to be incorporated into an IT-NETWORK

H.6.1 General

In the context of this standard, the information transmitted over an IT-NETWORK is that intended by the MANUFACTURER to be transmittable (i.e. not through illegal or illicit actions of unauthorized persons).

H.6.2 System integration responsibilities

ME EQUIPMENT and ME SYSTEMS will sometimes be used together on an IT-NETWORK. This is likely to become more frequent with the increasing use of computers to analyze clinical data and control treatment.

Sometimes ME EQUIPMENT will have been designed by the MANUFACTURER to work on an IT-NETWORK with other ME EQUIPMENT, however, it will often be the case that ME EQUIPMENT will not have been designed to work with all other ME EQUIPMENT on an IT-NETWORK. Someone has to be responsible for ensuring that all the separate ME EQUIPMENT on an IT-network work together satisfactorily; in other words, someone has to be responsible for designing the IT-NETWORK.

It is recognized that the IT-NETWORK integrator often has to comply with particular regulatory requirements.

In order to perform its function, the IT-NETWORK integrator needs to know:

– how the integrated IT-NETWORK is intended to be used;
– the required performance of the integrated IT-NETWORK;
– the intended configuration of the IT-NETWORK;
– the constraints on the extendibility of the IT-NETWORK;
– the specifications of all ME EQUIPMENT and other equipment to be integrated;
– the performance of each ME EQUIPMENT and other equipment; and
– the information flow in and around the IT-NETWORK.

This information will not be available to the individual MANUFACTURERS, and for this reason each individual MANUFACTURER cannot carry out the role of IT-NETWORK integrator. In any case the IT-NETWORK integrator has to be a single person or organisation that has overall responsibility, this overall responsibility can not be shared between several different MANUFACTURERS. The responsibility of a MANUFACTURER is limited to providing the required information on their equipment (see 14.13).

Obviously a RESPONSIBLE ORGANIZATION can employ a MANUFACTURER to integrate their IT-NETWORK. In this case the whole IT-NETWORK can become an ME SYSTEM and it will be the MANUFACTURER'S responsibility to provide a correctly integrated system. In this case the system could be separately regulated.

The IT-NETWORK integrator should be competent to assess and address the HAZARDS that are likely to arise from integrating a IT-NETWORK and to ensure that the RESIDUAL RISKS of the individual PEMS are maintained.

Typically a IT-NETWORK integrator would:

– plan the integration of any ME EQUIPMENT or ME SYSTEM and non-medical equipment in accordance with the instructions provided by the various MANUFACTURERS;
– perform RISK MANAGEMENT on the integrated IT-NETWORK; and
– pass on any MANUFACTURER'S instructions to the RESPONSIBLE ORGANIZATION where these are required for the safe operation of the integrated IT-NETWORK. These instructions should include warnings about the HAZARDS of any change of configuration.

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H.7 Design considerations for IT-NETWORKS

H.7.1 Overview

From the viewpoint of a PEMS MANUFACTURER, any type of an IT-NETWORK is a source of additional HAZARDOUS SITUATIONS. In principle any IT-NETWORK that is outside the control of the PEMS MANUFACTURER should never be presumed to be 100 % reliable.

H.7.2 Causes of HAZARDOUS SITUATIONS associated with IT-NETWORKS

In IT-NETWORKS, likely causes for HAZARDOUS SITUATIONS are:

– loss of data;
– inappropriate data interchange;
– corrupted data;
– inappropriate timing of data;
– unexpected receipt of data;
– unauthorized access to data.

Supplementing Annex E of ISO 14971:2007, at least the following initiating events or circumstances that can lead to HAZARDOUS SITUATIONS associated with IT-NETWORKS should be considered:

– remote servicing (external access to the network);
– operating system (compatibility of operating systems);
– modification/upgrades of software (operating systems, applications, etc.);
– interface compatibility (data collisions, data formats):
  - connections (modification of hardware, network connectors);
  - network interface boards (compatibility);
  - network protocols (DICOM, HL7, etc.);
– packet address structure/timing;
– normal network loads/bandwidth;
– peak network load;
– data media (longevity and retrievability);
– security (viruses, worms, unauthorized software updates or upgrades);
– maximum acceptable response time;
– acceptable failure rate of the network;
– availability of the network (planned and unplanned maintenance);
– inconsistency in interfaces/formats resulting in loss of fidelity during information transfer;
– heterogeneous network topologies.

Supplementing Annex C of ISO 14971:2007, the following questions should be taken into account when identifying the characteristics that could impact on safety:

a) Reasonably foreseeable misuses

   Is connection to the network inconsistent with the INTENDED USE of each constituent PEMS?

b) Incorrect data flow to or from each constituent PEMS

   What are the data transferred by the network used for, and to which tasks are they related? What are the consequences of a breakdown of the IT-NETWORK ?

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c) Deviation from the specified operational characteristics of any constituent PEMS

What are the operational characteristics of the PEMS and to what degree are they affected by the IT-NETWORK?

d) Incomplete characterization of IT-NETWORK parameters

Is the network topology, configuration, parameters (e.g. open or closed, bandwidth, transmission protocol) completely characterized? Are there any breakdown characteristics/concepts and what are these?

e) Excessive use/load of the IT-NETWORK by the network nodes

What is the planned number of network nodes and their assumed degree of use? Are the resources sufficient to meet the needs of both the IT-NETWORK itself and the devices connected to it?

f) Use errors

What skills are required by the OPERATOR for the effective operation of the system?

g) Inadequate configuration management

Do periodic service tasks alter the IT-NETWORK'S characteristics (e.g. after remote access, updates or upgrades)? Does the RESPONSIBLE ORGANIZATION ensure that modifications to each constituent PEMS are reviewed and approved?

h) Information in wrong place

Does data arrive at a convenient and predictable location? Is it accompanied by irrelevant data that could confuse the OPERATOR or obscure the wanted data? When it arrives, is its source adequately indicated?

H.7.3 Not used

Table H.1 – Not used

H.7.4 IT-NETWORK parameters

The use of an IT-NETWORK for exchange of data either between PEMS or between PEMS and other information technology equipment requires the knowledge about both the structure of the IT-NETWORK and the PROCESSES/functions running inside them. This is important because MANUFACTURERS of PEMS or IT-NETWORKS should select the configuration of their products such that:

– they comply with internationally recognized network standards (Ethernet, Fast Ethernet, GigaBitEthernet, FDDI, etc.) and use the available bandwidth appropriately according to the INTENDED USE;

– they achieve the optimal performance for their application

A mixture of different IT-NETWORK configurations/parameter settings can emerge which are not always compatible for the different IT-NETWORK nodes in spite of the fact that they comply to valid international standards.

To avoid or at least to minimize the resulting potential of disruption, a match of a minimum set of IT-NETWORK parameters derived from the relevant standards is required.

Figure H.4 contains a list of parameters potentially required to be specified. Due to the rapid evolution of IT-NETWORK technology, this table should be seen as a starting point. It should be clear if the table should be maintained and who should be responsible for maintaining it.

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Objects	Description		Value/Comment
Application and Operating System:			
Operating System / Version:			
Network protocols:			
Detailed data for specific application / transport protocol (if used)			
HL7	HL 7 version		
	Formats of message types used		
	Free fields (that are used)		
	Ports		
	HL7 Protocol (TCP/IP Lower Layer)		
DICOM Service classes	**A) Test:**	Verification	
	B) Transfer:	Storage	
		Query/Retrieve	
	C) Documentation:	Print management	
	D) Organization:	Modality work list management	
		Performed procedure step	
	E) Information:	Study contents notification	
		Patient management	
		Storage commitment	
		Study component management	
		Results management	
	F) External Storage:	Media storage	
DICOM Objects	e.g. COMPUTER RADIOGRAPHY IMAGE		
	Other Modality Objects		
DICOM host name			
DICOM AET called			
DICOM AET calling			
DICOM Port called			
DICOM Port calling			
Detailed Parameters with respect to the lower protocol layers			
Network data	**Physical connection**		
	Network interface card parameters		
Network-Administration			
Port number of connected Switch / HUB / Router			
IP-Address			
Subnet mask			
Host-Name			
IT-Domain			
Active-Directory / LDAP Server			
Default Gateway (Access via Router)			
Remote Control			
Remote Monitoring			
Modem Connection			
Remote Service IP-Address			
Other Parameters			

Figure H.4 – Example of potential parameters required to be specified for an IT-NETWORK

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Annex I
(informative)

ME SYSTEMS aspects

I.1 Combinations of ME EQUIPMENT and non-ME EQUIPMENT

I.1.1 Introduction

This annex provides a summary of situations that could occur when different combinations of equipment are used in various medical environments. To keep this summary short, no more than two items of equipment (A and B) are used per situation.

I.1.2 Localities in a medical environment

The following localities are foreseen (see also Table I.1):

– the PATIENT ENVIRONMENT as part of a medically used room;

– a medically used room, excluding the PATIENT ENVIRONMENT;

– the non-medically used room (a room not designed for medical treatment, for example, an office or a storage room).

A protective earth can be dedicated to each of the three localities listed above.

NOTE A potential difference *(V)* can exist between the protective earths in different localities. In case of an interruption of protective earthing (fault condition) for equipment in the PATIENT ENVIRONMENT, this potential difference can appear on the ENCLOSURE of the equipment resulting in a HAZARDOUS SITUATION for the OPERATOR or for the PATIENT if the OPERATOR simultaneously touches the equipment and the PATIENT, or for the PATIENT if the APPLIED PART is of TYPE B.

I.1.3 Basic principles

– PATIENTS should only be connected to APPLIED PARTS of ME EQUIPMENT complying with this standard. Other equipment should comply with relevant IEC or ISO standards.

– In fault condition the allowable TOUCH CURRENT is 500 μA.

– All equipment complying with the safety standard applicable to the originally intended, non-medical use, herein called IEC XXXXX, and placed in the PATIENT ENVIRONMENT needs measures to limit the TOUCH CURRENT, if this exceeds the values specified in 16.6.1.

I.1.4 Examples of ME SYSTEMS

Two items of equipment are placed within the PATIENT ENVIRONMENT (see situation No. 1 in Table I.1).

There are several possibilities designated 1a through 1f:

1a: Items A and B both comply with IEC 60601: Subclause 16.6 is satisfied.

1b: Items A and B both comply with IEC 60601 and are powered through a MULTIPLE SOCKET-OUTLET: LEAKAGE CURRENTS might be too high when the earth conductor in the MULTIPLE SOCKET-OUTLET is broken.

1c: Item A complies with IEC 60601 and item B complies with IEC XXXXX: only the TOUCH CURRENT of item B has to be limited when any single PROTECTIVE EARTH CONDUCTOR or the equivalent conductor of the equipment, is interrupted, if necessary, by applying an additional protective earth or a separating transformer to item B.

1d: Same as 1c, with both items powered through a MULTIPLE SOCKET-OUTLET: LEAKAGE CURRENTS might be too high for causes as listed under 1b and 1c.

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1e: Item A is powered from item B with item A complying to IEC 60601 and being an insert to item B, complying to IEC XXXXX. Item B needs the measures for a power supply as described by the MANUFACTURER and needs to fulfil the requirement of 16.3. If necessary, apply an additional protective earth or a separating transformer to item B.

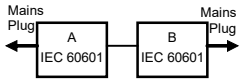
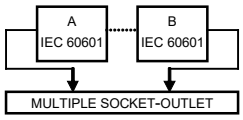
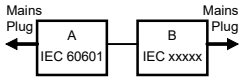
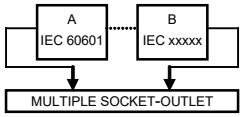
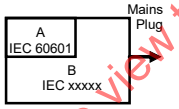
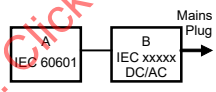
1f: Same as 1e, with item A not being an insert to item B: see 1e.

Situations 2 and 3 can be derived from situation 1 of Table I.1.

NOTE The practical means of compliance indicated in Table I.1 are not intended to be an exhaustive list.

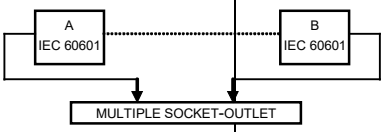
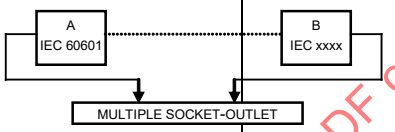
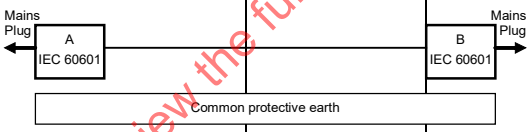
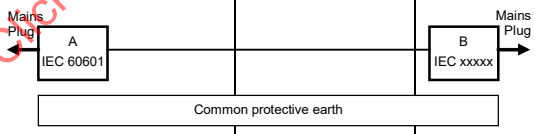
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Table I.1 – Some examples of ME SYSTEMS for illustration

Situation No.		Medically used room		Non-medically used room	Examples of possible causes for exceeding LEAKAGE CURRENT limits	Practical means of compliance Apply 16.5 in all situations
		Inside the PATIENT ENVIRONMENT	Outside the PATIENT ENVIRONMENT			
1	**1a** Items A and B are ME EQUIPMENT				Multiplied APPLIED PARTS of the same type can cause the total PATIENT LEAKAGE CURRENT to exceed limits See Note 1.	– Verify total PATIENT LEAKAGE CURRENT
	1b Items A and B are ME EQUIPMENT powered via a MULTIPLE SOCKET-OUTLET				Earth conductor of the MULTIPLE SOCKET-OUTLET is broken See also 1a.	– Additional PROTECTIVE EARTH CONNECTION (for A or B) or, – Separating transformer
	1c Item A is ME EQUIPMENT and B is Non-ME EQUIPMENT				Due to high TOUCH CURRENT of B	– Additional PROTECTIVE EARTH CONNECTION (for B) or, – Separating transformer (for B)
	1d Item A is ME EQUIPMENT and B is non-ME EQUIPMENT powered via a MULTIPLE SOCKET-OUTLET				The earth conductor of the MULTIPLE SOCKET-OUTLET is broken or, Due to high TOUCH CURRENT of B	– Additional PROTECTIVE EARTH CONNECTION (for A or B) or, – Separating transformer
	1e Item A is ME EQUIPMENT powered from specified power supply in item B				Due to high TOUCH CURRENT of B	– Additional PROTECTIVE EARTH CONNECTION (for B) or, – Separating transformer (for B)
	1f Item A is ME EQUIPMENT powered from NON-ME EQUIPMENT power supply in B					

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Table I.1 *(continued)*

Situation No.		Medically used room: Inside the PATIENT ENVIRONMENT	Medically used room: Outside the PATIENT ENVIRONMENT	Non-medically used room	Examples of possible causes for exceeding LEAKAGE CURRENT limits	Practical means of compliance Apply 16.5 in all situations
2	**2a** Items A and B are ME EQUIPMENT				No causes of exceeding LEAKAGE CURRENT	– No further measures are necessary
	2b Items A and item B are ME EQUIPMENT powered via a MULTIPLE SOCKET-OUTLET				Earth conductor of the MULTIPLE SOCKET-OUTLET is broken	– Additional PROTECTIVE EARTH CONNECTION (for A or B) or, – Separating transformer
	2c Item A is ME EQUIPMENT and item B is non-ME EQUIPMENT				Due to high TOUCH CURRENT of B See rationale for 16.5.	– Do not use metal connector housing or, – SEPARATION DEVICE
	2d Item A is ME EQUIPMENT and item B is non-ME EQUIPMENT powered via a MULTIPLE SOCKET-OUTLET				The earth conductor of the MULTIPLE SOCKET-OUTLET is broken	– Additional PROTECTIVE EARTH CONNECTION (for A or B) or, – Separating transformer
3	**3a** Items A and B are ME EQUIPMENT				No causes of exceeding LEAKAGE CURRENT	– No further measures are necessary
	3b Item A is ME EQUIPMENT and item B is non-ME EQUIPMENT				Due to high TOUCH CURRENT of B See rationale for 16.5.	– Do not use metal connector housing for SIGNAL INPUT/OUTPUT PART or, – SEPARATION DEVICE
	3c Item A is ME EQUIPMENT and item B in is ME EQUIPMENT or non-ME EQUIPMENT				a) Potential difference between PROTECTIVE EARTH CONNECTIONS of A and B b) Due to high TOUCH CURRENT of B See rationale for 16.5.	– Additional PROTECTIVE EARTH CONNECTION for (A), or – SEPARATION DEVICE, or – Do not use metal connector housing in the PATIENT ENVIRONMENT

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Table I.1 *(continued)*

NOTE 1 No causes of TOUCH CURRENT or EARTH LEAKAGE CURRENT exceeding limits.
NOTE 2 IEC 60601: MEDICAL ELECTRICAL EQUIPMENT in compliance with IEC 60601.
NOTE 3 IEC xxxxx: Non-medical equipment in compliance with relevant IEC safety standards.
NOTE 4 Separating transformer: see 16.9.2.1.
NOTE 5 If equipment "B" is outside the PATIENT ENVIRONMENT and if equipment "A" is a CLASS II equipment and has accessible conductive parts connected to the PROTECTIVE EARTH CONNECTION of equipment "B" then additional safety measures could be necessary, for example: additional protective earth for "B" or separating transformer or SEPARATION DEVICE.

I.2 Examples of application of MULTIPLE SOCKET-OUTLETS (MSO)

Figure I.1 shows an example of the construction of a MULTIPLE SOCKET-OUTLET. Figure I.2 shows some examples of application of MUPTILE SOCKET-OUTLETS.

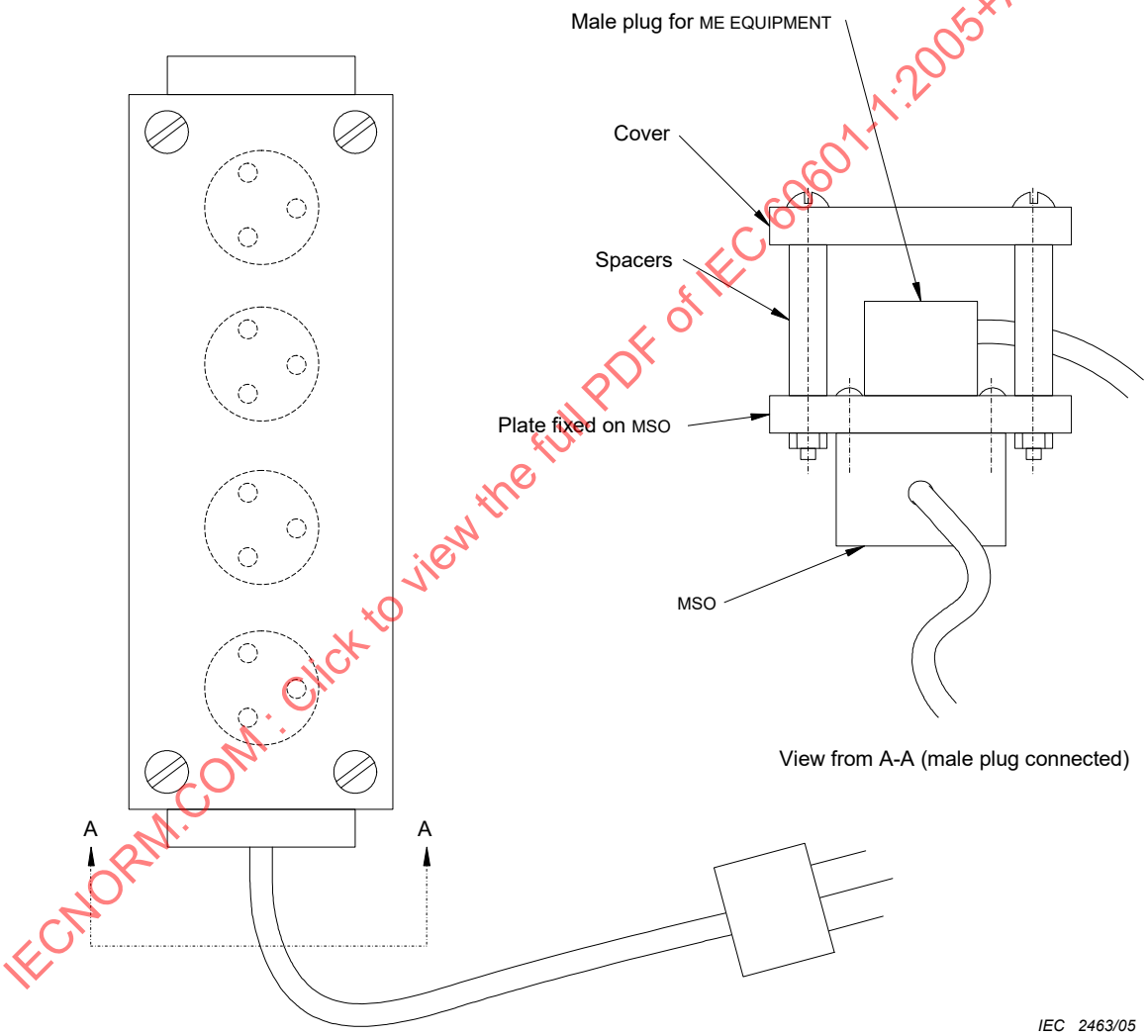


Figure I.1 – Example of the construction of a MULTIPLE SOCKET-OUTLET (MSO) (accessible only with the use of a TOOL)

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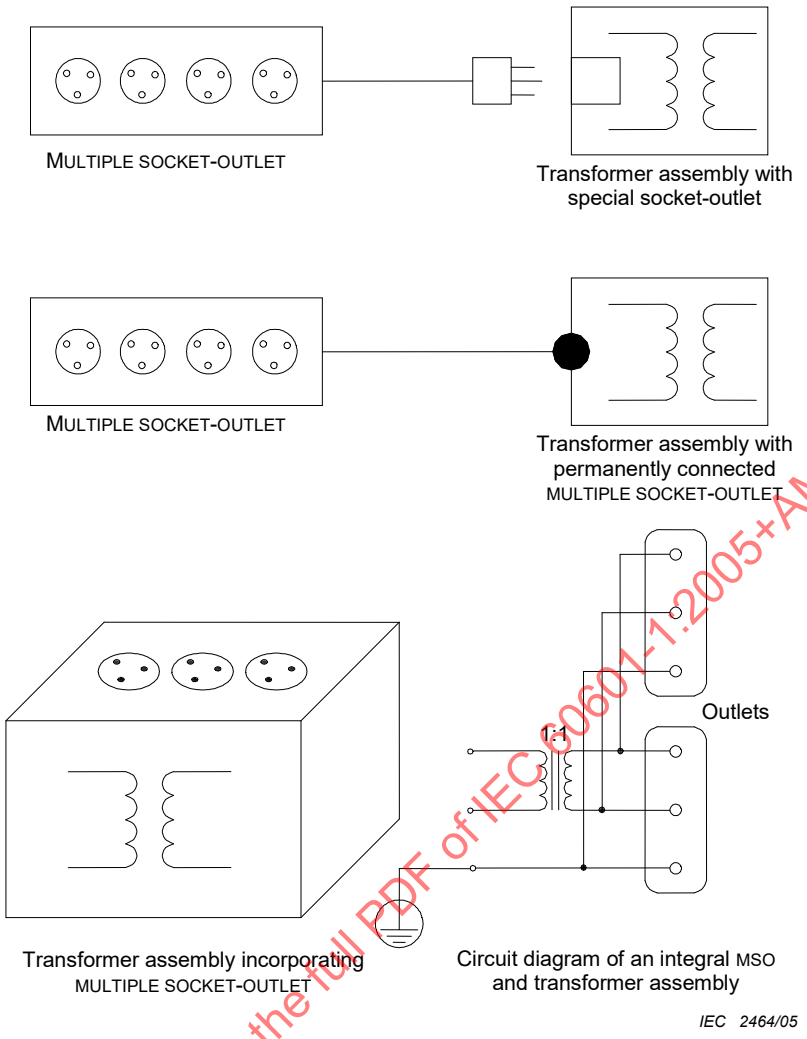


Figure I.2 – Examples of application of MULTIPLE SOCKET-OUTLETS (MSO)

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Annex J
(informative)

Survey of insulation paths

(see 8.5.1)

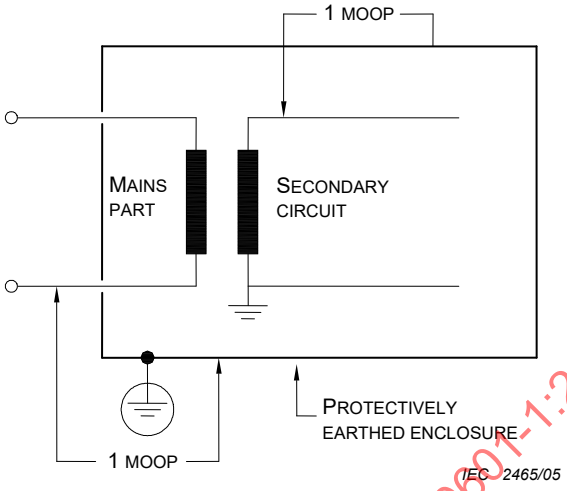


Figure J.1 – Insulation example 1

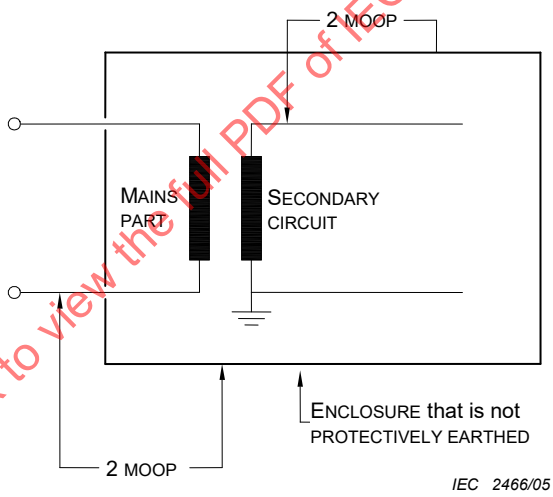


Figure J.2 – Insulation example 2

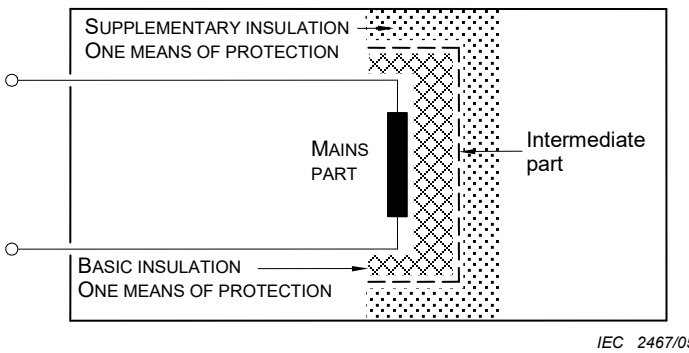


Figure J.3 – Insulation example 3

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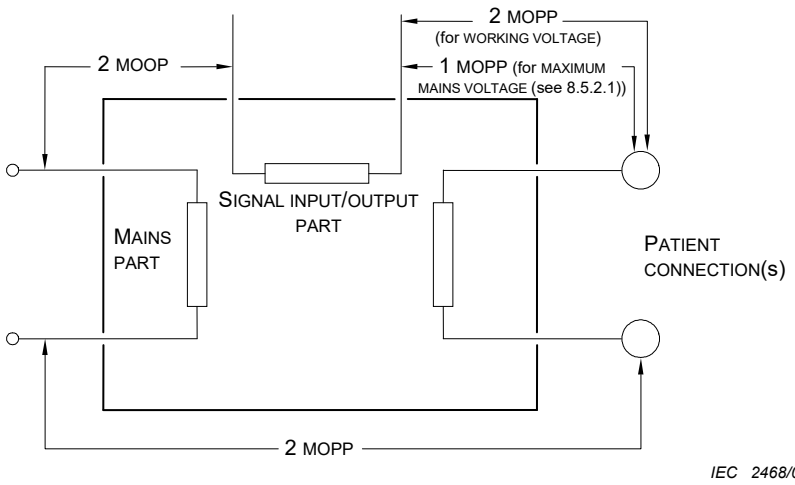


Figure J.4 – Insulation example 4

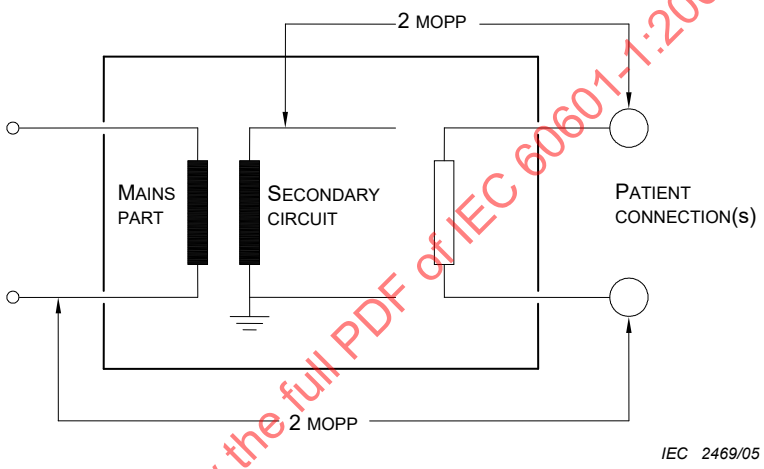


Figure J.5 – Insulation example 5

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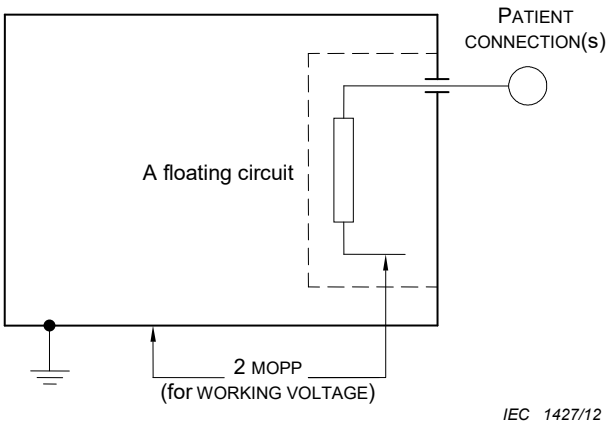
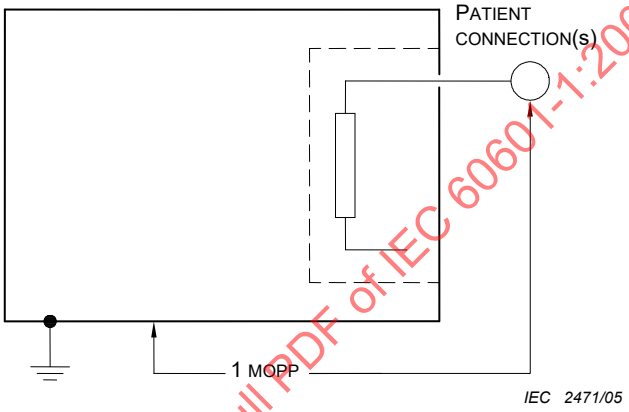


Figure J.6 – Insulation example 6



NOTE WORKING VOLTAGE is the MAXIMUM MAINS VOLTAGE.

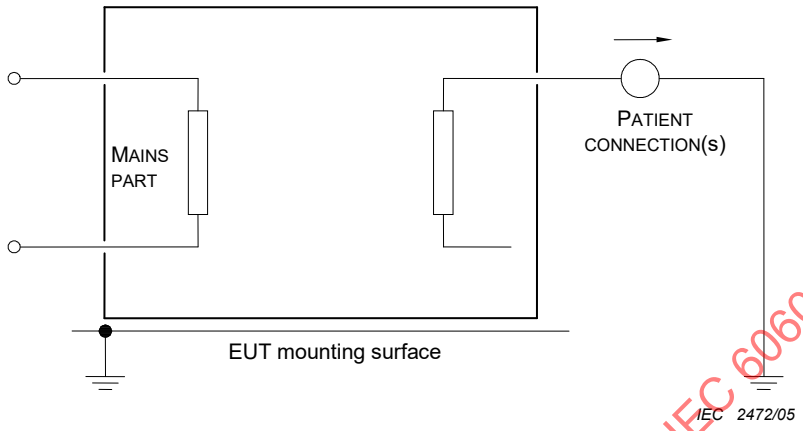
Figure J.7 – Insulation example 7

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Annex K
(informative)

Simplified PATIENT LEAKAGE CURRENT diagrams

Figure K.2, Figure K.4 and Figure K.5 illustrate a special test condition in Table 4, which is neither a NORMAL CONDITION nor a SINGLE FAULT CONDITION.

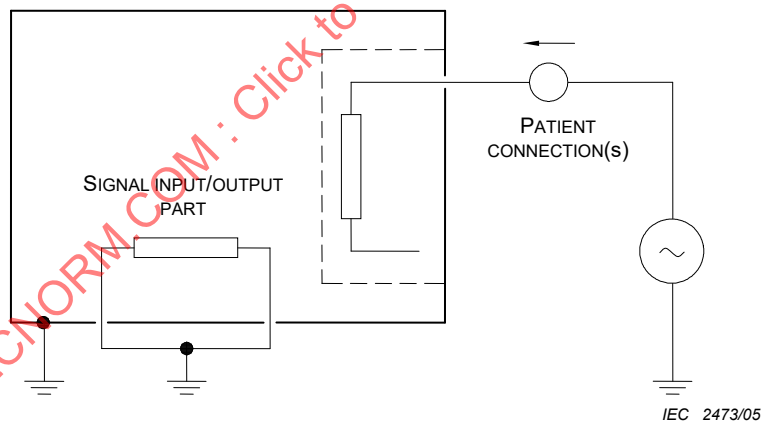


Current in μA

APPLIED PART TYPE	NORMAL CONDITION	SINGLE FAULT CONDITION
CF	10	50
BF	100	500
B	100	500

Example with the measuring supply circuit of Figure F.1.

Figure K.1 – ME EQUIPMENT with an ENCLOSURE made of insulating material
(simplified Figure 15)
(see 8.7.4.7 a))



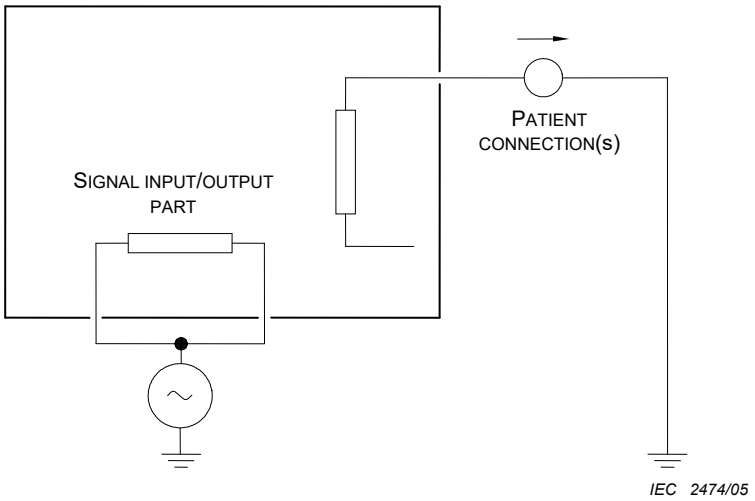
Current in μA

APPLIED PART TYPE	Special test condition
CF	50
BF	5 000
B	—

Example with the measuring supply circuit of Figure F.1.

Figure K.2 – ME EQUIPMENT with an F-TYPE APPLIED PART
(simplified Figure 16)
(see 8.7.4.7 b))

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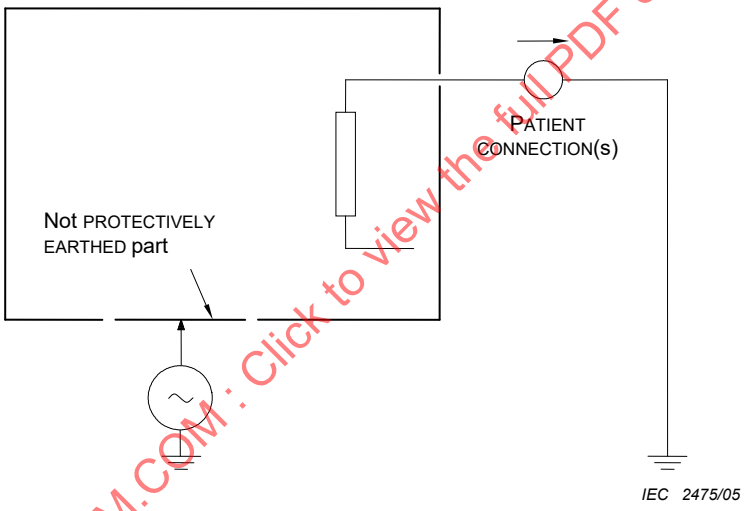


Current in μA

APPLIED PART TYPE	NORMAL CONDITION	SINGLE FAULT CONDITION
CF	10	50
BF	100	500
B	100	500

Example with the measuring supply circuit of Figure F.1.

Figure K.3 – ME EQUIPMENT with an APPLIED PART and a SIGNAL INPUT/OUTPUT PART
(simplified Figure 17)
(see 8.7.4.7 c))



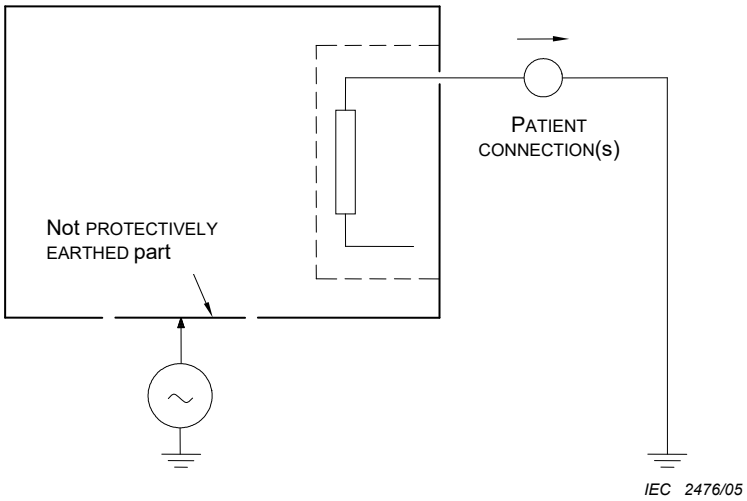
Current in μA

APPLIED PART TYPE	Special test condition
CF	—
BF	—
B	500

Example with the measuring supply circuit of Figure F.1.

Figure K.4 – ME EQUIPMENT with a PATIENT CONNECTION of a TYPE B APPLIED PART that is not PROTECTIVELY EARTHED
(simplified Figure 18)
(see 8.7.4.7 d))

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Current in μA

APPLIED PART TYPE	Special test condition
CF	—
BF	500
B	—

Example with the measuring supply circuit of Figure F.1.

Figure K.5 – ME EQUIPMENT with a PATIENT CONNECTION of a TYPE BF APPLIED PART that is not PROTECTIVELY EARTHED
(simplified Figure 18)
(see 8.7.4.7 d))

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Annex L
(normative)

Insulated winding wires for use without interleaved insulation
(see 8.8.2)

L.1 Introduction

This annex specifies winding wire whose insulation may be used to provide BASIC INSULATION, SUPPLEMENTARY INSULATION, DOUBLE INSULATION or REINFORCED INSULATION in wound components without interleaved insulation.

This annex covers round winding wires having diameters between 0,05 mm and 5,00 mm.

L.2 Wire construction

If the wire is insulated with two or more spirally wrapped layers of tape, the overlap of layers shall be adequate to ensure continued overlap during manufacture of the wound component. The layers of spirally wrapped wire insulation shall be sufficiently secured to maintain the amount of overlap.

L.3 TYPE TEST

The wire shall pass the tests of L.3.1 to L.3.4, carried out at a temperature between 15 °C and 35 °C and a relative humidity between 45 % and 75 %, unless specified otherwise.

L.3.1 Dielectric strength

The test sample is prepared according to IEC 60851-5:2008, Subclause 4.4.1 (for a twisted pair). The sample is then subjected to the test of 8.8.3 for the appropriate type and number of MOP(s). The test voltage is at least twice the appropriate voltage in Table 6 and Table 7 (see 8.8.3), with a minimum of:

– *3 000 V for BASIC INSULATION or SUPPLEMENTARY INSULATION; or*

– *6 000 V for REINFORCED INSULATION.*

L.3.2 Flexibility and adherence

The sample is subjected to test 8 of IEC 60851-3:2009, Subclause 5.1.1, using the mandrel diameters of Table L.1. The test sample is then examined in accordance with IEC 60851-3:2009, Subclause 5.1.1.4, followed by the test of 8.8.3, for the appropriate type and number of MOP(s), except that the test voltage is applied between the wire and the mandrel. The test voltage is at least the appropriate voltage in Table 6 and Table 7 (see 8.8.3) with a minimum of:

– *1 500 V for BASIC INSULATION or SUPPLEMENTARY INSULATION; or*

– *3 000 V for REINFORCED INSULATION.*

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Table L.1– Mandrel diameter

NOMINAL conductor diameter mm	Mandrel diameter mm ± 0,2 mm
0,05 – 0,34	4,0
0,35 – 0,49	6,0
0,50 – 0,74	8,0
0,75 – 2,49	10,0
2,50 – 5,00	four times the conductor diameter [a]
[a] In accordance with IEC 60317-43 [9].	

The tension to be applied to the wire during winding on the mandrel is calculated from the wire diameter to be equivalent to 118 MPa ± 11,8 MPa (118 N/mm² ± 11,8 N/mm²).

L.3.3 Heat shock

The sample is subjected to test 9 of IEC 60851-6:1996, followed by the dielectric strength test of 8.8.3 for the appropriate type and number of MOP(s), except that the test voltage is applied between the wire and the mandrel. The voltage is not less than the appropriate voltage in Table 6 and Table 7 (see 8.8.3) with a minimum of:

– *1 500 V for BASIC INSULATION or SUPPLEMENTARY INSULATION; or*

– *3 000 V for REINFORCED INSULATION.*

The oven temperature is the relevant temperature for the thermal class of insulation in Table L.2.

The mandrel diameter and tension applied to the wire during winding on the mandrel are as in L.3.2.

The electric strength test is conducted at room temperature after removal from the oven.

Table L.2 – Oven temperature

Thermal class	A (105)	E (120)	B (130)	F (155)	H (180)
Oven temperature °C ± 5 °C	200	215	225	240	260

L.3.4 Retention of electric strength after bending

Five samples are prepared as in L.3.2 above and tested as follows. Each sample is removed from the mandrel, placed in a container and positioned so that it can be surrounded by at least 5 mm of metal shot. The ends of the conductor in the sample are to be sufficiently long to avoid flash over. The shot is to be not more than 2 mm in diameter and consists of balls of stainless steel, nickel or nickel plated iron. The shot is gently poured into the container until the sample under test is covered by at least 5 mm of shot. The shot is cleaned periodically with a suitable solvent (for example, 1,1,1-trichloroethane).

NOTE The above test PROCEDURE is reproduced from 4.6.1.c) of IEC 60851-5:1988 (second edition including amendment 1), now withdrawn. It is not included in the fourth edition of that standard.

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The test voltage is at least the appropriate test voltage in Table 6 and Table 7 (see 8.8.3) for the appropriate type and number of MOP(s), with a minimum of:

– *1 500 V for BASIC INSULATION or SUPPLEMENTARY INSULATION; or*

– *3 000 V for REINFORCED INSULATION.*

The test voltage is applied between the shot and the conductor.

The mandrel diameter and tension applied to the wire during winding on the mandrel are as in L.3.2.

L.4 Tests during manufacture

L.4.1 General

The wire is subjected by the wire manufacturer to electric strength tests during manufacture as specified in L.4.2 and L.4.3.

L.4.2 Routine testing

The test voltage for routine testing is to be the appropriate voltage in Table 6 and Table 7 (see 8.8.3) for the appropriate type and number of MOP(s), with a minimum of:

– *1 500 V r.m.s. or 2 100 V peak for BASIC INSULATION or SUPPLEMENTARY INSULATION; or*

– *3 000 V r.m.s. or 4 200 V peak for REINFORCED INSULATION.*

L.4.3 Sampling tests

Twisted pair samples are tested in accordance with IEC 60851-5:2008, Subclause 4.4.1. The minimum breakdown voltage is twice the appropriate voltage in Table 6 and Table 7 (see 8.8.3) for the appropriate type and number of MOP(s),with a minimum of:

– *3 000 V r.m.s. or 4 200 V peak for BASIC INSULATION or SUPPLEMENTARY INSULATION; or*

– *6 000 V r.m.s. or 8 400 V peak for REINFORCED INSULATION.*

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Annex M
(normative)

Reduction of pollution degrees
(see 8.9.1.8)

Table M.1 shows additional protective measures that may be used to reduce the pollution degree.

Table M.1 – Reduction of the pollution degree of internal environment through the use of additional protection

Additional protection	From pollution degree 2 of external environment to:	From pollution degree 3 of external environment to:
ENCLOSURE IPX4 of IEC 60529	2	2
ENCLOSURE IPX5 or IPX6 of IEC 60529	2	2
ENCLOSURE IPX7 or IPX8 of IEC 60529	2 (see note)	2 (see note)
Hermetically sealed ENCLOSURE	1	1
Constantly heated	1	1
Encapsulated	1	1
Coated	1	2
NOTE Reduction can be to pollution degree 1, if the equipment is manufactured with a low internal humidity and the manufacturer's instructions specify that, after opening the ENCLOSURE, the ENCLOSURE is reassembled in a controlled humidity environment or a desiccant is used.		

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[1] IEC 60050-151:2001, *International Electrotechnical Vocabulary (IEV) – Part 151: Electrical and magnetic devices*

[2] IEC 60050-195:1998, *International Electrotechnical Vocabulary (IEV) – Part 195: Earthing and protection against electric shock*

Amendment 1 (2001)

[3] IEC 60050-441:2001, *International Electrotechnical Vocabulary (IEV) – Chapter 441: Switchgear, controlgear and fuses*

[4] IEC 60050-826:2004, *International Electrotechnical Vocabulary (IEV) – Part 826: Electrical installations*

[5] IEC 60073, *Basic and safety principles for man-machine interface, marking and identification – Coding principles for indication devices and actuators*

[6] IEC 60086-1, *Primary batteries - Part 1: General*

[7] IEC 60127-6, *Miniature fuses – Part 6: Fuse holders for miniature fuse links*

[8] IEC 60309-1, *Plugs, socket-outlets and couplers for industrial purposes – Part 1: General requirements*

[9] IEC 60317-43, *Specifications for particular types of winding wires – Part 43:Aromatic polyimide tape wrapped round copper wire, class 240*

[10] IEC 60364-7-710, *Electrical installations of buildings – Part 7-710: Requirements for special installations or locations – Medical locations*

[11] IEC 60479-1:1994, *Effects of current on human beings and livestock – Part 1: General aspects*

[12] IEC 60513:1994, *Fundamental aspects of safety standards for medical electrical equipment*

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[15] IEC 60601-2-4, *Medical electrical equipment – Part 2-4: Particular requirements for the safety of cardiac defibrillators*

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[17] IEC 60695-1-10, *Fire hazard testing – Part 1-10: Guidance for assessing the fire hazard of electrotechnical products – General guidelines*

[18] IEC 60721 (all parts), *Classification of environmental conditions*

[19] IEC 60788:2004, *Medical electrical equipment – Glossary of defined terms*

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INDEX OF ABBREVIATIONS AND ACRONYMS

Abbreviation	Term
a.c.	Alternating current
AEL	Accessible emission limit
AMSO	Auxiliary mains socket-outlet
AP	Anaesthetic-proof
APG	Anaesthetic-proof category G (gas)
CASE	Computer aided software engineering
CAT	Computer assisted tomography
CRT	Cathode ray tube
CTI	Comparative tracking index
d.c.	Direct current
DICOM	Digital imaging and communication in medicine
ELV	Extra-low voltage
EUT	Equipment under test
FDDI	Fibre distributed data interface
FMEA	Failure modes and effects analysis
FV	Flammability classification according to IEC 60695-11-10
HL7	Health Level 7
IBP	Invasive blood pressure catheter
ICRP	International commission for radiation protection
IEV	International Electrotechnical Vocabulary
IP	International protection in relation to the protection requirements of IEC 60529 or Internet protocol in relation to NETWORK/DATA COUPLING
IPS	Isolated power supply
IT	Information technology
LDAP	Light weight directory access protocol
LED	Light emitting diode
MAR	Minimum angle resolvable
MD	Measuring device, see 8.7.4.4
ME	MEDICAL ELECTRICAL, see 3.63 and 3.64
MOOP	MEANS OF OPERATOR PROTECTION, see 3.58
MOP	MEANS OF PROTECTION, see 3.60
MOPP	MEANS OF PATIENT PROTECTION, see 3.59
MPSO	Multiple portable socket-outlet
MSO	MULTIPLE SOCKET-OUTLET, see 3.67
OTS	Off the shelf
PEMS	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM, see 3.90
PESS	PROGRAMMABLE ELECTRONIC SUBSYSTEM, see 3.91
PTC	Positive temperature coefficient device
PTFE	Polytetrafluoroethylene
PVC	Polyvinyl chloride

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Abbreviation	Term
RFID	Radio-frequency identification
r.m.s.	Root mean square
SAR	Specific absorption rate
SELV	Safety extra-low voltage
SI	System international
SIP/SOP	SIGNAL INPUT/OUTPUT PART, see 3.115.
TCP	Transport connection protocol
TENS	Transcutaneous electronic nerve stimulator
TFE	Tetrafluoroethylene
UPS	Uninterruptible power supply
VDU	Video display unit

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INDEX

Abnormal condition, 36, 37
ACCESS COVER, 49, 50, 72, 73, 74, 123, 128
  Definition, 21
ACCESSIBLE PART, 210
ACCESSIBLE PART, 25, 70, 72, 75, 76, 88, 126, 211, 212, 219, 220, 228, 235, 236, 239
  Actuating mechanisms, 52
  Defibrillation protection, 244
  Definition, 21
  Determination of, 50, 71, 228, 236, 307
  Fuse-holder, 57
  Internal screens and internal wiring, 85, 248
  LEAKAGE CURRENTS, 72, 237
  MAXIMUM MAINS VOLTAGE on, 237
  MEANS OF PROTECTION, 74, 239
  Metal, 77, 100, 122, 246, 257
  Moving, 171
  of ENCLOSURES, 204
  TOUCH CURRENT, 238
  Voltage limits for, 170
ACCESSORY, 49, 55, 81, 137, 147, 215, 230, 268, 281
  ACCOMPANYING DOCUMENTS definition, 21
  Biocompatibility, 167
  Cleaning, 67, 166
  Definition, 21
  Definition of HAND-HELD, 28
  Definition of PORTABLE, 33
  Disposal, 68
  List of, 68
  ME EQUIPMENT definition, 31
  Means of attachment, 145
  Method of sterilization, 58
  Minimum marking, 54
  MODEL OR TYPE REFERENCE definition, 31
  Multiple cleanings/disinfections, 166
  Operating instructions, 67
  Other power source, 56
  Pneumatic and hydraulic parts, 142
  Single use, 54
  Start-up PROCEDURE, 67
  Sterile, 58, 68
  Sterilization, 166
ACCOMPANYING DOCUMENT, 30, 34, 49, 50, 54, 56, 59, 64, 70, 71, 85, 130, 137, 139, 140, 141, 145, 147, 150, 164, 179, 182, 194, 196, 199, 200, 222, 223, 229, 232, 233, 234, 245, 256, 268, 312, 330
  COMPONENT WITH HIGH-INTEGRITY CHARACTERISITCS, 211
  Consult, 55, 230, 314
  Defibrillation voltage and any recovery time, 78
  Definition, 21
  Inspection, 46, 64, 71, 140, 147, 151, 184, 189
  Instructions for use, 64, 313
  ME SYSTEM, 193, 302
  Mechanism for isolating the SUPPLY MAINS, 124
  MODEL OR TYPE REFERENCE, 215
  Recovery time, 81
  SAFE WORKING LOAD, 148
  Surface temperature, 202
  Technical description, 64, 313
  Working conditions, 48
Active implantable medical device, 16, 31
AIR CLEARANCE, 30, 70, 73, 75, 76, 77, 78, 106, 107, 108, 109, 110, 111, 113, 114, 115, 116, 117, 118, 119, 124, 126, 127, 128, 139, 147, 148, 157, 180, 195, 197, 213, 218, 219, 225, 236, 240, 260, 261, 262, 264, 269, 280, 288, 308, 331
  Complying with IEC 60950-1, 107, 240
  DEFIBRILLATION-PROOF APPLIED PARTS, 111, 263
  Definition, 21
  High altitude, 108
  Interpolation, 108, 263
  MEANS OF OPERATOR PROTECTION, 75
  MEANS OF PATIENT PROTECTION, 75
  Short circuit of, 70
  Transformer, 192
  Values, 107
AIR KERMA
  Definition, 39
ALARM CONDITION, 40, 223
  Definition, 39
ALARM SIGNAL, 40, 43, 212, 223
  Definition, 40
ALARM SYSTEM, 40, 167, 223
  Definition, 40
Ambient humidity, 48, 58, 183, 234, 363
Ambient illuminance, 54
Ambient pressure, 32, 48, 217, 234
Ambient temperature, 25, 48, 106, 155, 157, 190, 234, 281, 300, 332, 336, 337
APPLIANCE COUPLER, 22, 26, 29, 66, 124, 125, 265
  Definition, 21
APPLIANCE INLET, 21, 29, 59, 82, 83, 98, 118, 129, 137
  Definition, 22
APPLIED PART, 21, 26, 27, 31, 32, 36, 38, 44, 52, 57, 70, 71, 75, 76, 77, 78, 79, 80, 81, 85, 87, 88, 98, 100, 101, 155, 156, 166, 169, 170, 196, 204, 207, 208, 209, 224, 235, 237, 245, 246, 252, 261, 289, 304, 351, 360, 361
  Classification, 53, 71
  Cold, 155
  Definition, 22
  Determination of, 50, 307
  DIRECT CARDIAC APPLICATION, 71, 211
  DIRECT CARDIAC APPLICATION, 26
  HAND-HELD, 297
  High altitude, 282
  Intended to supply heat, 155
  Marking of, 57
  Maximum surface temperature, 281
  Maximum temperature, 169
  MEANS OF PROTECTION, 74
  Moving, 171

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Multiple, 76, 241
Not intended to supply heat, 155, 281
Specified in the instructions for use, 66
Temperature, 155
BASIC INSULATION, 25, 26, 37, 102, 193, 198, 210, 211, 212, 214, 219, 225, 237, 239, 240, 247, 258, 260, 261, 304, 363, 364, 365
Definition, 22
MEANS OF PROTECTION, 236
BASIC SAFETY, 16, 17, 21, 26, 43, 48, 71, 81, 139, 147, 148, 165, 166, 167, 175, 176, 177, 178, 179, 180, 200, 202, 203, 210, 211, 215, 219, 220, 224, 225, 227, 228, 229, 230, 233, 235, 239, 245, 269, 278, 279, 281, 291, 301, 303, 305
Defibrillation protection, 78
Definition, 25
Flow rate, 58
Loss of, 197
Testing, 69
Batch or lot identifier
ACCESSORY, 55
ME EQUIPMENT, 54
Biocompatibility, 167, 220, 297, 307
BODY-WORN, 78
Definition, 40
Equipment, 38
CATEGORY AP, 164, 286, 306, 310, 311, 312, 328, 329, 330, 331, 332
Definition, 25
Symbol, 318
CATEGORY APG, 164, 286, 306, 310, 311, 312, 329, 330, 331, 337
Definition, 25
Symbol, 318
CLASS I, 34, 52, 65, 99, 128, 195, 198, 225, 233, 237, 246, 253, 255, 266, 304
Definition, 25
CLASS II, 25, 52, 56, 84, 99, 128, 212, 248, 255, 312, 316, 355
Definition, 25
Class III, 229
CLEARLY LEGIBLE, 53, 54, 57, 60, 137, 138, 229
Definition, 25
COLD CONDITION, 172, 309
Definition, 25
Comparative tracking index, 108
COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS, 44, 45, 46, 70, 170, 177, 189, 211, 225, 294
Definition, 25
CONTINUOUS OPERATION, 53, 57, 156, 174, 196, 211, 229, 290, 337
Definition, 25
DUTY CYCLE, 211
Non-, 53, 57, 156, 173, 175, 196, 211, 229, 290
CREEPAGE DISTANCE, 30, 70, 73, 75, 76, 77, 78, 102, 106, 107, 112, 116, 117, 118, 119, 124, 126, 127, 128, 139, 147, 148, 157, 180, 195, 197, 213, 218, 225, 236, 240, 242, 260, 261, 262, 263, 264, 269, 280, 288, 299, 308, 331
Complying with IEC 60950-1, 107, 240
DEFIBRILLATION-PROOF APPLIED PARTS, 111, 263
Definition, 26
High altitude, 108
Interpolation, 108, 263
MEANS OF OPERATOR PROTECTION, 75, 111
MEANS OF PATIENT PROTECTION, 75
Moulded transformer, 193
Short circuit of, 70
SINGLE FAULT CONDITION, 227
Transformer, 192
Values, 107
WORKING VOLTAGE above 1 000 V, 262
Date of manufacture
ACCESSORY, 55
ME EQUIPMENT, 54
DEFIBRILLATION-PROOF APPLIED PART, 78, 211, 230, 244, 246
Classification, 53, 76, 78
Common-mode test, 79
CREEPAGE DISTANCES and AIR CLEARANCES, 111
Definition, 26
Differential-mode test, 80
Energy reduction test, 81
Marking of, 57
WORKING VOLTAGE, 78, 244
Design documentation
Evaluation of, 170
Inspection, 106, 184
DETACHABLE POWER SUPPLY CORD, 83, 98, 137, 211, 242, 247, 331
Definition, 26
Non-, 69, 83, 127, 265
Diagnostic or therapeutic radiation, 168
DIRECT CARDIAC APPLICATION, 38, 71, 211, 219, 220, 238, 249, 302
Definition, 26
DOUBLE INSULATION, 25, 45, 70, 78, 211, 225, 236, 240, 260, 261, 267, 363
Definition, 26
MEANS OF PROTECTION, 26, 236
Short circuiting, 85, 248
WORKING VOLTAGE, 244
DUTY CYCLE, 63, 156, 173, 211, 281
Definition, 26
Marking of, 57
EARTH LEAKAGE CURRENT, 29, 85, 87, 99, 216, 250, 355
Definition, 26
Measurement, 88, 99, 256
MULTIPLE SOCKET-OUTLET, 304
Total, 196
Value, 85, 86
Value for a MULTIPLE SOCKET-OUTLET, 195
Electrical equipment, 65, 70, 71, 97, 199, 202, 228, 301
ACCESS COVER definition, 21
ACCESSIBLE PART definition, 21
APPLIANCE COUPLER definition, 21
APPLIANCE INLET definition, 22
CLASS II definition, 25
COLD CONDITION definition, 25
DETACHABLE POWER SUPPLY CORD definition, 26
INTERNAL ELECTRICAL POWER SOURCE definition, 28
INTERNALLY POWERED definition, 29

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

MAINS CONNECTOR definition, 29
MAINS PLUG definition, 29
MAINS TRANSIENT VOLTAGE definition, 29
ME EQUIPMENT definition, 31
PEAK WORKING VOLTAGE definition, 33
POTENTIAL EQUALIZATION CONDUCTOR definition, 33
POWER SUPPLY CORD definition, 33
SELF-RESETTING THERMAL CUT-OUT definition, 36
SIGNAL INPUT/OUTPUT PART definition, 36
TERMINAL DEVICE definition, 37
THERMAL CUT-OUT definition, 37
WORKING VOLTAGE definition, 39
ENCLOSURE, 28, 38, 73, 74, 76, 78, 85, 97, 99, 100, 101, 103, 118, 124, 131, 162, 204, 211, 219, 235, 236, 238, 245, 250, 260, 261, 268, 271, 303, 306, 328, 329, 331, 332, 336, 337, 351
ACCESS COVER, 21, 228
ACCESSIBLE PART, 204
Ball-pressure test, 106
Definition, 26
Deformation of, 169
Fire, 157, 163, 170, 269, 285, 289, 310
Greater than IPX0, 50
HAND HELD switches and footswitches, 264
HIGH VOLTAGE parts, 231
Impact, 181, 298
Impairment of cooling, 171
IP Classification, 53, 57, 166, 189, 203, 228, 287
IPX0, 50
Main, 99, 248
ME SYSTEM, 195, 301
Minimum marking, 54
Moulded, 183
MULTIPLE SOCKET-OUTLET, 198
Non-conductive, 97
Opening in, 72, 73, 331
Rigidity, 181, 297
Separate, 71
TOUCH CURRENT, 38, 256
Equipment, 55, 56, 66, 68, 193, 194, 195, 197, 198, 204, 214, 215, 216, 219, 226, 229, 261, 265, 268, 269, 279, 287, 297, 300, 301, 302, 303, 304, 347, 351
ACCESSORY definition, 21
ACCOMPANYING DOCUMENTS definition, 21
BODY-WORN, 38
Class III, 229
GUARD definition, 27
HAND-HELD definition, 28
IT-NETWORK, 179
MAINS SUPPLY TRANSFORMER definition, 29
ME SYSTEM definition, 31
MOBILE, 38, 270
MOBILE definition, 31
MODEL OR TYPE REFERENCE definition, 31
NETWORK/DATA COUPLING definition, 31
PERMANENTLY INSTALLED, 322
Polyphase, 243
PORTABLE, 38
PROTECTIVE EARTH TERMINAL definition, 34
SAFE WORKING LOAD definition, 36
Separate power supply, 49
SERVICE PERSONNEL definition, 36
STATIONARY definition, 36
TRANSPORTABLE definition, 33, 38
TRAPPING ZONE definition, 38
TYPE TEST definition, 38
ESSENTIAL PERFORMANCE, 211
ESSENTIAL PERFORMANCE, 16, 17, 21, 26, 43, 48, 81, 139, 147, 148, 165, 166, 175, 176, 177, 178, 179, 185, 200, 202, 203, 210, 211, 215, 220, 221, 225, 227, 230, 231, 245, 269, 270, 278, 291, 293, 294, 305, 307
d.c. SUPPLY MAINS, 71
Defibrillation protection, 78
Definition, 26
Disclosure of, 69
Flow rate, 58
Information about, 69
Testing, 69
VERIFICATION, 178, 296
EXPECTED SERVICE LIFE, 25, 36, 44, 45, 46, 52, 54, 64, 71, 83, 106, 145, 151, 152, 166, 184, 223, 224, 225, 226, 247, 259, 276
Definition, 26
Disposal, 68
Faults, 227
Simultaneous independent, 48, 227
Fire, 59, 129, 157, 158, 161, 162, 163, 164, 165, 186, 200, 239, 266, 274, 284, 285, 289, 290, 301, 310
FIXED
APPLIANCE INLET, 22
Connections, 247
Definition, 27
GUARD, 131
Installations, 216
Mains socket-outlets, 216
ME EQUIPMENT, 53, 99, 136, 137, 138, 163, 181, 298
POWER SUPPLY CORD, 33
PROTECTIVE EARTH CONDUCTOR, 82
Supply conductors, 82
SUPPLY MAINS, 27
Terminals, 128
Wiring, 128
FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, 25, 286, 329, 336
Definition, 27
FLAMMABLE ANAESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE, 25, 329, 330, 331, 337, 341
Definition, 27
Flammable anaesthetic mixtures, 201, 306, 328
F-TYPE APPLIED PART, 33, 38, 76, 78, 100, 205, 206, 241, 242, 251, 261
Classification, 27
Definition, 27
F-TYPE ISOLATED (FLOATING) APPLIED PART. See F-TYPE APPLIED PART
Function, 21, 22, 25, 53, 58, 60, 64, 66, 67, 69, 76, 84, 100, 101, 102, 130, 150, 151, 161, 167, 170, 177, 178, 184, 185, 187, 197, 200, 205, 207, 208, 209, 211, 217, 226, 237, 241, 245, 247, 252, 254, 257, 258, 268, 269, 294, 296, 297, 311, 312, 313, 343, 347, 349
FUNCTIONAL CONNECTION, 31, 195, 212
Definition, 27

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

FUNCTIONAL EARTH CONDUCTOR, 25, 63, 248, 255
Definition, 27
LEAKAGE CURRENT
Value, 86
FUNCTIONAL EARTH TERMINAL, 25, 27, 80, 84, 85, 97, 212
Definition, 27
Marking of, 58, 59
Functional test
ESSENTIAL PERFORMANCE, 43
Speed of movement, 134, 149
Strength of PATIENT or OPERATOR support or suspension systems, 147
Fuseholder, 50, 72, 228
GUARD, 130, 268
ACCESS COVER, 21
Definition, 27
FIXED, 131
Hot or cold accessible surfaces, 157
Movable, 133
TRAPPING ZONE, 131
HAND-HELD, 40
ACCESSORY, 182
APPLIED PART, 297
Control device, 123, 188
Definition, 28
ME EQUIPMENT, 47, 136, 156, 172, 175, 181, 182, 298
Part, 123, 136, 181, 182
Switches and footswitches, 264
HARM, 223
HARM, 28, 35, 57, 133, 135, 139, 147, 148, 180, 211, 212, 221, 222, 224, 245, 267, 269, 271, 273, 274, 279, 281, 289
Definition, 28
HAZARD, 16, 25, 28, 30, 32, 35, 36, 38, 41, 42, 43, 57, 59, 69, 130, 134, 135, 136, 140, 145, 176, 177, 184, 186, 193, 196, 200, 201, 204, 210, 212, 214, 217, 220, 221, 222, 224, 226, 228, 230, 231, 233, 235, 242, 243, 250, 252, 263, 264, 265, 267, 268, 269, 273, 274, 275, 284, 286, 287, 288, 294, 297, 299, 300, 301, 303, 307, 311, 313, 331, 347, 348, 351
Definition, 28
Excessive temperatures, 153, 280
Expelled parts, 130, 141, 271, 309
Impairment of cooling, 171
Instability, 136, 269, 308
Moving parts, 308
Rough surfaces, corners and edges, 136, 269, 308
Support systems, 145, 274, 309
Temperature of APPLIED PARTS, 281
Unwanted and excessive radiation, 151, 279
HAZARDOUS SITUATION, 39, 41, 42, 43, 45, 48, 70, 71, 88, 129, 162, 169, 170, 186, 212, 221, 222, 242, 265, 285, 288, 291, 303, 304, 309, 348
Adjustment of controls, 187
Battery replacement, 186
Conditions or faults, 41
Damage during assembly, 123
Damage to insulation, 123
Definition, 28
Detachment of conductors and connectors, 71, 122, 123
Exhaustion of a battery, 299
Failure of any one component at a time, 169
Failure of components, 45
Heaters, 187
Incorrect connection, 197
Ingress of water and particulate matter, 166, 287
Interruption of SUPPLY MAINS, 167
Interruption of the power supply, 197, 287
Limitation of movement, 188
Mechanism for isolating the SUPPLY MAINS, 124
Overflow, 165
Overheating of transformers, 189, 191
Poor contact, 122
Prolonged operation, 187
Short circuiting of a battery, 186
Short circuiting of CREEPAGE DISTANCES or AIR CLEARANCES, 116
Speed of movement, 134
Spillage, 166
THERMAL CUT-OUTS and OVER-CURRENT RELEASES, 184, 185
THERMOSTAT, 184
Transformer failure, 191
Health care professional, 216
HIGH VOLTAGE, 58
Defibrillation protection, 244
Definition, 28
Part, 231, 328
Part, Marking of, 59, 314
Humidity preconditioning, 49, 85, 103, 117, 191, 228, 260, 308
HYDRAULIC TEST PRESSURE, 143, 144
Definition, 28
Installation instruction
Transient current, 195
Instructions for use, 32, 47, 48, 49, 50, 53, 57, 62, 64, 65, 66, 69, 72, 73, 81, 84, 98, 101, 103, 130, 137, 138, 148, 155, 165, 166, 194, 200, 201, 216, 225, 228, 230, 232, 233, 245, 302, 313, 330
Inspection, 68, 72, 156
Unique version identifier, 68
INSULATION CO-ORDINATION
Definition, 28
IEC 60950-1, 75, 76, 101, 107, 219, 220
INTENDED USE, 21, 33, 40, 65, 130, 142, 151, 184, 210, 216, 221, 233, 246, 263, 268, 271, 286, 299, 348, 349
Definition, 28
ESSENTIAL PERFORMANCE, 211
EXPECTED SERVICE LIFE, 223
Identification of ESSENTIAL PERFORMANCE, 43
NORMAL USE definition, 32
INTERNAL ELECTRICAL POWER SOURCE, 29, 36, 46, 49, 66, 186, 187, 233, 299
Definition, 28
INTERNALLY POWERED, 52, 77, 98, 99, 110, 243, 244
Definition, 29
IP Classification, 53, 57, 188, 198
Isolated power supply (IPS), 195
IT-NETWORK, 179, 297, 347, 348

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Configuration, 179
Connection of additional items, 179
Definition, 40
Disconnecting items, 179
Update of equipment, 179
Upgrade of equipment, 179
Lampholder, 59, 72, 157
Layperson, 35, 216
LEAKAGE CURRENT, 29, 38, 72, 77, 85, 86, 97, 98, 170, 195, 204, 217, 221, 227, 232, 235, 237, 239, 241, 242, 243, 248, 249, 250, 252, 255, 256, 265, 303, 304, 308, 309, 351
Definition, 29
Measurement, 71, 76, 77, 84, 88, 98, 165, 166, 167, 196, 228, 237, 249, 255, 256
SINGLE FAULT CONDITION, 227
TYPE B APPLIED PART, 242
Value, 86
OPERATOR, 39
LEDs, 280
MAINS CONNECTION
Total protective earth path, 198
MAINS CONNECTOR, 21, 29, 126, 127, 242, 243, 265
Definition, 29
MAINS PART, 26, 49, 85, 103, 104, 106, 107, 109, 110, 111, 113, 114, 116, 123, 124, 128, 129, 213, 219, 227, 235, 258, 261, 263, 267, 309
Definition, 29
Overvoltage category, 110
Separation from SECONDARY CIRCUIT, 36
MAINS PLUG, 66
MAINS PLUG, 70, 83, 84, 124, 125, 197, 198, 213, 239, 304, 305
Definition, 29
Total protective earth path, 198
MAINS SUPPLY TRANSFORMER, 189, 198, 300, 301, 309
Definition, 29
MAINS TERMINAL DEVICE, 127, 128, 129, 198, 266, 312
Definition, 29
MAINS TRANSIENT VOLTAGE, 109, 110, 113, 124
Definition, 29
MAINS VOLTAGE, 77, 88, 97, 113, 114, 206, 213, 251, 253, 255, 256, 257, 261, 333, 338
Definition, 29
NOMINAL, 31, 109
RATED, 152
RATED, 85, 109, 151, 196, 243, 244
MANUFACTURER
ESSENTIAL PERFORMANCE, 222, 223
MANUFACTURER, 28, 31, 32, 34, 35, 41, 42, 43, 53, 66, 68, 69, 70, 76, 83, 99, 108, 118, 126, 129, 140, 142, 143, 144, 145, 147, 152, 153, 155, 162, 165, 166, 167, 168, 169, 175, 176, 178, 180, 184, 185, 187, 199, 201, 202, 203, 208, 209, 211, 220, 225, 226, 229, 230, 231, 232, 233, 240, 241, 243, 246, 256, 266, 270, 271, 273, 274, 276, 281, 286, 287, 289, 291, 292, 293, 294, 296, 298, 299, 305, 347, 352
Acceptance criteria, 42, 221
Alternative measure or test method, 44
Alternative RISK CONTROL measures, 271, 276
Calculations or test results, 152
Calculations or test results, 42, 43
calculations, analyses or test results, 221, 222
Definition, 30
Detachable components, 55
Equivalent safety, 224
ESSENTIAL PERFORMANCE, 26, 211
Expected service life, 26, 44, 223, 224
Flammable anaesthetic mixtures, 306
Identification of ESSENTIAL PERFORMANCE, 43
INTENDED USE, 64
Marking of name or trademark and contact information, 54
Marking of name or trade-name, 64
Marking of name or trade-name and address, 65
Marking of name or trade-name and contact information, 55
ME SYSTEM, 193, 194, 195, 215, 220, 301, 302, 304
PEMS, 179, 348, 349
Qualification of SERVICE PERSONNEL, 69
Reasonably foreseeable misuse, 220
RISK ASSESSMENT, 276
Single use, 67
Specification of overvoltage category, 47
System integration, 347
Marking, 222
Overflow, 165
Material group classification, 108
MAXIMUM MAINS VOLTAGE, 70, 76, 77, 85, 88, 99, 100, 195, 213, 237, 243, 252, 257, 359
Definition, 30
MAXIMUM PERMISSIBLE WORKING PRESSURE, 143, 144, 214, 273, 274
Definition, 30
ME EQUIPMENT
FIXED, 136
PERMANENTLY INSTALLED, 266
See MEDICAL ELECTRICAL EQUIPMENT, 31
ME SYSTEM
Large transient currents, 195
See MEDICAL ELECTRICAL SYSTEM, 31
MEANS OF OPERATOR PROTECTION, 75, 107, 111, 118, 186, 189, 195, 214, 240, 263, 286, 299, 300, 301, 371
Additional AIR CLEARANCE, 114
Capacitors, 75
Classification, 74, 76
Definition, 30
IEC 60950-1, 76, 82, 101, 107, 108
Minimum AIR CLEARANCE, 113, 115
Minimum CREEPAGE DISTANCE, 111, 116
PROTECTIVE EARTH CONNECTION, 75
Solid insulation forming, 75
Test voltage for, 105
Test voltage for solid insulation, 104
MEANS OF OPERTOR PROTECTION
Coatings, etc. complying with IEC 60950-1, 74
MEANS OF PATIENT PROTECTION, 82, 108, 118, 162, 192, 205, 206, 214, 240, 301, 331, 337, 371
Capacitors, 75
Classification, 74, 76

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Coatings, etc. complying with IEC 60950-1, 74
Definition, 30
F-TYPE APPLIED PART, 76, 241
PATIENT CONNECTION, 77
PROTECTIVE EARTH CONNECTION, 75
Solid insulation forming, 75
Spacing, 112, 262
Test voltage for solid insulation, 104
TYPE B APPLIED PART, 77
Y capacitors, 241
MEANS OF PROTECTION, 22, 26, 29, 30, 74, 107, 126, 128, 148, 223, 363, 364, 365, 371
AIR CLEARANCE, 116
Ball-pressure test, 173
Classification, 74, 76
Coatings, etc. not considered as, 74
Components and wiring, 74
Components used as, 45
CREEPAGE DISTANCE or AIR CLEARANCE not considered as, 75
CREEPAGE DISTANCE or AIR CLEARANCE, 75, 118, 127
Definition, 30
DOUBLE INSULATION, 78
Insulating characteristics and mechanical strength, 106
Insulating material in which heating conductors are embedded, 106
Internal screens and internal wiring, 85, 248
Pollution degree 4, 109
REINFORCED INSULATION, 34, 101, 102
Resistors bridging, 225
SECONDARY CIRCUIT, 36
Separation from MAINS PART, 123
Sheath of a flexible cord, 123
Short circuit of, 70, 128, 157
Short circuit of CREEPAGE DISTANCE or AIR CLEARANCE, 70
SUPPLEMENTARY INSULATION, 37, 102
Test voltage for, 191, 260
Test voltage for solid insulation, 104
Transformer, 192
Transformers forming, 192
Wetting of, 165
WORKING VOLTAGE for, 77
RISK CONTROL, 271
RISK CONTROL, 279
MECHANICAL HAZARD, 129, 131, 133, 170, 172, 196, 201, 267, 304
Definition, 30
Sharp edges, 136
MECHANICAL PROTECTIVE DEVICE, 44, 146, 149, 150, 151, 279, 311
Definition, 30
When not required, 151
Medical device, 30, 41, 175, 202, 291, 293, 346
MEDICAL ELECTRICAL EQUIPMENT, 189
a.c SUPPLY MAINS, 49
Accessibility of connections, 128
Acoustic energy and vibration, 141
Adapting, 30
Applicability of requirements, 16
Arrangement of controls and indicators, 180
Automatically or remotely controlled, 171
Battery, 66, 186
Battery replacement, 186
Biocompatibility, 167
CATEGORY AP, 328, 329, 330, 331, 332
CATEGORY APG, 329, 330, 331, 337
CLASS I, 65, 99, 128
CLASS II, 56, 84, 99, 128
Classification, 52
Cleaning, 67, 166
Compatibility with substances, 167
Component, 41, 45, 164
COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS, 25, 46
Condition for application, 40
Conductors and connectors, 122
Connection to SUPPLY MAINS, 70
Connectors, 184
CONTINUOUS OPERATION, 53, 57, 156
Contraindication, 64
Controls, 187
Cooling provisions, 58
d.c., 77
d.c. SUPPLY MAINS, 49, 71
Definition, 31
Description, 66, 69
Detachable components, 55
Diagnostic or therapeutic radiation, 168
Disabling of controls, 173
Disposal, 68
DUTY CYCLE, 26, 173
Educational materials, 65
Emergency stop, 135, 136
Emitting radiation, 68
Equivalent safety, 44
Excessive radiation, 168
EXPECTED SERVICE LIFE, 44, 45, 52, 54, 71, 83, 106, 145, 151, 152, 184
Expelled parts, 141
FIXED, 53, 99, 137, 138, 163
FIXED or HAND-HELD, 136
Fixing of components, 122
Fluid reservoir, 165
Foot-operated control device, 188
Function, 22, 66, 69
Guiding rollers, 123
Hand loaded, 175
HAND-HELD, 47, 156, 172, 175, 181, 182
HAND-HELD control device, 188
Heating elements, 156, 173
Identification, 54, 64
Identification of ESSENTIAL PERFORMANCE, 43
In vitro diagnostic equipment, 16
Indicator lights, 187
Input supply voltage, 77
Inspection, 74, 189
Instability, 136
Installation, 66
INTENDED USE, 64, 130, 142, 184, 221
INTERNALLY POWERED, 52, 77, 98, 99, 110
Interruption and short circuiting of motor capacitors, 171
Interruption of SUPPLY MAINS, 167
IP Classification, 166, 189
Isolation from SUPPLY MAINS, 69, 124
Large, 183
Load-reducing device, 175
Mains operated, 66

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Manual MOBILE, 139
Manually switched on, 175
Maximum supply pressure, 143
MECHANICAL PROTECTIVE DEVICE, 150
MEDICAL ELECTRICAL SYSTEM, 31
Method of sterilization, 58
MOBILE, 58, 138, 139, 140, 165, 182, 183, 189, 231, 269, 271
MOBILE Part, 182, 183
MOBILE, power-driven, 139
Modification, 69
Motor, 174
Motor operated, 156, 172
Motor-driven MOBILE, 139
Moving parts, 130, 133, 136
Multiple cleanings/disinfections, 166
Multiple PATIENT CONNECTION, 101
MULTIPLE SOCKET-OUTLET, 56, 65, 125
Non-, 45, 193, 194, 195, 197, 305
Non-SI Units, 61
Oil-filled, 69, 189
Operating instructions, 67
Overcharging, 186
Overtravel, 134
Overvoltage category, 109
OXYGEN RICH ENVIRONMENT, 53
Part, 25, 30, 36, 49, 50, 52, 53, 54, 57, 58, 60, 66, 67, 70, 71, 73, 76, 82, 84, 122, 133, 134, 137, 138, 140, 145, 147, 153, 154, 156, 164, 169, 180, 189, 329, 330, 332, 336, 337, 338, 341
Part biocompatibility, 167
Part cleaning, 67, 166
Part sterilization, 166
Part, HAND-HELD, 181, 182
Part, heating, 173
Part, multiple cleanings/disinfections, 166
Parts that contact the PATIENT, 44
PATIENT ENVIRONMENT, 32
PERMANENTLY INSTALLED, 54, 56, 59, 60, 69, 70, 80, 83, 86, 98, 124, 127, 128
PERMANENTLY INSTALLED, 142
Physiological effects, 57
Physiological function, 16
Platen glass, 182
Pneumatic and hydraulic parts, 142
Polyphase, 70, 77, 175
PORTABLE, 140, 182, 189
PORTABLE part, 182
Power input, 47
Pressure control device, 144
Pressure relief device, 144
PROTECTIVE EARTH CONNECTION, 63
Protective measure, 133
RATED altitude, 108
RATED voltage, 49
Ready for NORMAL USE, 187
Rechargeable battery, 68
Reciprocal interference, 65
Release of PATIENT, 136
RESPONSIBLE ORGANIZATION, 35
RISK
of fire, 158
RISK MANAGEMENT PROCESS, 41
Rough surfaces, sharp corners and edges, 136
Routine maintenance, 67
Separate power supply, 49, 55, 66, 68, 71, 194
Shutdown PROCEDURE, 67
SI Units, 61
SINGLE FAULT CONDITION, 44
SINGLE FAULT CONDITION definition, 36
SINGLE FAULT SAFE, 44
Single use, 54
Single-phase, 98
Source of power, 46
Spark source, 158
Spillage, 165
Stand-by or a warm-up state, 187
Start-up PROCEDURE, 67
STATIONARY, 127, 163
Sterile, 58, 68
Sterilization, 166
SUPPLY MAINS, 47
Surface, 154
Surface coating, 84
Thermostatically controlled, 173
Timer, 175
Transformer, 189, 191, 192
TRANSPORTABLE, 53, 163, 165, 287
Unpacking, 58
MEDICAL ELECTRICAL SYSTEM, 36, 37, 66, 68, 71, 84, 162, 164, 165, 193, 194, 195, 196, 197, 198, 199
Adapting, 30
Applicability or requirements, 16
Biocompatibility, 167
Cleaning, 166
Component, 41
Components, 45
Condition for application, 40
Creation of, 65, 66
Definition, 31
Equivalent safety, 44
EXPECTED SERVICE LIFE, 44
Function, 22
Identification of ESSENTIAL PERFORMANCE, 43
INTENDED USE, 130, 221
IP Classification, 166
Multiple cleanings/disinfections, 166
OXYGEN RICH ENVIRONMENT, 53
Part, 195
Parts that contact the PATIENT, 44
PATIENT ENVIRONMENT, 32
Physiological function, 16
Power input, 47
RESPONSIBLE ORGANIZATION, 35
RISK MANAGEMENT PROCESS, 41
RISK of fire, 158
Spillage, 165
Sterilization, 166
Supplied from a UPS or IPS, 195
SUPPLY MAINS, 47
Total PATIENT LEAKAGE CURRENT, 196
Total protective earth path, 198
TOUCH CURRENT, 195
Medical gas pipeline system, 16
MOBILE, 139, 270, 313
Definition, 31

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

EQUIPMENT, 38
ME EQUIPMENT, 58, 138, 139, 140, 165, 181, 182, 183, 189, 231, 269, 271, 298
ME EQUIPMENT parts, 182, 183
MODEL OR TYPE REFERENCE, 54, 55, 64, 65, 215, 230
Definition, 31
Detachable components, 55
MOOP
See MEANS OF OPERATOR PROTECTION, 30
MOP
See MEANS OF PROTECTION, 30
MOPP
See MEANS OF PATIENT PROTECTION, 30
MSO
See MULTIPLE SOCKET-OUTLET, 31
MULTIPLE SOCKET-OUTLET, 31, 56, 65, 125, 194, 195, 196, 197, 198, 215, 216, 255, 265, 303, 304, 305, 311, 351, 355, 371
Definition, 31
NETWORK/DATA COUPLING, 66, 176, 178, 216, 297, 348, 349
Definition, 31
NOMINAL
Capacitance, 75
Conductor diameter, 364
Cross-sectional area of conductors, 125, 128
Definition, 31
Frequency, 47, 56
MAINS VOLTAGE, 31, 47, 109, 110, 113, 114, 115
Supply voltage, 56
NORMAL CONDITION, 25, 32, 44, 45, 60, 70, 71, 72, 75, 76, 78, 85, 86, 87, 89, 101, 124, 134, 141, 143, 153, 155, 158, 161, 165, 166, 169, 170, 173, 193, 195, 196, 200, 216, 217, 235, 236, 237, 239, 248, 249, 250, 251, 252, 253, 257, 261, 273, 274, 285, 287, 288, 289, 304,329, 332, 336, 337, 338, 360
Definition, 32
Identification of ESSENTIAL PERFORMANCE, 43
NORMAL USE, 22, 25, 31, 32, 36, 37, 38, 39, 40, 48, 50, 53, 54, 57, 60, 66, 67, 72, 73, 74, 78, 84, 100, 101, 103, 123, 125, 131, 134, 136, 137, 138, 139, 140, 141, 142, 144, 147, 148, 151, 152, 153, 156, 162, 165, 166, 175, 182, 183, 184, 187, 188, 189, 190, 191, 196, 197, 200, 205, 207, 208, 209, 212, 221, 225, 244, 245, 268, 269, 271, 274, 281, 284, 285, 287, 289, 298, 299, 300, 303, 305, 306, 331, 332, 336, 337, 338
Definition, 32
INTENDED USE definition, 28
OBJECTIVE EVIDENCE, 39, 42, 221, 222, 302
Definition, 32
Operating temperature, 60, 85, 88, 103, 153, 154, 196, 260, 284, 308, 332, 336, 337
OPERATOR, 21, 32, 38, 39, 40, 54, 55, 57, 62, 64, 65, 67, 68, 72, 84, 133, 136, 147, 150, 161, 168, 172, 179, 187, 193, 195, 200, 201, 202, 204, 207, 211, 212, 214, 215, 216, 223, 224, 225, 226, 228, 229, 230, 232, 233, 239, 240, 245, 246, 250, 260, 267, 268, 269,272, 288, 290, 298, 300, 302, 303, 304, 313, 349, 351
Contact with, 99, 194, 235, 236, 238, 245, 282
Contact with PATIENT, 72
Definition, 32
Emergency stop, 135
Expected position of, 66, 141, 279
Exposure to hazardous materials, 66
Home use, 35
Interface, 39
Language acceptable to, 62
Mass of, 147, 276
Mechanism for isolating the SUPPLY MAINS, 124
MOBILE MEDICAL ELECTRIC EQUIPMENT, 231
Moving parts, 131, 134
RISK to, 314
Sensitivity to acoustic energy and vibration, 141
Sensitivity to vibration, 142
Spurious microwave radiation, 152
Spurious X-radiation, 151
Support, 147, 148, 151, 274
Unwanted or excessive radiation, 168
OVER-CURRENT RELEASE, 59, 107, 128, 129, 170, 184, 185, 186, 225, 231, 237, 263, 266, 328
Definition, 32
OXYGEN RICH ENVIRONMENT, 53, 158, 160, 161, 162, 172, 217, 284, 285, 301
Definition, 32
PATIENR LEAKAGE CURRENT, 225
PATIENT, 22, 26, 30, 31, 32, 33, 38, 40, 44, 57, 60, 136, 147, 151, 179, 187, 200, 201, 202, 204, 210, 211, 214, 216, 219, 222, 226, 247, 250, 252, 267, 269, 300, 303, 304, 329
Acting as an OPERATOR, 232
Adult human, 147
APPLIED PART exceed 41°C, 155
APPLIED PARTS intended to supply heat to, 155
APPLIED PARTS not intended to supply heat to, 155
Cable, 57, 98, 184, 196, 197, 205, 207, 209, 230, 244, 256
Circuit, 205, 206
Condition, 255
Contact with, 44, 67, 72, 77, 99, 100, 134, 155, 194, 201, 204, 205, 207, 211, 217, 224, 236, 238, 239, 240, 242, 246, 249, 250, 251, 256, 258, 261, 268, 282, 301, 313, 351
Current flowing in, 32, 217, 219, 220, 243, 257
Defibrillation of, 78, 231, 244, 245, 246
Definition, 32
Disconnection from, 101, 257
Earthing of, 33, 78, 217, 242, 251, 252, 261
Electric shock to, 30, 229
Expected position of, 66, 67, 141
Exposure to hazardous materials, 66
Exposure to toxic gases, 162
Heart, 26, 211, 235, 302
Home use, 35, 216
Incorrect delivery of energy or substances, 168, 289
Lead, 77, 78, 184, 197, 205, 207, 209, 242
Mass of, 147, 276, 311, 312

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Moving of, 130, 148
Moving parts, 130, 131, 136
Number of APPLIED PARTS, 252
PATIENT ENVIRONMENT, 32
PATIENT is an intended OPERATOR, 65
Release of, 136, 269
RISK to, 211, 254, 314
Sensitivity to acoustic energy, 271
Sensitivity to acoustic energy and vibration, 141
Sensitivity to vibration, 142, 272
Special needs, 134, 289
Support, 138, 147, 148, 151, 205, 218, 228, 238, 267, 274
Support of, 278, 279
Transfer of energy, 71, 72, 238
Unintended voltage on, 27, 33, 213, 242, 243, 253, 257, 351
Unwanted or excessive radiation, 168, 279
PATIENT AUXILIARY CURRENT, 72, 85, 87, 98, 101, 205, 207, 217, 225, 251, 258, 308, 309, 324
Definition, 32
Limit, 38
Measurement, 88, 101, 217
Value, 85, 253
Values, 238, 239, 249
PATIENT CONNECTION, 22, 27, 32, 33, 38, 71, 72, 76, 77, 78, 79, 81, 87, 97, 100, 101, 103, 204, 205, 207, 208, 209, 217, 218, 227, 230, 235, 238, 239, 250, 253, 255, 256, 258
DEFIBRILLATION-PROOF APPLIED PART, 78, 80, 244
Definition, 32
Energy reduction test, 81
F-TYPE APPLIED PART, 78, 88, 241, 251, 261
Multiple, 101, 257
Single, 101, 257
TYPE B APPLIED PART, 100, 219, 242, 257
TYPE BF APPLIED PART, 219, 257
TYPE CF APPLIED PART, 220, 236, 252
WORKING VOLTAGE, 78
PATIENT ENVIRONMENT, 193, 194, 195, 197, 218, 301, 302, 303, 304, 305, 351
Definition, 32
PATIENT LEAKAGE CURRENT, 29, 87, 88, 97, 101, 205, 207, 217, 233, 250, 251
Definition, 33
Limit, 27, 38, 72, 76, 84, 252, 256, 257
ME SYSTEM, 196, 304
Measurement, 88, 100, 101, 256, 258
MULTIPLE SOCKET-OUTLET, 196
Total, 87, 88, 101, 196, 252, 253, 304
TYPE B APPLIED PART, 242
TYPE BF APPLIED PART, 253, 257
TYPE CF APPLIED PART, 220, 251
Value, 85, 88, 251, 253
PEAK WORKING VOLTAGE, 101, 104, 105, 109, 110, 114, 213, 218, 220
Definition, 33
Interpolation, 108
PEMS
See PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM, 34
PEMS DEVELOPMENT LIFE-CYCLE, 175, 176, 292, 293, 294, 296, 343, 346
Definition, 33
PEMS VALIDATION, 33, 296, 346
Definition, 33
Methods, 178
Plan, 176, 178, 292
Results, 178
Team, 178
PERMANENTLY INSTALLED
Definition, 33
ME EQUIPMENT, 54, 56, 60, 69, 70, 80, 83, 86, 98, 124, 127, 128, 142, 234, 266
MEDICAL ELECTRICAL EQUIPMENT, 59
Non-, 86, 124, 195
PESS
See PROGRAMMABLE ELECTRONIC SUBSYSTEM, 34
Placed into service, 28, 31, 33, 36, 38
Pollution degree 1, 118
Pollution degree 2, 118
Pollution degree 3, 118
Pollution degree classification, 109
PORTABLE
Definition, 33
Equipment, 38
ME EQUIPMENT, 140, 181, 182, 189, 298
ME EQUIPMENT part, 182
POTENTIAL EQUALIZATION CONDUCTOR, 63, 84, 248, 311, 313
Definition, 33
POWER SUPPLY CORD, 29, 126, 265, 266, 284, 305
Clamping means, 82
CLASS II ME EQUIPMENT, 84
Colour of conductors, 63, 212
Conductors, 126
Cord anchorage, 126
Cord connection, 123, 127, 331
Cord guard, 127
Cross-sectional area of conductors, 125, 129
Definition, 33
Incorporating switches, 124
Insulation of, 126
MAINS PLUG, 125
MULTIPLE SOCKET-OUTLET, 198, 216
Neutral conductor, 63
POTENTIAL EQUALIZATION CONDUCTOR, 84
PROTECTIVE EARTH CONDUCTOR, 82
Replaceable, 69, 128
Sheathing, 125
Strain relief, 126
Testing with, 98, 118, 137
PRIMARY OPERATING FUNCTION, 134
Definition, 40
PROCEDURE, 35, 240, 250, 285, 292, 294, 296
Cleaning, 166, 194
Definition, 33
Document control, 176
Energy reduction test, 81
LEAKAGE CURRENT measurement, 88
Maintenance, 250
Measuring X-radiation, 280
Modification/change, 179
RISK CONTROL, 177
RISK MANAGEMENT, 220
Shutdown, 67
Start-up, 67, 204
Sterilization, 85, 103, 166

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Test, 99, 152, 153, 165, 166, 245, 261, 364
Thermal cycling, 117
PROCESS, 22, 28, 41
Assessment of APPLIED PARTS, 204
Cleaning, 313
Cleaning or disinfection, 166
Definition, 34
Design, 220
Handling of PATIENT, 148
Manufacturing, 84, 145, 226, 289
Multiple cleanings/disinfections, 166
PEMS DEVELOPMENT LIFE-CYCLE, 175, 290, 291, 292, 293, 294, 295, 343, 346
PEMS VALIDATION, 33
Procedure, 33
RISK ASSESSMENT, 35
RISK CONTROL, 35
RISK EVALUATION, 35
RISK MANAGEMENT, 38, 41, 42, 43, 44, 45, 71, 74, 77, 142, 152, 153, 155, 161, 165, 166, 167, 168, 169, 171, 175, 176, 180, 187, 189, 199, 201, 204, 206, 212, 220, 221, 223, 224, 226, 231, 269, 272, 284, 287, 291, 298, 307
Software development, 175, 176
Thermoforming, 298
USABILITY ENGINEERING, 64, 167, 180, 220, 232, 288
USABILITY ENGINEERING, 40
VERIFICATION, 293
PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM (PEMS), 33, 34, 55, 175, 176, 177, 178, 179, 202, 290, 297, 371
PROGRAMMABLE ELECTRONIC SUBSYSTEM (PESS), 34, 175, 177, 371
Definition, 34
PROPERLY INSTALLED, 57, 130
Definition, 34
PROTECTIVE EARTH CONDUCTOR, 26, 29, 33, 34, 38, 63, 70, 80, 82, 83, 97, 99, 126, 127, 129, 195, 198, 216, 225, 233, 248, 250, 266, 303, 305, 351
Definition, 34
ME SYSTEM, 198
Non-PERMANENTLY INSTALLED, 195
PROTECTIVE EARTH CONNECTION, 30, 70, 75, 76, 82, 83, 84, 85, 198, 214, 216, 231, 236, 237, 242, 245, 246, 247, 248, 256, 258, 260, 264, 266, 287, 304, 355
Colour of, 63
Definition, 34
ME SYSTEM, 198
PROTECTIVE EARTH TERMINAL, 34, 59, 82, 83, 97, 127, 198, 231, 240, 247
Definition, 34
PROTECTIVELY EARTHED, 25, 38, 77, 79, 81, 83, 84, 97, 99, 110, 198, 219, 239, 240, 242, 246, 303, 305
Definition, 34
Non-, 85, 88, 99, 100, 126, 219, 236, 244
RATED
Altitude, 108
CATEGORY AP, 286
CATEGORY APG, 286
Characteristics, 123
Components, 198
Current, 69, 83, 125, 191
Definition, 34
DUTY CYCLE, 173
Fire protection device, 186
Flow rate, 58
Frequency, 49, 85, 189, 191, 260, 300
Input, 47
Input power, 47, 56
IP Classification, 228
Load, 144
MAINS VOLTAGE, 109, 114, 151, 152, 243, 244
Marked, 56
Maximum supply pressure, 143
Non-CONTINUOUS OPERATION, 173, 175
On and off periods, 156, 196
Operating time, 173
Operation, 211, 229, 290
Output current or power, 57
Output power, 198
Output voltage, 56
Phase to neutral supply voltage, 77
Pressure, 58
Protection against particulate matter, 287
Supply frequency, 56
Supply frequency range, 56
SUPPLY MAINS, 48
SUPPLY MAINS voltage, 74
Supply voltage, 55, 77, 173, 196, 244, 255, 256
Supply voltage range, 55
Temperature, 125
Voltage, 47, 49, 68, 73, 74, 77, 156, 171, 172, 174, 175, 189, 191, 242
Voltage (maximum), 156
Voltage (minimum), 156
Voltage range, 56, 77, 175
SUPPLY MAINS, 56
Reasonably foreseeable misuse, 25, 40, 46, 130, 131, 134, 157, 178, 200, 220, 228, 271, 290, 298
RECORD, 35, 42, 175, 221, 297
Definition, 34
Examination of, 41
USABILITY ENGINEERING FILE, 40
REINFORCED INSULATION, 25, 44, 45, 101, 102, 106, 139, 180, 211, 219, 236, 239, 240, 258, 260, 261, 267, 304, 363, 364, 365
Definition, 34
Removable protective means, 58
RESIDUAL RISK, 41, 222, 223
Acceptability criteria, 42, 43
Acceptability of, 240, 246, 267, 302
Alternative measure or test method, 224
Definition, 35
Equivalent safety, 224
ESSENTIAL PERFORMANCE, 222
Evaluation, 42
Identifiable safety requirements, 294
Indication of, 137, 268
Moving parts, 130
of fire, 161
SERVICE PERSONNEL, 216
System integrator, 347
Unacceptable, 222
RESPONSIBLE ORGANIZATION, 21, 30, 36, 64, 65, 67, 69, 73, 179, 193, 194, 196, 223, 227,

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230, 232, 233, 249, 279, 281, 285, 302, 304, 305, 330, 347, 349
Definition, 35
EXPECTED SERVICE LIFE, 224
Home use, 35
Instructions for use, 65
Mechanism for isolating the SUPPLY MAINS, 124
Periodic inspection and maintenance, 299
HAZARDOUS SITUATION, 179
RISK, 42, 43, 221, 222
Acceptability criteria, 42
Acceptability of, 222
Acceptable, 30, 35, 42, 43, 44, 135, 136, 177, 212, 221, 222, 271, 291, 297
Acceptance criteria, 35
Accidental disconnection, 84
Accidental selection of excessive output values, 168
Accuracy of controls and instruments, 167
Alpha, beta, gamma and neutron radiation, 152
Arrangement of controls and indicators, 180
Benefit analysis, 222
Burn, 239, 249, 255
Compatibility with substances, 167
COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS, 294
Consequent, 294
Definition, 35
Diagnostic or therapeutic acoustic pressure, 169
Diagnostic or therapeutic radiation, 168
Disconnection, 266
Earthing the PATIENT, 241
Electric shock, 30
Electric shock to others than the PATIENT, 30
Electric shock to PATIENT, 30
Electromagnetic compatibility, 199
ESSENTIAL PERFORMANCE, 222
Evaluation, 42
Expelled parts, 141
Explanation, 194
Failure of component, 45
Fault, 266
Fire, 289
Flammable agent, 286
HIGH VOLTAGE, 231
Identification of ESSENTIAL PERFORMANCE, 43
Identified, 177
Ignition, 162
Incorrect delivery of energy or substances, 168
Incorrect output, 168
Infra- and ultrasound, 142
Infrared radiation, 153
Initial movement, 139, 140
Insulation breakdown, 227, 240
Intentional exceeding of safety limits, 167
Mechanical rupture, 273
Mix-up, 297, 299
Moulding and mechanical stress, 180
Moving part, 267
Moving parts, 130
Multiple PATIENT CONNECTIONS, 255, 257, 258
New, 179
of accumulation and ignition, 186
of contact, 242
of explosion, 328
of fire, 158, 266
Overbalancing, 138, 311
Overtravel, 134
PATIENT ENVIRONMENT, 302
PATIENT support, 147
PEMS, 292
PEMS problem resolution, 176
Poor USABILITY, 167
Pre-set controls, 187
Previously unidentified, 179
Radiotherapy, 168
Reciprocal interference, 65
Reduction, 36, 44, 45, 274, 294
Replacement of lithium batteries or fuel cells, 59
Safety sign, 62
Servicing, 216
Sharp edge, 269
SINGLE FAULT CONDITION, 227
Slow, unwanted movement, 271
Spillage, 287
to PATIENT, 204, 212, 224, 243, 252, 254
to PATIENT or OPERATOR, 314
TYPE B APPLIED PART, 77
Ultraviolet radiation, 153
Unacceptable, 25, 26, 36, 42, 45, 46, 58, 60, 66, 69, 71, 77, 106, 122, 131, 133, 134, 136, 138, 139, 141, 142, 143, 144, 145, 146, 147, 148, 149, 155, 158, 165, 166, 170, 175, 180, 181, 182, 183, 184, 185, 186, 188, 193, 197, 211, 212, 222, 224, 229, 269, 270, 276, 289, 298, 302
USABILITY ENGINEERING, 288
Ventricular fibrillation, 249, 251
Vibration, 272
Visible electromagnetic radiation, 153
RISK ANALYSIS, 222
COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS, 225
Definition, 35
Identification of ESSENTIAL PERFORMANCE, 43
Identification of failures, 288
Interruption of any one power-carrying conductor, 71
PEMS DEVELOPMENT LIFE-CYCLE, 291
Results of, 45
Revision of, 48
RISK ASSESSMENT, 35
Second fault, 225
Shorting of gaps, 289
SINGLE FAULT CONDITION, 252
Support system, 145
TOUCH CURRENT, 250
RISK ASSESSMENT, 276
Definition, 35
HAND-HELD APPLIED PARTS, 297
PEMS DEVELOPMENT LIFE-CYCLE, 291, 292, 295
Source of ignition, 162
RISK ASSESSMENT, 43
RISK CONTROL, 41, 222
Alternative measure or test method, 44
Alternative measures, 44
Compatibility with substances, 167

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Definition, 35
Measure, 41, 130, 133, 175, 177, 178, 221, 222, 223, 224, 226, 230, 271, 291, 293, 294, 295, 296
Measures, 43
Option analysis, 223
PEMS DEVELOPMENT LIFE-CYCLE, 177, 291
RESIDUAL RISK, 35
RISK EVALUATION, 221
Definition, 35
RISK ASSESSMENT, 35
RISK MANAGEMENT, 43, 175
Activities, 176
Application of, 201, 205, 207, 208, 209, 220, 252, 301
Contents of, 35
Definition, 35
Methods, 193, 302
PEMS DEVELOPMENT LIFE-CYCLE, 175, 291
Plan, 42, 43, 176, 222, 292
PROCESS, 22, 35, 38, 41, 42, 43, 44, 45, 71, 74, 77, 142, 152, 153, 155, 161, 165, 166, 167, 168, 169, 171, 175, 176, 180, 187, 189, 199, 201, 204, 206, 212, 220, 221, 223, 224, 226, 231, 269, 272, 284, 287, 291, 298, 307
RECORD, 42
RECORDS required by this standard, 42, 43
Report, 297
Results of, 293
SINGLE FAULT CONDITION, 45
Support systems, 276
System integration, 347
Temperature limits, 282
RISK MANAGEMENT FILE, 42, 43, 48, 221
Alternative means of compliance, 163
Alternative methods of temperature measurement, 157
Cleaning/disinfection, 166
Contents of, 178, 221, 264, 287, 291, 292, 298
Definition, 35
Equivalent safety, 224
Examination of, 42, 43
EXPECTED SERVICE LIFE, 44
Fuses and OVER-CURRENT RELEASES, 129
Inspection, 44, 46, 52, 72, 77, 83, 106, 122, 123, 129, 133, 134, 136, 141, 142, 143, 144, 145, 146, 147, 148, 151, 152, 153, 156, 162, 165, 166, 167, 168, 169, 171, 180, 181, 182, 183, 184, 185, 186, 187, 189, 197, 199, 221, 222
Omission of OVER-CURRENT RELEASES, 186
Probability and duration of contact, 156
Professional relationships of PEMS VALIDATION TEAM members, 178
Spillage, 166
Temperature limits, 154, 155
Temperature test corner, 155
Worst case limits of oxygen concentration of flammable fuels, 158
RISK MANAGEMENT FILE, 134
RISK MANAGEMENT FILE, 149
SAFE WORKING LOAD, 37, 58, 134, 139, 140, 147, 148, 149, 151, 182, 183, 312
Definition, 36
MOBILE MEDICAL ELECTRIC EQUIPMENT, 231
Safety notice
Overflow, 165
Safety sign, 53, 55, 57, 58, 59, 62, 65, 69, 137, 138, 150, 197, 230, 231, 311, 314, 316, 320, 321
SECONDARY CIRCUIT, 104, 110, 115, 219, 236, 255, 260, 261
Definition, 36
SELF-RESETTING THERMAL CUT-OUT, 185
Definition, 36
Non-, 173, 184, 341
SEPARATION DEVICE, 195, 219, 303, 354, 355
Definition, 36
Serial number
ACCESSORY, 55
ME EQUIPMENT, 54
SERVICE PERSONNEL, 37, 48, 55, 59, 65, 68, 69, 70, 72, 84, 127, 150, 216, 228, 231, 235, 265, 266, 300
Definition, 36
Mechanism for isolating the SUPPLY MAINS, 124
Qualification of, 69
Rough surfaces, corners and edges, 269
Spurious microwave radiation, 152
Spurious X-radiation, 151
Servicing, 180, 216, 265, 268, 348
SEVERITY, 35, 212, 222, 224, 245, 271
Definition, 36
SIGNAL INPUT/OUTPUT PART, 66, 70, 78, 87, 93, 97, 99, 100, 103, 219, 245, 256, 303, 354, 361, 372
Definition, 36
SINGLE FAULT CONDITION, 25, 30, 32, 36, 41, 44, 45, 70, 72, 73, 76, 84, 85, 86, 87, 88, 89, 90, 91, 93, 95, 97, 99, 122, 133, 134, 143, 155, 158, 161, 162, 165, 166, 169, 170, 171, 172, 189, 200, 216, 221, 225, 227, 235, 236, 237, 239, 245, 248, 249, 250, 251, 252, 253, 256, 257, 264, 273, 274, 279, 284, 285, 287, 289, 290, 304, 305, 329, 337, 338, 360
Definition, 36
Identification of ESSENTIAL PERFORMANCE, 43
Undetected, 227
SINGLE FAULT SAFE, 44, 133, 171, 224, 285, 299, 300
Definition, 36
SIP/SOP
See SIGNAL INPUT/OUTPUT PART, 36
Software, 176, 179, 233, 291, 346
Maintenance, 291
STATIONARY
Definition, 36
Equipment, 268
ME EQUIPMENT, 53, 127, 163, 181
SUPPLEMENTARY INSULATION, 26, 101, 102, 106, 139, 180, 211, 214, 240, 260, 363, 364, 365
Definition, 37
SUPPLY MAINS, 29, 30, 31, 33, 43, 46, 47, 52, 56, 66, 69, 70, 71, 74, 81, 84, 97, 98, 107, 110, 129, 137, 192, 195, 196, 213, 214, 215, 216, 219, 223, 229, 233, 242, 243, 245, 255, 260, 261, 325
a.c., 49, 110, 244
Apparent impedance of, 69, 234

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Characteristics of, 47, 249
d.c., 49, 71, 244
Definition, 37
Interruption of, 167, 287, 308
Isolation from, 69, 124, 233, 235, 265
Overvoltage category, 109, 110, 261
Polyphase, 77, 124, 175, 326
RATED values, 48
Single-phase, 77
Socket-outlet, 27
Switch, 124
Symbol, 38, 54, 55, 56, 57, 58, 59, 60, 62, 63, 65, 67, 74, 84, 124, 135, 231, 255, 311, 314, 330
Technical description, 30, 47, 48, 50, 60, 64, 65, 66, 68, 69, 74, 124, 216, 313
Ambient temperature, 106
Inspection, 74, 189
Installation instructions, 156
Operating temperature, 153, 157
Transient current, 195
Unique version identifier, 69
TENSILE SAFETY FACTOR, 44, 45, 145, 146, 149, 151, 274, 275, 276, 277, 278, 279
Definition, 37
TENSILE STRENGTH, 37, 146
Definition, 37
TERMINAL DEVICE
Definition, 37
HIGH-VOLTAGE, 58, 231
MAINS TERMINAL DEVICE, 29
THERMAL CUT-OUT, 59, 153, 157, 170, 172, 173, 184, 185, 231
Definition, 37
Manual reset, 185
SELF-RESETTING THERMAL CUT-OUT, 36
THERMAL STABILITY, 156, 172, 173, 174, 175, 190, 191, 196
Definition, 37
THERMOSTAT, 173, 185, 312
Definition, 37
Failure of, 170, 184
TOOL, 21, 27, 33, 37, 49, 50, 52, 54, 58, 59, 71, 72, 73, 74, 82, 84, 122, 128, 131, 133, 144, 150, 151, 152, 157, 184, 187, 195, 197, 198, 228, 239, 268, 297, 299, 305, 331, 332, 355
Definition, 37
TOTAL LOAD, 37, 145, 146, 149, 275
Definition, 37
TOUCH CURRENT, 29, 87, 225, 233, 238, 250, 251, 304, 353, 355
Definition, 38
Limit, 72, 84, 195, 219, 237, 286, 303, 351
ME SYSTEM, 86
Measurement, 88, 90, 99, 256
MULTIPLE SOCKET-OUTLET, 196, 304
SINGLE FAULT CONDITION, 216, 305
Value, 85, 86, 304
Transport and storage
Conditions, 58, 69, 184, 194, 234
Covers used during, 49
Data for, 68
Protective packaging, 58
TRANSPORTABLE
Definition, 38
Equipment, 31, 33, 40
ME EQUIPMENT, 53, 163, 165, 287
TRAPPING ZONE, 130, 131, 133, 268, 269
Definition, 38
TYPE B APPLIED PART, 38, 77, 100, 101, 219, 238, 242, 257, 361
Classification, 38, 44, 53, 71, 238, 249
DEFIBRILLATION-PROOF symbol, 319
Definition, 38
Marking of, 38, 57
Measurement, 96
PATIENT LEAKAGE CURRENT, 251
Symbol, 318
Total PATIENT LEAKAGE CURRENT, 252
TYPE BF APPLIED PART, 38, 100, 101, 219, 224, 238, 242, 252, 257, 258, 362
Classification, 27, 38, 44, 53, 71, 76, 238, 249
DEFIBRILLATION-PROOF symbol, 319
Definition, 38
Marking of, 38, 57
MEASUREMENT, 96
PATIENT LEAKAGE CURRENT, 251, 252
Symbol, 318
Total PATIENT LEAKAGE CURRENT, 253
TYPE CF APPLIED PART, 71, 88, 100, 101, 220, 224, 236, 238, 242, 250, 251, 257, 258
Classification, 27, 44, 53, 71, 76, 238, 249
DEFIBRILLATION-PROOF symbol, 319
Definition, 38
Marking of, 38, 57
MEASUREMENT, 96
PATIENT LEAKAGE CURRENT, 252
Symbol, 318
Total PATIENT LEAKAGE CURRENT, 252, 253
TYPE TEST, 48, 102, 227, 363
COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS, 226
Definition, 38
Samples, 48, 227
Uninterruptible power supply (UPS), 195
USABILITY, 39, 167, 201, 229, 233, 288, 307
Definition, 39
USABILITY ENGINEERING, 64, 167, 220, 288
Definition, 39
PROCESS, 40, 180, 232
USABILITY ENGINEERING FILE
Definition, 40
Use by date
ACCESSORY, 55
ME EQUIPMENT, 54
VERIFICATION
Coverage criteria, 178, 291, 293, 294, 295
Definition, 39
fuse or OVER-CURRENT RELEASE, 129
Methods, 176
Milestones, 178
of Markings, 310
PEMS, 178, 343
Plan, 178, 296
Polymer properties, 299
Results, 178, 293
RISK CONTROL measures, 296
Strategies, 178, 346
Tools, 178, 296, 297

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Warning, 53, 57, 59, 62, 64, 65, 66, 67, 69, 124, 130, 137, 138, 142, 194, 230, 233, 265, 268, 270, 303, 304, 311, 313, 314, 320, 347
Overflow, 165
WORKING VOLTAGE, 33, 76, 77, 78, 102, 103, 111, 112, 113, 115, 116, 191, 192, 195, 213, 219, 220, 225, 236, 240, 244, 260, 261, 262, 359
Definition, 39
Interpolation, 108, 263
Y1 Capacitor, 75
Y2 Capacitor, 75

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Publication IEC 60601-1 (Troisième édition – 2005) I-SH 01

APPAREILS ÉLECTROMÉDICAUX – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles

FEUILLE D'INTERPRÉTATION 1

La présente feuille d'interprétation a été établie par le SC 62A: Aspects généraux des équipements électriques utilisés en pratique médicale.

Le texte de la présente feuille d'interprétation est issu des documents suivants:

ISH	Rapport de vote
62A/599/ISH	62A/613/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette feuille d'interprétation.

Paragraphe 1.1

Ce paragraphe est clarifié par ce qui suit:

L'IEC 60601-1 ne s'applique pas aux systèmes de distribution de gaz médicaux couverts par l'ISO 7396-1, *Systèmes de distribution de gaz médicaux – Partie 1: Systèmes de distribution de gaz médicaux comprimés et de vide*.

NOTE Le paragraphe 6.3 de l'ISO 7396-1 applique l'exigence de l'IEC 60601-1-8 à certains signaux de surveillance et d'alarme.

Cette clarification reste valable jusqu'à la publication d'une nouvelle version de l'IEC 60601-1.

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Publication IEC 60601-1 (Troisième édition – 2005) I-SH 02

APPAREILS ÉLECTROMÉDICAUX –

Partie 1: Exigences générales pour la sécurité de base et les performances essentielles

FEUILLE D'INTERPRÉTATION 2

La présente feuille d'interprétation a été établie par le sous-comité 62A: Aspects généraux des équipements électriques utilisés en pratique médicale, du comité d'études 62 de l'IEC: Equipements électriques dans la pratique médicale.

Le texte de la présente feuille d'interprétation est issu des documents suivants:

ISH	Rapport de vote
62A/634/ISH	62A/640/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette feuille d'interprétation.

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Paragraphe 11.3

Ce paragraphe est clarifié par ce qui suit:

Tel qu'il est énoncé dans les justifications pour ce paragraphe, les ENVELOPPES pare-feu sont destinées à être utilisées uniquement lorsqu'il existe une probabilité importante de feu à cause de la présence d'une source d'inflammation (comme décrit dans le paragraphe) *et* une source *importante* de combustible. La plupart des matériaux utilisés pour la fabrication des APPAREILS EM ne sont pas considérés comme étant une source de combustible, sauf s'ils se trouvent en présence d'un ENVIRONNEMENT RICHE EN OXYGENE. Il convient que les fabricants déterminent, par des analyses documentées dans le DOSSIER DE GESTION DES RISQUES, si l'APPAREIL EM comprend des matériaux combustibles (carburant) dans des quantités suffisantes pour alimenter la combustion conjointement avec des sources d'inflammation (capables de dissiper plus de 900 J).

Paragraphe 13.1.2

Ce paragraphe est clarifié par ce qui suit:

Tel qu'il est énoncé au paragraphe 4.7, c'est l'ANALYSE DE RISQUE du FABRICANT qui détermine quels sont les composants susceptibles aux défaillances à l'essai, basé sur les RISQUE associés. Lorsque le RISQUE associé de feu dépasse les critères du fabricant pour l'acceptabilité du RISQUE, il convient d'accepter l'analyse de la simulation du fabricant (telle que l'analyse de modes de défaillance et de leurs effets – *FMEA, en anglais*) à la place de l'essai physique. Tel qu'il est également énoncé en 4.7, il est nécessaire de prendre en compte la fiabilité et les caractéristiques du composant dans les analyses de simulation de défaillance. Il convient que les composants électroniques usuels, dont l'historique d'utilisation ne les mentionne pas comme avoir été la cause d'incendies dans les appareils, ne soient pas considérés comme une source probable d'inflammation.

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Lorsque le paragraphe identifie "l'émission de flammes, de métal fondu, de substance toxique ou inflammable, en quantités dangereuses" comme une situation dangereuse, il est fait référence aux émissions de l'*ENVELOPPE*, et non pas des composants eux même. Lorsque le paragraphe identifie le "dépassement de 1,5 fois les valeurs autorisées pour 'autres composants et matières' identifiés au Tableau 22, moins 12,5 °C", cela s'applique uniquement au cas où cette situation aurait comme résultat un RISQUE inacceptable (tel qu'identifié dans l'ANALYSE DE RISQUE du FABRICANT selon 4.7). Typiquement, il s'agit des cas où les PERFORMANCES ESSENTIELLES ne seraient pas maintenues ou lorsque des énergies supérieures à 900 J seraient dissipées en présence de matériaux inflammables qui pourraient alimenter la combustion.

La première exemption à l'analyse de défaut ou à l'essai identifiée en 13.1.2 ("La construction ou le circuit d'alimentation limite la puissance dissipée en CONDITION DE PREMIER DÉFAUT à moins de 15 W ou l'énergie dissipée à moins de 900 J") est prévue pour être appliquée lorsque la conception même du composant ("La construction") ou l'utilisation de fusibles (ou d'autres dispositifs limiteurs de courant) dans le circuit d'alimentation ("ou le circuit d'alimentation") assurent le fait que l'énergie dissipée pendant les défaillances ne dépassera pas les limites. Pour la plupart des composants habituels des circuits, prévus pour fonctionner à une puissance inférieure à 5 Watt, l'énergie dissipée lorsque l'on court-circuite les sorties ne dépassera pas la limite de 900 J.

Cette clarification restera valable jusqu'à la publication d'une nouvelle version de l'IEC 60601-1.

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SC 62A/Publication IEC 60601-1:2005, y inclus l'Amendement 1:2012,
Troisième édition/I-SH 03

APPAREILS ÉLECTROMÉDICAUX – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles

FEUILLE D'INTERPRÉTATION 3

Cette feuille d'interprétation a été établie par le sous-comité 62A: Aspects généraux des équipements électriques utilisés en pratique médicale, du comité d'études 62 de l'IEC: Equipements électriques dans la pratique médicale.

Le texte de cette feuille d'interprétation est issue des documents suivants:

ISH	Rapport de vote
62A/858/ISH	62A/875/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette feuille d'interprétation.

Paragraphe 13.1.2 quatrième tiret (Emissions, déformation d'ENVELOPPE ou dépassement de température maximale)

Ce paragraphe stipule ce qui suit:

Les SITUATIONS DANGEREUSES suivantes ne doivent pas apparaître:

– ....

– températures de parties d'APPAREILS EM qui ne sont pas des PARTIES APPLIQUEES mais qui sont susceptibles d'être touchées et qui dépassent les valeurs autorisées du Tableau 23 lorsqu'elles sont mesurées et réglées comme indiqué en 11.1.3;

Ce point est clarifié comme suit:

L'exigence ci-dessus est considérée comme satisfaite conformément au Paragraphe 4.5 pour les températures à la surface de l'enveloppe, si les conditions suivantes sont remplies:

– la température maximale autorisée sur les surfaces accessibles à l'OPERATEUR en CONDITION DE PREMIER DEFAUT est de 105 °C; et

– les instructions d'utilisation contiennent un avertissement indiquant que, dans certaines CONDITIONS DE PREMIER DEFAUT, la température de: (*indiquer la surface concernée*) peut devenir très élevée créant un RISQUE potentiel de brûlure en cas de contact, et

– si l'ANALYSE DE RISQUE démontre qu'un symbole d'avertissement est nécessaire sur l'ENVELOPPE, le signe de sécurité ISO 7010-W018 () doit être utilisé sur où près de l'emplacement chaud sur l'ENVELOPPE; et

– l'APPRECIATION DU RISQUE démontre que la température atteinte en CONDITION DE PREMIER DEFAUT est acceptable, et

– l'APPRECIATION DU RISQUE démontre que l'application des mesures alternatives de GESTION DES RISQUES dans la présente feuille d'interprétation engendre un RISQUE RESIDUEL qui est comparable au RISQUE RESIDUEL qui résulte de l'application de l'exigence de la norme.

NOTE 1 La présente feuille d'interprétation est destinée à être utilisée à la fois avec l'Edition 3.0 et avec l'Edition 3.1 de l'IEC 60601-1.

Mai 2013 ICS 11.040

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NOTE 2 Un exemple d'une analyse qui démontre une probabilité jugée suffisamment faible d'apparition de DOMMAGE est donné ci-dessous.

Exemple d'APPRECIATION DU RISQUE:

Le taux de défaillance cumulé pour les parties qui pourraient augmenter la température de surface des parties de l'enveloppe de l'appareil XYZ touchables uniquement par l'OPERATEUR à des valeurs supérieures à celles du Tableau 23 obtenu par calcul est de 60 FIT (1 FIT = 1E-9/h) selon la norme américaine MIL-HDBK-217F où FIT est l'abréviation de "failure in time" (en français "fréquence de défaillance"). Dans le cas de telles défaillances, l'appareil émettrait une odeur et ne fonctionnerait plus correctement. On estime que dans un cas sur trois seulement l'appareil ne serait pas mis hors tension immédiatement et la surface chaude entraînerait une brûlure.

La probabilité globale qui résulterait d'un tel DOMMAGE lorsqu'un signe approprié est indiqué dans les instructions d'utilisation avec le signe de sécurité ISO 7010 W018 serait: probabilité = 1/3 * 60 FIT = 2 E-8/h =approx. 0,0002 par an.

Dans cet exemple, le critère d'acceptation du RISQUE WXW pour la société exige qu'un DOMMAGE de cette sévérité ait une probabilité inférieure à 0,0003 par an pour que le RISQUE associé soit considéré acceptable. Sur la base de ce critère d'acceptation du RISQUE, le RISQUE associé à la température excessive de l'ENVELOPPE causé par des défauts isolés dans les circuits est acceptable.

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SOMMAIRE

AVANT-PROPOS 397
INTRODUCTION 400
INTRODUCTION À L'AMENDEMENT 402
1 Domaine d'application, objet et normes connexes 403
1.1 * Domaine d'application 403
1.2 Objet 403
1.3 * Normes collatérales 403
1.4 * Normes particulières 404
2 * Références normatives 404
3 * Terminologie et définitions 408
4 Exigences générales 429
4.1 * Conditions d'application aux APPAREILS EM ou aux SYSTEMES EM 429
4.2 * PROCESSUS de GESTION DES RISQUES pour les APPAREILS EM ou SYSTEMES EM 430
4.3 * PERFORMANCE ESSENTIELLE 432
4.4 * DUREE DE VIE PREVUE 433
4.5 * Mesures de MAITRISE DU RISQUE ou méthodes d'essai alternatives pour les APPAREILS EM ou les SYSTEMES EM 433
4.6 * Parties D'APPAREIL EM ou de SYSTEME EM en contact avec le PATIENT 433
4.7 * CONDITION DE PREMIER DEFAUT pour APPAREILS EM 434
4.8 * Composants des APPAREILS EM 434
4.9 * Utilisation de COMPOSANTS AUX CARACTERISTIQUES A HAUTE FIABILITE dans les APPAREILS EM 435
4.10 * Alimentation 436
4.11 Puissance absorbée 437
5 * Exigences générales relatives aux essais des APPAREILS EM 438
5.1 * ESSAIS DE TYPE 438
5.2 * Nombre de spécimens 438
5.3 Température ambiante, humidité, pression atmosphérique 438
5.4 Autres conditions 438
5.5 Tensions d'alimentation, type de courant, nature de l'alimentation, fréquence 439
5.6 Réparations et modifications 439
5.7 * Pré-conditionnement humide 440
5.8 Ordre des essais 440
5.9 * Détermination des PARTIES APPLIQUEES ET DES PARTIES ACCESSIBLES 440
6 * Classification des APPAREILS EM ET DES SYSTEMES EM 443
6.1 Généralités 443
6.2 * Protection contre les chocs électriques 443
6.3 * Protection contre les effets nuisibles de la pénétration d'eau ou de corps solides 444
6.4 Méthode(s) de stérilisation 444
6.5 Adaptation à l'utilisation dans un ENVIRONNEMENT RICHE EN OXYGENE 444
6.6 * Mode de fonctionnement 444
7 Identification, marquage et documentation des APPAREILS EM 444
7.1 Généralités 444
7.2 Marquage sur l'extérieur des APPAREILS EM ou parties d'APPAREILS EM (voir aussi Tableau C.1) 445

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7.3 Marquage à l'intérieur des APPAREILS EM ou parties d'APPAREILS EM (voir aussi Tableau C.2) 450
7.4 Marquage des organes de commande et des instruments (voir aussi Tableau C.3) 452
7.5 Signes de sécurité 454
7.6 Symboles 454
7.7 Couleurs de l'isolation des conducteurs 455
7.8 * Voyants lumineux et organes de commande 455
7.9 DOCUMENTS D'ACCOMPAGNEMENT 456
8 * Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM 462
8.1 Règle fondamentale de protection contre les chocs électriques 462
8.2 Exigences liées aux sources d'énergie électrique 463
8.3 Classification des PARTIES APPLIQUEES 464
8.4 Limitation de la tension, du courant ou de l'énergie 464
8.5 Séparation des parties 467
8.6 * Mise à la terre de protection, mise à la terre fonctionnelle et égalisation des potentiels des APPAREILS EM 476
8.7 COURANTS DE FUITE et COURANTS AUXILIAIRES PATIENT 479
8.8 Isolation 496
8.9 * LIGNES DE FUITE ET DISTANCES DANS L'AIR 503
8.10 Composants et câblage 518
8.11 PARTIES RELIEES AU RESEAU, composants et montage 520
9 * Protection contre les DANGERS MECANIQUES des APPAREILS EM et SYSTEMES EM 526
9.1 DANGERS MECANIQUES des APPAREILS EM 526
9.2 * DANGERS MECANIQUES associés aux parties en mouvement 526
9.3 * DANGER MECANIQUE associé aux surfaces, angles et arêtes 532
9.4 * DANGERS d'instabilité 532
9.5 * DANGER de projections de pièces 537
9.6 Energie acoustique (y compris infra- et ultrasons) et vibrations 537
9.7 * Réservoirs et parties sous pression pneumatique et hydraulique 538
9.8 * DANGERS MECANIQUES associés aux systèmes de support 541
10 * Protection contre les DANGERS dus aux rayonnements involontaires ou excessifs 547
10.1 Rayonnements X 547
10.2 Rayonnements alpha, bêta, gamma, neutroniques et d'autres particules 548
10.3 Rayonnements à micro-ondes 548
10.4 * Lasers 549
10.5 Autres rayonnements électromagnétiques visibles 549
10.6 Rayonnements infrarouges 549
10.7 Rayonnements ultraviolets 549
11 * Protection contres les températures excessives et les autres DANGERS 549
11.1 * Températures excessives à l'intérieur des APPAREILS EM 549
11.2 * Prévention du feu 554
11.3 * Exigences de construction pour les ENVELOPPES contre le feu des APPAREILS EM 559
11.4 * APPAREILS EM et SYSTEMES EM destinés à être utilisés avec des produits anesthésiques inflammables 562
11.5 * APPAREILS EM et SYSTEMES EM destinés à être utilisés avec des produits inflammables 562

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

11.6 Débordement, renversement, fuites, pénétration d'eau ou de particules, nettoyage, désinfection, stérilisation et compatibilité avec des substances utilisées avec des APPAREILS EM 562
11.7 Biocompatibilité des APPAREILS EM et des SYSTEMES EM 564
11.8 * Coupure de l'alimentation / du RESEAU D'ALIMENTATION vers L'APPAREIL EM 564
12 * Précision des commandes, des instruments et protection contre les caractéristiques de sortie présentant des risques 564
12.1 Précision des commandes et des instruments 564
12.2 APTITUDE A L'UTILISATION de l'APPAREIL EM 564
12.3 SYSTEMES D'ALARME 565
12.4 Protection contre les caractéristiques de sortie présentant des risques 565
13 * SITUATIONS DANGEREUSES et conditions de défaut pour les APPAREILS EM 566
13.1 SITUATIONS DANGEREUSES particulières 566
13.2 CONDITIONS DE PREMIER DEFAUT 568
14 * SYSTEMES ELECTROMEDICAUX PROGRAMMABLES (SEMP) 573
14.1 * Généralités 573
14.2 * Documentation 574
14.3 * Plan de GESTION DES RISQUES 574
14.4 * CYCLE DE DEVELOPPEMENT DE SEMP 574
14.5 * Résolution des problèmes 574
14.6 PROCESSUS de GESTION DES RISQUES 575
14.7 * Spécification des exigences 575
14.8 * Architecture 575
14.9 * Conception et réalisation 576
14.10 * VERIFICATION 576
14.11 * VALIDATION SEMP 576
14.12 * Modification 577
14.13 * SEMP destiné à être incorporé dans un RESEAU INFORMATIQUE 577
15 Construction de L'APPAREIL EM 578
15.1 * Groupements des commandes et indicateurs des APPAREILS EM 578
15.2 * Aptitude à l'entretien 578
15.3 Résistance mécanique 578
15.4 Composants et assemblage général des APPAREILS EM 582
15.5 * TRANSFORMATEURS D'ALIMENTATION des APPAREILS EM et transformateurs assurant la séparation conformément à 8.5 588
16 * SYSTEMES EM 592
16.1 * Exigences générales pour les SYSTEMES EM 592
16.2 * DOCUMENTS D'ACCOMPAGNEMENT d'un SYSTEME EM 592
16.3 * Alimentation 593
16.4 ENVELOPPES 594
16.5 * DISPOSITIFS DE SEPARATION 594
16.6 * COURANTS DE FUITE 594
16.7 * Protection contre les DANGERS MECANIQUES 595
16.8 Interruption de l'alimentation électrique de parties d'un SYSTEME EM 595
16.9 Connexions et câblage de SYSTEME EM 596
17 * Compatibilité électromagnétique des APPAREILS ET DES SYSTEMES EM 598
Annexe A (informative) Lignes directrices générales et justifications 599
Annexe B (informative) Ordre des essais 714

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Annexe C (informative) Guide pour le marquage et exigences d'étiquetage pour les APPAREILS EM et les SYSTEMES EM 718
Annexe D (informative) Symboles des marquages (voir Article 7) 722
Annexe E (informative) Exemples de connexion du dispositif de mesure (DM) pour la mesure du COURANT DE FUITE PATIENT et du COURANT AUXILIAIRE PATIENT (voir 8.7) 731
Annexe F (informative) Circuits d'alimentation de mesure adaptés 733
Annexe G (normative) Protection contre les DANGERS d'inflammation des mélanges anesthésiques inflammables 736
Annexe H (informative) Structure de SEMP, CYCLE DE DEVELOPPEMENT SEMP et documentation 752
Annexe I (informative) Aspects des SYSTEMES EM 761
Annexe J (informative) Etude des chemins d'isolation 767
Annexe K (informative) Schémas simplifiés de COURANT DE FUITE PATIENT 770
Annexe L (normative) Fils de bobinage isolés pour utilisation sans isolation intercalée 773
Annexe M (normative) Réduction des degrés de pollution 776
Bibliographie 777
INDEX 781
INDEX DES ABREVIATIONS ET ACRONYMES 801

Figure 1 – Raccordement au réseau non fixé à demeure (voir définitions) 410
Figure 2 – Exemple de bornes et conducteurs définis (voir définitions) 411
Figure 3 – Exemple d'APPAREIL EM DE CLASSE I 412
Figure 4 – Exemple d' APPAREIL EM DE CLASSE II sous enveloppe métallique 412
Figure 5 – Schéma fonctionnel pour la qualification des composants 436
Figure 6 – Doigt d'essai normalisé 442
Figure 7 – Crochet d'essai 443
Figure 8 – Broche d'essai 466
Figure 9 – Application de la tension d'essai à des CONNEXIONS PATIENT reliées entre elles pour les PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION 473
Figure 10 – Application de la tension d'essai à des CONNEXIONS PATIENT individuelles pour les PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION 474
Figure 11 – Application de la tension d'essai pour tester l'énergie de défibrillation délivrée 476
Figure 12 – Exemple de dispositif de mesure et de ses caractéristiques de fréquence 481
Figure 13 – Circuit de mesure pour le COURANT DE FUITE A LA TERRE des APPAREILS EM de la CLASSE I, avec ou sans PARTIE APPLIQUEE 484
Figure 14 – Circuit de mesure pour le COURANT DE CONTACT 485
Figure 15 – Circuit de mesure pour le COURANT DE FUITE PATIENT provenant de la CONNEXION PATIENT à la terre 486
Figure 16 – Circuit de mesure pour le COURANT DE FUITE PATIENT via la (les) CONNEXION(S) PATIENT d'une PARTIE APPLIQUEE DE TYPE F à la terre, provoqué par une tension externe sur la (les) CONNEXION(S) PATIENT 487
Figure 17 – Circuit de mesure pour le COURANT DE FUITE PATIENT de la ou des CONNEXION(S) PATIENT à la terre, provoqué par une tension externe sur une ENTREE/SORTIE DE SIGNAL 488

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Figure 18 – Circuit de mesure pour le COURANT DE FUITE PATIENT de la ou des CONNEXION(S) PATIENT à la terre, provoqué par une tension externe sur une PARTIE ACCESSIBLE métallique qui n'est pas PROTEGEE PAR MISE A LA TERRE) 489

Figure 19 – Circuit de mesure pour le COURANT AUXILIAIRE PATIENT 490

Figure 20 – Circuit de mesure pour le COURANT DE FUITE PATIENT total avec toutes les CONNEXIONS PATIENT de toutes les PARTIES APPLIQUEES du même type (PARTIES APPLIQUEES DE TYPE B, BF ou TYPE CF) connectées ensemble 491

Figure 21 – Appareillage pour l'essai à la bille 503

Figure 22 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 1 515

Figure 23 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 2 515

Figure 24 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 3 515

Figure 25 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 4 516

Figure 26 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 5 516

Figure 27 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 6 516

Figure 28 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 7 517

Figure 29 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 8 517

Figure 30 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 9 517

Figure 31 – LIGNE DE FUITE et DISTANCE DANS L'AIR – Exemple 10 518

Figure 32 – Rapport entre la PRESSION d'essai HYDRAULIQUE et la PRESSION MAXIMALE ADMISSIBLE DE FONCTIONNEMENT 540

Figure 33 – Module de chariot supérieur représentant le corps 546

Figure 34 – Appareillage d'essai d'inflammation par étincelles 556

Figure 35 – Courant maximal admissible *I* en fonction de la tension maximale admissible *U* mesuré dans un circuit purement résistif dans un ENVIRONNEMENT RICHE EN OXYGENE 556

Figure 36 – Tension maximale admissible *U* en fonction de la capacité *C* mesurée dans un circuit capacitif utilisé dans un ENVIRONNEMENT RICHE EN OXYGENE 557

Figure 37 – Courant maximal admissible *I* en fonction de l'inductance *L* mesurée dans un circuit inductif dans un ENVIRONNEMENT RICHE EN OXYGENE 557

Figure 38 – Déflecteur 561

Figure 39 – Zone du fond d'une ENVELOPPE comme spécifié en 11.3 b) 1) 561

Figure A.1 – Identification de l'APPAREIL EM, des PARTIES APPLIQUEES et des CONNEXIONS PATIENT dans un moniteur d'électrocardiogramme 605

Figure A.2 – Exemple d'isolation d'une PARTIE APPLIQUEE DE TYPE F avec isolation incorporée dans l'APPAREIL EM 606

Figure A.3 – Identification de l'APPAREIL EM, DES PARTIES APPLIQUEES et des CONNEXIONS PATIENT dans un moniteur PATIENT avec dispositifs de surveillance endovasculaire de la pression 606

Figure A.4 – Identification de l'APPAREIL EM, DES PARTIES APPLIQUEES et des CONNEXIONS PATIENT dans un moniteur PATIENT multifonctions avec dispositifs de surveillance endovasculaire de la pression 607

Figure A.5 – Identification des PARTIES APPLIQUEES et des CONNEXIONS PATIENT dans un SYSTEME EM A RAYONS X 608

Figure A.6 – Identification de l'APPAREIL EM, des PARTIES APPLIQUEES et des CONNEXIONS PATIENT dans un neurostimulateur électrique transcutané (TENS) destiné à être porté sur la ceinture du PATIENT et connecté à des électrodes sur le haut du bras du PATIENT 609

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Figure A.7 – Identification de l'APPAREIL EM ou du SYSTEME EM, des PARTIES APPLIQUEES et des CONNEXIONS PATIENT dans un micro-ordinateur avec un module d'électrocardiogramme 610

Figure A.8 – Représentation graphique de la relation du DANGER, de la séquence d'évènements, de SITUATION DANGEREUSE et de DOMMAGE 613

Figure A.9 – Exemple d'ENVIRONNEMENT DU PATIENT 618

Figure A.10 – Circuit flottant 638

Figure A.11 – Interruption d'un conducteur d'alimentation entre des parties de l'APPAREIL EM dans des ENVELOPPES séparées 640

Figure A.12 – Identification des MOYENS DE PROTECTION DU PATIENT et des MOYENS DE PROTECTION DE L'OPERATEUR 643

Figure A.13 – Impédance de terre de protection admissible avec courant de défaut limité 651

Figure A.14 – Probabilité de fibrillation ventriculaire 657

Figure A.15 – Exemple d'un circuit de mesure pour le COURANT DE FUITE PATIENT entre une CONNEXION PATIENT et la terre pour un APPAREIL EM avec CONNEXIONS PATIENT multiples 662

Figure A.16 – Conditions de l'essai d'instabilité 674

Figure A.17 – Exemple de détermination du FACTEUR DE TRACTION DE SECURITE au moyen du Tableau 21 681

Figure A.18 – Exemple de détermination des charges de calcul et d'essai 682

Figure A.19 – Exemple de distribution de masse du corps humain 682

Figure A.20 – Relations entre les termes utilisés pour décrire les appareils, les ACCESSOIRES ou les parties d'appareils 615

Figure A.21 – Exemple d'APPAREIL EM disposant de deux fonctions différentes sur un circuit commun de PARTIE APPLIQUEE 648

Figure A.22 – Température autorisée maximale pour les surfaces et les PARTIES APPLIQUEES à des altitudes plus élevées 687

Figure A.23 – Exemple de MOYEN DE PROTECTION DE L'OPERATEUR nécessaire entre les bornes d'une ALIMENTATION ELECTRIQUE INTERNE et un dispositif de protection complémentaire 706

Figure E.1 – PARTIE APPLIQUEE DE TYPE B 731

Figure E.2 – PARTIE APPLIQUEE DE TYPE BF 731

Figure E.3 – PARTIE APPLIQUEE DE TYPE CF 732

Figure E.4 – Courant auxiliaire patient 732

Figure E.5 – Charge des CONNEXIONS PATIENT si elles sont spécifiées par le FABRICANT 732

Figure F.1 – Circuit d'alimentation de mesure avec un côté du RESEAU D'ALIMENTATION approximativement au potentiel de terre 733

Figure F.2 – Circuit d'alimentation de mesure avec RESEAU D'ALIMENTATION approximativement symétrique au potentiel de terre 733

Figure F.3 – Circuit d'alimentation de mesure pour les APPAREILS EM polyphasés spécifiés pour connexion à un RESEAU D'ALIMENTATION polyphasé 734

Figure F.4 – Circuit d'alimentation de mesure pour les APPAREILS EM monophasés spécifiés pour connexion à un RESEAU D'ALIMENTATION polyphasé 734

Figure F.5 – Circuit d'alimentation de mesure pour les APPAREILS EM ayant une unité d'alimentation séparée ou destiné à recevoir sa puissance d'un autre appareil du SYSTEME EM 735

Figure G.1 – Courant maximal admissible I_{ZR} en fonction de la tension maximale admissible U_{ZR} mesuré dans un circuit purement résistif avec le mélange le plus facilement inflammable de vapeur d'éther et d'air 742

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Figure G.2 – Tension maximale admissible U_{ZC} en fonction de la capacité C_{max} mesurée dans un circuit capacitif avec le mélange le plus facilement inflammable de vapeur d'éther et d' air 743

Figure G.3 – Courant maximal admissible I_{ZL} en fonction de l'inductance L_{max} mesurée dans un circuit inductif avec le mélange le plus facilement inflammable de vapeur d'éther et d'air 743

Figure G.4 – Courant maximal admissible I_{ZR} en fonction de la tension maximale admissible U_{ZR} mesuré dans un circuit purement résistif avec le mélange le plus facilement inflammable de vapeur d'éther et d'oxygène 748

Figure G.5 – Tension maximale admissible U_{ZC} en fonction de la capacité C_{max} mesurée dans un circuit capacitif avec le mélange le plus facilement inflammable de vapeur d'éther et d'oxygène 749

Figure G.6 – Courant maximal admissible I_{ZL} en fonction de l'inductance L_{max} mesurée dans un circuit inductif avec le mélange le plus facilement inflammable de vapeur d'éther et d'oxygène 749

Figure G.7 – Appareillage d'essai 751

Figure H.1 – Exemples de structures SEMP/ SSEP 753

Figure H.2 – Modèle de CYCLE DE DEVELOPPEMENT DE SEMP 754

Figure H.3 – Non utilisée 755

Figure H.4 – Exemple de paramètres potentiels dont la spécification peut être exigée pour un RESEAU INFORMATIQUE 760

Figure I.1 – Exemple de construction de SOCLE DE PRISES MULTIPLES (SPM) (accessible uniquement à l'aide d'un outil) 765

Figure I.2 – Exemples d'application de SOCLES DE PRISES MULTIPLES (SPM) 766

Figure J.1 – Isolation, exemple 1 767

Figure J.2 – Isolation, exemple 2 767

Figure J.3 – Isolation, exemple 3 767

Figure J.4 – Isolation, exemple 4 768

Figure J.5 – Isolation, exemple 5 768

Figure J.6 – Isolation, exemple 6 768

Figure J.7 – Isolation, exemple 7 769

Figure K.1 – APPAREIL EM avec ENVELOPPE en matière isolante 770

Figure K.2 – APPAREIL EM avec PARTIE APPLIQUEE DE TYPE F 770

Figure K.3 – APPAREIL EM avec une PARTIE APPLIQUEE et une PARTIE E/S DE SIGNAL 771

Figure K.4 – APPAREIL EM avec une CONNEXION PATIENT d'une PARTIE APPLIQUEE DE TYPE B qui n'est pas PROTEGEE PAR MISE A LA TERRE 771

Figure K.5 – APPAREIL EM avec une CONNEXION PATIENT d'une PARTIE APPLIQUEE DE TYPE BF qui n'est pas PROTEGEE PAR MISE A LA TERRE 772

Tableau 1 – Unités n'appartenant pas au système SI qui peuvent être utilisées sur les APPAREILS EM 453

Tableau 2 – Couleurs des voyants lumineux et leur signification pour les APPAREILS EM 456

Tableau 3 – * Valeurs admissibles des COURANTS DE FUITE PATIENT et des COURANTS AUXILIAIRES PATIENT EN CONDITION NORMALE ET EN CONDITION DE PREMIER DEFAUT 482

Tableau 4 – * Valeurs admissibles des COURANTS DE FUITE PATIENT dans les conditions d'essais particulières identifiées en 8.7.4.7 483

Tableau 5 – Légendes des symboles pour les Figures 9 à 11 et 13 à 20, Figure A.15, Annexes E et F 492

IECNORM.COM : Click to view the full PDF of IEC 60601-1:2005+AMD1:2012 CSV

Tableau 6 – Tensions d'essai pour l'isolation solide formant un MOYEN DE PROTECTION 500
Tableau 7 – Tensions d'essai pour les MOYENS DE PROTECTION DE L'OPERATEUR 501
Tableau 8 – Facteurs de multiplication pour les distances dans l'air pour des altitudes jusqu'à 5 000 m 504
Tableau 9 – Classification des groupes de matériaux 505
Tableau 10 – TENSION TRANSITOIRE RESEAU 506
Tableau 11 – Non utilisé 507
Tableau 12 – LIGNES DE FUITE et DISTANCES DANS L'AIR minimales assurant des MOYENS DE PROTECTION DU PATIENT 508
Tableau 13 – DISTANCES DANS L'AIR minimales assurant un MOYEN DE PROTECTION à L'OPERATEUR vis à vis de la PARTIE RELIEE AU RESEAU 509
Tableau 14 – DISTANCES DANS L'AIR complémentaires pour l'isolation dans les PARTIES RELIEES AU RESEAU avec des TENSIONS DE SERVICE CRETE dépassant la valeur de crête de la TENSION RESEAU NOMINALE [a] 510
Tableau 15 – DISTANCES DANS L'AIR minimales pour MOYENS DE PROTECTION DE L'OPERATEUR dans des CIRCUITS SECONDAIRES 511
Tableau 16 – LIGNES DE FUITE minimales assurant un MOYEN DE PROTECTION DE L'OPERATEUR [a] 512
Tableau 17 – Section NOMINALE des conducteurs d'un CABLE D'ALIMENTATION 522
Tableau 18 – Essais des dispositifs d'arrêt de traction 523
Tableau 19 – DANGERS MECANIQUES couverts par le présent article 526
Tableau 20 – Espaces acceptables [a] 528
Tableau 21 – Détermination du FACTEUR DE SECURITE EN TRACTION 542
Tableau 22 – Températures maximales admissibles des parties 550
Tableau 23 – Températures maximales admissibles pour les parties des APPAREILS EM qui sont susceptibles d'être touchées 550
Tableau 24 – Températures maximales admissibles pour le contact de la peau avec des PARTIES APPLIQUEES des APPAREILS EM 551
Tableau 25 – Perforation acceptable du fond d'une ENVELOPPE 560
Tableau 26 – * Limites de température des enroulements de moteurs 570
Tableau 27 – Température maximale stabilisée d'un enroulement moteur 572
Tableau 28 – Matrice d'essai de résistance mécanique 579
Tableau 29 – Hauteur de chute 580
Tableau 30 – Couples d'essai pour les commandes par rotation 586
Tableau 31 – Températures maximales admissibles des enroulements des transformateurs dans des conditions de surcharge et de court-circuit à une température ambiante de 25 °C (± 5 °C) 588
Tableau 32 – Courant d'essai pour les transformateurs 589
Tableau 33 – Conditions d'essai pour l'essai des butées d'extrémité pour dépassement de course 531
Tableau A.1 – Valeurs de la DISTANCE DANS L'AIR et de la LIGNE DE FUITE tirées du Tableau 7 de l'IEC 61010-1:2001 et du Tableau 12 665
Tableau A.2 – LIGNES DE FUITE pour éviter les défaillances dues au cheminement de l'IEC 60664-1 666
Tableau A.3 – Conditions de l'essai d'instabilité 674
Tableau A.4 – Durée d'exposition admissible pour le niveau d'accélération 677

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Tableau A.5 – Conseils sur les températures de surface pour les APPAREILS EM qui génèrent des températures basses (fraîches) pour des besoins thérapeutiques ou dans le cadre de leur fonctionnement 686
Tableau C.1 – Marquage à l'extérieur des APPAREILS EM, des SYSTEMES EM ou de leurs parties 718
Tableau C.2 – Marquage à l'intérieur des APPAREILS EM, des SYSTEMES EM ou de leurs parties 719
Tableau C.3 – Marquage des commandes et des instruments 719
Tableau C.4 – DOCUMENTS D'ACCOMPAGNEMENT, généralités 720
Tableau C.5 – DOCUMENTS D'ACCOMPAGNEMENT, instructions d'utilisation 720
Tableau D.1 – Symboles généraux 723
Tableau D.2 – Signes de sécurité 728
Tableau D.3 – Codes généraux 730
Tableau G.1 – Etanchéité aux gaz des entrées de câbles 745
Tableau H.1 – Non utilisé 758
Tableau I.1 – Exemples de SYSTEMES EM pour illustration 763
Tableau L.1 – Diamètre du mandrin 774
Tableau L.2 – Température du four 774
Tableau M.1 – Réduction du degré de pollution de l'environnement interne grâce à l'utilisation d'une protection supplémentaire 776

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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APPAREILS ÉLECTROMÉDICAUX –

Partie 1: Exigences générales pour la sécurité de base et les performances essentielles

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8) L'attention est attirée sur les références normatives citées dans cette publication. L'utilisation de publications référencées est obligatoire pour une application correcte de la présente publication.
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Cette version consolidée n'est pas une Norme IEC officielle, elle a été préparée par commodité pour l'utilisateur. Seules les versions courantes de cette norme et de son(ses) amendement(s) doivent être considérées comme les documents officiels.

Cette version consolidée de l'IEC 60601-1 porte le numéro d'édition 3.1. Elle comprend la troisième édition (2005-12) [documents 62A/505A/FDIS et 62A/512/RVD] et son amendement 1 (2012-07) [documents 62A/805/FDIS et 62A/820/RVD]. Le contenu technique est identique à celui de l'édition de base et à son amendement.

Cette version consolidée inclut le contenu des corrigenda 1 (2006-12) et 2 (2007-12), le contenu du corrigendum à l'Amendement 1 (2014-07), ainsi que les feuilles d'interprétation 1 (2008-04), 2 (2009-01) et 3 (2013-05).

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Cette version Finale ne montre pas les modifications apportées au contenu technique par l'amendement 1. Une version Redline montrant toutes les modifications est disponible dans cette publication.

La Norme internationale IEC 60601-1 a été établie par le sous-comité 62A: Aspects généraux des équipements électriques utilisés en pratique médicale, du comité d'études 62 de l'IEC: Equipements électriques dans la pratique médicale.

Cette troisième édition annule et remplace la deuxième édition publiée en 1988, son Amendement 1 (1991) et son Amendement 2 (1995), la deuxième édition de l'IEC 60601-1-1 publiée en 2000 et la première édition de l'IEC 60601-1-4 publiée en 1996 ainsi que son Amendement 1 (1999). Cette édition constitue une révision technique. Des modifications importantes de structure ont été apportées à la présente édition. L'alignement des exigences électriques sur celles applicables aux matériels de traitement de l'information couverts par l'IEC 60950-1 a été poursuivi et il a été ajouté l'exigence d'inclure un PROCESSUS de GESTION DES RISQUES. Se reporter à l'Annexe A.3 pour une description développée de cette révision.

Cette publication a été rédigée selon les Directives ISO/IEC, Partie 2.

Dans la présente norme, les caractères suivants sont employés:

– Exigences et définitions: caractères romains

– *Modalités d'essais : caractères italiques*

– Les indications de nature informative apparaissant hors des tableaux, comme les notes, les exemples et les références: petits caractères. Le texte normatif à l'intérieur des tableaux est également en petits caractères.

– TERMES UTILISES DANS LA PRESENTE NORME QUI SONT DEFINIS A L'ARTICLE 3 ET EGALEMENT INDIQUES DANS L'INDEX: PETITES MAJUSCULES.

Concernant la structure de la présente norme, le terme:

– "article" désigne l'une des dix-sept sections numérotées dans la table des matières, avec toutes ses subdivisions (par exemple, l'Article 7 inclut les Paragraphes 7.1, 7.2, etc.) ;

– "paragraphe" désigne une subdivision numérotée d'un article (par exemple 7.1, 7.2 et 7.2.1 sont tous des paragraphes appartenant à l'Article 7).

Dans la présente norme, les références à des articles sont précédées du mot "Article" suivi du numéro de l'article concerné. Dans la présente norme, les références aux paragraphes utilisent uniquement le numéro du paragraphe concerné.

Dans la présente norme, la conjonction "ou" est utilisée avec la valeur d'un "ou inclusif", ainsi un énoncé est vrai si une combinaison des conditions quelle qu'elle soit est vraie.

Les formes verbales utilisées dans la présente norme sont conformes à l'usage donné à l'Annexe G des Directives ISO/IEC, Partie 2. Pour les besoins de la présente norme:

– "devoir" mis au présent de l'indicatif signifie que la satisfaction à une exigence ou à un essai est obligatoire pour la conformité à la présente norme ;

– "il convient/il est recommandé" signifie que la satisfaction à une exigence ou à un essai est recommandée mais n'est pas obligatoire pour la conformité à la présente norme ;

– "pouvoir" mis au présent de l'indicatif est utilisé pour décrire un moyen admissible pour satisfaire à une exigence ou à un essai.

Lorsqu'un astérisque (*) est utilisé comme premier caractère devant un titre, au début d'un titre d'alinéa ou de tableau, il indique l'existence d'une ligne directrice ou d'une justification à consulter à l'Annexe A.

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Le comité a décidé que le contenu de la publication de base et de son amendement ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "http://webstore.iec.ch" dans les données relatives à la publication recherchée. A cette date, la publication sera

- reconduite;
- supprimée;
- remplacée par une édition révisée, ou
- amendée.

NOTE L'attention des Comités Nationaux est attirée sur le fait que les fabricants d'appareils et les organismes d'essai peuvent avoir besoin d'une période transitoire après la publication d'une nouvelle publication IEC ou ISO, ou d'une publication amendée ou révisée, pour fabriquer des produits conformes aux nouvelles exigences et pour adapter leurs équipements aux nouveaux essais ou aux essais révisés. Le comité recommande que le contenu de cette publication soit entériné au niveau national au plus tôt 3 ans après la date de publication.

IMPORTANT – Le logo *"colour inside"* qui se trouve sur la page de couverture de cette publication indique qu'elle contient des couleurs qui sont considérées comme utiles à une bonne compréhension de son contenu. Les utilisateurs devraient, par conséquent, imprimer cette publication en utilisant une imprimante couleur.

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INTRODUCTION

En 1976, le sous-comité 62A a publié la première édition de l'IEC/TR 60513, *Aspects fondamentaux des normes de sécurité pour les appareils électromédicaux*. La première édition de l'IEC/TR 60513 a servi de base à l'établissement:

– de la première édition de l'IEC 60601-1 (la norme de SECURITE CHAPEAU pour les APPAREILS ELECTROMEDICAUX) ;

– de la série IEC 60601-1-xx des normes collatérales pour les APPAREILS ELECTROMEDICAUX ;

– de la série IEC 60601-2-xx des normes particulières pour les différents types D'APPAREILS ELECTROMEDICAUX, et

– de la série IEC 60601-3-xx des normes de performances pour les différents types D'APPAREILS ELECTROMEDICAUX.

Consciente qu'il était nécessaire et urgent d'avoir une norme traitant des appareils utilisés dans la pratique médicale, la majorité des comités nationaux a émis, en 1977, un vote favorable pour la première édition de l'IEC 60601-1, issue d'un projet qui, à l'époque, représentait une première approche de ce problème. L'étendue du domaine d'application, la complexité des appareils concernés, la spécificité de certaines mesures de protection et des essais de vérification correspondants avaient exigé des années d'effort pour aboutir à cette première norme dont on peut à présent affirmer qu'elle a servi de référence universelle depuis sa publication.

L'application fréquente de la première édition a cependant montré que des améliorations étaient possibles. Ces améliorations étaient d'autant plus souhaitables que cette norme a connu un large succès depuis sa publication.

Le travail de révision qui a été entrepris et poursuivi avec soin pendant des années a donné lieu à la deuxième édition en 1988. Cette édition comporte toutes les améliorations qu'il était raisonnable d'envisager à l'époque. D'autres développements ont fait l'objet d'études de manière suivie. La deuxième édition a été modifiée en 1991 puis une nouvelle fois en 1995.

A l'origine, l'approche de l'IEC consistait à établir séparément des normes de "SECURITE DE BASE" et des normes de "PERFORMANCES ESSENTIELLES" pour les APPAREILS ELECTROMEDICAUX. Cela s'inscrivait naturellement dans l'approche historique qui prévalait au niveau national et international pour d'autres normes sur les appareils électriques (par exemple celles pour les appareils électrodomestiques), à savoir que la SECURITE DE BASE obéissait à des normes obligatoires mais que les autres spécifications de "performances" obéissaient aux demandes du marché. Dans ce contexte, il a été dit que "L'aptitude d'une bouilloire électrique à faire bouillir de l'eau est sans importance pour son utilisation en toute sécurité!"

Il est maintenant reconnu que cela ne correspond pas à la situation de nombreux éléments constituant les APPAREILS ELECTROMEDICAUX, et les ORGANISMES RESPONSABLES doivent se référer à des normes pour assurer à la fois les PERFORMANCES ESSENTIELLES et la SECURITE DE BASE. Parmi ces domaines, il y a la précision avec laquelle l'appareil contrôle la délivrance d'énergie ou de substances thérapeutiques à un PATIENT ou traite et affiche les données physiologiques qui influeront sur le suivi du patient.

Reconnaître cela signifie qu'il est d'une certaine façon inapproprié de séparer la "SECURITE DE BASE" et les "performances" lorsqu'on s'intéresse aux DANGERS qui résultent d'une conception inadéquate des APPAREILS ELECTROMEDICAUX. De nombreuses normes particulières de la série IEC 60601-2-xx traitent d'un ensemble d'exigences de PERFORMANCES ESSENTIELLES qui ne peuvent pas être directement évaluées par L'ORGANISME RESPONSABLE si celui-ci n'applique pas de telles normes. (Cependant, la série actuelle IEC 60601 comprend moins d'exigences de PERFORMANCES ESSENTIELLES que de SECURITE DE BASE).

Dans la perspective d'une troisième édition de l'IEC 60601-1, le sous-comité 62A de l'IEC avait établi, en 1994, une deuxième édition de l'IEC/TR 60513 [12] [1)]. Il était prévu que la deuxième édition de l'IEC/TR 60513 de l'IEC donnerait des lignes directrices pour

1) Les chiffres entre crochets se réfèrent à la Bibliographie.

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l'établissement de la présente édition de l'IEC 60601-1 et pour l'évolution ultérieure des séries IEC 60601-1-xx et IEC 60601-2-xx.

Pour assurer la cohérence entre les normes internationales, pour répondre aux attentes actuelles des milieux médicaux et pour s'aligner sur les évolutions dans la série IEC 60601-2-xx, la deuxième édition de l'IEC/TR 60513 inclut deux principes majeurs nouveaux:

– la première modification concerne le concept de "SECURITE" qui a été étendu à partir des aspects de SECURITE DE BASE dans la première et dans la deuxième édition de l'IEC 60601-1 pour inclure les aspects de PERFORMANCES ESSENTIELLES (par exemple la précision des appareils de surveillance physiologique). L'application de ce principe conduit à la modification du titre de "Appareils électromédicaux – Partie 1: Règles générales de sécurité" dans la deuxième édition en "Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles";

– la deuxième modification concerne la spécification d'exigences minimales de sécurité, prévoyant l'évaluation de l'adéquation du PROCESSUS de conception lorsque celle-ci constitue la seule méthode pratique d'évaluation de la sécurité de certaines technologies comme les systèmes électroniques programmables. L'application de ce principe est un des facteurs qui conduit à l'introduction d'une exigence générale d'application d'un PROCESSUS de GESTION DES RISQUES. Parallèlement à la préparation de cette troisième édition de l'IEC 60601-1, un projet conjoint avec le TC 210 de l'ISO a donné lieu à la publication d'une norme générale pour la GESTION DES RISQUES des appareils médicaux. La conformité avec la présente édition de l'IEC 60601-1 nécessite que le FABRICANT mette en place un PROCESSUS de GESTION DES RISQUES qui soit conforme aux parties de l'ISO 14971 (voir 4.2).

La présente norme contient les exigences concernant la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES qui sont généralement applicables aux APPAREILS ELECTROMEDICAUX. Pour certains types D'APPAREIL ELECTROMEDICAUX, ces exigences sont soit complétées soit modifiées par des exigences spécifiques données dans une norme collatérale ou une norme particulière. Lorsqu'il existe une norme particulière, il est recommandé de ne pas utiliser la présente norme générale seule.

L'Amendement 1 à la présente norme est destiné à traiter:

– les sujets identifiés par les Comités Nationaux et d'autres parties prenantes depuis la publication de l'IEC 60601-1:2005;

– la manière dont la GESTION DES RISQUES a été introduite dans l'IEC 60601-1:2005; et

– la manière dont le concept de PERFORMANCE ESSENTIELLE est utilisé dans la IEC 60601-1:2005.

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INTRODUCTION À L'AMENDEMENT

La troisième édition de l'IEC 60601-1 a été publiée en 2005. À la date de la publication, l'on trouvait 94 commentaires des Comités nationaux sur le 2ème CDV et le FDIS qui furent différés à un amendement ou une révision futur(e). Chacun de leurs commentaires différés a été saisi dans une fiche spéciale par le secrétariat du SC 62A. Au moment de la réunion d'Auckland en avril 2008, les Sous-comités avaient développé deux fiches d'interprétation et le secrétariat du SC 62A avait reçu 15 commentaires supplémentaires des Comités nationaux et d'autres parties prenantes.

À la réunion d'Auckland, l'IEC/CE 62 a approuvé un projet de développement du 1er amendement à l'IEC 60601-1:2005 basé sur les sujets en cours à ce moment. Le CE a approuvé le développement du 1er amendement en vue de traiter les problèmes en cours, comprenant sans limitation:

– ceux qui sont énumérés dans le 62A/593/DC et le 62A/602/INF;
– la manière dont la gestion des risques a été introduite dans l'IEC 60601-1:2005; et
– la manière dont le concept de performances essentielles est utilisé dans l'IEC 60601-1:2005.

Depuis la réunion d'Auckland, le secrétariat a reçu 73 commentaires supplémentaires des Comités nationaux ou d'autres parties prenantes, pour un total de 182 fiches. Le présent amendement est destiné à traiter ces sujets.

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APPAREILS ÉLECTROMÉDICAUX –

Partie 1: Exigences générales pour la sécurité de base et les performances essentielles

1 Domaine d'application, objet et normes connexes

1.1 * Domaine d'application

La présente Norme internationale s'applique à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des APPAREILS ELECTROMEDICAUX et des SYSTEMES ELECTROMEDICAUX, désignés ci-après sous le terme APPAREILS EM et SYSTEMES EM.

Si un article ou un paragraphe est spécifiquement destiné à être applicable uniquement aux APPAREILS EM ou uniquement aux SYSTEMES EM, le titre et le contenu de cet article ou de ce paragraphe l'indiquent. Si cela n'est pas le cas, l'article ou le paragraphe s'applique à la fois aux APPAREILS EM et aux SYSTEMES EM, selon le cas.

Les DANGERS inhérents à la fonction physiologique prévue de L'APPAREIL EM ou des SYSTEMES EM dans le cadre du domaine d'application de la présente norme ne sont pas couverts par des exigences spécifiques contenues dans la présente norme, à l'exception de 7.2.13 et 8.4.1.

NOTE 1 Voir aussi 4.2.

La série de normes IEC 60601 ne s'applique pas aux:

– appareils de diagnostic in vitro qui n'entrent pas dans la définition des APPAREILS EM, qui sont couverts par la série IEC 61010 [61];
– pièces implantables de dispositifs médicaux implantables actifs couverts par la série ISO 14708 [69]; ou
– systèmes de distribution de gaz médicaux couverts par l'ISO 7396-1 [68].

NOTE 2 L'ISO 7396-1 applique l'exigence de l'IEC 60601-1-8 à certains signaux de surveillance et d'alarme.

1.2 Objet

La présente Norme est destinée à spécifier des exigences générales et à servir de base pour les normes particulières.

1.3 * Normes collatérales

Dans la série IEC 60601, les normes collatérales spécifient des exigences générales pour la SECURITE DE BASE et pour les PERFORMANCES ESSENTIELLES applicables à:

– un sous-groupe d'APPAREILS EM (par exemple appareils de radiologie) ;
– une caractéristique spécifique à tous les APPAREILS EM qui n'est pas complètement traitée dans la présente norme.

Les normes collatérales applicables prennent une valeur normative à la date de leur publication et elles doivent s'appliquer avec la présente norme.

NOTE 1 Lors de l'évaluation de la conformité à l'IEC 60601-1, il est admissible d'évaluer de manière indépendante la conformité aux normes collatérales.

NOTE 2 Lorsqu'il déclare qu'un appareil est conforme à l'IEC 60601-1, il convient que le déclarant donne spécifiquement la liste des normes collatérales qui ont été appliquées. Cela permet à toute personne lisant la déclaration de connaître quelles normes collatérales ont fait partie de l'évaluation.

NOTE 3 Les normes collatérales de la famille IEC 60601 sont numérotées IEC 60601-1-xx. L'IEC tient à jour un fichier des Normes Internationales en vigueur. Il convient que les utilisateurs de la présente norme consultent ce fichier sur le site "http://webstore.iec.ch" pour déterminer quelles normes collatérales ont été publiées.

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Si une norme collatérale s'applique à des APPAREILS EM pour lesquels il existe une norme particulière, cette norme particulière prévaut sur la norme collatérale.

1.4 * Normes particulières

Dans la série IEC 60601, des normes particulières peuvent modifier, remplacer ou supprimer des exigences contenues dans la présente norme en fonction de ce qui est approprié à l'APPAREIL EM considéré et elles peuvent ajouter d'autres exigences de SECURITE DE BASE et de PERFORMANCES ESSENTIELLES.

NOTE Les normes particulières de la famille IEC 60601, développées par les comités IEC, sont numérotées IEC 60601-2-xx. De plus, les normes particulières développées par des projets conjoints entre l'ISO et l'IEC peuvent être numérotées, soit IEC 80601-2-xx, soit ISO 80601-2-xx, selon le comité qui a géré le projet. L'IEC et l'ISO tiennent à jour des fichiers des Normes Internationales en vigueur. Il convient que les utilisateurs de la présente norme consultent ces fichiers sur les sites "http://webstore.iec.ch" et "http://www.iso.org/iso/store.htm" pour déterminer quelles normes particulières ont été publiées.

Une exigence d'une norme particulière prévaut sur l'exigence correspondante de la présente norme.

2 * Références normatives

Les documents de référence suivants sont indispensables pour l'application du présent document. Pour les références datées, seule l'édition citée s'applique. Pour les références non datées, la dernière édition du document de référence s'applique (y compris les éventuels amendements).

ATTENTION: Les normes collatérales complémentaires de la série des IEC 60601, qui sont émises après la publication de la présente norme, deviennent normatives à la date de leur publication et doivent être considérées comme incluses dans les références normatives indiquées ci- après. Voir 1.3.

NOTE Une liste de références informatives est donnée dans la Bibliographie.

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IEC 60065:2001, *Appareils audio, vidéo et appareils électroniques analogues – Exigences de sécurité* [2)]
Amendement 1:2005
Amendement 2:2010

IEC 60068-2-2:2007, *Essais d'environnement – Partie 2-2: Essais – Essais B : Chaleur sèche*

IEC 60079-0, *Matériel électrique pour atmosphères explosives gazeuses – Partie 0: Règles générales*

IEC 60079-2, *Matériel électrique pour atmosphères explosives gazeuses – Partie 2: Enveloppes à surpression interne "p"*

IEC 60079-5, *Matériel électrique pour atmosphères explosives gazeuses – Partie 5: Remplissage pulvérulent "q"*

IEC 60079-6, *Matériel électrique pour atmosphères explosives gazeuses – Partie 6: Immersion dans l'huile "o"*

IEC 60083, *Prises de courant pour usages domestiques et analogues normalisées par les pays membres de l'IEC*

IEC 60085, *Isolation électrique – Classification thermique*

IEC 60086-4, *Piles électriques – Partie 4: Sécurité des piles au lithium*

IEC 60112, *Méthode de détermination des indices de résistance et de tenue au cheminement des matériaux isolants solides*

IEC 60127-1, *Coupe-circuit miniatures – Première partie: Définitions pour coupe-circuit miniatures et prescriptions générales pour éléments de remplacement miniatures*

IEC 60227-1:2007, *Conducteurs et câbles isolés au polychlorure de vinyle, de tension nominale au plus égale à 450/750 V – Partie 1: Exigences générales*

IEC 60245-1:2003, *Conducteurs et câbles isolés au caoutchouc – Tension assignée au plus égale à 450/750 V – Partie 1: Exigences générales* [3]
Amendement 1:2007

IEC 60252-1, *Condensateurs des moteurs à courant alternatif – Partie 1: Généralités – Caractéristiques fonctionnelles, essais et valeurs assignées – Règles de sécurité – Guide d'installation et d'utilisation*

IEC 60320-1, *Connecteurs pour usages domestiques et usages généraux analogues – Partie 1: Prescriptions générales*

IEC 60335-1:2010, *Appareils électrodomestiques et analogues – Sécurité – Partie 1: Exigences générales*

IEC 60364-4-41, *Installations électriques des bâtiments – Partie 4-41: Protection pour assurer la sécurité – Protection contre les chocs électriques*

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2 Il existe une édition consolidée 7.2 comprenant l'IEC 60065:2001 et son Amendement 1 (2005) et son Amendement 2 (2010).

3 Il existe une édition consolidée 4.1 comprenant l'IEC 60245-1:2003 et son Amendement 1 (2007).

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IEC 60384-14:2005, *Fixed capacitors for use in electronic equipment – Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains*

IEC 60417, *Symboles graphiques utilisables sur le matériel*
Disponible à <http://www.graphical-symbols.info/equipment>

IEC 60445, *Principes fondamentaux et de sécurité pour les interfaces homme-machines, le marquage et l'identification – Identification des bornes de matériels et des extrémités de certains conducteurs désignés et règles générales pour un système alphanumérique*

IEC 60447, *Principes fondamentaux et de sécurité pour l'interface homme-machine, le marquage et l'identification – Principes de manœuvre*

IEC 60529:1989, *Degrés de protection procurés par les enveloppes (code IP)*[4)]
Amendement 1 (1999)

IEC 60601-1-2, *Appareils électromédicaux – Partie 1-2: Règles générales de sécurité – Norme Collatérale: Compatibilité électromagnétique – Prescriptions et essais*

IEC 60601-1-3, *Appareils électromédicaux – Partie 1-3: Exigences générales pour la sécurité de base et les performances essentielles: Norme collatérale: Radioprotection dans les appareils à rayonnement X de diagnostic*

IEC 60601-1-6, *Appareils électromédicaux – Partie 1-6: Règles générales de sécurité – Norme collatérale: Aptitude à l'utilisation*

IEC 60601-1-8, *Appareils électromédicaux – Partie 1-8: Règles générales de sécurité – Norme collatérale: Règles générales, essais et guides pour les systèmes d'alarme dans l'équipement électromédical et les systèmes électromédicaux*

IEC 60664-1:2007, *Coordination de l'isolement des matériels dans les systèmes (réseaux) à basse tension - Partie 1: Principes, prescriptions et essais*

IEC 60695-11-10, *Essais relatifs aux risques du feu – Partie 11-10: Flammes d'essai – Méthodes d'essai horizontale et verticale à la flamme de 50 W*

IEC 60730-1:2010, *Dispositifs de commande électrique automatiques à usage domestique et analogue – Partie 1: Exigences générales*

IEC 60825-1:2007, *Sécurité des appareils à laser – Partie 1: Classification des matériels et exigences*

IEC 60851-3:2009, *Fils de bobinage – Méthodes d'essai – Partie 3: Propriétés mécaniques*

IEC 60851-5:2008, *Fils de bobinage – Méthodes d'essai – Partie 5: Propriétés électriques*

IEC 60851-6:1996, *Fils de bobinage – Méthodes d'essai – Partie 6: Propriétés thermiques*
Amendement 1 (1997)

IEC 60884-1, *Prises de courant pour usages domestiques et analogues – Partie 1: Règles générales*

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4) Il existe une édition consolidée 2.1 comprenant l'IEC 60529:1989 et son Amendement 1 (1999).

IEC 60950-1:2001, *Matériels de traitement de l'information – Sécurité – Partie 1: Prescriptions générales*

IEC 61058-1:2000, *Interrupteurs pour appareils – Partie 1: Règles générales* [5]
Amendement 1:2001
Amendement 2:2007

IEC 61558-2-1, *Sécurité des transformateurs, blocs d'alimentation et analogues – Partie 2: Règles particulières pour les transformateurs d'isolement à enroulement séparés pour usage général*

IEC 61672-1, *Electroacoustique – Sonomètres – Partie 1: Spécifications*

IEC 61672-2, *Electroacoustique – Sonomètres – Partie 2: Essais d'évaluation d'un modèle*

IEC 61965, *Sécurité mécanique des tubes cathodiques*

IEC 62133, *Accumulateurs alcalins et autres accumulateurs à électrolyte non acide – Exigences de sécurité pour les accumulateurs portables étanches, et pour les batteries qui en sont constituées, destinés à l'utilisation dans les applications portables*

IEC 62304:2006, *Logiciels de dispositifs médicaux – Processus du cycle de vie du logiciel*

ISO 780, *Emballages – Marquages graphiques relatifs à la manutention des marchandises*

ISO 1853, *Caoutchoucs vulcanisés ou thermoplastiques conducteurs et dissipants – Mesurage de la résistivité*

ISO 2878, *Caoutchouc vulcanisé – Produits antistatiques et conducteurs – Détermination de la résistance électrique*

ISO 2882 [6], *Caoutchouc vulcanisé – Produits antiélectrostatiques et conducteurs à usage médico-hospitalier – Limites pour la résistance électrique*

ISO 3746, *Acoustique – Détermination des niveaux de puissance acoustique émis par les sources de bruit à partir de la pression acoustique – Méthode de contrôle employant une surface de mesure enveloppante au-dessus d'un plan réfléchissant*

ISO 3864-1:2002, *Symboles graphiques – Couleurs de sécurité et signaux de sécurité – Partie 1: Principes de conception pour les signaux de sécurité sur les lieux de travail et dans les lieux publics*

ISO 5349-1, *Vibrations mécaniques – Mesurage et évaluation de l'exposition des individus aux vibrations transmises par la main – Partie 1: Exigences générales*

ISO 7000-DB:2004 [7], *Symboles graphiques utilisables sur le matériel – Index et tableau synoptique*

ISO 7010:2011, *Symboles graphiques – Couleurs de sécurité et signaux de sécurité – Signaux de sécurité enregistrés*

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[5] Il existe une édition consolidée 3.2 comprenant l'IEC 61058-1:2000, son Amendement 1 (2001) et son Amendement 2 (2007).

[6] L'ISO 2882 a été annulée le 1er février 2005 et aucune norme de remplacement n'a été identifiée.

[7] "DB" se réfère à la base de données en ligne conjointe de l'IEC et de l'ISO.

ISO 9614-1, *Acoustique – Détermination par intensimétrie des niveaux de puissance acoustique émis par les sources de bruit – Partie 1: Mesurages par points*

ISO 10993 (toutes les parties), *Evaluation biologique des dispositifs médicaux*

ISO 11135-1:2007, *Stérilisation des produits de santé – Oxyde d'éthylène – Partie 1: Exigences de développement, de validation et de contrôle de routine d'un processus de stérilisation pour des dispositifs médicaux*

ISO 11137-1:2006, *Stérilisation des produits de santé – Irradiation – Partie 1: Exigences relatives à la mise au point, à la validation et au contrôle de routine d'un procédé de stérilisation pour les dispositifs médicaux*

ISO 13857:2008, *Sécurité des machines – Distances de sécurité empêchant les membres supérieurs et inférieurs d'atteindre les zones dangereuses*

ISO 14971:2007, *Dispositifs médicaux – Application de la gestion des risques aux dispositifs médicaux*

ISO 15223-1:2012, *Dispositifs médicaux – Symboles à utiliser avec les étiquettes, l'étiquetage et les informations à fournir relatifs aux dispositifs médicaux – Partie 1: Exigences générales*

ISO 17665-1:2006, *Stérilisation des produits de santé – Chaleur humide – Partie 1: Exigences pour le développement, la validation et le contrôle de routine d'un processus de stérilisation des dispositifs médicaux*

ISO 23529, *Caoutchouc – Procédures générales pour la préparation et le conditionnement des éprouvettes pour les méthodes d'essais physiques* (disponible en anglais seulement)

ISO 80000-1:2009, *Grandeurs et unités – Partie 1: Généralités*

3 * Terminologie et définitions

Pour les besoins du présent document, les termes et définitions suivants s'appliquent.

NOTE 1 Dans le cadre de la présente norme, les termes "tension" et "courant", là où ils sont utilisés, signifient, sauf indication contraire, des valeurs efficaces des tensions ou courants d'un courant alternatif, continu ou complexe.

NOTE 2 Le terme "appareil électrique" est utilisé dans le sens d'appareil em ou autre appareil électrique (voir 3.63). La présente norme utilise le terme "appareil" pour appareil em ou autre appareil électrique ou non électrique dans le cadre d'un système em (voir 3.64).

NOTE 3 Lorsque le terme "sécurité" est utilisé dans le présent document en caractères romains ou italiques, il ne signifie pas "sécurité" tel que ce terme est défini dans l'ISO 14971 mais est plutôt utilisé pour signifier "l'existence d'une protection ou d'une barrière contre une blessure ou une lésion; l'absence de tout danger".

NOTE 4 Un index est donné à la page 748.

3.1
CAPOT D'ACCES
partie d'une ENVELOPPE ou d'une PROTECTION permettant d'accéder à des parties de l'appareil électrique en vue d'un réglage, d'une inspection, d'un remplacement ou d'une réparation

3.2
PARTIE ACCESSIBLE
partie d'un appareil électrique autre qu'une PARTIE APPLIQUEE qui peut être touchée au moyen d'un doigt d'essai normalisé

NOTE Voir aussi 5.9.2.1.

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3.3
ACCESSOIRE
composant additionnel destiné à être utilisé avec l'appareil de manière à:

– assurer son UTILISATION PREVUE,
– l'adapter à une utilisation spécifique,
– faciliter son utilisation,
– accroître ses performances, ou
– permettre l'intégration de ses fonctions à celles d'autres appareils

[IEC 60788:2004, rm-83-06 modifiée]

3.4
DOCUMENT D'ACCOMPAGNEMENT
document accompagnant un APPAREIL EM, un SYSTEME EM, un appareil ou un ACCESSOIRE et qui contient des informations pour l'ORGANISME RESPONSABLE ou l'OPERATEUR concernant en particulier la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES

3.5
DISTANCE DANS L'AIR
trajet le plus court dans l'air entre deux parties conductrices

NOTE Adapté de l'IEC 60664-1, définition 3.2.

3.6
CONNECTEUR
dispositif permettant d'effectuer sans OUTIL, la liaison d'un câble souple avec un appareil électrique et comprenant deux parties: une PRISE RESEAU et un SOCLE DE CONNECTEUR

NOTE Voir Figure 1.

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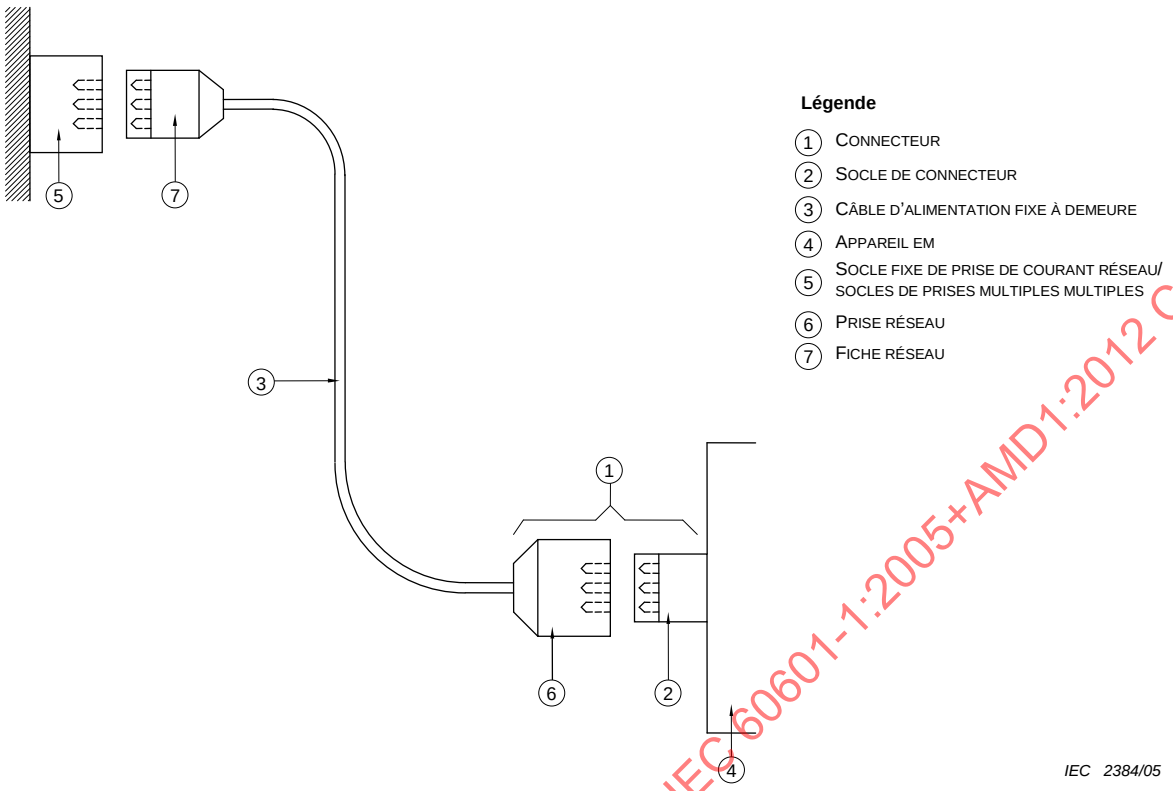


Figure 1 – Raccordement au réseau non fixé à demeure
(voir définitions)

3.7
SOCLE DE CONNECTEUR
élément d'un CONNECTEUR qui est soit intégré dans l'appareil électrique soit FIXE sur celui-ci

NOTE Voir Figures 1 et 2.

3.8
*** PARTIE APPLIQUEE**
partie de L'APPAREIL EM qui en UTILISATION NORMALE vient nécessairement en contact physique avec le PATIENT pour que L'APPAREIL EM ou le SYSTEME EM assure sa fonction

NOTE 1 Voir la Figure 3, la Figure 4 et les Figures A.1 à A.7 (comprise).

NOTE 2 Voir aussi 4.6 concernant le traitement des parties qui n'entrent pas dans la définition des PARTIES APPLIQUEES mais qui doivent être traitées comme de telles parties lorsqu'on applique le PROCESSUS de GESTION DES RISQUES.

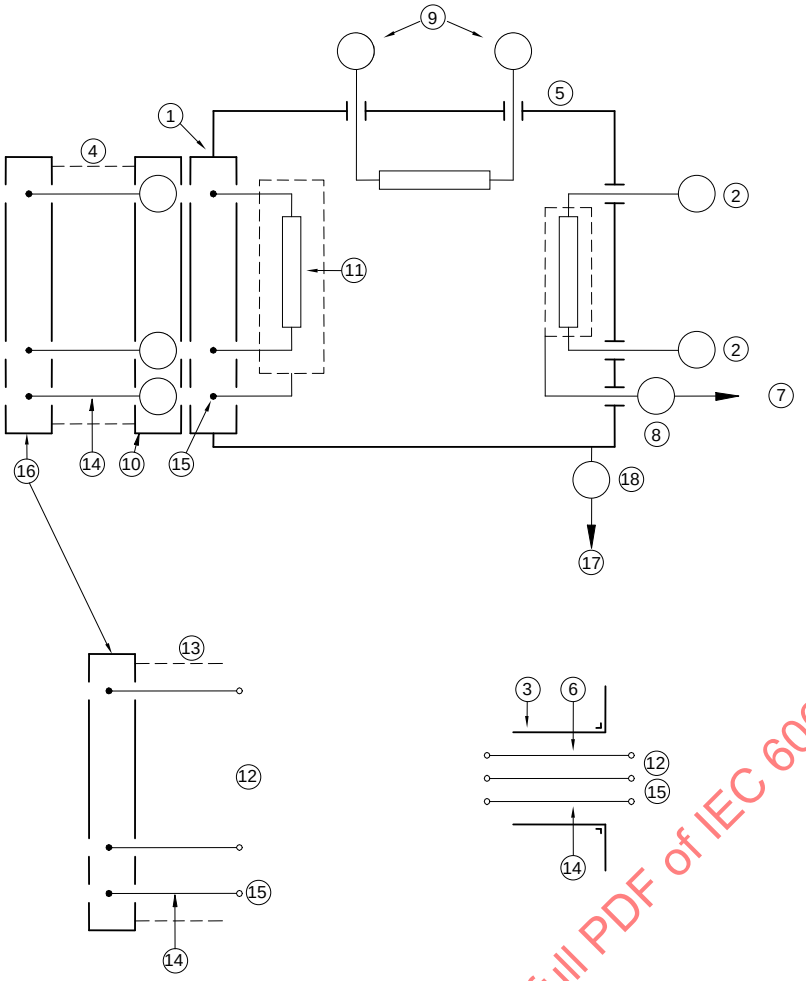
NOTE 3 Voir aussi 3.78 pour la définition du terme associé CONNEXION PATIENT.

3.9
*** ISOLATION PRINCIPALE**
isolation assurant la protection principale contre les chocs électriques

[VEI 826-12-14, modifiée]

NOTE L'ISOLATION PRINCIPALE fournit un MOYEN DE PROTECTION.

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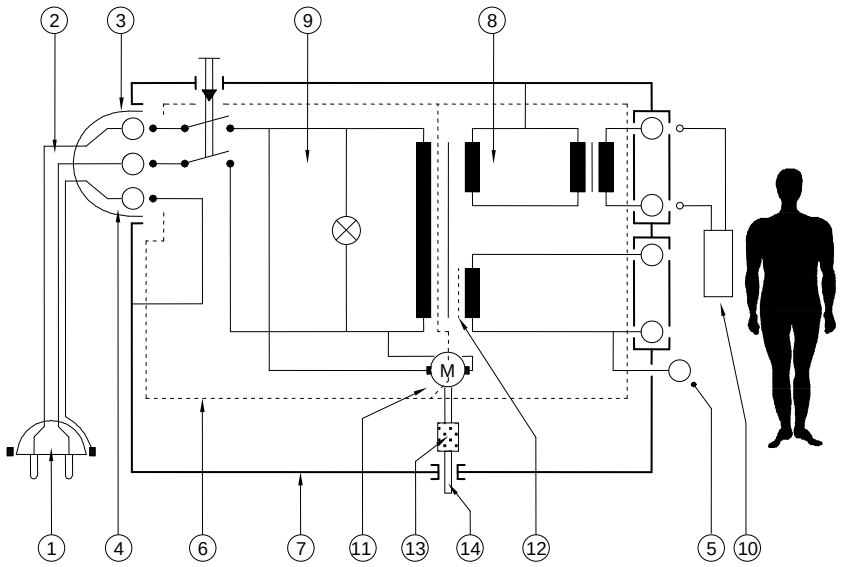
Légende

1. SOCLE DE CONNECTEUR (voir aussi Figure 1)
2. CONNEXION PATIENT
3. Conduit
4. CABLE D'ALIMENTATION NON FIXE A DEMEURE
5. ENVELOPPE
6. CÂBLAGE FIXE À DEMEURE
7. CONDUCTEUR DE TERRE FONCTIONNELLE
8. BORNE DE TERRE FONCTIONNELLE
9. PARTIE ENTRÉE/SORTIE DE SIGNAUX
10. ~~FICHE~~PRISE RÉSEAU
11. PARTIE RELIÉE AU RÉSEAU
12. DISPOSITIF DE RACCORDEMENT AU RÉSEAU
13. CÂBLE D'ALIMENTATION
14. CONDUCTEUR DE TERRE DE PROTECTION
15. BORNE DE TERRE DE PROTECTION
16. FICHE RÉSEAU
17. CONDUCTEUR D'ÉGALISATION DES POTENTIELS
18. Borne pour la connexion d'un CONDUCTEUR D'EGALISATION DES POTENTIELS

IEC 2385/05

Figure 2 – Exemple de bornes et conducteurs définis
(voir définitions)

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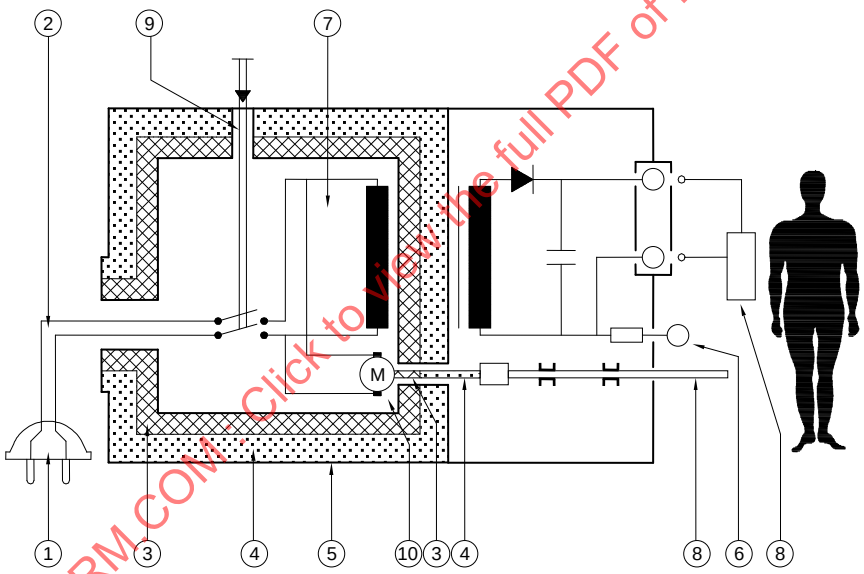


Légende

1. FICHE RÉSEAU AVEC CONTACT DE TERRE DE PROTECTION
2. CÂBLE D'ALIMENTATION NON FIXE À DEMEURE
3. CONNECTEUR
4. CONTACT ET BROCHE DE TERRE DE PROTECTION
5. BORNE DE TERRE DE PROTECTION
6. ISOLATION PRINCIPALE
7. CONDUCTEUR DE TERRE FONCTIONNELLE
8. CIRCUIT SECONDAIRE
9. PARTIE RELIÉE AU RÉSEAU
10. PARTIE APPLIQUÉE
11. Moteur
12. ECRAN PROTÉGÉ PAR MISE À LA TERRE
13. ISOLATION SUPPLÉMENTAIRE
14. Arbre de rotation qui est une partie accessible

IEC 2386/05

Figure 3 – Exemple d'APPAREIL EM DE CLASSE I
(voir définitions)



Légende

1. FICHE RÉSEAU
2. CÂBLE D'ALIMENTATION
3. ISOLATION PRINCIPALE
4. ISOLATION SUPPLÉMENTAIRE
5. ENVELOPPE
6. BORNE DE TERRE FONCTIONNELLE
7. PARTIE RELIÉE AU RÉSEAU
8. PARTIE APPLIQUÉE
9. ISOLATION RENFORCÉE
10. Moteur

IEC 2387/05

Figure 4 – Exemple d' APPAREIL EM DE CLASSE II sous enveloppe métallique
(voir définitions)

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3.10
*** SECURITE DE BASE**
absence de RISQUE inacceptable directement causé par des DANGERS physiques lorsque l'APPAREIL EM est utilisé dans des CONDITIONS NORMALES et dans des CONDITIONS DE PREMIER DEFAUT

3.11
CATEGORIE AP
caractéristiques d'un APPAREIL EM ou d'une partie d'APPAREIL EM conforme aux exigences spécifiées en ce qui concerne la construction, le marquage et la documentation afin d'éviter l'apparition de sources d'inflammation dans un MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'AIR

3.12
CATEGORIE APG
caractéristiques d'un APPAREIL EM ou d'une partie d'APPAREIL EM conforme aux exigences spécifiées en ce qui concerne la construction, le marquage et la documentation afin d'éviter l'apparition de sources d'inflammation dans un MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'OXYGENE OU DU PROTOXYDE D'AZOTE

3.13
CLASSE I
terme faisant référence à un appareil électrique dans lequel la protection contre les chocs électriques ne repose pas uniquement sur l'ISOLATION PRINCIPALE, mais qui comporte une mesure de sécurité supplémentaire dans laquelle les PARTIES ACCESSIBLES métalliques ou les parties internes métalliques sont PROTEGEES PAR MISE A LA TERRE

NOTE Voir Figure 3.

3.14
CLASSE II
terme faisant référence à un appareil électrique dans lequel la protection contre les chocs électriques ne repose pas uniquement sur l'ISOLATION PRINCIPALE, mais qui comporte des mesures complémentaires de sécurité telles que la DOUBLE ISOLATION ou l'ISOLATION RENFORCEE, cette protection est réalisée sans moyen de mise à la terre de protection et ne dépendant pas des conditions d'installation

NOTE 1 Voir Figure 4.

NOTE 2 Les appareils de la CLASSE II peuvent être équipés d'une BORNE DE TERRE FONCTIONNELLE ou d'un CONDUCTEUR DE TERRE FONCTIONNELLE. Voir aussi 8.6.8 et 8.6.9.

3.15
*** CLAIREMENT LISIBLE**
qui peut être lu par une personne ayant une vision normale

NOTE Voir l'essai en 7.1.2.

3.16
CONDITION A FROID
condition obtenue lorsque l'appareil électrique a été mis hors tension suffisamment longtemps pour lui permettre de revenir à la température ambiante

3.17
*** COMPOSANT AUX CARACTERISTIQUES A HAUTE FIABILITE**
composant dont une ou plusieurs caractéristiques assurent que sa fonction ne présente aucun défaut par rapport aux exigences de sécurité de la présente norme au cours de la DUREE DE VIE PREVUE d'un APPAREIL EM en UTILISATION NORMALE et en cas de mauvais usage raisonnablement prévisible

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3.18
*** SERVICE CONTINU**
fonctionnement en UTILISATION NORMALE d'une durée illimitée sans dépassement des limites de température spécifiées

3.19
LIGNE DE FUITE
distance la plus courte à la surface d'un matériau isolant entre deux parties conductrices

[VEI 151-15-50, modifiée]

3.20
*** PARTIE APPLIQUEE PROTEGEE CONTRE LES CHOCS DE DEFIBRILLATION**
PARTIE APPLIQUEE qui est protégée contre les effets d'une décharge d'un défibrillateur cardiaque appliquée au PATIENT

3.21
*** CABLE D'ALIMENTATION NON FIXE A DEMEURE**
câble souple destiné à être relié à l'appareil électrique à l'aide d'un CONNECTEUR approprié pour l'alimentation réseau

NOTE Voir Figure 1, Figure 2 et Figure 3.

3.22
*** APPLICATION CARDIAQUE DIRECTE**
utilisation d'une PARTIE APPLIQUEE qui peut entrer en contact direct avec le cœur du PATIENT

3.23
*** DOUBLE ISOLATION**
isolation comprenant à la fois une ISOLATION PRINCIPALE et une ISOLATION SUPPLEMENTAIRE

[VEI 195-06-08]

NOTE La double isolation fournit deux moyens de protection.

3.24
*** CYCLE D'UTILISATION**
durée maximale d'activation (de marche) suivie de la durée minimale de désactivation (d'arrêt) nécessaire au fonctionnement en toute sécurité de l'APPAREIL EM

3.25
COURANT DE FUITE A LA TERRE
courant qui s'écoule de la PARTIE RELIEE AU RESEAU dans le CONDUCTEUR DE MISE A LA TERRE DE PROTECTION ou une connexion fonctionnelle mise à la terre conforme à 8.6.9, en traversant ou contournant l'isolation

3.26
*** ENVELOPPE**
surface externe de l'appareil électrique ou de parties de celui-ci

NOTE A des fins d'essais selon la présente norme, une feuille métallique, de dimensions spécifiées, mise en contact avec des parties de la surface externe en matériau de faible conductivité ou en matière isolante est considérée comme une partie de l'ENVELOPPE (voir Figures 2, 3 et 4).

3.27
*** PERFORMANCES ESSENTIELLES**
performance d'une fonction clinique différente de celle relative à la SECURITE DE BASE, pour laquelle la perte ou la dégradation au-delà des limites précisées par le FABRICANT entraîne un RISQUE inacceptable

NOTE Le terme PERFORMANCE ESSENTIELLE est plus facilement compris lorsqu'on examine si son absence ou sa dégradation donnerait lieu à un risque inacceptable.

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3.28
DUREE DE VIE PREVUE
période spécifiée par le FABRICANT durant laquelle l'APPAREIL EM ou le SYSTEME EM est censé rester d'utilisation sûre (c'est-à-dire censé assurer la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES)

NOTE La maintenance peut être nécessaire pendant la DUREE DE VIE PREVUE

3.29
PARTIE APPLIQUEE ISOLEE DE TYPE F (FLOTTANTE) (ABREGE EN PARTIE APPLIQUEE DE TYPE F)
PARTIE APPLIQUEE dans laquelle les CONNEXIONS PATIENT sont isolées des autres parties de l'APPAREIL EM à un degré tel qu'aucun courant supérieur au COURANT DE FUITE PATIENT admissible ne s'écoule si une tension non voulue provenant d'une source externe est connectée au patient, et de ce fait appliquée entre la CONNEXION PATIENT et la terre

NOTE Les PARTIES APPLIQUEES DU TYPE F sont soit des PARTIES APPLIQUEES DU TYPE BF soit des PARTIES APPLIQUEES DU TYPE CF.

3.30
FIXE
terme qui signifie assujetti ou fixé d'une autre manière à un emplacement spécifié soit de manière permanente soit en ne pouvant être enlevé qu'à l'aide d'un OUTIL

EXEMPLE 1 Fixé de manière permanente par soudage, etc.

EXEMPLE 2 Fixé au moyen de dispositifs (vis, écrous, etc.) rendant le retrait ou l'ouverture impossible sans l'aide d'un OUTIL.

NOTE Voir la taxinomie de la définition 3.63 dans les justifications.

3.31
MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'AIR
mélange de gaz anesthésiques inflammables et d'air d'une concentration telle qu'une inflammation peut avoir lieu dans des conditions spécifiées

3.32
MELANGE ANESTHESIQUE INFLAMMABLE AVEC DE L'OXYGENE OU DU PROTOXYDE D'AZOTE
mélange de gaz anesthésiques inflammables et d'oxygène ou de protoxyde d'azote d'une concentration telle qu'une inflammation peut avoir lieu dans des conditions spécifiées

3.33
*** CONNEXION FONCTIONNELLE**
tout raccordement, électrique ou autre, y compris ceux qui sont destinés à transférer des signaux, des données, de l'énergie ou des substances

NOTE Le raccordement à un socle FIXE de prise de courant RESEAU, simple ou multiple, n'est pas considéré comme une CONNEXION FONCTIONNELLE.

3.34
CONDUCTEUR DE TERRE FONCTIONNELLE
conducteur à relier à une BORNE DE TERRE FONCTIONNELLE

NOTE Voir Figure 2.

3.35
*** BORNE DE TERRE FONCTIONNELLE**
borne directement reliée à un circuit ou à une partie servant d'écran destiné à être mis à la terre dans un but fonctionnel

NOTE Voir Figure 2, Figure 3 et Figure 4.

3.36
BARRIERE
partie d'un appareil spécifiquement utilisée pour assurer la protection au moyen d'une barrière physique

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NOTE Selon sa construction, une BARRIERE peut être désignée par le terme boîtier, couvercle, écran, porte, protection enveloppante, etc. Une BARRIERE peut agir:

– seule; elle n'est alors efficace que lorsqu'elle est en place ;

– avec un dispositif de verrouillage avec ou sans verrouillage de la BARRIERE; dans ce cas, la protection est assurée quelle que soit la position de la BARRIERE.

3.37
PORTATIF
terme faisant référence à un appareil qui, une fois installé et mis en service, est destiné à être tenu à la main

NOTE 1 L'appareil peut se référer aux ACCESSOIRES ou aux parties de l'équipement.

NOTE 2 Voir la taxinomie de la définition 3.63 dans les justifications.

3.38
*** DOMMAGE**
blessure physique ou atteinte à la santé des personnes ou des animaux ou atteinte aux biens ou à l'environnement
[ISO 14971:2007, définition 2.2, modifiée]

3.39
DANGER
PHENOMENE DANGEREUX
source potentielle de DOMMAGE
[ISO 14971:2007, définition 2.3]

3.40
*** SITUATION DANGEREUSE**
circonstance dans laquelle les personnes, les biens ou l'environnement sont exposés à un ou plusieurs DANGER(S)
[ISO 14971:2007, définition 2.4]

3.41
HAUTE TENSION
tension supérieure à 1 000 V en courant alternatif ou à 1 500 V en courant continu ou en valeur crête

3.42
PRESSION D'ESSAI HYDRAULIQUE
pression appliquée pour mettre à l'essai tout ou partie d'un réservoir

NOTE Voir 9.7.5.

3.43
COORDINATION DE L'ISOLEMENT
corrélation entre les caractéristiques d'isolement d'un appareil électrique tenant compte du micro-environnement attendu et d'autres contraintes exerçant une influence

NOTE Ceci inclut les types d'isolement, les LIGNES DE FUITE, les DISTANCES DANS L'AIR, les distances dans l'isolation, les revêtements, l'encapsulation, les aspects environnementaux, etc.

3.44
UTILISATION PREVUE
USAGE PREVU
utilisation pour laquelle un produit, un PROCESSUS ou un service est prévu conformément aux spécifications, aux instructions et aux informations fournies par le FABRICANT

[ISO 14971:2007, définition 2.5]

NOTE Il convient de ne pas confondre UTILISATION PREVUE et UTILISATION NORMALE. Si les deux expressions intègrent le concept de l'utilisation telle qu'elle est prévue par le FABRICANT, l'UTILISATION PREVUE se concentre sur le but médical tandis que l'UTILISATION NORMALE ne se limite pas au but médical mais englobe aussi la maintenance, l'entretien, le transport, etc.

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3.45
SOURCE D'ENERGIE ELECTRIQUE INTERNE
source d'énergie électrique qui fait partie de l'appareil, destinée au fonctionnement de celui-ci et qui produit le courant électrique à partir d'une autre forme d'énergie

EXEMPLE Chimique, mécanique, solaire ou nucléaire.

NOTE Une SOURCE D'ENERGIE ELECTRIQUE INTERNE peut se situer à l'intérieur de la partie principale de l'appareil, être fixée à l'extérieur ou être contenue dans une ENVELOPPE séparée.

3.46
ALIMENTE DE MANIERE INTERNE
terme faisant référence à un appareil électrique qui peut fonctionner à partir d'une SOURCE D'ENERGIE ELECTRIQUE INTERNE

3.47
COURANT DE FUITE
courant non fonctionnel

NOTE Les COURANTS DE FUITE suivants sont définis: COURANT DE FUITE A LA TERRE, COURANT DE CONTACT et COURANT DE FUITE PATIENT.

3.48
PRISE RESEAU
partie intégrante d'un CONNECTEUR ou prévue pour être fixée au câble souple destiné à être relié au RESEAU D'ALIMENTATION

NOTE Une PRISE RESEAU est destinée à être insérée dans le socle de CONNECTEUR de l'appareil électrique (voir Figure 1 et Figure 2).

3.49
*** PARTIE RELIEE AU RESEAU**
partie d'un équipement électrique formant un circuit destiné à être connecté au RESEAU D'ALIMENTATION

NOTE 1 La PARTIE RELIEE AU RESEAU comprend toutes les parties conductrices qui ne sont pas séparées du RESEAU D'ALIMENTATION par au moins un MOYEN DE PROTECTION.

NOTE 2 Pour les besoins de cette définition, le CONDUCTEUR DE TERRE DE PROTECTION n'est pas considéré comme un élément de la PARTIE RELIEE AU RESEAU (voir Figure 2 et Figure 3).

3.50
*** FICHE RESEAU**
partie intégrante du CABLE D'ALIMENTATION ou destinée à être fixée au CABLE D'ALIMENTATION d'un appareil électrique, destinée à être insérée dans un socle de prise de courant réseau

NOTE 1 Voir Figure 1.

NOTE 2 Voir également l'IEC 60083 et l'IEC 60309-1 [8].

3.51
TRANSFORMATEUR D'ALIMENTATION RESEAU
partie statique d'un appareil avec au moins deux enroulements qui, par induction électro-magnétique, transforme une tension et un courant alternatif provenant du RESEAU D'ALIMENTATION en une autre tension et un autre courant généralement de différentes valeurs à la même fréquence

3.52
DISPOSITIF DE RACCORDEMENT AU RESEAU
DISPOSITIF DE RACCORDEMENT assurant la liaison électrique avec le RESEAU D'ALIMENTATION

NOTE Voir Figure 2.

3.53
TENSION TRANSITOIRE RESEAU
tension crête la plus élevée attendue à l'entrée de puissance de l'appareil électrique, provenant des transitoires externes sur le RESEAU D'ALIMENTATION

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3.54
TENSION RESEAU
tension d'un RESEAU D'ALIMENTATION entre deux conducteurs de phase d'un système polyphasé, ou tension entre le conducteur de phase et le conducteur neutre d'un système monophasé

3.55
FABRICANT
personne physique ou légale ayant une responsabilité dans la conception, la fabrication, l'emballage ou l'étiquetage des APPAREILS EM, qui assemble un APPAREIL EM ou qui adapte un APPAREIL EM ou un SYSTEME EM, que ces opérations soient réalisées par cette personne ou par délégation de celle-ci à un tiers

NOTE 1 L'ISO 13485 [30] définit l'"étiquetage" comme un élément écrit, imprimé ou graphique

– apposé sur un dispositif médical ou sur l'un de ses conteneurs ou emballages, ou

– qui accompagne un dispositif médical,

concernant l'identification, la description technique et l'utilisation du dispositif médical à l'exclusion des documents de transport. Dans la présente norme, ces éléments sont décrits comme des marquages et des DOCUMENTS D'ACCOMPAGNEMENT.

NOTE 2 "Adapter" inclut la réalisation de modifications substantielles sur les APPAREILS EM ou sur un SYSTEME EM déjà en utilisation.

NOTE 3 Dans certaines juridictions, l'ORGANISME RESPONSABLE peut être considéré comme un FABRICANT lorsque celui-ci est impliqué dans les activités décrites.

NOTE 4 Adapté de l'ISO 14971:2007, définition 2.8.

3.56
*** TENSION RESEAU MAXIMALE**
tension utilisée dans le cadre des essais liés à la tension du RESEAU D'ALIMENTATION et reliée à certaines parties d'APPAREILS EM

NOTE La valeur de la TENSION RESEAU MAXIMALE est déterminée conformément à 8.5.3.

3.57
*** PRESSION MAXIMALE ADMISSIBLE DE FONCTIONNEMENT**
pression maximale admise sur un composant d'après la déclaration du FABRICANT de ce composant

3.58
*** MOYEN DE PROTECTION DE L'OPERATEUR**
MOOP

MOYEN DE PROTECTION destiné à réduire le RISQUE dû au choc électrique sur des personnes autres que le PATIENT

3.59
*** MOYEN DE PROTECTION DU PATIENT**
MOPP

MOYEN DE PROTECTION destiné à réduire le RISQUE dû au choc électrique sur le PATIENT

3.60
*** MOYENS DE PROTECTION**
MOP

moyen destiné à réduire le RISQUE dû au choc électrique conformément aux exigences de la présente norme

NOTE Le MOYEN DE PROTECTION inclut l'isolation, les DISTANCES DANS L'AIR, les LIGNES DE FUITE, les impédances et les CONNEXIONS DE TERRE DE PROTECTION.

3.61
DANGER MECANIQUE
DANGER lié ou produit par une force physique

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3.62
DISPOSITIF DE PROTECTION MECANIQUE
dispositif qui élimine ou réduit le RISQUE mécanique à un niveau acceptable et qui fonctionne en cas de CONDITION DE PREMIER DEFAUT

3.63
*** APPAREIL ELECTROMEDICAL (APPAREIL EM)**
appareil électrique qui possède une PARTIE APPLIQUEE ou qui transfère de l'énergie vers le PATIENT ou à partir de celui-ci ou qui détecte un tel transfert d'énergie vers le PATIENT ou à partir de celui-ci et qui est:

a) équipé au plus d'un moyen de raccordement à un RESEAU D'ALIMENTATION donné ; et

b) destiné par son FABRICANT à être utilisé:

1) pour le diagnostic, le traitement ou la surveillance d'un PATIENT ou

2) pour la compensation ou l'atténuation d'une maladie, d'une blessure ou d'une incapacité

NOTE 1 L'APPAREIL EM comprend les ACCESSOIRES tels qu'ils sont définis par le FABRICANT qui sont nécessaires pour permettre l'UTILISATION NORMALE de l'APPAREIL ELECTROMEDICAL.

NOTE 2 Tous les appareils électriques utilisés en pratique médicale n'entrent pas dans cette définition (par exemple certains appareils de diagnostic *in vitro).*

NOTE 3 Les parties implantables des dispositifs médicaux implantables actifs peuvent entrer dans le cadre de cette définition mais elles sont exclues du domaine d'application de la présente norme par le libellé approprié de l'Article 1.

NOTE 4 La présente norme utilise le terme "appareil électrique" dans le sens d'APPAREIL EM ou d'autre appareil électrique.

NOTE 5 Voir aussi 4.10.1, 8.2.1 et 16.3.

3.64
*** SYSTEME ELECTROMEDICAL (SYSTEME EM)**
combinaison, telle qu'elle est spécifiée par son FABRICANT, d'éléments d'appareils, dont au moins un est un APPAREIL EM, destinés à être interconnectés par une CONNEXION FONCTIONNELLE ou par l'utilisation d'un SOCLE A PRISES DE COURANT MULTIPLES

NOTE Il convient de considérer que les appareils mentionnés dans la présente norme incluent des APPAREILS EM.

3.65
MOBILE
terme faisant référence à un appareil TRANSPORTABLE qui, une fois installé et mis en service, est destiné à être déplacé d'un emplacement à un autre sur ses propres roues ou par un moyen équivalent

NOTE Voir la taxinomie de la définition 3.63 dans les justifications.

3.66
*** REFERENCE DU MODELE OU DU TYPE**
combinaison de chiffres, de lettres ou des deux, utilisée pour identifier un modèle particulier d'appareil ou d'ACCESSOIRE

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3.67
*** SOCLES DE PRISES MULTIPLES**
SPM (en anglais MSO**)**

un ou plusieurs socles délivrant la tension du RESEAU D'ALIMENTATION ou une tension équivalente, destinés à être reliés ou à être intégrés à des câbles souples, des cordons ou des APPAREILS EM

NOTE Un SOCLE DE PRISES MULTIPLES peut être un élément séparé ou peut faire partie intégrante de l'appareil.

3.68
*** COUPLAGE DE RESEAU/DONNEES**
tout moyen pour émettre des informations vers d'autres appareils ou en recevoir conformément aux spécifications du FABRICANT

3.69
NOMINALE (valeur)
valeur citée comme référence et affectée de tolérances agréées

EXEMPLE TENSION RESEAU NOMINALE ou diamètre NOMINAL d'une vis.

3.70
CONDITION NORMALE
condition réalisée quand tous les moyens prévus de protection contre les DANGERS sont intacts

3.71
UTILISATION NORMALE
fonctionnement, y compris lors des vérifications périodiques et des réglages faits par un OPERATEUR, ainsi que dans l'état en attente, selon les instructions d'utilisation

NOTE Il convient de ne pas confondre UTILISATION PREVUE et UTILISATION NORMALE. Si les deux expressions intègrent le concept de l'utilisation telle qu'elle est prévue par le FABRICANT, L'UTILISATION PREVUE se concentre sur le but médical tandis que L'UTILISATION NORMALE ne se limite pas au but médical mais englobe aussi la maintenance, le transport etc.

3.72
PREUVE TANGIBLE
données démontrant l'existence ou la véracité de quelque chose

NOTE La preuve tangible est obtenue par observation, mesurage, essai ou un autre moyen.

[ISO 14971:2007, définition 2.10]

3.73
*** OPERATEUR**
personne manipulant un appareil

NOTE Voir aussi 3.101.

3.74
DECLENCHEUR A MAXIMUM DE CURANT (DISJONCTEUR)
dispositif de protection interrompant un circuit avec ou sans temporisation, quand le courant y dépasse une valeur prédéterminée

[VEI 441-16-33, modifié]

3.75
*** ENVIRONNEMENT RICHE EN OXYGENE**
environnement dans lequel la concentration en oxygène est:

a) supérieure à 25 % pour les pressions ambiantes jusqu'à 110 kPa; ou

b) la pression partielle de l'oxygène est supérieure à 27,5 kPa aux pressions ambiantes supérieures à 110 kPa

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3.76
PATIENT
être vivant (personne ou animal) soumis à une PROCEDURE de nature médicale, chirurgicale ou dentaire

NOTE Un PATIENT peut être un OPERATEUR.

3.77
*** COURANT AUXILIAIRE PATIENT**
courant s'écoulant à travers le PATIENT en UTILISATION NORMALE entre toute CONNEXION PATIENT et toutes les autres CONNEXIONS PATIENT et qui n'est pas destiné à produire un effet physiologique

3.78
*** CONNEXION PATIENT**
point individuel sur la PARTIE APPLIQUEE à travers lequel le courant peut s'écouler entre le patient et L'APPAREIL EM en CONDITION NORMALE ou en CONDITION DE PREMIER DEFAUT

3.79
*** ENVIRONNEMENT DU PATIENT**
tout volume à l'intérieur duquel il peut se produire un contact intentionnel ou non intentionnel entre un PATIENT et des parties de l'APPAREIL EM ou du SYSTEME EM ou entre un PATIENT et d'autres personnes touchant des parties de l'APPAREIL EM ou du SYSTEME EM

3.80
COURANT DE FUITE PATIENT
courant:

– s'écoulant des CONNEXIONS PATIENT vers la terre à travers le PATIENT ou

– dû à l'apparition non voulue sur le PATIENT d'une tension provenant d'une source externe et courant s'écoulant du PATIENT vers la terre par l'intermédiaire des CONNEXIONS PATIENT d'une PARTIE APPLIQUEE DE TYPE F

3.81
*** TENSION DE SERVICE CRETE** valeur de crête ou continue la plus élevée d'une TENSION DE SERVICE, en prenant en compte les impulsions répétitives de crête générées dans l'appareil électrique, mais en excluant les perturbations transitoires provenant de l'extérieur

[IEC 60950-1:2005, définition 1.2.9.8, modifiée]

3.82
CYCLE DE VIE DE DEVELOPPEMENT DU SEMP
activités nécessaires intervenant pendant la période qui commence à la phase de conception d'un projet et s'achève lorsque la VALIDATION du SEMP est terminée

NOTE Voir aussi 3.90.

3.83
VALIDATION DU SEMP
PROCESSUS d'évaluation d'un SEMP ou d'un de ses composants au cours ou à l'issue du PROCESSUS de développement, pour déterminer s'il satisfait aux exigences de son UTILISATION PREVUE

NOTE Voir aussi 3.90.

3.84
INSTALLE DE FAÇON PERMANENTE
terme qui signifie que l'appareil est relié électriquement au RESEAU D'ALIMENTATION au moyen d'une liaison permanente qui ne peut être supprimée qu'à l'aide d'un OUTIL

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3.85
PORTABLE
terme faisant référence à un appareil TRANSPORTABLE qui, une fois installé et mis en service, est destiné à être déplacé d'un emplacement à un autre en étant porté par une ou plusieurs personnes

NOTE 1 L'appareil peut se référer aux ACCESSOIRES ou aux parties de l'appareil.

NOTE 2 Voir la taxinomie de la définition 3.63 dans les justifications.

3.86
CONDUCTEUR D'EGALISATION DES POTENTIELS
conducteur autre qu'un CONDUCTEUR DE TERRE DE PROTECTION ou un conducteur neutre assurant une connexion directe entre l'appareil électrique et la barre d'égalisation des potentiels de l'installation électrique

NOTE Voir Figure 2.

3.87
CABLE D'ALIMENTATION
câble souple, FIXE à ou assemblé avec un appareil électrique pour la connexion au RESEAU D'ALIMENTATION

NOTE Voir Figure 1 à Figure 4 (incluse).

3.88
PROCEDURE
manière spécifique de mener à bien une activité ou un PROCESSUS

[ISO 14971:2007, définition 2.12]

3.89
PROCESSUS
ensemble d'activités corrélées ou interactives liées qui transforme des éléments d'entrée en éléments de sortie

[ISO 14971:2007, définition 2.13]

3.90
SYSTEME ELECTROMEDICAL PROGRAMMABLE
SEMP (en anglais PEMS**)**

APPAREIL EM ou SYSTEME EM comprenant un ou plusieurs SOUS-SYSTEMES ELECTRONIQUES PROGRAMMABLES (SSEP)

3.91
SOUS-SYSTEME ELECTRONIQUE PROGRAMMABLE
SSEP (en anglais PESS**)**

système basé sur une ou plusieurs unités centrales de traitement, y compris les logiciels et les interfaces

3.92
CORRECTEMENT INSTALLE

installé conformément aux DOCUMENTS D'ACCOMPAGNEMENT

3.93
CONDUCTEUR DE TERRE DE PROTECTION
conducteur destiné à être connecté entre la BORNE DE TERRE DE PROTECTION et un système de mise à la terre de protection externe

NOTE Voir Figure 2.

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3.94
CONNEXION DE TERRE DE PROTECTION
connexion à la BORNE DE TERRE DE PROTECTION dans un but de protection et conforme aux exigences de la présente norme

3.95
BORNE DE TERRE DE PROTECTION
borne connectée aux parties conductrices d'un appareil de CLASSE I à des fins de sécurité destinée à être connectée à un système de mise à la terre de protection extérieur par un CONDUCTEUR DE TERRE DE PROTECTION

NOTE Voir Figure 2.

3.96
PROTEGE PAR MISE A LA TERRE
connecté à la BORNE DE TERRE DE PROTECTION dans un but de protection par des moyens conformes aux exigences de la présente norme

3.97
ASSIGNEE (VALEUR)
terme qui fait référence à une valeur attribuée par le FABRICANT pour une condition de fonctionnement spécifiée

3.98
ENREGISTREMENT
document faisant état de résultats obtenus ou apportant la preuve de la réalisation d'activités

[ISO 14971:2007, définition 2.14]

3.99
*** ISOLATION RENFORCEE**
système d'isolation unique qui fournit deux MOYENS DE PROTECTION

3.100
RISQUE RESIDUEL
RISQUE subsistant après que des mesures de MAITRISE DU RISQUE ont été prises

[ISO 14971:2007, définition 2.15]

3.101
ORGANISME RESPONSABLE
entité responsable de l'utilisation et de la maintenance d'un APPAREIL EM ou d'un SYSTEME EM

NOTE 1 L'entité responsable peut être par exemple un hôpital, un clinicien à titre individuel ou une personne sans compétence médicale. Dans les applications utilisées à domicile, le PATIENT, l'OPERATEUR et l'ORGANISME RESPONSABLE peuvent être une seule et même personne.

NOTE 2 Les domaines de l'enseignement et de la formation sont inclus dans "utilisation".

3.102
RISQUE
combinaison de la probabilité d'apparition d'un DOMMAGE et de la GRAVITE de ce DOMMAGE

[ISO 14971:2007, définition 2.16]

3.103
ANALYSE DE RISQUE
usage systématique des informations disponibles pour identifier les DANGERS et estimer le RISQUE

[ISO 14971:2007, définition 2.17]

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3.104
APPRECIATION DU RISQUE
PROCESSUS englobant une ANALYSE DE RISQUE et une EVALUATION DU RISQUE

[ISO 14971:2007, définition 2.18]

3.105
MAITRISE DU RISQUE
PROCESSUS au cours duquel les décisions sont prises et les mesures visant à réduire les RISQUES ou à les maintenir dans les limites spécifiées sont mises en place

[ISO 14971:2007, définition 2.19]

3.106
EVALUATION DU RISQUE
PROCESSUS de comparaison du RISQUE estimé avec les critères de RISQUE donnés afin de déterminer l'acceptabilité du RISQUE

[ISO 14971:2007, définition 2.21]

3.107
GESTION DES RISQUES
application systématique des politiques de gestion, des PROCEDURES et des pratiques à des tâches d'analyse, d'évaluation et de maîtrise des RISQUES

NOTE Pour les besoins de la présente norme, la GESTION DES RISQUES n'inclut pas la planification ni la surveillance des informations de la production et post-production; tandis que celles-ci sont requises conformément à l'ISO 14971 (voir 4.2.2).

[ISO 14971:2007, définition 2.22]

3.108
DOSSIER DE GESTION DES RISQUES
ensemble des ENREGISTREMENTS et d'autres documents produits par la GESTION DES RISQUES

[ISO 14971:2007, définition 2.23]

NOTE Toutes les informations liées à la sécurité y compris les calculs du FABRICANT, les résultats d'essais etc. sont considérées comme faisant partie du DOSSIER DE GESTION DES RISQUES. Voir aussi 4.2.

3.109
CHARGE DE FONCTIONNEMENT EN SECURITE
charge (masse) mécanique extérieure maximale sur un appareil ou une partie d'un appareil qui est admise en UTILISATION NORMALE

3.110
*** CIRCUIT SECONDAIRE**
circuit qui est séparé de la PARTIE RELIEE AU RESEAU par au moins un MOYEN DE PROTECTION et qui tient sa puissance d'un transformateur, d'un convertisseur ou d'un dispositif d'isolation équivalent ou d'une SOURCE ELECTRIQUE INTERNE

NOTE Voir aussi 8.9.1.12.

3.111
COUPE-CIRCUIT THERMIQUE A REENCLENCHEMENT AUTOMATIQUE
COUPE-CIRCUIT THERMIQUE rétablissant automatiquement le courant lorsque la partie appropriée de l'appareil électrique s'est refroidie

3.112
*** DISPOSITIF DE SEPARATION**
composant ou configuration de composants avec des entrées et des sorties qui, pour des raisons de sécurité, empêchent un transfert de tension non voulue ou de courant non voulu entre les parties d'un SYSTEME EM

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3.113
PERSONNEL D'ENTRETIEN
individus ou entité rendant compte à l'ORGANISME RESPONSABLE qui installent, assemblent, entretiennent ou réparent l'APPAREIL EM, les SYSTEMES EM ou d'autres appareils

3.114
GRAVITE
mesure des conséquences possibles d'un DANGER

[ISO 14971:2007, définition 2.25]

3.115
*** ENTREE/SORTIE DE SIGNAL (en anglais SIP/SOP)**
partie d'un APPAREIL EM, qui n'est pas une PARTIE APPLIQUEE, destinée à envoyer des signaux à un appareil électrique ou à en recevoir de celui-ci, par exemple pour l'affichage, l'enregistrement ou le traitement de données

NOTE Voir Figure 2.

3.116
CONDITION DE PREMIER DEFAUT
condition d'un APPAREIL EM par laquelle un seul moyen de réduction d'un RISQUE est défectueux ou lorsqu'une seule condition anormale est présente

NOTE Voir 4.7 et 13.2.

3.117
SECURISE EN PREMIER DEFAUT
caractéristique d'un APPAREIL EM ou de ses parties par laquelle il n'y a pas de RISQUE inacceptable pendant la DUREE DE VIE PREVUE dans des CONDITIONS DE PREMIER DEFAUT

NOTE Voir 4.7.

3.118
STATIONNAIRE
terme se référant à un appareil qui, une fois installé et mis en service, n'est pas destiné à être déplacé d'un endroit à un autre

NOTE Voir la taxinomie de la définition 3.63 dans les justifications.

3.119
ISOLATION SUPPLEMENTAIRE
isolation indépendante appliquée en plus de l'ISOLATION PRINCIPALE en vue d'assurer la protection contre les chocs électriques en cas de défaut de l'ISOLATION PRINCIPALE

[VEI 826-12-15, modifiée]

NOTE L'ISOLATION SUPPLEMENTAIRE fournit un MOYEN DE PROTECTION.

3.120
*** RESEAU D'ALIMENTATION**
source d'énergie électrique ne faisant pas partie d'un APPAREIL EM ou d'un SYSTEME EM

NOTE Ce terme englobe aussi les systèmes de batteries et de convertisseurs des ambulances et des installations similaires.

3.121
FACTEUR DE SECURITE EN TRACTION
rapport entre la RESISTANCE A LA TRACTION et la contrainte correspondant à la CHARGE TOTALE

3.122
RESISTANCE A LA TRACTION
contrainte de traction maximale à laquelle une pièce en essai résiste avant de se rompre

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3.123
DISPOSITIF DE RACCORDEMENT
partie d'un appareil électrique permettant de réaliser la connexion électrique

NOTE Un DISPOSITIF DE RACCORDEMENT peut contenir plusieurs contacts individuels.

3.124
COUPE-CIRCUIT THERMIQUE
dispositif qui, en condition anormale, limite la température d'un appareil électrique ou de parties de celui-ci en ouvrant automatiquement le circuit ou en réduisant le courant, et dont la construction ne permet une modification de son réglage que par un PERSONNEL D'ENTRETIEN qualifié

3.125
STABILITE THERMIQUE
condition dans laquelle la température d'un objet n'augmente pas de plus de 2 °C en 1 h

3.126
THERMOSTAT
dispositif de commande thermosensible, destiné à maintenir une température dans les limites d'une plage spécifique ou au-dessus/en dessous d'une valeur préréglée

3.127
OUTIL
objet extracorporel qui peut être utilisé pour serrer ou desserrer des moyens de fixation ou pour faire des réglages

NOTE Les pièces de monnaie et les clés sont considérées comme des OUTILS dans le cadre de la présente norme.

3.128
CHARGE TOTALE
charge totale maximale d'une partie incluant la CHARGE DE FONCTIONNEMENT EN SECURITE maximale, le cas échéant, et les forces statiques et dynamiques qui apparaissent en UTILISATION NORMALE

NOTE 1 Les forces causées par l'accélération ou la décélération des masses sont des exemples de forces dynamiques.

NOTE 2 Lorsqu'une charge est divisée sur plusieurs parties du support parallèles et que la répartition sur ces parties n'est pas déterminée sans équivoque, la possibilité la plus défavorable est prise en considération.

3.129
COURANT DE CONTACT
COURANT DE FUITE s'écoulant de l'ENVELOPPE ou de parties de celle-ci, à l'exclusion des CONNEXIONS PATIENT, accessibles à tout OPERATEUR ou au PATIENT en UTILISATION NORMALE, par un chemin externe autre que le CONDUCTEUR DE TERRE DE PROTECTION, vers la terre ou une autre partie de l'ENVELOPPE

NOTE La signification de ce terme est la même que celle de "COURANT DE FUITE A TRAVERS L'ENVELOPPE" dans la première et la deuxième édition de la présente norme. Le terme a été modifié pour s'aligner sur l'IEC 60950-1 et pour refléter le fait que la mesure s'applique maintenant également aux parties qui sont PROTEGEES PAR MISE A LA TERRE.

3.130
TRANSPORTABLE
terme se référant à un appareil qui, une fois installé et mis en service, est destiné à être déplacé d'un endroit à un autre qu'il soit ou non relié à une alimentation et sans restriction notable de son rayon d'utilisation

EXEMPLE Appareils MOBILES, appareils PORTABLES et appareil PORTE

NOTE Voir la taxinomie de la définition 3.63 dans les justifications.

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3.131
ZONE DE PIEGEAGE
emplacement accessible sur ou à l'intérieur d'un APPAREIL EM ou d'un SYSTEME EM ou dans l'environnement de l'appareil où le corps d'une personne ou une partie du corps est exposé aux DANGERS de piégeage, d'écrasement, de cisaillement, d'impact, de coupures, d'embrouillement, d'étirage, de piqûre ou d'abrasion

3.132
*** PARTIE APPLIQUEE DE TYPE B**
PARTIE APPLIQUEE conforme aux exigences spécifiées de la présente norme pour assurer une protection contre les chocs électriques, en ce qui concerne particulièrement le COURANT DE FUITE PATIENT admissible et le COURANT AUXILIAIRE PATIENT

NOTE 1 Une PARTIE APPLIQUEE DE TYPE B est marquée avec le symbole IEC 60417-5840 (2002-10) (voir Tableau D.1, symbole 19) ou, le cas échéant, avec le symbole IEC 60417-5841 (2002-10) (Voir Tableau D.1, symbole 25). Voir aussi 3.20.

NOTE 2 Les PARTIES APPLIQUEES DE TYPE B ne sont pas adaptées à l'APPLICATION CARDIAQUE DIRECTE.

NOTE 3 Voir aussi 4.6 concernant le traitement des parties qui n'entrent pas dans la définition des PARTIES APPLIQUEES mais qui doivent être traitées comme de telles PARTIES APPLIQUEES lorsqu'on applique le PROCESSUS de GESTION DES RISQUES.

3.133
*** PARTIE APPLIQUEE DE TYPE BF**
PARTIE APPLIQUEE DE TYPE F conforme aux exigences spécifiées dans la présente norme pour assurer une protection contre les chocs électriques de degré plus élevé que celui procuré par les PARTIES APPLIQUEES DE TYPE B

NOTE 1 Une PARTIE APPLIQUEE DE TYPE BF est marquée avec le symbole IEC 60417-5333 (2002-10) (voir Tableau D.1, symbole 20) ou, le cas échéant, avec le symbole IEC 60417-5334 (2002-10) (voir Tableau D.1, symbole 26). Voir aussi 3.20.

NOTE 2 Les PARTIES APPLIQUEES DE TYPE BF ne sont pas adaptées à l'APPLICATION CARDIAQUE DIRECTE.

NOTE 3 Voir aussi 4.6 concernant le traitement des parties qui n'entrent pas dans la définition des PARTIES APPLIQUEES mais qui doivent être traitées comme de telles PARTIES APPLIQUEES lorsqu'on applique le PROCESSUS de GESTION DES RISQUES.

3.134
*** PARTIE APPLIQUEE DE TYPE CF**
PARTIE APPLIQUEE DE TYPE F conforme aux exigences spécifiées dans la présente norme pour assurer une protection contre les chocs électriques de degré plus élevé que celui procuré par les PARTIES APPLIQUEES DE TYPE BF

NOTE 1 Une PARTIE APPLIQUEE DE TYPE CF est marquée avec le symbole IEC 60417-5335 (2002-10) (voir Tableau D.1, symbole 21) ou, le cas échéant, avec le symbole IEC 60417-5336 (2002-10) (Voir Tableau D.1, symbole 27). Voir aussi 3.20.

NOTE 2 Voir aussi 4.6 concernant le traitement des parties qui n'entrent pas dans la définition des PARTIES APPLIQUEES mais qui doivent être traitées comme de telles PARTIES APPLIQUEES lorsqu'on applique le PROCESSUS de GESTION DES RISQUES.

NOTE 3 Voir les justifications pour la définition de l'APPLICATION CARDIAQUE DIRECTE (3.22) concernant les parties appliquées qui sont nécessairement des PARTIES APPLIQUEES DE TYPE CF.

3.135
ESSAI DE TYPE
essai sur un spécimen représentatif de l'appareil en vue de déterminer si celui-ci, tel qu'il est conçu et construit, peut satisfaire aux exigences de la présente norme

3.136
APTITUDE A L'UTILISATION
caractéristique de l'interface de l'OPERATEUR qui établit l'efficacité, le rendement, la simplicité d'apprentissage de l'OPERATEUR et la satisfaction de L'OPERATEUR

[IEC 62366:2007, définition 3.17, modifiée]

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3.137
INGENIERIE DE L'APTITUDE A L'UTILISATION
application des connaissances concernant le comportement, les capacités, les limitations des personnes et d'autres caractéristiques liées à la conception des outils, des dispositifs, des systèmes, des tâches, des emplois et des environnements pour obtenir une APTITUDE A L'UTILISATION adéquate

[IEC 62366:2007, définition 3.18]

3.138
VERIFICATION
confirmation, par des PREUVES TANGIBLES, que les exigences spécifiées ont été satisfaites

NOTE 1 Le terme “vérifié” désigne l'état correspondant.

NOTE 2 La confirmation peut couvrir des activités telles que:

– la réalisation d'autres calculs,
– la comparaison d'une spécification de conception nouvelle avec une spécification de conception similaire éprouvée,
– la réalisation d'essais et de démonstrations,
– la revue de documents avant diffusion.

[ISO 14971:2007, définition 2.28]

3.139
*** TENSION DE SERVICE**
tension la plus élevée à laquelle se trouve, ou peut se trouver, l'isolation ou le composant étudié lorsque l'appareil électrique fonctionne dans les conditions D'UTILISATION NORMALE

[IEC 60950-1:2005, définition 1.2.9.6]

3.140
kérma dans l’air
K
quotient de dE_{tr} par dm, où dE_{tr} est la somme des énergies cinétiques initiales de toutes les particules chargées libérées par des particules non chargées dans une masse d'air dm, soit

$$K = \frac{dE_{tr}}{dm}$$

Unité: J kg^{-1}

Le nom spécial de l’unité de KERMA DANS L’AIR est le gray (Gy) (ICRU 60)

[IEC 60601-1-3:2008, définition 3.4]

3.141
condition d’alarme
état d'un SYSTEME D’ALARME lorsqu’il a déterminé qu’il existe une SITUATION DANGEREUSE potentielle ou réelle pour laquelle l'attention ou une réponse de l’OPERATEUR est requise

NOTE 1 Une CONDITION D’ALARME peut être invalide, c'est-à-dire qu'il peut s'agir d'une fausse CONDITION D’ALARME positive.

NOTE 2 Une CONDITION D’ALARME peut passer inaperçue, c'est-à-dire qu'il peut s'agir d’une fausse CONDITION D’ALARME négative.

[IEC 60601-1-8:2006 / Amendement 1(2012), définition 3.1]

3.142
signal d’alarme
type de signal généré par le SYSTEME D’ALARME pour indiquer la présence (ou l'apparition) d’une CONDITION D’ALARME

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[IEC 60601-1-8:2006, définition 3.9]

3.143
système d'alarme
parties d'un APPAREIL EM ou d'un SYSTEME EM qui détectent des CONDITIONS D'ALARME et, selon ce qui est approprié, génèrent des SIGNAUX D'ALARME

[IEC 60601-1-8:2006, définition 3.11]

3.144
porté sur le corps
terme faisant référence à un appareil TRANSPORTABLE dont l'UTILISATION PREVUE correspond à un fonctionnement pendant qu'il est porté par un PATIENT ou fixé au vêtement d'un PATIENT

NOTE 1 Un appareil TRANSPORTABLE peut être à la fois PORTE et PORTATIF.

[IEC 60601-1-11:2010, définition 3.1]

NOTE 2 Voir la taxinomie de la définition 3.63 dans les justifications.

3.145
réseau TI
réseau de technologies de l'information
un ou plusieurs systèmes composés de noeuds de communication et de liaisons de transmission afin de garantir une transmission à liaison physique ou sans fil entre au moins deux noeuds de communication précis

[IEC 80001-1:2010, définition 2.12]

3.146
fonction principale de service

fonction, qui implique une interaction avec l'OPERATEUR, qui est fréquemment utilisée ou liée à la sécurité de l'APPAREIL EM,

[IEC 62366:2007, définition 3.14, modifiée]

3.147
dossier d'ingenierie de l'aptitude a l'utilisation

ensemble des ENREGISTREMENTS et autres documents qui sont produits par le PROCESSUS D'INGENIERIE DE L'APTITUDE A L'UTILISATION

[IEC 62366:2007, définition 3.19]

4 Exigences générales

4.1 * Conditions d'application aux APPAREILS EM ou aux SYSTEMES EM

Sauf spécification contraire, les exigences de la présente norme doivent s'appliquer en UTILISATION NORMALE et en cas de mauvais usage raisonnablement prévisible.

Lorsque la présente norme est appliquée à des APPAREILS EM ou SYSTEMES EM destinés à la compensation ou l'atténuation de maladie, de blessure ou d'incapacité, les définitions et les exigences qui utilisent le terme PATIENT doivent être considérées comme s'appliquant à la personne à laquelle L'APPAREIL EM ou le SYSTEME EM est destiné.

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4.2 * PROCESSUS de GESTION DES RISQUES pour les APPAREILS EM ou SYSTEMES EM

4.2.1 Introduction à la GESTION DES RISQUES

Le paragraphe 4.2 spécifie le processus de GESTION DES RISQUES requis pour la conformité avec la présente norme. Ce PROCESSUS de GESTION DES RISQUES est destiné à servir les objectifs suivants:

a) Identifier si les exigences normatives spécifiées aux Articles 5 à 17 de la présente norme, jointes aux exigences des normes collatérales et particulières applicables, couvrent tous les DANGERS associés à l'APPAREIL EM ou au SYSTEME EM considéré.

b) Identifier la manière dont il convient d'appliquer certains des essais particuliers spécifiés dans la présente norme à un APPAREIL EM ou à un SYSTEME EM particulier.

c) Identifier si des DANGERS particuliers ou des SITUATIONS DANGEREUSES particulières, pour lesquels la présente norme ne fournit pas de critères d'acceptation spécifiques, entraînent des RISQUES pour un APPAREIL EM ou un SYSTEME EM particulier et, si oui, établir des niveaux de RISQUE acceptables et évaluer les RISQUES RESIDUELS.

d) Évaluer la possibilité de stratégies de MAITRISE DU RISQUE alternatives en comparant les RISQUES RESIDUELS à ceux qui existent en appliquant pleinement les exigences de la présente norme.

Bien que le PROCESSUS de GESTION DES RISQUES spécifié dans la présente norme doive être conforme aux exigences concernées de l'ISO 14971, il n'est pas aussi complet et n'inclut pas tous les éléments requis pour la conformité avec l'ISO 14971. Par exemple, le PROCESSUS de GESTION DES RISQUES requis pour la conformité avec la présente norme n'inclut pas la surveillance de la production et de la post-production requise dans l'ISO 14971. De plus, la vérification de la conformité avec les exigences de GESTION DES RISQUES de la présente norme peut être accomplie par l'examen des ENREGISTREMENTS et autres documents requis par la présente norme et l'évaluation des processus cités dans la présente norme et ne requiert pas l'audit du PROCESSUS de GESTION DES RISQUES.

4.2.2 Exigences générales pour la GESTION DES RISQUES

Un PROCESSUS de GESTION DES RISQUES conforme à l'ISO 14971 doit être exécuté. Pour la conformité avec la présente norme, tous les éléments du PROCESSUS de GESTION DES RISQUES de l'ISO 14971:2007 doivent s'appliquer, à l'exception:

– de la planification et de l'exécution de la surveillance de la production et de la post-production (paragraphe 3.1, quatrième tiret, paragraphe 3.4, point f), et Article 9 de l'ISO 14971:2007), et

– des revues périodiques de l'adéquation du PROCESSUS de GESTION DES RISQUES (paragraphe 3.2, quatrième tiret, de l'ISO 14971:2007).

Lors de l'application d'une exigence de l'ISO 14971:

– le terme "dispositif médical" doit avoir la même signification qu'APPAREIL EM ou SYSTEME EM; et

– le terme "conditions de défaut" auquel il est fait référence dans l'ISO 14971 doit inclure mais sans s'y limiter, les CONDITIONS DE PREMIER DEFAUT identifiées dans la présente norme.

NOTE 1 La présente norme spécifie des exigences qui sont généralement applicables aux RISQUES associés aux APPAREILS EM ou aux SYSTEMES EM. Ces exigences sont destinées à faciliter le PROCESSUS de GESTION DES RISQUES. Le PROCESSUS de GESTION DES RISQUES ne vise pas seulement à identifier les DANGERS couverts par la présente norme mais tous les DANGERS, leurs RISQUES associés et les mesures de MAITRISE DU RISQUE.

NOTE 2 Les conditions ou les défauts qui peuvent donner lieu à des SITUATIONS DANGEREUSES sont identifiés dans les articles de la présente norme. Dans ces cas, il est souvent nécessaire de conduire un PROCESSUS de GESTION DES RISQUES pour déterminer quelles sont les SITUATIONS DANGEREUSES réelles et les essais qui doivent être réalisés pour montrer que les SITUATIONS DANGEREUSES identifiées n'apparaissent pas dans les circonstances spécifiées.

NOTE 3 Il est reconnu que le FABRICANT pourrait ne pas être en mesure de suivre tous les PROCESSUS identifiés dans la présente norme pour chaque composant constituant de l'APPAREIL EM ou du SYSTEME EM tel que les composants propriétaires, les sous-systèmes d'origine non médicale et les dispositifs classiques. Dans ce cas, le

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FABRICANT pourrait tenir particulièrement compte des besoins en matière de mesures supplémentaires de MAITRISE DU RISQUE.

NOTE 4 Lorsque les exigences de la présente norme font référence à l'absence de RISQUE inacceptable, l'acceptabilité ou la non-acceptabilité de ce RISQUE est déterminée par le FABRICANT conformément à la politique du FABRICANT pour déterminer le RISQUE acceptable.

NOTE 5 Tous les RISQUES associés aux APPAREILS EM ou aux SYSTEMES EM ne sont pas nécessairement couverts par des exigences spécifiques de la présente norme (voir 1.1).

La conformité est vérifiée par:

– *l'inspection de la politique du FABRICANT en matière de détermination des critères d'acceptabilité du RISQUE;*
– *l'inspection du plan de GESTION DES RISQUES pour l'APPAREIL EM ou le SYSTEME EM particulier concerné; et*
– *la confirmation du fait que le FABRICANT a préparé un DOSSIER DE GESTION DES RISQUES contenant les ENREGISTREMENTS DE GESTION DES RISQUES et les autres documents requis par la présente norme pour l'APPAREIL EM ou le SYSTEME EM particulier concerné.*

NOTE 6 Il est utile de garder un index contenant les références ou les indications relatives aux ENREGISTREMENTS DE GESTION DES RISQUES et les autres documents requis par la présente norme.

4.2.3 Évaluation du RISQUE

4.2.3.1 DANGERS identifiés dans la série IEC 60601

Les exigences de la présente norme doivent être appliquées de la manière suivante lors de l'évaluation du RISQUE:

a) Lorsque la présente norme ou ses normes collatérales ou particulières spécifient des exigences couvrant des DANGERS particuliers ou des SITUATIONS DANGEREUSES particulières, ainsi que des critères d'acceptation spécifiques, la conformité avec ces exigences est présumée établir le fait que les RISQUES RESIDUELS ont été réduits à des niveaux acceptables, sauf s'il existe des PREUVES TANGIBLES du contraire.

EXEMPLE 1 Paragraphe 8.5.1.2, MOYENS DE PROTECTION DU PATIENT (MOPP)

EXEMPLE 2 Paragraphe 9.4.2.1, Instabilité en position de transport

La conformité est vérifiée par la satisfaction des exigences concernées de la présente norme et de ses normes collatérales et particulières.

b) Lorsque la présente norme ou ses normes collatérales ou particulières spécifient des exigences couvrant des DANGERS particuliers ou des SITUATIONS DANGEREUSES particulières mais ne donnent pas de critères d'acceptation spécifiques, le FABRICANT doit fournir les critères d'acceptation définis dans le plan de GESTION DES RISQUES. Ces critères d'acceptation doivent garantir que le RISQUE RESIDUEL est acceptable selon les critères d'acceptabilité du RISQUE enregistrés dans le plan de GESTION DES RISQUES.

EXEMPLE 3 Paragraphe 9.8.3.3, Forces dynamiques dues à la charge des personnes

EXEMPLE 4 Paragraphe 11.6.3, Renversement sur un APPAREIL EM et sur un SYSTEME EM

La conformité est vérifiée en confirmant que les ENREGISTREMENTS du DOSSIER DE GESTION DES RISQUES démontrent que, après l'application des exigences spécifiques de la présente norme, les critères d'acceptation déterminés par le FABRICANT sont satisfaits. Seules les parties appropriées du DOSSIER DE GESTION DES RISQUES doivent être revues, par exemple les calculs ou résultats d'essais du FABRICANT, ou la détermination de l'acceptabilité du RISQUE.

c) Lorsque la présente norme ou ses normes collatérales ou particulières identifient des DANGERS particuliers ou des SITUATIONS DANGEREUSES particulières à examiner mais ne donnent pas d'exigences techniques spécifiques:

– le FABRICANT doit déterminer si ces DANGERS ou ces SITUATIONS DANGEREUSES existent pour l'APPAREIL EM ou le SYSTEME EM particulier, et

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– lorsque de tels DANGERS ou SITUATIONS DANGEREUSES existent pour l'APPAREIL EM ou le SYSTEME EM particulier, le FABRICANT doit évaluer et (si nécessaire) maîtriser ces RISQUES à la suite du PROCESSUS de GESTION DES RISQUES spécifié en 4.2.2.

EXEMPLE 5 Paragraphe 10.2, Rayonnements alpha, bêta, gamma, neutroniques et d'autres particules

La conformité est vérifiée en confirmant que les ENREGISTREMENTS du DOSSIER DE GESTION DES RISQUES démontrent que le RISQUE RESIDUEL est acceptable en utilisant les critères d'acceptabilité du RISQUE enregistrés dans le plan de GESTION DES RISQUES , c'est-à-dire qu'il ne subsiste aucun RISQUE inacceptable. Seules les parties appropriées du DOSSIER DE GESTION DES RISQUES doivent être revues, par exemple les calculs ou résultats d'essais du FABRICANT, ou la détermination de l'acceptabilité du RISQUE.

NOTE Lorsqu'un APPAREIL EM ou un SYSTEME EM a été conçu de telle sorte que, pour un certain type de DANGER, il n'existe aucune SITUATION DANGEREUSE, aucune EVALUATION DU RISQUE supplémentaire n'est nécessaire pour ce DANGER. Ceci peut être vérifié au moyen d'essais ou d'inspections.

4.2.3.2 DANGERS non identifiés dans la série IEC 60601

Pour les DANGERS ou les SITUATIONS DANGEREUSES qui sont identifiés pour l'APPAREIL EM ou le SYSTEME EM particulier mais qui ne sont pas spécifiquement couverts par la présente norme ou ses normes collatérales ou particulières, le FABRICANT doit traiter ces DANGERS dans le PROCESSUS de GESTION DES RISQUES comme spécifié en 4.2.2.

EXEMPLE APPAREIL EM ou SYSTEME EM pour lequel il existe des RISQUES particuliers mais aucune norme particulière.

La conformité est vérifiée par l'inspection du DOSSIER DE GESTION DES RISQUES.

4.3 * PERFORMANCE ESSENTIELLE

Durant l'ANALYSE DES RISQUES, le FABRICANT doit identifier les performances des fonctions cliniques de l'APPAREIL EM ou du SYSTEME EM, autres que celles relatives à la SECURITE DE BASE, qui sont nécessaires à l'exécution de l'UTILISATION PREVUE ou qui pourraient affecter la sécurité de l'APPAREIL EM ou du SYSTEME EM.

Le FABRICANT doit également spécifier les limites de la performance entre la fonctionnalité entière et la perte totale de la performance identifiée dans les CONDITIONS NORMALES comme dans les CONDITIONS DE PREMIER DEFAUT.

Le FABRICANT doit ensuite évaluer le RISQUE de perte ou de dégradation de la performance identifiée au-delà des limites spécifiées par le FABRICANT. Si le RISQUE résultant est inacceptable, alors la performance identifiée constitue une PERFORMANCE ESSENTIELLE de l'APPAREIL EM ou du SYSTEME EM.

Le FABRICANT doit mettre en œuvre des mesures de MAITRISE DU RISQUE afin de réduire le RISQUE de perte ou de dégradation des performances identifiées à un niveau acceptable.

NOTE 1 La performance de la mesure de MAITRISE DU RISQUE peut tout à fait devenir un aspect des PERFORMANCES ESSENTIELLES de l'APPAREIL EM ou du SYSTEME EM. Par exemple, la génération du SIGNAL D'ALARME indiquant la coupure du RESEAU D'ALIMENTATION peut être "essentielle" si une coupure du RESEAU D'ALIMENTATION peut entraîner un RISQUE inacceptable si le problème n'est pas résolu.

Le FABRICANT doit spécifier les méthodes utilisées pour vérifier l'efficacité des mesures de MAITRISE DU RISQUE. Celles-ci doivent inclure les évaluations réalisées pour déterminer si une vérification est nécessaire.

NOTE 2 Suivant les principes de la GESTION DES RISQUES, le FABRICANT a l'obligation de vérifier l'efficacité de chaque mesure de MAITRISE DU RISQUE. Ceci peut impliquer la démonstration de l'efficacité de la mesure de MAITRISE DU RISQUE en présence de conditions entraînant la perte ou la dégradation des performances identifiées.

EXEMPLE 1 Lorsqu'une PERFORMANCE ESSENTIELLE est perdue en raison d'une coupure du RESEAU D'ALIMENTATION, un système d'alarme destiné à signaler à l'OPERATEUR que le RESEAU D'ALIMENTATION est coupé devrait être équipé d'une source d'alimentation de secours, afin que la génération du SIGNAL D'ALARME ne dépende pas du RESEAU D'ALIMENTATION.

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EXEMPLE 2 Si la défaillance d'un composant entraîne la perte d'une PERFORMANCE ESSENTIELLE, il serait nécessaire que la conception de l'APPAREIL EM ou du SYSTEME EM soit telle que la défaillance du composant ne compromette pas l'efficacité des mesures de MAITRISE DU RISQUE mises en place afin d'atténuer le RISQUE découlant de la perte de la PERFORMANCE ESSENTIELLE.

NOTE 3 Chaque norme collatérale ou particulière de la série IEC 60601 ou de la série IEC/ISO 80601 peut énumérer des PERFORMANCES ESSENTIELLES potentielles afin de guider le FABRICANT dans l'identification de PERFORMANCES ESSENTIELLES particulières conformes à 4.3.

La conformité est *vérifiée par l'inspection du DOSSIER DE GESTION DES RISQUES*.

Lorsque la présente norme prescrit qu'une PERFORMANCE ESSENTIELLE doit être conservée à la suite d'un essai particulier, la conformité est vérifiée par inspection et, si nécessaire, par un(des) essai(s) fonctionnel(s) qui démontre(nt) que les limites spécifiées par le FABRICANT sont maintenues ou que l'APPAREIL EM ou le SYSTEME EM passe dans un état sûr tel que défini par le FABRICANT.

4.4 * DUREE DE VIE PREVUE

Le FABRICANT doit stipuler la DUREE DE VIE PREVUE de L'APPAREIL EM ou du SYSTEME EM dans le DOSSIER DE GESTION DES RISQUES.

La conformité est vérifiée par inspection du DOSSIER DE GESTION DES RISQUES.

4.5 * Mesures de MAITRISE DU RISQUE ou méthodes d'essai alternatives pour les APPAREILS EM ou les SYSTEMES EM

Lorsque la présente norme spécifie une mesure de MAITRISE DU RISQUE ou une méthode d'essai particulière, une mesure de MAITRISE DU RISQUE ou une méthode d'essai alternative est acceptable dès lors que le FABRICANT peut démontrer au moyen de données scientifiques, d'analyses cliniques ou d'études comparatives que le RISQUE RESIDUEL résultant de l'application de la mesure de MAITRISE DU RISQUE ou des méthodes d'essai alternatives reste acceptable et est comparable au RISQUE RESIDUEL résultant de l'application des exigences de la présente norme.

Dans ce contexte, les études comparatives signifient des études comparant l'effet de la mesure de MAITRISE DU RISQUE ou de la méthode d'essai alternative avec la mesure de MAITRISE DU RISQUE ou la méthode d'essai spécifiée dans la présente norme.

NOTE Des mesures de MAITRISE DU RISQUE alternatives peuvent permettre un dépassement des limites spécifiées dans la présente norme ou dans ses normes collatérales ou particulières si des mesures de compensation complémentaires sont prévues.

La conformité est vérifiée par l'inspection du DOSSIER DE GESTION DES RISQUES.

4.6 * Parties D'APPAREIL EM ou de SYSTEME EM en contact avec le PATIENT

Le PROCESSUS de GESTION DES RISQUES doit inclure une évaluation déterminant si des parties qui peuvent venir en contact avec le PATIENT mais qui n'entrent pas dans la définition des PARTIES APPLIQUEES doivent être soumises aux exigences applicables aux PARTIES APPLIQUEES. Pour les parties concernées, les exigences applicables à une PARTIE APPLIQUEE DE TYPE B doivent s'appliquer sauf si l'évaluation identifie le fait que les exigences applicables à une PARTIE APPLIQUEE DE TYPE BF ou à une PARTIE APPLIQUEE DE TYPE CF doivent s'appliquer.

Si le PROCESSUS de GESTION DES RISQUES détermine que de telles parties sont soumises aux exigences applicables aux PARTIES APPLIQUEES, alors toutes les exigences et tous les essais appropriés de la présente norme et des normes collatérales et particulières appropriées doivent s'appliquer, à l'exception de 7.2.10 qui ne s'applique pas à de telles parties.

La conformité est vérifiée par l'inspection du DOSSIER DE GESTION DES RISQUES.

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4.7 * CONDITION DE PREMIER DEFAUT pour APPAREILS EM

Les APPAREILS EM doivent être conçus et construits de manière à rester SECURISES EN PREMIER DEFAUT ou bien à ce que le RISQUE reste acceptable tel qu'il est déterminé en 4.2.

NOTE 1 Les CONDITIONS NORMALES identifiées en 8.1 a) sont prises en compte au cours de l'évaluation de la conformité avec toute exigence de la présente norme que ces conditions pourraient affecter.

Les APPAREILS EM sont considérés comme SECURISES EN PREMIER DEFAUT si:

a) ils emploient un seul moyen de réduction du RISQUE, moyen qui a une probabilité de défaillance négligeable (par exemple ISOLATION RENFORCEE, système de masses suspendues sans DISPOSITIFS DE PROTECTION MECANIQUE avec un FACTEUR DE SECURITE EN TRACTION de 8 X, COMPOSANT AUX CARACTERISTIQUES A HAUTE FIABILITE), ou

b) une condition de premier défaut apparaît mais:

   – le défaut initial est détecté au cours de la DUREE DE VIE PREVUE de L'APPAREIL EM et avant la défaillance d'un deuxième moyen de réduction du RISQUE (par exemple système de masses suspendues avec des DISPOSITIFS DE PROTECTION MECANIQUE) ; ou

   – la probabilité que le deuxième moyen de réduction du RISQUE soit défaillant au cours de la DUREE DE VIE PREVUE de L'APPAREIL EM est négligeable.

Lorsqu'une CONDITION DE PREMIER DEFAUT cause une autre CONDITION DE PREMIER DEFAUT, ces deux défaillances sont considérées comme une seule CONDITION DE PREMIER DEFAUT.

Au cours de tout essai dans des CONDITIONS DE PREMIER DEFAUT, un seul défaut doit être appliqué à la fois.

NOTE 2 Les défauts sont généralement divisés en 3 catégories de probabilités:

a) si improbables qu'ils peuvent être ignorés. Les RISQUES provenant des ces défauts sont considérés comme acceptables;

b) Suffisamment probables pour qu'il soit nécessaire de les prendre en compte, mais pas suffisamment pour qu'ils soient pris en compte un par un (défaut unique). Les défauts de cette catégorie englobent tous ceux qui sont identifiés comme CONDITIONS DE PREMIER DEFAUT dans la présente norme et tous les autres défauts identifiés en appliquant l'ISO 14971, qui satisfont aux critères des CONDITIONS DE PREMIER DEFAUT;

c) si probables, si imprévisibles ou indétectables qu'ils sont considérés comme une CONDITION NORMALE et sont pris en compte de manière individuelle et de manière collective.

Les résultats de l'ANALYSE DE RISQUE doivent être utilisés pour déterminer quelles défaillances doivent faire l'objet d'essais. La défaillance de tout composant à un moment qui causerait une SITUATION DANGEREUSE, y compris celles mentionnées en 13.1, doit être simulée, physiquement ou de manière théorique. L'évaluation destinée à déterminer si un composant est soumis à la simulation de défaillance doit tenir compte du RISQUE associé à la défaillance du composant au cours de la DUREE DE VIE PREVUE de L'APPAREIL EM. Cette évaluation doit être réalisée en appliquant les principes de la GESTION DES RISQUES. L'évaluation doit tenir compte des problèmes tels que la fiabilité, les FACTEURS DE SECURITE DE TRACTION et les caractéristiques des composants. De plus, au cours de la simulation des CONDITIONS DE PREMIER DEFAUT, les défaillances de composant qui sont très probables ou indétectables doivent être simulées.

NOTE 3 Voir aussi la Note 2 de 4.2.

Cette exigence et les essais correspondants ne doivent pas être appliqués aux défaillances de DOUBLE ISOLATION ou d'ISOLATION RENFORCEE ou aux COMPOSANTS AUX CARACTERISTIQUES A HAUTE FIABILITE.

La conformité est déterminée en appliquant les exigences spécifiques et les essais associés aux CONDITIONS DE PREMIER DEFAUT identifiées en 13.2 et aux essais pour les défaillances identifiées à partir de l'évaluation des résultats de L'ANALYSE DE RISQUES. La conformité est confirmée si l'introduction d'une des CONDITIONS DE PREMIER DEFAUT décrites en 13.2 une à la fois, ne conduit pas directement à des SITUATIONS DANGEREUSES décrites en 13.1, ou à toute autre situation donnant lieu à un RISQUE inacceptable.

4.8 * Composants des APPAREILS EM

Tous les composants y compris le câblage, dont la défaillance pourrait donner lieu à une SITUATION DANGEREUSE, doivent être utilisés conformément à leurs caractéristiques spécifiées

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à moins qu'une exception spécifique ne soit faite dans la présente norme ou dans le cadre du PROCESSUS de GESTION DES RISQUES. La fiabilité des composants qui sont utilisés comme MOYEN DE PROTECTION doit être évaluée pour les conditions d'utilisation dans les APPAREILS EM. Ils doivent être conformes avec un des éléments ci-dessous (voir aussi 4.5):

a) les exigences de sécurité applicables d'une norme IEC ou ISO pertinente.

NOTE 1 Pour les composants, il n'est pas nécessaire de réaliser des essais identiques ou équivalents déjà réalisés pour vérifier la conformité avec la norme de composant.

b) en l'absence de norme IEC ou ISO pertinente, les exigences de la présente norme doivent s'appliquer.

NOTE 2 En l'absence d'exigences à la fois dans la présente norme et dans les normes IEC ou ISO, toute autre source applicable (par exemple normes pour d'autres types d'appareils, normes nationales) pourrait être utilisée pour démontrer la conformité avec le PROCESSUS de GESTION DES RISQUES.

Voir Figure 5 pour un schéma fonctionnel de a) et b).

La conformité est vérifiée par examen et, si nécessaire par un essai. Les essais de la présente norme pour les moteurs (voir 13.2.8 et 13.2.13.3) et les transformateurs (voir 15.5.3) sont considérés comme complets et, avec l'évaluation du système d'isolation du moteur ou du système d'isolation du transformateur selon le Tableau 22, ils représentent tous les essais exigés par la présente norme. Les composants des SYSTEMES EM qui assurent une isolation par rapport aux APPAREILS non EM sont évalués selon l'Article 16.

4.9 * Utilisation de COMPOSANTS AUX CARACTERISTIQUES A HAUTE FIABILITE dans les APPAREILS EM

Un COMPOSANT AUX CARACTERISTIQUES A HAUTE FIABILITE doit être utilisé lorsqu'un défaut d'un composant particulier peut générer un RISQUE inacceptable. Les COMPOSANTS AUX CARACTERISTIQUES A HAUTE FIABILITE doivent être choisis et évalués de manière cohérente avec leurs conditions d'utilisation et de leurs mauvais usage raisonnablement prévisible au cours de la DUREE DE VIE PREVUE de l'APPAREIL EM.

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La conformité est vérifiée par inspection du DOSSIER DE GESTION DES RISQUES *et des critères de sélection pour les* COMPOSANTS AUX CARACTERISTIQUES A HAUTE FIABILITE.

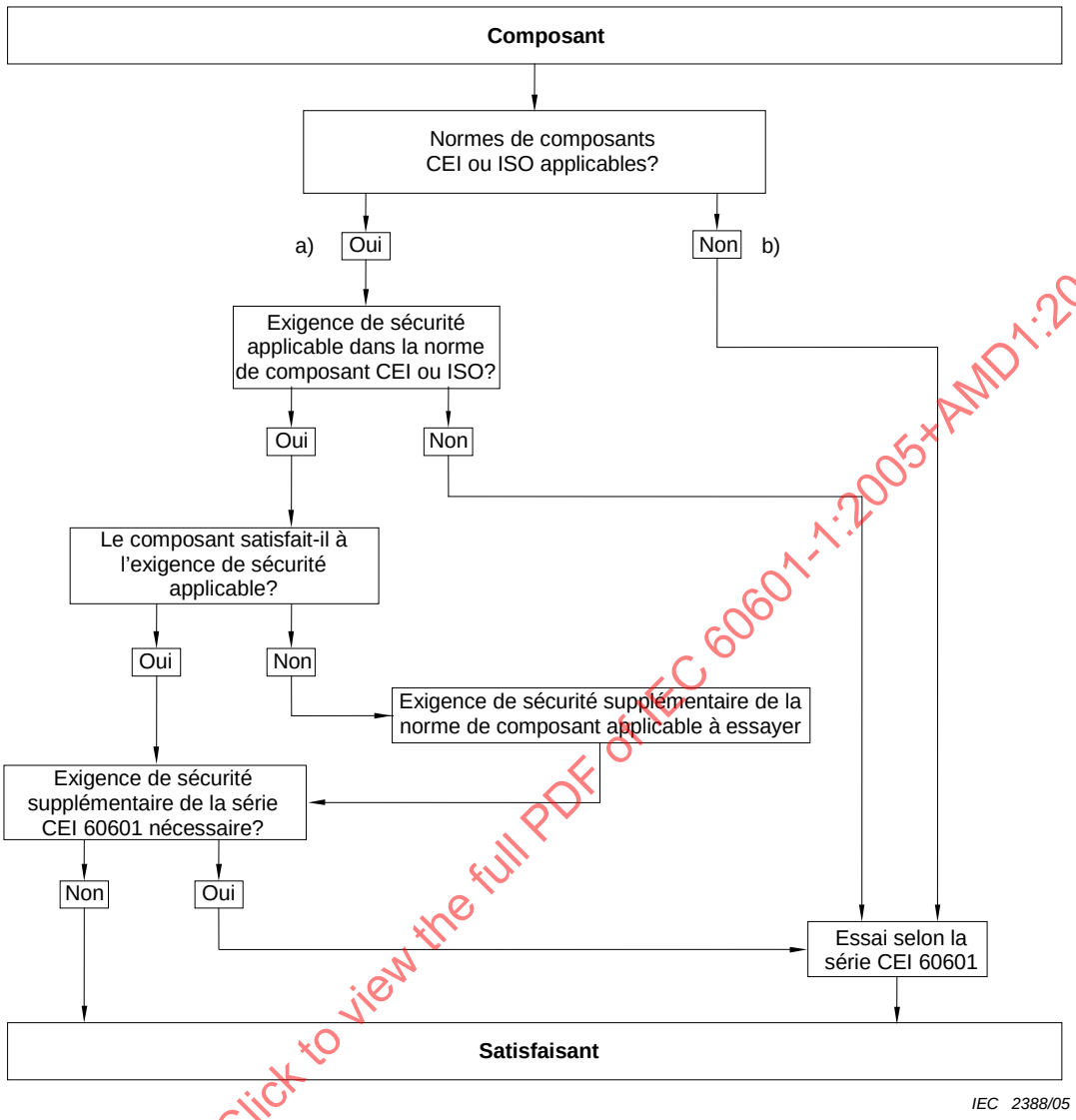


Figure 5 – Schéma fonctionnel pour la qualification des composants
(voir 4.8)

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4.10 * Alimentation

4.10.1 Source d'alimentation pour APPAREIL EM

LES APPAREILS EM doivent être adaptés à une connexion au RESEAU, être spécifiés pour être reliés à une alimentation séparée ou pour être alimentés par une SOURCE ELECTRIQUE INTERNE. Sinon, une combinaison de ces sources peut être utilisée.

La conformité est vérifiée par inspection des DOCUMENTS D'ACCOMPAGNEMENT.

4.10.2 RESEAU D'ALIMENTATION pour APPAREILS EM et SYSTEMES EM

Pour les APPAREILS EM destinés à être reliés au RESEAU D'ALIMENTATION, les tensions ASSIGNEES suivantes ne doivent pas être dépassées:

– 250 V pour les APPAREILS EM PORTATIFS ;

– 250 V courant continu ou courant alternatif monophasé ou 500 V courant alternatif polyphasé pour les APPAREILS EM et les SYSTEMES EM présentant une puissance absorbée ASSIGNEE ≤ 4 kVA ; ou

– 500 V pour tous les autres APPAREILS EM et SYSTEMES EM.

Dans la présente norme, le RESEAU D'ALIMENTATION doit être considéré comme présentant les caractéristiques suivantes:

– catégorie de surtension II pour les transitoires réseau sauf si une catégorie supérieure est spécifiée par le FABRICANT ;

– aucune tension supérieure à 110 % ou inférieure à 90 % de la tension NOMINALE entre chacun des conducteurs du système ou entre l'un de ces conducteurs et la terre (voir 7.9.3.1) ;

NOTE 1 L'IEC 60601-1-2 contient des exigences et des essais concernant les chutes de tension, les interruptions de courte durée et les variations de tension sur le RESEAU D'ALIMENTATION. Voir aussi 1.3.

– tensions pratiquement sinusoïdales et formant un réseau d'alimentation pratiquement symétrique en cas d'alimentation polyphasée ;

– une fréquence ≤ 1 kHz ;

– un écart de fréquence ≤ 1 Hz par rapport à la valeur NOMINALE jusqu'à 100 Hz et ≤ 1 % par rapport à la valeur NOMINALE entre 100 Hz et 1 kHz ;

– les mesures de protection décrites dans l'IEC 60364-4-41 ;

NOTE 2 Si un APPAREIL EM ou un SYSTEME EM est destiné à être alimenté par un RESEAU D'ALIMENTATION dont les caractéristiques diffèrent de celles du RESEAU D'ALIMENTATION décrit dans ce paragraphe, des mesures complémentaires de SECURITE pourraient être nécessaires.

– une tension en courant continu (telle que mesurée par un appareil de mesure à bobine mobile ou une méthode équivalente) présentant une ondulation crête à crête ne dépassant pas 10 % de la valeur moyenne.

Lorsque l'ondulation crête à crête dépasse 10 % de la valeur moyenne, la tension de crête doit être appliquée.

4.11 Puissance absorbée

La puissance, mesurée en régime stabilisé, des APPAREILS EM ou des SYSTEMES EM à la tension ASSIGNEE et avec les réglages de fonctionnement indiqués dans les instructions d'utilisation ne doit pas dépasser les valeurs indiquées de plus de 10 % (voir 7.2.7).

La conformité est vérifiée par inspection et par les essais suivants.

– *On fait fonctionner l'APPAREIL EM ou le SYSTEME EM comme spécifié dans les instructions d'utilisation jusqu'à ce que la puissance absorbée ait atteint une valeur stable. La puissance absorbée est mesurée et comparée avec les marquages et les indications de la description technique*.

– *L'APPAREIL EM ou le SYSTEME EM comportant un marquage avec une ou plusieurs plages de tensions ASSIGNEES est soumis aux essais à la fois aux limites supérieures et inférieures de la plage, sauf si chaque marquage de la puissance absorbée ASSIGNEE a trait à la valeur moyenne de la plage de tension correspondante, auquel cas l'essai est effectué à une tension égale à la valeur moyenne de cette plage.*

– *Le courant en régime stabilisé est mesuré à l'aide d'un instrument de mesure donnant une vraie valeur efficace*.

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Si la puissance absorbée, est exprimée en voltampères, elle est soit mesurée à l'aide d'un voltampèremètre soit déterminée par le produit du courant en régime stabilisé (mesuré comme indiqué ci-dessus) par la tension d'alimentation.

NOTE 1 Les détails techniques d'un compteur donnant une vraie valeur efficace peuvent être trouvés dans l'IEC 62354 [63].

NOTE 2 Des informations du fournisseur peuvent être utilisées pour compléter les mesures ci-dessus, telles qu'une indication de la puissance absorbée.

5 * Exigences générales relatives aux essais des APPAREILS EM

5.1 * ESSAIS DE TYPE

Les essais décrits dans la présente norme sont des ESSAIS DE TYPE. Les essais à réaliser sont déterminés en prenant en compte les exigences de l'Article 4 et en particulier celles de 4.2.

Il n'est pas nécessaire de réaliser un essai si l'analyse montre que la condition soumise aux essais a été correctement évaluée dans le cadre d'autres essais ou méthodes.

La combinaison de défauts indépendants simultanés, susceptibles de donner lieu à une SITUATION DANGEREUSE, doit être documentée dans le DOSSIER DE GESTION DES RISQUES (voir également 4.7). Lorsque des essais sont nécessaires pour démontrer que la SECURITE DE BASE et les PERFORMANCES ESSENTIELLLES sont conservées en présence de tels défauts indépendants simultanés, les essais concernés peuvent être limités aux situations les plus défavorables.

NOTE 1 Les résultats d'essais pourraient nécessiter une révision de l'ANALYSE DE RISQUES.

NOTE 2 Lorsque l'on considère l'utilisation des essais décrits dans la présente norme en tant qu'essais de routine, voir l'Annexe K de l'IEC/TR 62354 (essais de ligne de production) ou voir l'IEC 62353 (essais récurrents).

5.2 * Nombre de spécimens

Les ESSAIS DE TYPE sont effectués sur un spécimen représentatif du produit à vérifier.

NOTE Il est admis d'utiliser plusieurs spécimens simultanément si la validité des résultats n'est pas affectée de manière significative.

5.3 Température ambiante, humidité, pression atmosphérique

a) Après avoir mis l'APPAREIL EM à soumettre aux essais en condition d'UTILISATION NORMALE (conformément à 5.7), les essais sont effectués dans la plage des conditions d'environnement indiquées dans la description technique (voir 7.9.3.1).

b) Les APPAREILS EM sont protégés des autres influences (par exemple les courants d'air) qui pourraient affecter la validité des essais.

c) S'il n'est pas possible de maintenir la température ambiante, les conditions de l'essai doivent être modifiées et les résultats corrigés en conséquence.

5.4 Autres conditions

a) Sauf indication contraire dans la présente norme, l'APPAREIL EM doit être essayé dans les conditions de service les moins favorables. Les conditions de service sont spécifiées dans les DOCUMENTS D'ACCOMPAGNEMENT. Les conditions de service les moins favorables doivent être documentées pour chaque essai où elles s'appliquent.

b) Les APPAREILS EM dont certains paramètres de fonctionnement peuvent être ajustés ou commandés par une personne n'appartenant pas au PERSONNEL D'ENTRETIEN doivent être ajustés, au cours des essais, aux valeurs les moins favorables pour l'essai correspondant, mais conformément aux instructions d'utilisation.

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c) Si les résultats des essais sont affectés par la pression d'entrée et le débit ou par la composition chimique d'un liquide de refroidissement, l'essai est effectué dans les limites de ces caractéristiques telles qu'elles sont prescrites dans la description technique.

d) Lorsque de l'eau de refroidissement est nécessaire, de l'eau potable est utilisée.

5.5 Tensions d'alimentation, type de courant, nature de l'alimentation, fréquence

a) Si les résultats des essais sont influencés par des fluctuations des caractéristiques du RESEAU D'ALIMENTATION par rapport à leurs valeurs ASSIGNEES, l'effet de ces fluctuations est pris en considération.

Les valeurs utilisées durant les essais sont conformes à 4.10.2 ou conformes aux valeurs indiquées sur l'APPAREIL EM (voir 7.2.6), la moins favorable étant retenue.

NOTE 1 Pour la(les) valeur(s) ASSIGNEE(S) indiquée(s) sur l'APPAREIL EM, les fluctuations du RESEAU D'ALIMENTATION telles qu'indiquées en 4.10.2 n'ont à être soumises à l'essai que si les fluctuations ont un impact négatif sur la SECURITE DE BASE ou les PERFORMANCES ESSENTIELLES.

b) Les APPAREILS EM qui possèdent une PARTIE RELIEE AU RESEAU D'ALIMENTATION destinée à être raccordée à un RESEAU en courant alternatif sont seulement soumis aux essais avec le courant alternatif à la fréquence ASSIGNEE. Les APPAREILS EM marqués d'une plage de fréquences ASSIGNEES sont soumis aux essais à la fréquence la moins favorable dans les limites de cette plage.

c) Les APPAREILS EM conçus pour fonctionner sous plus d'une tension ASSIGNEE, à la fois en courant alternatif et en courant continu, ou à la fois avec une alimentation externe et une SOURCE ELECTRIQUE INTERNE, sont soumis à l'essai dans les conditions (décrites en 5.4) correspondant à la tension et à la nature de l'alimentation les moins favorables, par exemple nombre de phases (à l'exception de l'alimentation monophasée) et type de courant. Il pourrait être nécessaire d'effectuer certains essais plus d'une fois pour déterminer quelle est la configuration d'alimentation la moins favorable.

d) Les APPAREILS EM possédant une PARTIE RELIEE AU RESEAU D'ALIMENTATION destinés à être raccordés à un RESEAU en courant continu sont seulement soumis aux essais en courant continu. Au cours des essais, l'influence possible de la polarité sur leur fonctionnement est prise en compte, conformément aux instructions d'utilisation. Voir aussi 8.2.2.

e) Les APPAREILS EM pour lesquels des ACCESSOIRES ou des composants interchangeables spécifiés dans les DOCUMENTS D'ACCOMPAGNEMENT (voir 7.9.2.14 et 7.9.3.2) sont disponibles sont soumis à l'essai avec les ACCESSOIRES ou les composants qui créent les conditions les moins favorables.

f) Si les instructions d'utilisation spécifient que l'APPAREIL EM est destiné à recevoir son énergie d'une alimentation séparée, il est connecté à une telle alimentation. Voir aussi 7.2.5 et 8.2.1.

NOTE 2 Ce qui était désigné dans la première et dans la deuxième édition de la présente norme comme une "alimentation spécifiée" est désormais considéré soit comme une autre partie du même APPAREIL EM soit comme un autre appareil dans un SYSTEME EM.

5.6 Réparations et modifications

Dans le cas de réparations ou de modifications rendues nécessaires à la suite d'une défaillance ou de la probabilité d'une défaillance future au cours de la séquence d'essais, le laboratoire d'essais et le fournisseur de l'APPAREIL EM peuvent se mettre d'accord, soit sur la présentation d'un nouveau spécimen sur lequel tous les essais influençant le résultat sont réalisés à nouveau, soit, de préférence, sur l'exécution de toutes les réparations ou modifications nécessaires, à la suite desquelles seuls les essais concernés sont répétés.

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5.7 * Pré-conditionnement humide

Avant d'effecteur les essais de 8.7.4 et de 8.8.3, tous les APPAREILS EM ou leurs parties doivent être soumis à un pré-conditionnement humide.

LES APPAREILS EM ou leurs parties doivent être complètement montés (ou le cas échéant partiellement). Les protections utilisées pendant le transport et le stockage sont retirées.

Ce traitement n'est appliqué qu'aux parties des APPAREILS EM qui sont susceptibles d'être influencées par les conditions climatiques qui sont simulées par l'essai.

Les parties amovibles sans OUTIL sont détachées mais sont soumises au traitement en même temps que la partie principale.

Les CAPOTS D'ACCES dont l'ouverture ou l'enlèvement est possible sans OUTIL sont ouverts et détachés.

Le préconditionnement humide est effectué dans une enceinte humide contenant de l'air à une humidité relative de 93 % ± 3 % dans laquelle sont placés l'APPAREIL EM ou ses parties. Les conditions d'humidité en d'autres endroits de la chambre peuvent varier de ± 6 %. La température de l'air dans l'enceinte, à tous les endroits où l'APPAREIL EM ou ses parties peuvent être placés, doit être maintenue dans les limites de 2 °C de toute valeur *T* appropriée dans la plage de +20 °C à +30 °C. Avant de les introduire dans l'enceinte humide, on amène l'APPAREIL EM ou ses parties à une température comprise entre *T* et *T* + 4 °C en le maintenant à cette température pendant au moins 4 h avant le début du traitement humide.

Conserver l'APPAREIL EM et ses parties, lorsque l'ENVELOPPE est de classe IPX0, dans l'enceinte humide pendant 48 h.

Conserver l'APPAREIL EM et ses parties, lorsque l'ENVELOPPE est conçue pour offrir une meilleure protection contre l'infiltration de liquides, dans l'enceinte humide pendant 168 h.

Après le traitement, l'APPAREIL EM est remonté, si nécessaire.

5.8 Ordre des essais

Sauf indication contraire, les essais de la présente norme sont réalisés dans un ordre tel que les résultats d'un essai n'influencent pas les résultats d'un essai effectué ensuite.

NOTE Il est recommandé que tous les essais soient réalisés selon l'ordre indiqué à l'Annexe B.

5.9 * Détermination des PARTIES APPLIQUEES ET DES PARTIES ACCESSIBLES

5.9.1 PARTIES APPLIQUEES

Les PARTIES APPLIQUEES sont identifiées par inspection et en se référant aux DOCUMENTS D'ACCOMPAGNEMENT. Voir aussi 4.6.

5.9.2 PARTIE ACCESSIBLE

5.9.2.1 * Doigt d'essai

Les parties de l'APPAREIL EM qui doivent être considérées comme des PARTIES ACCESSIBLES sont identifiées par inspection et si cela est nécessaire par un essai. En cas de doute, l'accessibilité est déterminée par un essai avec le doigt d'essai normalisé représenté à la Figure 6 appliqué en position articulée ou rigide:

– pour toutes les positions de l'APPAREIL EM lorsqu'il fonctionne comme en UTILISATION NORMALE,

– même après ouverture des CAPOTS D'ACCES et retrait de parties, y compris les lampes, les fusibles et porte-fusibles sans l'utilisation d'un OUTIL ou selon les instructions d'utilisation.

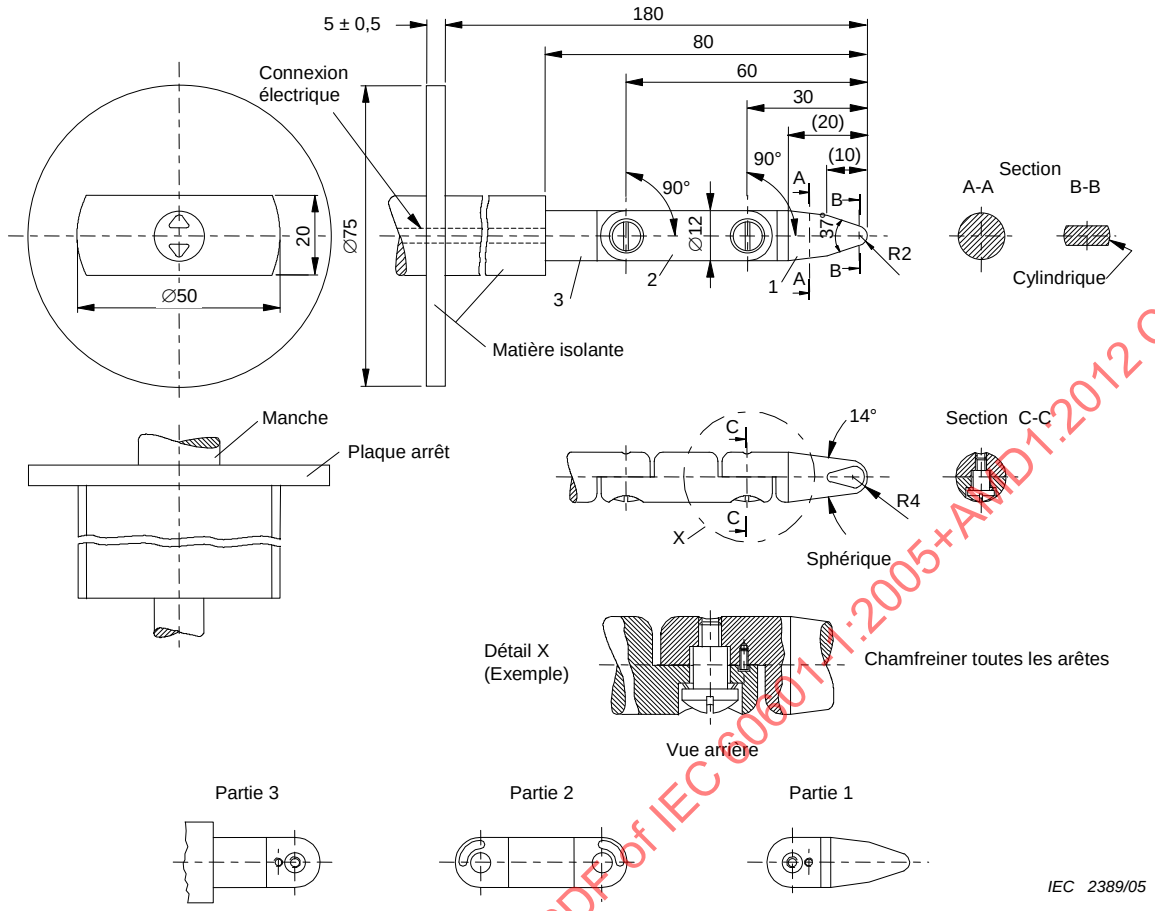
Le doigt d'essai normalisé est appliqué sans force appréciable dans chaque position possible, à l'exception des APPAREILS EM destinés à être utilisés sur le sol et dont la masse dépasse

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45 kg quelles que soient les conditions de fonctionnement, qui eux ne sont pas inclinés. Les APPAREILS EM qui, conformément à la description technique, sont destinés à être montés dans une armoire, sont soumis aux essais dans leur position de montage définitive.

Les ouvertures interdisant l'entrée du doigt d'essai normalisé de la Figure 6 sont soumises à l'essai mécanique avec un doigt d'essai rigide non articulé de mêmes dimensions, qui est appliqué avec une force de 30 N. Si ce doigt entre, l'essai avec le doigt d'essai normalisé de la Figure 6 est répété, le doigt étant poussé à travers l'ouverture si nécessaire.

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Dimensions linéaires en millimètres

Tolérances des dimensions sans tolérances spécifiques:

– angles de 14º et 37º: ±15´

– sur les rayons ± 0,1 mm

– sur les dimensions linéaires:

≤ 15 mm: $^{0}_{-0,1}$ mm

> 15 mm ≤ 25 mm: ± 0,1 mm

> 25 mm: ± 0,3 mm

Matériau du doigt : acier trempé à chaud par exemple.

Les deux articulations du doigt d'essai peuvent être pliées selon un angle de 90 $^{+10°}_{0°}$ mais dans une seule et même direction uniquement.

NOTE 1 L'utilisation de la solution pointe-rainure n'est qu'une des solutions possibles pour limiter l'angle de pliage à 90º. Pour cette raison, les dimensions et tolérances de ces détails ne sont pas indiquées sur le dessin. Il faut que la conception réelle assure un angle de pliage de 90º avec tolérance de 0º à +10º.

NOTE 2 Les dimensions entre parenthèses sont données à titre d'information seulement.

NOTE 3 Le doigt d'essai est pris de l'IEC 60950-1, Figure 2A. Ce doigt d'essai est basé sur l'IEC 61032[8)], Figure 2, calibre d'essai B. Dans certains cas, les tolérances sont différentes.

Figure 6 – Doigt d'essai normalisé (voir 5.9.2.1)

8) IEC 61032:1997, *Protection des personnes et des matériels par les enveloppes - Calibres d'essai pour la vérification*

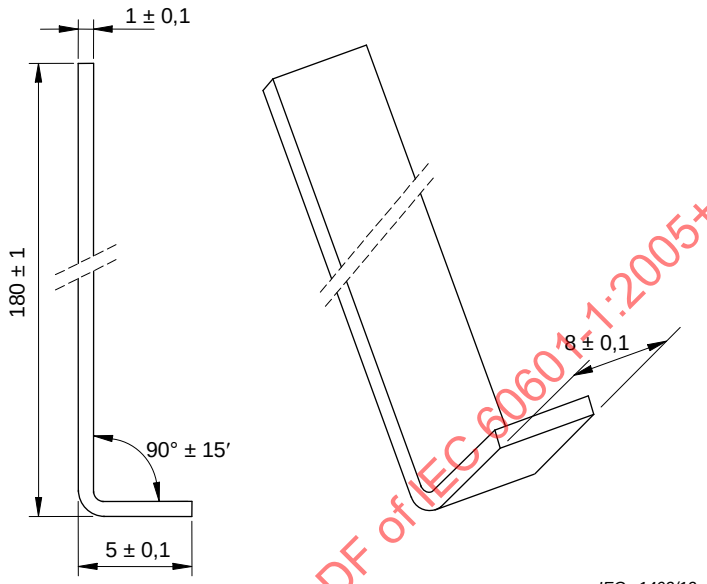
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5.9.2.2 Crochet d'essai

Les ouvertures des APPAREILS EM sont soumises à l'essai mécanique du crochet d'essai (voir Figure 7), si celui-ci peut être introduit.

Le crochet d'essai est introduit dans toutes les ouvertures concernées et il est ensuite tiré avec une force de 20 N pendant 10 s dans une direction sensiblement perpendiculaire à la surface comportant l'ouverture en cause. Toute partie complémentaire qui est devenue accessible est identifiée en utilisant le doigt d'essai normalisé de la Figure 6 et par inspection.

Dimensions en millimètres



Matériau: acier

Figure 7 – Crochet d'essai
(voir 5.9.2.2)

5.9.2.3 Mécanismes de manœuvre

Les parties conductrices des mécanismes de manœuvre des commandes électriques qui sont accessibles après enlèvement des poignées, des boutons, des leviers et pièces similaires sont considérées comme des PARTIES ASSESSIBLES. Les parties conductrices des mécanismes de manœuvre ne sont pas considérées comme des PARTIES ACCESSIBLES lorsque l'enlèvement des poignées, boutons, etc. nécessite l'utilisation d'un.

La conformité est vérifiée par des essais conformes à 5.9.2.1 et 15.4.6.1.

6 * Classification des APPAREILS EM ET DES SYSTEMES EM

6.1 Généralités

Pour les besoins de la présente norme, les APPAREILS EM ou les parties de ces appareils, y compris les PARTIES APPLIQUEES, doivent être classés comme suit.

6.2 * Protection contre les chocs électriques

Les APPAREILS EM alimentés par une source électrique externe doivent être classés APPAREILS EM DE LA CLASSE I ou APPAREILS EM DE LA CLASSE II (voir 7.2.6). Les autres APPAREILS EM doivent être classés comme APPAREILS EM A SOURCE ELECTRIQUE INTERNE.

Les APPAREILS EM A SOURCE ELECTRIQUE INTERNE ayant un moyen de raccordement au RESEAU D'ALIMENTATION doivent être conformes aux exigences pour les APPAREILS EM DE LA CLASSE I ou

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de la CLASSE II lorsqu'ils sont connectés, et aux exigences pour les APPAREILS EM à SOURCE ELECTRIQUE INTERNE lorsqu'ils ne sont pas connectés.

Les PARTIES APPLIQUEES doivent être classées comme PARTIES APPLIQUEES DE TYPE B comme PARTIES APPLIQUEES DE TYPE BF ou comme PARTIES APPLIQUEES DE TYPE CF (voir 7.2.10 et 8.3). Les PARTIES APPLIQUEES peuvent être classées comme PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION (voir 8.5.5).

6.3 * Protection contre les effets nuisibles de la pénétration d'eau ou de corps solides

Les ENVELOPPES doivent être classées en fonction du degré de protection contre les effets nuisibles de la pénétration d'eau et de corps solides comme détaillé dans l'IEC 60529 (voir 7.2.9 et 11.6.5).

NOTE 1 Cette classification est IPN_1N_2 où:

– N_1 est un nombre entier indiquant le degré de protection contre la pénétration de corps solides ou la lettre "X",

– N_2 est un nombre entier indiquant le degré de protection contre la pénétration d'eau ou la lettre "X".

NOTE 2 Voir aussi le Tableau D.3.

6.4 Méthode(s) de stérilisation

Les APPAREILS EM ou leurs parties qui sont destinés à être stérilisés doivent être classés selon la ou les méthodes de stérilisation indiquées dans les instructions d'utilisation (voir 7.9.2.12 et 11.6.7).

EXEMPLE 1 Au gaz d'oxyde d'éthylène.

EXEMPLE 2 Par rayonnement, comme le rayonnements gamma.

EXEMPLE 3 A la chaleur humide, comme avec un autoclave.

EXEMPLE 4 Par d'autres méthodes validées et décrites par le FABRICANT.

6.5 Adaptation à l'utilisation dans un ENVIRONNEMENT RICHE EN OXYGENE

Les APPAREILS EM et les SYSTEMES EM qui sont destinés à être utilisés dans un environnement riche en oxygène doivent être classés pour une telle utilisation (voir 11.2.2).

6.6 * Mode de fonctionnement

Les APPAREILS EM doivent être classés pour SERVICE CONTINU ou bien pour SERVICE NON CONTINU (voir 7.2.11).

7 Identification, marquage et documentation des APPAREILS EM

NOTE L'Annexe C contient un guide pour aider le lecteur à localiser les exigences de marquage et d'étiquetage concernant les APPAREILS et les SYSTEMES EM traités dans d'autres articles de la présente norme.

7.1 Généralités

7.1.1 * APTITUDE A L'UTILISATION de l'identification, du marquage et de la documentation

Voir 12.2.

7.1.2 * Lisibilité des marquages

Les marquages exigés par 7.2, 7.3, 7.4, 7.5 et 7.6 doivent être CLAIREMENT LISIBLES dans les conditions suivantes:

– pour les avertissements, les instructions, les signes de sécurité et les dessins situés sur l'extérieur de L'APPAREIL EM: à partir de l'emplacement prévu de la personne assurant la fonction associée;

– pour les APPAREILS EM INSTALLES A POSTE FIXE: lorsque L'APPAREIL EM est monté dans sa position d'UTILISATION NORMALE;

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– pour les APPAREILS EM TRANSPORTABLES et pour les APPAREILS EM FIXES qui ne sont pas des APPAREILS EM INSTALLES A POSTE FIXE: en UTILISATION NORMALE ou après avoir écarté L'APPAREIL EM d'un mur contre lequel il était placé ou après rotation de L'APPAREIL EM par rapport à sa position en UTILISATION NORMALE et, dans le cas d'éléments modulaires amovibles, après retrait de ces derniers de l'ensemble;

– pour les marquages à l'intérieur des APPAREILS EM ou des parties D'APPAREILS EM: lorsqu'ils sont vus à partir de l'emplacement prévu de la personne assurant la fonction associée.

La conformité de bonne lisibilité est vérifiée par l'essai suivant:

L'APPAREIL EM ou ses parties sont positionnés de sorte que la position de vue corresponde à la position prévue de l'OPERATEUR. Si la position prévue de l'OPERATEUR n'est pas spécifiée et si elle n'est pas claire, la position de vue se trouve en un point quelconque dans la base d'un cône sous-tendu par un angle de 30 ° par rapport à l'axe normal au centre du plan du marquage et à une distance de 1 m. L'éclairage ambiant est au niveau le moins favorable dans la plage comprise entre 100 lx et 1 500 lx.

L'observateur a une acuité visuelle, corrigée si nécessaire, de:

– *0 sur l'échelle d'Angle Minimal de Résolution (log MAR) ou de 6/6 (20/20); et*

– *est capable de lire le niveau N6 du test de Jaeger;*

dans des conditions d'éclairage normales (environ 500 lx).

L'observateur lit correctement le marquage depuis la position de vue.

7.1.3 * Résistance des marquages

Les marquages exigés par 7.2, 7.3, 7.4, 7.5 et 7.6 ne doivent pouvoir être retirés qu'avec un OUTIL ou avec une force appréciable et ils doivent être suffisamment durables pour rester CLAIREMENT LISIBLES pendant la DUREE DE VIE PREVUE de L'APPAREIL EM. Lors de l'examen de la durabilité des marquages, l'effet de l'UTILISATION NORMALE doit être pris en compte.

La conformité est vérifiée par inspection et par les essais suivants:

a) *Après réalisation de tous les essais de la présente norme (voir l'ordre recommandé des essais à l'Annexe B):*

– *les marquages sont soumis aux essais des exigences de 7.1.2; et*

– *les étiquettes adhésives ne doivent pas être décollées, ou avoir roulé aux angles.*

b) Pour les marquages exigés par 7.2, 7.3, 7.4, 7.5 et 7.6, un essai supplémentaire de durabilité doit être réalisé. Les marquages sont frottés à la main, sans pression excessive, d'abord pendant 15 s avec un chiffon imbibé d'eau distillée, puis pendant 15 s avec un chiffon imbibé éthanol à 96 % à brûler à la température ambiante et enfin pendant 15 s avec un chiffon imbibé d'alcool isopropylique.

7.2 Marquage sur l'extérieur des APPAREILS EM ou parties d'APPAREILS EM
(voir aussi Tableau C.1)

7.2.1 Exigences minimales pour le marquage sur les APPAREILS EM et sur les parties interchangeables

Si la taille de l'APPAREIL EM, d'une partie de l'APPAREIL EM ou d'un ACCESSOIRE D'APPAREIL EM ou la nature de son ENVELOPPE ne permet pas l'inscription de tous les marquages spécifiés de 7.2.2 à 7.2.20 (inclus), alors au minimum les marquages indiqués en 7.2.2, 7.2.5, 7.2.6 (à l'exception des APPAREILS EM INSTALLES DE FAÇON PERMANENTE), 7.2.10 et 7.2.13 (si applicable) doivent être apposés et les marquages restants doivent être mentionnés in extenso dans les DOCUMENTS D'ACCOMPAGNEMENT. Lorsque aucun marquage de L'APPAREIL EM

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n'est réalisable en pratique, il est admis que les marquages soient apposés sur l'emballage individuel.

Tout matériau, composant, ACCESSOIRE ou APPAREIL EM qui est destiné à un usage unique ou son emballage doit porter le marquage suivant "À usage unique", “Ne pas réutiliser” ou le symbole ISO 7000-1051 (2004-01) (voir Tableau D.1, symbole 28).

NOTE Voir aussi 7.9.2.12.

7.2.2 * Identification

L’APPAREIL EM doit porter les marquages suivants:

– le nom ou la marque de fabrique et des informations permettant de contacter le FABRICANT;

– une REFERENCE DE MODELE OU DE TYPE;

– un numéro de série ou un identifiant de lot; et

– la date de construction ou la date limite d’utilisation, le cas échéant.

NOTE Voir l’ISO 15223-1 pour les symboles du FABRICANT, du numéro de série, du lot de l’année de construction et de la date limite d’utilisation.

Le numéro de série, l’identifiant du lot et la date de construction peuvent être fournis sous forme de code lisible à l’œil humain ou par l’intermédiaire de technologies d’identification automatique telles que les codes barres ou la technologie RFID.

Les composants non fixés à demeure de l’APPAREIL EM doivent indiquer:

– le nom ou la marque de fabrique du FABRICANT; et

– une REFERENCE DE MODELE OU DE TYPE;

sauf si une mauvaise identification n’entraîne aucun RISQUE INACCEPTABLE.

Un logiciel faisant partie d'un SYSTEME ELECTROMEDICAL PROGRAMMABLE (SEMP) doit être identifié de manière unique, par exemple par le niveau de révision ou la date de parution/d'édition. L'identification doit être à la disposition des personnes désignées, par exemple le PERSONNEL D'ENTRETIEN. Il n'est pas nécessaire que l'identification soit apposée sur l'extérieur de L'APPAREIL EM.

7.2.3 * Consultation des DOCUMENTS D'ACCOMPAGNEMENT

Lorsque cela est approprié, le symbole ISO 7000-1641 (2004-01) (voir Tableau D.1, symbole 11) peut être utilisé pour engager L'OPERATEUR à consulter les DOCUMENTS D'ACCOMPAGNEMENT. Lorsque la consultation des DOCUMENTS D'ACCOMPAGNEMENT est une action obligatoire, le signe de sécurité ISO 7010-M002 (voir Tableau D.2, signe de sécurité 10) doit être utilisé à la place du symbole ISO 7000-1641.

7.2.4 * ACCESSOIRES

Les ACCESSOIRES doivent porter les marquages suivants:

– le nom ou la marque de fabrique et des informations permettant de contacter le FABRICANT;

– une REFERENCE DE MODELE OU DE TYPE;

– un numéro de série ou un identifiant de lot; et

– la date de construction ou la date limite d’utilisation, le cas échéant.

NOTE Voir l’ISO 15223-1 pour les symboles du FABRICANT, du numéro de série, du lot, de l’année de construction et de la date limite d’utilisation.

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Le numéro de série, l'identifiant du lot et la date de construction peuvent être fournis sous forme de code lisible à l'œil humain ou par l'intermédiaire de technologies d'identification automatique telles les codes barres ou la technologie RFID.

Lorsqu'aucun marquage des ACCESSOIRES n'est réalisable en pratique, il est admis que les marquages soient apposés sur l'emballage individuel.

7.2.5 APPAREILS EM destinés à être alimentés par d'autres appareils

Si l'APPAREIL EM est destiné à être alimenté par d'autres appareils électriques dans un SYSTEME EM et si la conformité avec les exigences de la présente norme dépend de ces autres appareils, un des éléments ci-dessous doit être fourni:

– le nom ou la marque du FABRICANT des autres appareils électriques ainsi qu'une REFERENCE DE MODELE OU DE TYPE des autres appareils spécifiés à proximité du point de connexion concerné;

– la mise en place d'un signe de sécurité ISO 7010-M002 (voir Tableau D.2, signe de sécurité 10) à proximité du point de connexion concerné et l'énumération des détails requis dans les instructions d'utilisation; ou

– l'utilisation d'un modèle spécial de connecteur, qui n'est pas couramment disponible sur le marché, et l'énumération des détails requis dans les instructions d'utilisation.

Voir aussi 7.9.2.3, 8.2.1 et 16.3.

7.2.6 Raccordement au RESEAU D'ALIMENTATION

Les APPAREILS EM doivent porter les marquages suivants:

– la ou les tensions d'alimentation ASSIGNEES ou la ou les plages de tensions ASSIGNEES auxquelles ils peuvent être reliés. Dans une plage de tensions d'alimentation ASSIGNEE, un trait d'union (-) doit séparer les tensions minimale et maximale. Lorsque plusieurs tensions d'alimentation ASSIGNEES ou plusieurs plages de tensions d'alimentation ASSIGNEES sont indiquées, elles doivent être séparées par une barre oblique (/) ;

  EXEMPLE 1 Plage de tensions d'alimentation ASSIGNEE 100-240 V. Cela signifie que l'APPAREIL EM est conçu pour être connecté à un RESEAU D'ALIMENTATION d'une tension NOMINALE comprise entre 100 V et 240 V.

  EXEMPLE 2 Tensions d'alimentation ASSIGNEES multiples: 120/220/240 V. Cela signifie que l'APPAREIL EM est conçu pour être commuté afin de permettre le raccordement à un RESEAU D'ALIMENTATION d'une tension NOMINALE de 120 V ou 220 V ou 240 V.

  NOTE 1 Le marquage de la tension ASSIGNEE d'alimentation est celui donné dans l'IEC 61293[9)].

– nature de l'alimentation, par exemple nombre de phases (sauf pour l'alimentation monophasée) et type de courant. Il est admis d'utiliser les symboles IEC 60417-5032, 5032-1, 5032-2, 5031 et 5033 (tous 2002-10) dans ce but (voir Tableau D.1, Symboles 1, 2, 3, 4 et 5);

  NOTE 2 Pour le courant alternatif, la fréquence ASSIGNEE en hertz est suffisante pour identifier le type de courant.

– la fréquence d'alimentation ASSIGNEE ou la plage de fréquences ASSIGNEE en hertz;

  EXEMPLE 3 Plage de fréquences d'alimentation ASSIGNEES: 50-60 Hz. Cela signifie que l'APPAREIL EM est conçu pour être raccordé à un RESEAU D'ALIMENTATION d'une fréquence NOMINALE comprise entre 50 Hz et 60 Hz.

– pour les APPAREILS EM DE LA CLASSE II, symbole IEC 60417-5172 (2003-02) (voir Tableau D.1, symbole 9).

Sauf pour les APPAREILS EM INSTALLES DE FAÇON PERMANENTE, ces marquages doivent apparaître sur l'extérieur de la partie qui contient la connexion au RESEAU D'ALIMENTATION et de préférence près du point de connexion. Pour les APPAREILS EM INSTALLES DE FAÇON PERMANENTE, la tension d'alimentation ou la plage de tensions NOMINALE à laquelle ils peuvent

9) IEC 61293: 1994, *Marquage des matériels électriques avec des caractéristiques assignées relatives à l'alimentation électrique – Prescriptions de sécurité*

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être connectés peut être marquée à l'intérieur ou à l'extérieur de l'APPAREIL EM, de préférence à proximité de la connexion au RESEAU D'ALIMENTATION.

7.2.7 Puissance absorbée du RESEAU D'ALIMENTATION

La puissance absorbée ASSIGNEE du RESEAU D'ALIMENTATION doit être marquée sur l'APPAREIL EM. La puissance absorbée ASSIGNEE doit être donnée en:

– ampères ou volt-ampères, ou

– si le facteur de puissance dépasse 0,9, en ampères, volt-ampères ou watts.

Pour les APPAREILS EM qui ont une ou plusieurs plages de tensions ASSIGNEES, la puissance absorbée ASSIGNEE doit toujours être donnée pour les limites supérieures et inférieures de ces plages, lorsque l'étendue de celles-ci est supérieure à ±10 % de la valeur moyenne de la plage considérée.

Si les limites de la plage ne s'écartent pas de plus de 10 % de la valeur moyenne, le marquage de la puissance absorbée à la valeur moyenne de la plage est suffisant.

Si les caractéristiques d'un APPAREIL EM comprennent à la fois des niveaux permanents et des niveaux instantanés de courant et de volt-ampère, le marquage doit comporter à la fois le niveau de volt-ampère permanent et le niveau le plus approprié de puissance instantanée, chacun de ces niveaux étant distinctement identifié et indiqué dans les DOCUMENTS D'ACCOMPAGNEMENT.

La puissance absorbée marquée D'UN APPAREIL EM muni de sorties destinées au branchement de conducteurs d'alimentation d'autres appareils électriques doit comprendre la puissance de sortie ASSIGNEE (et marquée) de ces sorties.

7.2.8 Connecteurs de sortie

7.2.8.1 Sortie de puissance réseau

Pour les SOCLES DE PRISES MULTIPLES qui sont intégrés aux APPAREILS EM, voir 16.9.2.1 b).

7.2.8.2 Autres sources de puissance

A l'exception des SOCLES DE PRISES MULTIPLES ou des connecteurs destinés uniquement aux appareils, parties d'appareils ou ACCESSOIRES spécifiés, les connecteurs de sorties des APPAREILS EM destinés à fournir du courant doivent porter un marquage comportant les informations suivantes:

– tension de sortie ASSIGNEE;

– courant ou puissance ASSIGNES (si applicable);

– fréquence de sortie (si applicable).

7.2.9 Classification IP

Les APPAREILS EM ou les parties d'APPAREILS EM doivent être marqués avec un symbole, utilisant les lettres IP suivies par les désignations décrites dans l'IEC 60529, en fonction de la classification de 6.3 (voir Tableau D.3, Code 2).

Il n'est pas nécessaire que les APPAREILS EM classés IPX0 ou IP0X soient marqués comme tels.

7.2.10 * PARTIES APPLIQUEES

Cette exigence ne s'applique pas aux parties qui ont été identifiés conformément à 4.6.

Le degré de protection contre les chocs électriques selon 6.2 pour toutes les PARTIES APPLIQUEES doit être marqué avec le symbole pertinent, par exemple, PARTIES APPLIQUEES DE TYPE B, avec le symbole IEC 60417-5840 (2002-10), PARTIES APPLIQUEES DE TYPE BF, avec le symbole IEC 60417-5333 (2002-10) ou PARTIES APPLIQUEES DE TYPE CF avec le symbole IEC 60417-5335 (2002-10) (voir Tableau D.1, symboles 19, 20 et 21).

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Pour les PARTIES APPLIQUEES PROTEGEES CONTRE LES CHOCS DE DEFIBRILLATION, les symboles IEC 60417-5841, IEC 60417-5334 ou IEC 60417-5336 (tous 2002-10) doivent être utilisés selon celui qui est applicable (voir Tableau D.1, symboles 25, 26 et 27).

Le symbole pertinent doit être marqué à proximité ou sur le connecteur de la PARTIE APPLIQUEE, sauf:

– s'il n'y a pas un tel connecteur, auquel cas le marquage doit être placé sur la PARTIE APPLIQUEE ; ou
– si le connecteur est utilisé pour plus d'une PARTIE APPLIQUEE et si les différentes PARTIES APPLIQUEES ont des classifications différentes, auquel cas chaque PARTIE APPLIQUEE doit être marquée avec le symbole pertinent.

Pour assurer une bonne différentiation avec le symbole IEC 60417-5333, le symbole IEC 60417-5840 ne doit pas être appliqué de manière à donner l'impression d'être inscrit à l'intérieur d'un carré. (voir Tableau D.1, symboles 19 et 20).

Si la protection contre l'effet de décharge d'un défibrillateur cardiaque est partiellement dans le câble PATIENT, le signe de sécurité ISO 7010-W001 doit être placé à proximité du socle concerné (voir Tableau D.2, signe de sécurité 2). Les instructions d'utilisation doivent expliquer que la protection des APPAREILS EM contre les effets de la décharge d'un défibrillateur cardiaque dépend de l'utilisation des câbles appropriés.

7.2.11 Mode de fonctionnement

En l'absence de marquage, on présume que l'APPAREIL EM est adapté au SERVICE CONTINU. Pour les APPAREILS EM destinés au SERVICE NON CONTINU, le TAUX D'UTILISATION doit être indiqué en utilisant un marquage approprié donnant la durée maximale de fonctionnement et la durée minimale d'arrêt.

7.2.12 * Fusibles

Lorsque le porte-fusible est une PARTIE ACCESSIBLE, le type et les caractéristiques complètes du fusible (tension, intensité, vitesse de fonctionnement et pouvoir de coupure) doivent être marqués à proximité du porte-fusible.

7.2.13 Effets physiologiques (signes de sécurité et avertissements)

Les APPAREILS EM qui produisent des effets physiologiques qui ne sont pas manifestes pour l'OPERATEUR et qui peuvent entraîner des DOMMAGES au PATIENT ou à l'OPERATEUR doivent porter un signe de sécurité approprié (voir 7.5). Le signe de sécurité doit apparaître à un emplacement en vue, de manière à être CLAIREMENT LISIBLE en UTILISATION NORMALE après INSTALLATION CORRECTE de l'APPAREIL EM.

Les instructions d'utilisation doivent décrire la nature du DANGER et les précautions pour l'éviter ou en minimiser le RISQUE associé.

7.2.14 DISPOSITIFS DE RACCORDEMENT HAUTE TENSION

Les DISPOSITIFS DE RACCORDEMENT HAUTE TENSION sur l'extérieur des APPAREILS EM qui sont accessibles sans l'utilisation d'un OUTIL doivent être marqués avec le symbole IEC 60417-5036 (2002-10) (voir Tableau D.1, symbole 24).

NOTE Les DISTANCES DANS L'AIR et les LIGNES DE FUITE entre les contacts haute tension et le doigt d'essai standard sont soumises aux exigences de 8.9.

7.2.15 Conditions de refroidissement

Les exigences relatives aux dispositions de refroidissement pour les APPAREILS EM (par exemple, alimentation en eau et en air) doivent être indiquées par marquage.

7.2.16 Stabilité mécanique

Pour les exigences concernant les APPAREILS EM à stabilité limitée, voir 9.4.

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7.2.17 Emballage de protection

Si des mesures spéciales de manutention doivent être prises pendant le transport ou le stockage, l'emballage doit être marqué en conséquence (voir l'ISO 780).

Les conditions environnementales admissibles pour le transport et le stockage doivent être marquées sur l'extérieur de l'emballage (voir 7.9.3.1 et l'ISO 15223-1).

Si le déballage prématuré d'un APPAREIL EM ou des ses parties peut donner lieu à un RISQUE inacceptable, l'emballage doit porter un marquage avec le signe de sécurité approprié (voir 7.5).

EXEMPLE 1 APPAREILS EM sensibles à l'humidité.

EXEMPLE 2 APPAREILS EM contenant des substances et des matières dangereuses.

L'emballage des APPAREILS EM ou des ACCESSOIRES fournis stériles doit être marqué comme étant stérile et indiquer la méthode de stérilisation (voir l'ISO 15223-1).

7.2.18 Source de pression externe

A proximité de chaque connecteur d'entrée, l'APPAREIL EM doit être marqué avec:

– la pression d'alimentation maximale ASSIGNEE fournie par une source externe, et

– la vitesse d'écoulement ASSIGNEE, si nécessaire pour maintenir la SECURITE DE BASE ou les PERFORMANCES ESSENTIELLES.

7.2.19 BORNES DE TERRE FONCTIONNELLE

Une BORNE DE TERRE FONCTIONNELLE doit être marquée avec le symbole IEC 60417-5017 (2006-08) (voir Tableau D.1, symbole 7).

7.2.20 Moyens de protection amovibles

Si un APPAREIL EM a différentes applications qui exigent le retrait d'un moyen de protection pour utiliser une fonction particulière, ce moyen de protection doit porter un marquage indiquant la nécessité de sa remise en place lorsque la fonction concernée n'est plus nécessaire. Aucun marquage n'est exigé lorsqu'il existe un verrouillage.

La conformité avec les exigences de 7.2 est vérifiée par examen et par l'application des essais et des critères de 7.1.2 et 7.1.3.

7.2.21 * Masse de l'APPAREIL EM MOBILE

UN APPAREIL EM MOBILE doit porter un marquage indiquant sa masse et comprenant sa CHARGE DE FONCTIONNEMENT EN SECURITE en kilogrammes. Le marquage doit être réalisé de manière à s'appliquer de manière évidente à l'APPAREIL EM MOBILE dans son entier lorsqu'il est chargé à sa CHARGE DE FONCTIONNEMENT EN SECURITE, et est séparé et distinct de tout marquage relatif aux exigences applicables à la charge maximale des coffres, des tablettes ou des tiroirs.

7.3 Marquage à l'intérieur des APPAREILS EM ou parties d'APPAREILS EM (voir aussi Tableau C.2)

7.3.1 Eléments chauffants ou douilles

La puissance consommée maximale des éléments chauffants ou des douilles des lampes chauffantes doit être marquée à proximité du corps chauffant ou dans le corps chauffant lui-même.

Pour les éléments chauffants ou les douilles qui sont conçus pour être utilisés avec des lampes chauffantes qui ne peuvent être remplacées que par le PERSONNEL D'ENTRETIEN avec utilisation d'un OUTIL, un marquage d'identification se référant à une information indiquée dans les DOCUMENTS D'ACCOMPAGNEMENT est suffisant.

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7.3.2 * Parties à HAUTE TENSION

La présence de parties à HAUTE TENSION doit être marquée avec le symbole IEC 60417-5036 (2002-10) (voir Tableau D.1, symbole 24) ou avec le signe de sécurité 3 (voir Tableau D.2, signe de sécurité 3). Voir aussi 7.5.

7.3.3 Batteries d'accumulateurs

Le type de batterie d'accumulateurs et le mode de montage (si applicable) doivent être indiqués (voir 15.4.3.2).

Pour les batteries d'accumulateurs qui sont prévues pour être remplacées uniquement par le PERSONNEL D'ENTRETIEN à l'aide d'un OUTIL, un marquage d'identification se référant à une information indiquée dans les DOCUMENTS D'ACCOMPAGNEMENT est suffisant.

Lorsque des batteries d'accumulateurs au lithium ou des piles à combustible sont incorporées et qu'un remplacement incorrect pourrait entraîner un RISQUE inacceptable, un avertissement indiquant que le remplacement par un personnel sans formation appropriée pourrait entraîner un DANGER (par exemple températures excessives, incendie, explosion) doit être donné en plus du marquage d'identification faisant référence aux informations contenues dans les DOCUMENTS D'ACCOMPAGNEMENT.

7.3.4 * Fusibles, COUPE-CIRCUIT THERMIQUES et DISJONCTEURS

Les fusibles et les COUPE-CIRCUIT THERMIQUES remplaçables et les DISJONCTEURS qui sont accessibles uniquement à l'aide d'un OUTIL doivent être identifiés soit par le type et les caractéristiques complètes placés près du composant (tension, intensité, vitesse de fonctionnement et pouvoir de coupure) soit par une référence à l'information donnée dans les DOCUMENTS D'ACCOMPAGNEMENT.

Les fusibles et les COUPE-CIRCUIT THERMIQUES remplaçables ainsi que les DISJONCTEURS qui sont accessibles uniquement à l'aide d'un OUTIL doivent être identifiés soit par une spécification (tension, courant, vitesse de fonctionnement, taille, pouvoir de coupure) située à proximité du composant, soit par une référence aux informations données dans les DOCUMENTS D'ACCOMPAGNEMENT.

La nomenclature de l'IEC 60127-1 peut être utilisée.

7.3.5 * BORNES DE TERRE DE PROTECTION

Les BORNES DE TERRE DE PROTECTION doivent être marquées avec le symbole IEC 60417-5019 (2006-08) (voir Tableau D.1, symbole 6) sauf si la BORNE DE TERRE DE PROTECTION se trouve dans un SOCLE DE CONNECTEUR conformément à l'IEC 60320-1.

Les marquages qui se trouvent sur ou à proximité des BORNES DE TERRE DE PROTECTION ne doivent pas être apposés sur des parties qui doivent être retirées pour réaliser la connexion. Ils doivent rester visibles à l'issue de la connexion.

7.3.6 BORNES DE TERRE FONCTIONNELLE

Les BORNES DE TERRE FONCTIONNELLE doivent être marquées avec le symbole IEC 60417-5017 (2006-08) (voir Tableau D.1, symbole 7).

7.3.7 Bornes d'alimentation

Les bornes pour les conducteurs d'alimentation doivent être marquées à proximité des bornes sauf s'il peut être démontré qu'aucun RISQUE inacceptable ne peut résulter d'une inversion lors du branchement.

Si l'APPAREIL EM est petit au point que les marquages de borne ne puissent être indiqués, ceux-ci doivent être inclus dans les DOCUMENTS D'ACCOMPAGNEMENT.

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Les bornes qui sont prévues exclusivement pour le raccordement du conducteur neutre dans un APPAREIL EM INSTALLE DE FAÇON PERMANENTE doivent être marquées avec le code approprié de l'IEC 60445 (voir Tableau D.3, Code 1).

Si le marquage pour raccordement à une alimentation triphasée est nécessaire, celui-ci doit être conforme à l'IEC 60445.

Les marquages qui sont situés sur ou à proximité des points de raccordement électrique ne doivent pas être apposés sur des parties devant être retirées pour réaliser le raccordement. Ils doivent rester visibles après réalisation du raccordement.

7.3.8 Température des bornes d'alimentation

Si un point quelconque à l'intérieur d'un boîtier ou d'un compartiment de raccordement des conducteurs d'alimentation pour APPAREILS EM INSTALLES DE FAÇON PERMANENTE (y compris ces conducteurs eux-mêmes) peut atteindre une température supérieure à 75 °C en UTILISATION NORMALE et en CONDITION NORMALE à la température ambiante de fonctionnement maximale indiquée dans la description technique (voir 7.9.3.1), alors l'APPAREIL EM doit être marqué comme suit ou avec une indication équivalente:

> "Pour le raccordement à l'alimentation, utiliser des câbles et conducteurs adaptés à une température d'au moins X °C".

où "X" est supérieur à la température maximale mesurée dans le boîtier ou dans le compartiment de raccordement en UTILISATION NORMALE et en CONDITION NORMALE.

Cette indication doit être placée sur ou à proximité du point où doit être réalisé le raccordement. Cette indication ne doit pas être apposée sur des parties qui doivent être retirées pour réaliser le raccordement. Elle doit être CLAIREMENT LISIBLE après la réalisation du raccordement.

La conformité avec les exigences de 7.3 est vérifiée par inspection et par l'application des essais et des critères de 7.1.2 et 7.1.3.

7.4 Marquage des organes de commande et des instruments (voir aussi Tableau C.3)

7.4.1 * Interrupteurs

Les positions "marche" et "arrêt" des interrupteurs utilisés pour commander l'alimentation des APPAREILS EM ou de leurs parties, y compris les interrupteurs réseau, doivent être indiquées comme suit:

– marquage avec les symboles IEC 60417-5007 (2002-10) et IEC 60417-5008 (2002-10) (voir Tableau D.1, symboles 12 et 13) ; ou

– par un voyant lumineux placé à proximité ; ou

– par tout autre moyen non ambigu.

Si un bouton poussoir à positions bistables est utilisé:

– il doit être marqué avec le symbole IEC 60417-5010 (2002-10) (voir Tableau D.1, symbole 14) ; et

– le statut doit être indiqué par un voyant lumineux placé à proximité ou par tout autre moyen non ambigu.

Si un bouton poussoir à position "marche" par action maintenue est utilisé:

– il doit être marqué avec le symbole IEC 60417-5011 (2002-10) (voir Tableau D.1, symbole 15) ; ou

– le statut doit être indiqué par un voyant lumineux placé à proximité ; ou

– le statut doit être indiqué par tout autre moyen non ambigu.

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7.4.2 * Dispositifs de commande

Les différentes positions des dispositifs de commande et des interrupteurs placés sur les APPAREILS EM doivent être indiquées par des chiffres, des lettres ou d'autres moyens visuels, par exemple par l'utilisation des symboles IEC 60417-5264 (2002-10) et IEC 60417-5265 (2002-10) (voir Tableau D.1, symboles 16 et 17).

Si en UTILISATION NORMALE la modification du réglage d'un organe de commande peut entraîner un RISQUE inacceptable pour le PATIENT, ces organes doivent être équipés:

– soit d'un dispositif indicateur associé, par exemple appareils de mesure ou échelle, soit

– d'une indication donnant le sens dans lequel la grandeur de la fonction varie. Voir aussi 15.4.6.2.

Un dispositif de commande ou un interrupteur qui amène l'APPAREIL EM dans l'état "d'attente" peut être indiqué au moyen du symbole IEC 60417-5009 (2002-10) (voir Tableau D.1, Symbole 29).

7.4.3 Unités de mesurage

Les indications numériques des paramètres des APPAREILS EM doivent être exprimées en unités du système SI conformément à l'ISO 80000-1 sauf pour les grandeurs de base données dans le Tableau 1, qui peuvent être exprimées dans les unités indiquées qui ne font pas partie du système SI.

Pour l'application des unités du SI, de leurs multiples et de certaines autres unités, c'est l'ISO 80000-1 qui s'applique.

La conformité avec les exigences de 7.4 est vérifiée par examen et par l'application des essais et des critères de 7.1.2 et 7.1.3.

Tableau 1 – Unités n'appartenant pas au système SI qui peuvent être utilisées sur les APPAREILS EM

Grandeur de base	Unité	
	Nom	Symbole
Angle plan	tour	r
	gon	gon ou grade
	degré	°
	minute d'angle	′
	seconde d'angle	″
Durée	minute	min
	heure	h
	jour	j
Energie	électron volt	eV
Volume	litre	l [a]
Pression des gaz du sang, du sang et d'autres fluides corporels:	millimètres de mercure	mmHg
	Centimètres d'eau	cmH_2O
Pression des gaz	bar	bar
	millibar	mbar

[a] Pour des raisons de cohérence, seul le symbole "l" est utilisé dans les normes internationales pour désigner le litre, bien que le symbole "L" soit également donné dans l'ISO 80000-1.

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7.5 Signes de sécurité

Pour les besoins de cet article, les marquages utilisés pour indiquer un avertissement, une interdiction ou une action obligatoire qui permettent de réduire un RISQUE qui n'est pas manifeste pour l'OPERATEUR doivent être des signes de sécurité tirés de l'ISO 7010. Si un signe de sécurité ayant une signification établie est utilisé de manière appropriée, l'utilisation du signe d'avertissement général ISO 7010:2003-W001 (voir Tableau D.2, signe de sécurité 2) n'est pas requise.

NOTE 1 Dans ce contexte, un avertissement est utilisé pour indiquer "il existe un certain danger" ; une interdiction est utilisée pour indiquer "Vous ne devez pas..." ; une action obligatoire est utilisée pour indiquer "Vous devez...".

En l'absence de signe de sécurité pour la signification particulière souhaitée, celle-ci peut être obtenue par l'une des méthodes suivantes.

a) En construisant un signe de sécurité conforme à l'ISO 3864-1:2002, Article 7 (pour les modèles correspondants, voir le Tableau D.2, signes de sécurité 1,4 et 8).

b) En utilisant le signe d'avertissement général ISO 7010:2003-W001(voir Tableau D.2, signe de sécurité 2) placé avec un symbole ou un texte supplémentaire. Le texte associé au signe d'avertissement général doit être une indication affirmative (c'est-à-dire une indication de sécurité) décrivant le ou les RISQUES principaux prévus (par exemple “Cause des brûlures”, “Risque d'explosion”, etc.).

c) En utilisant le signe d'interdiction général ISO 7010:2003-P001(voir Tableau D.2, signe de sécurité 4) placé avec un symbole ou un texte supplémentaire. Le texte associé au signe d'interdiction général doit être une indication (c'est-à-dire une indication de sécurité) décrivant ce qui est interdit (par exemple “Ne pas ouvrir”, “Ne pas laisser tomber”, etc.).

d) En utilisant le signe d'action obligatoire général ISO 7010:2003-M001(voir Tableau D.2, signe de sécurité 9) placé avec un symbole ou un texte supplémentaire. Le texte associé au signe d'action obligatoire général doit être une indication (c'est-à-dire une indication de sécurité) décrivant l'action exigée (par exemple “Porter des lunettes de protection”, “Frotter avant d'entrer”, etc.).

S'il n'y a pas assez d'espace pour placer l'indication affirmative avec le signe de sécurité sur L'APPAREIL EM, il est admis de la placer dans les instructions d'utilisation.

NOTE 2 Les couleurs utilisées pour les signes de sécurité sont spécifiées dans l'ISO 3864-1 et il est important d'utiliser la couleur spécifiée.

NOTE 3 Il convient qu'une indication de sécurité mentionne les précautions appropriées ou des instructions sur la manière de réduire le RISQUE (par exemple “Ne pas utiliser pour... ”, “Tenir à l'écart de...”, etc.).

Les signes de sécurité, y compris tout symbole ou texte supplémentaire, doivent faire l'objet d'une explication dans les instructions d'utilisation (voir 7.9.2).

Lorsqu'un texte complémentaire accompagne les signes de sécurité, le texte complémentaire doit être dans une langue compréhensible par l'OPERATEUR prévu.

NOTE 4 Dans certains pays, plusieurs langues sont requises.

La conformité est vérifiée par inspection.

7.6 Symboles

7.6.1 Explication des symboles

La signification des symboles utilisés pour le marquage doit être donnée dans les instructions d'utilisation.

7.6.2 Symboles de l'Annexe D

Les symboles exigés par la présente norme doivent être conformes aux exigences des publications IEC et ISO citées en référence. L'Annexe D donne les symboles graphiques accompagnés de leur description sous forme de référence rapide.

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7.6.3 Symboles pour les organes de commande et les performances

Les symboles utilisés pour les organes de commande et les performances doivent être conformes aux exigences de la publication ISO ou IEC dans laquelle le symbole est défini, lorsque cela est applicable. Voir aussi 7.2.13.

NOTE L'IEC 60878 [60] donne une liste des titres, des descriptions et des représentations graphiques des symboles pour les appareils électriques utilisés dans la pratique médicale.

La conformité aux exigences de 7.6 est vérifiée par inspection.

7.7 Couleurs de l'isolation des conducteurs

7.7.1 CONDUCTEUR DE TERRE DE PROTECTION

Un CONDUCTEUR DE TERRE DE PROTECTION doit être identifié sur toute sa longueur par une isolation de couleur vert-jaune.

7.7.2 CONNEXIONS DE TERRE PROTECTION

Toute isolation de conducteurs à l'intérieur d'APPAREILS EM qui forment des CONNEXIONS DE TERRE DE PROTECTION doit être identifiée par les couleurs verte et jaune au moins à l'extrémité des conducteurs.

EXEMPLE Les conducteurs d'un cordon multibrins qui sont connectés en parallèle, lorsque la résistance maximale autorisée des CONNEXIONS DE TERRE DE PROTECTION est dépassée si seul le conducteur vert et jaune était utilisé.

7.7.3 Isolation vert-jaune

L'identification par une isolation vert-jaune ne doit être utilisée que pour:

– les CONDUCTEURS DE TERRE DE PROTECTION (voir 8.6.2) ;

– les conducteurs spécifiés en 7.7.2 ;

NOTE Dans d'autres normes de sécurité telles que l'IEC 60950-1, des connexions internes entre des parties conductrices et la terre de protection principale sont appelées des conducteurs de liaison de protection.

– les CONDUCTEURS D'EGALISATION DES POTENTIELS (voir 8.6.7) ;

– les CONDUCTEURS DE TERRE FONCTIONNELLE (voir 8.6.9).

7.7.4 Conducteur neutre

Les conducteurs des CABLES D'ALIMENTATION destinés à être raccordés au conducteur neutre du système d'alimentation doivent être de couleur “bleu clair” comme spécifié dans la IEC 60227-1 ou l'IEC 60245-1.

7.7.5 Conducteurs de CABLES D'ALIMENTATION

Les couleurs des conducteurs dans les CABLES D'ALIMENTATION doivent être conformes à l'IEC 60227-1 ou à l'IEC 60245-1.

La conformité aux exigences de 7.7 est vérifiée par inspection.

7.8 * Voyants lumineux et organes de commande

7.8.1 Couleurs des voyants lumineux

Les couleurs des voyants lumineux et leur signification doivent être conformes au Tableau 2.

NOTE L'IEC 60601-1-8 contient des exigences spécifiques pour la couleur, la fréquence de clignotement et le TAUX D'UTILISATION des voyants lumineux d'alarme.

Les affichages par matrice et les affichages alphanumériques ne sont pas considérés comme des voyants lumineux.

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Tableau 2 – Couleurs des voyants lumineux et leur signification pour les APPAREILS EM

Couleur	Signification
Rouge	Avertissement – réponse immédiate de l'OPERATEUR exigée
Jaune	Prudence – réponse rapide de L'OPERATEUR exigée
Vert	Prêt à fonctionner
Toute autre couleur	Signification autre que rouge, jaune ou vert

7.8.2 Couleurs des organes de commande

La couleur rouge doit être utilisée exclusivement pour une commande interrompant une fonction en cas d'urgence.

La conformité aux exigences de 7.8 est vérifiée par inspection. Voir aussi 15.4.4.

7.9 DOCUMENTS D'ACCOMPAGNEMENT

7.9.1 * Généralités (voir aussi Tableau C.4)

LES APPAREILS EM doivent être accompagnés de documents comprenant au moins des instructions d'utilisation et une description technique. Les DOCUMENTS D'ACCOMPAGNEMENT doivent être considérés comme faisant partie des APPAREILS EM.

NOTE Le but des DOCUMENTS D'ACCOMPAGNEMENT est de promouvoir l'usage en toute sécurité des APPAREILS EM au cours de leur DUREE DE VIE PREVUE.

Les DOCUMENTS D'ACCOMPAGNEMENT doivent identifier les APPAREILS EM en incluant, lorsque applicable, les éléments suivants:

– le nom ou la marque de fabrique du FABRICANT, et une information de contact à laquelle l'ORGANISME RESPONSABLE peut s'adresser;

– la REFERENCE DU MODELE OU DU TYPE (voir 7.2.2).

Les DOCUMENTS D'ACCOMPAGNEMENT peuvent être fournis sur support électronique, par exemple fichier électronique sur CD-ROM. Si les DOCUMENTS D'ACCOMPAGNEMENT sont fournis sur support électronique, le PROCESSUS D'INGENIERIE D'APTITUDE A L'UTILISATION doit définir quelles informations doivent également être fournies sur papier ou sous forme de marquages sur les APPAREILS EM (voir 12.2).

EXEMPLE Informations pour couvrir un fonctionnement d'urgence.

NOTE Les DOCUMENTS D'ACCOMPAGNEMENT fournis sur support électronique pourraient ne pas être acceptables dans toutes les juridictions.

Les DOCUMENTS D'ACCOMPAGNEMENT doivent spécifier toute aptitude, formation et connaissances spéciales requises de l'OPERATEUR prévu ou de l'ORGANISME RESPONSABLE et toute restriction concernant les emplacements ou les environnements dans lesquels les APPAREILS EM peuvent être utilisés.

Les DOCUMENTS D'ACCOMPAGNEMENT doivent être rédigés pour un niveau correspondant au niveau scolaire, à la formation et à tout besoin spécifique de la ou des personnes auxquelles ils sont destinés.

La conformité est vérifiée par l'inspection des DOCUMENTS D'ACCOMPAGNEMENT, et, lorsqu'ils sont fournis sous forme électronique, comme spécifié dans l'IEC 60601-1-6.

7.9.2 Instructions d'utilisation (voir aussi Tableau C.5)

7.9.2.1 * Généralités

Les instructions d'utilisation doivent indiquer:

– l'utilisation de L'APPAREIL EM comme prévu par le FABRICANT;

– les fonctions utilisées fréquemment;

– toute(s) contre-indication(s) connue(s) liée(s) à l'utilisation de L'APPAREIL EM; et

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– les parties de l'APPAREIL EM qui ne doivent subir ni entretien ni maintenance lorsqu'elles sont utilisées avec un PATIENT.

Lorsque le PATIENT est un OPERATEUR prévu, les instructions d'utilisation doivent indiquer:

– que le PATIENT est un OPERATEUR prévu;

– un avertissement contre tout entretien et toute maintenance pendant que l'APPAREIL EM est en cours d'utilisation;

– quelles fonctions le PATIENT peut utiliser en toute sécurité et, le cas échéant, les fonctions que le PATIENT ne peut pas utiliser en toute sécurité; et

– quelle maintenance le PATIENT peut effectuer (changer les piles, par exemple).

NOTE 1 Pour un APPAREIL EM dont l'UTILISATION PREVUE inclut l'activation totale ou partielle de l'APPAREIL EM par le PATIENT, le PATIENT devient un OPERATEUR.

NOTE 2 Pour un APPAREIL EM pour lequel le PATIENT est autorisé à effectuer une maintenance restreinte, le PATIENT devient un PERSONNEL D'ENTRETIEN.

Les instructions d'utilisation doivent indiquer:

– le nom ou la marque de fabrique et l'adresse du FABRICANT;

– une REFERENCE DE MODELE OU DE TYPE.

Les instructions d'utilisation doivent inclure toutes les classifications applicables spécifiées à l'Article 6, tous les marquages spécifiés en 7.2 et l'explication des signes de sécurité et des symboles (figurant comme marquage sur L'APPAREIL EM).

NOTE 3 Les instructions d'utilisation sont destinées à L'OPERATEUR et à L'ORGANISME RESPONSABLE. et il convient qu'elles contiennent uniquement les informations les plus susceptibles d'être utiles à L'OPERATEUR et à L'ORGANISME RESPONSABLE. Des détails complémentaires peuvent être contenus dans la description technique. Voir aussi 7.9.3.

NOTE 4 Le guide pour la préparation des instructions d'utilisation se trouve dans l'IEC 62079 [25]. Un guide sur la préparation des supports de formation pour les APPAREILS EM se trouve dans le TR 61258 de l'IEC [24].

Les instructions d'utilisation doivent être dans une langue compréhensible par l'OPERATEUR prévu.

NOTE 5 Dans certains pays, plusieurs langues sont requises.

7.9.2.2 * Avertissement et consignes de sécurité

Les instructions d'utilisation doivent inclure tous les avertissements et toutes les consignes de sécurité.

NOTE Il convient que les avertissements et les consignes de sécurité d'ordre général soient placés dans une section spécialement identifiée des instructions d'utilisation. Il convient qu'un avertissement ou une consigne de sécurité qui s'applique uniquement à une instruction ou une action spécifique précède l'instruction à laquelle elle s'applique.

Pour les APPAREILS EM de la CLASSE I, un avertissement comme celui ci-après doit être inclus dans les instructions d'utilisation: "AVERTISSEMENT: Pour éviter tout risque de choc électrique, cet appareil doit être raccordé uniquement à un réseau d'alimentation équipé d'une terre de protection."

Les instructions d'utilisation doivent fournir à l'OPERATEUR ou à l'ORGANISME RESPONSABLE les avertissements concernant tout RISQUE significatif d'interférence réciproque se posant en présence de l'APPAREIL EM au cours d'examens ou de traitements spécifiques.

Les instructions d'utilisation doivent inclure des informations sur les interférences potentielles qu'elles soient d'origine électromagnétique ou autre entre L'APPAREIL EM et d'autres appareils avec des conseils sur la manière d'éviter ou de minimiser de telles interférences.

Si L'APPAREIL EM intègre un SOCLE A PRISES MULTIPLES, les instructions d'utilisation doivent contenir un avertissement indiquant que le fait de raccorder l'appareil électrique au SOCLE A PRISES MULTIPLES conduit effectivement à créer un SYSTEME EM et que cela peut entraîner un niveau réduit de sécurité. Pour les exigences qui sont applicables à un SYSTEME EM, L'ORGANISME RESPONSABLE doit être renvoyé à la présente norme.

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7.9.2.3 APPAREILS EM spécifiés pour être raccordés à une alimentation séparée

Si l'APPAREIL EM est destiné à être raccordé à une alimentation séparée, soit l'alimentation doit être spécifiée comme partie de l'APPAREIL EM soit la combinaison doit être spécifiée comme un SYSTEME EM. Les instructions d'utilisation doivent indiquer cette spécification.

7.9.2.4 Source d'alimentation électrique

Pour les APPAREILS EM alimentés par le réseau qui possèdent une source d'alimentation complémentaire qui n'est pas maintenue automatiquement en charge totale, les instructions d'utilisation doivent inclure un avertissement indiquant la nécessité de vérification ou de remplacement périodiques de ces sources complémentaires.

Si une fuite provenant d'une batterie peut entraîner un RISQUE inacceptable, les instructions d'utilisation doivent inclure un avertissement demandant de retirer la batterie si l'APPAREIL EM est susceptible de rester inutilisé pendant un certain temps.

Si une ALIMENTATION ELECTRIQUE INTERNE est remplaçable, les instructions d'utilisation doivent indiquer ses spécifications.

Si la perte de la source d'alimentation peut entraîner un RISQUE inacceptable, les instructions d'utilisation doivent contenir un avertissement indiquant que L'APPAREIL EM doit être raccordé à une source d'alimentation appropriée.

EXEMPLE Batteries d'accumulateurs internes ou externes, alimentations sans interruption (ASI) ou générateur de secours institutionnel.

7.9.2.5 Description de l'APPAREIL EM

Les instructions d'utilisation doivent inclure:

– une brève description de l'APPAREIL EM;

– la manière dont l'APPAREIL EM fonctionne ; et

– les caractéristiques physiques et de performances les plus importantes de l'APPAREIL EM.

Si cela est applicable, cette description doit inclure les positions attendues de l'OPERATEUR, du PATIENT et des autres personnes à proximité de l'APPAREIL EM en UTILISATION NORMALE (voir 9.2.2.3).

Les instructions d'utilisation doivent inclure des informations sur les matériaux ou les substances auxquels le PATIENT ou l'OPERATEUR est exposé si une telle exposition peut constituer un RISQUE inacceptable (voir 11.7).

Les instructions d'utilisation doivent spécifier toute restriction concernant un autre appareil ou des COUPLAGE DE RESEAUX / DONNEES, autres que ceux faisant partie d'un SYSTEME EM, auxquels une ENTREE/SORTIE DE SIGNAL peut être connectée.

Les instructions d'utilisation doivent indiquer toute PARTIE APPLIQUEE existante.

7.9.2.6 * Installation

Si l'installation de l'APPAREIL EM ou de ses parties est requise, les instructions d'utilisation doivent contenir:

– une référence de l'endroit où les instructions d'installation peuvent être trouvées (par exemple dans la description technique), ou

– des informations permettant de contacter les personnes désignées par le FABRICANT comme qualifiées pour réaliser l'installation.

7.9.2.7 * Isolation avec le RESEAU D'ALIMENTATION

Si un CONNECTEUR ou une FICHE RESEAU ou une autre fiche séparable est utilisé comme moyen d'isolation pour satisfaire à 8.11.1 a), les instructions d'utilisation doivent contenir une

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instruction demandant de ne pas positionner l'APPAREIL EM de telle manière qu'il soit difficile d'utiliser le dispositif de déconnexion.

7.9.2.8 PROCEDURE de démarrage

Les instructions d'utilisation doivent contenir les informations nécessaires, comprenant les éléments tels que les réglages de commande initiaux, le raccordement au PATIENT, ou le positionnement de celui-ci, etc., pour que l'OPERATEUR mette l'APPAREIL EM en fonctionnement.

Les instructions d'utilisation doivent détailler tout traitement ou toute manipulation nécessaire avant que l'APPAREIL EM, ses parties ou ACCESSOIRES puissent être utilisés.

EXEMPLE Une liste de contrôle avant utilisation.

7.9.2.9 Instructions de fonctionnement

Les instructions d'utilisation doivent contenir toutes les informations nécessaires au fonctionnement de l'APPAREIL EM conformément à sa spécification. Elles doivent comporter des explications concernant les fonctions des commandes, affichages et signaux, la séquence de fonctionnement, la connexion et la déconnexion des parties amovibles et des ACCESSOIRES, et le remplacement des matières qui sont consommées au cours de l'utilisation.

La signification des chiffres, des symboles, des avertissements, des abréviations et des voyants sur les APPAREILS EM doit être expliquée dans les instructions d'utilisation.

7.9.2.10 Messages

Les instructions d'utilisation doivent donner la liste de tous les messages système, messages d'erreur et messages de défaut qui sont générés, sauf si ces messages sont compréhensibles par eux-mêmes.

NOTE 1 Ces listes peuvent être identifiées par groupes.

La liste doit inclure une explication des messages y compris les causes importantes et l'action possible de L'OPERATEUR, le cas échéant, nécessaires pour apporter une solution à la situation révélée par le message.

NOTE 2 Les exigences et les lignes directrices concernant les messages générés par un système d'alarme sont données dans l'IEC 60601-1-8.

7.9.2.11 PROCEDURE d'arrêt

Les instructions d'utilisation doivent contenir les informations nécessaires à l'OPERATEUR pour arrêter en toute sécurité le fonctionnement de l'APPAREIL EM.

7.9.2.12 Nettoyage, désinfection et stérilisation

Pour les APPAREILS EM dont des parties ou des ACCESSOIRES peuvent être contaminés en UTILISATION NORMALE par contact avec le PATIENT, par des fluides corporels ou des gaz expirés, les instructions d'utilisation doivent contenir:

– des informations détaillées concernant le nettoyage et les méthodes de désinfection ou de stérilisation qu'il est admis d'utiliser; et

– la liste des paramètres applicables comme les limites de température, de pression, d'humidité, de temps et de nombre de cycles que de telles parties D'APPAREILS EM ou ACCESSOIRES peuvent tolérer.

Voir aussi 11.6.6 et 11.6.7.

Cette exigence ne s'applique pas aux matériaux, composants, ACCESSOIRES ou APPAREILS EM marqués comme étant à usage unique sauf si le FABRICANT spécifie que le matériau, le composant, L'ACCESSOIRE ou L'APPAREIL EM concerné doit être nettoyé, désinfecté ou stérilisé avant utilisation (voir 7.2.1).

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7.9.2.13 Maintenance

Les instructions d'utilisation doivent instruire de manière suffisamment détaillée L'OPERATEUR ou L'ORGANISME RESPONSABLE sur les opérations d'inspection préventive, de maintenance et d'étalonnage qu'ils doivent réaliser, y compris sur la fréquence d'une telle maintenance.

Les instructions d'utilisation doivent fournir des informations permettant la réalisation en toute sécurité d'une telle maintenance de routine qui est nécessaire pour assurer une utilisation continuelle en toute sécurité de l'APPAREIL EM.

De plus, les instructions d'utilisation doivent identifier les parties sur lesquelles une inspection et une maintenance préventives doivent être réalisées par le PERSONNEL D'ENTRETIEN, y compris les périodicités à appliquer, mais pas nécessairement avec les informations détaillées concernant la réalisation réelle de cette maintenance.

Dans le cas D'APPAREILS EM contenant des batteries rechargeables dont la maintenance incombe à toute personne n'appartenant pas au PERSONNEL D'ENTRETIEN, les instructions d'utilisation doivent contenir des instructions pour assurer une maintenance adéquate.

7.9.2.14 ACCESSOIRES, équipements supplémentaires, fournitures utilisées

Les instructions d'utilisation doivent inclure une liste des ACCESSOIRES, des pièces détachées et des fournitures dont le FABRICANT a déterminé qu'ils étaient destinés à être utilisés avec l'APPAREIL EM.

Si l'APPAREIL EM est prévu pour être alimenté par un autre appareil inclus dans un SYSTEME EM, les instructions d'utilisation doivent spécifier cet autre appareil de manière suffisante afin d'assurer la conformité avec les exigences de la présente norme (par exemple référence de pièce, tension ASSIGNEE, puissances maximale ou minimale, classe de protection, tâche intermittente ou continue).

NOTE Ce qui était désigné dans la première et dans la deuxième édition de cette norme comme une “alimentation spécifiée” est désormais considéré soit comme une autre partie du même APPAREIL EM soit comme un autre appareil dans un SYSTEME EM. De même, un chargeur de batterie est considéré soit comme une partie d'un APPAREIL EM soit comme un autre appareil dans un SYSTEME EM.

7.9.2.15 Protection de l'environnement

Les instructions d’utilisation doivent donner des avis sur l’évacuation appropriée des déchets, résidus, etc. et sur celle de l’APPAREIL EM et des ACCESSOIRES à la fin de leur DUREE DE VIE PREVUE.

7.9.2.16 Référence à la description technique

Les instructions d'utilisation doivent contenir les informations spécifiées en 7.9.3 ou une référence à l'endroit où les éléments spécifiés en 7.9.3 peuvent être trouvés (par exemple dans un manuel d'entretien).

7.9.2.17 APPAREIL EM émettant des rayonnements

Pour les APPAREILS EM émettant des rayonnements à des fins médicales, le cas échéant, les instructions d’utilisation doivent indiquer la nature, le type, l’intensité et la distribution de ces rayonnements.

7.9.2.18 APPAREIL EM et ACCESSOIRES fournis stériles

Les instructions d’utilisation pour les APPAREILS EM ou les ACCESSOIRES fournis stériles doivent indiquer qu’ils ont été stérilisés et donner la méthode de stérilisation.

Les instructions d’utilisation doivent donner les instructions nécessaires en cas de détérioration de l’emballage stérile et le cas échéant, détailler les méthodes de re-stérilisation appropriées (voir aussi 7.9.2.12).

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7.9.2.19 * Identifiant unique

Les instructions d'utilisation doivent contenir un identifiant unique, par exemple leur date de publication.

EXEMPLE Mois et année.

La conformité aux exigences de 7.9.2 est vérifiée par examen des instructions d'utilisation dans une langue d'un OPERATEUR prévu.

7.9.3 Description technique (voir aussi Tableau C.6)

7.9.3.1 * Généralités

La description technique doit fournir toutes les données qui sont essentielles à un fonctionnement, un transport et un stockage en toute sécurité ainsi que les mesures ou conditions nécessaires à l'installation d'un APPAREIL EM et à sa préparation pour son utilisation. Ces données doivent comprendre:

– les conditions environnementales d'utilisation admissibles y compris les conditions pour le transport et le stockage. Voir aussi 7.2.17;

– toutes les caractéristiques de l'APPAREIL EM, y compris la ou les plages de réglage, l'exactitude et la précision des valeurs affichées ou l'indication où l'on peut les trouver;

– toute exigence particulière d'installation comme l'impédance apparente maximale admissible du RESEAU D'ALIMENTATION;

NOTE 1 L'impédance apparente du RESEAU D'ALIMENTATION est la somme de l'impédance du réseau de distribution plus l'impédance de la source d'alimentation.

– si un liquide est utilisé pour le refroidissement, la plage admissible des valeurs de pression et de flux d'entrée ainsi que la composition chimique de ce liquide de refroidissement;

– une description des moyens d'isolation de l'APPAREIL EM, du RESEAU D'ALIMENTATION, si de tels moyens ne sont pas incorporés à l'APPAREIL EM (voir 8.11.1 b));

– le cas échéant, une description des moyens de vérification du niveau d'huile dans les APPAREILS EM ou leurs parties qui sont remplis d'huile et partiellement scellés (voir 15.4.9);

– un avertissement mettant en garde contre les DANGERS qui peuvent résulter d'une modification non autorisée de L'APPAREIL EM, par exemple un avertissement comme suit:

  - " AVERTISSEMENT: Modification de L'APPAREIL EM interdite."
  - " AVERTISSEMENT: Interdiction de modification de cet appareil sans l'autorisation du fabricant."
  - " AVERTISSEMENT: Si l'APPAREIL EM est modifié, un contrôle et un essai appropriés doivent être réalisés pour s'assurer que l'APPAREIL EM est toujours utilisable en toute sécurité."

– informations relatives aux PERFORMANCES ESSENTIELLES et à tout essai récurrent nécessaire concernant les PERFORMANCES ESSENTIELLES et la SECURITE DE BASE, y compris les détails des moyens, les méthodes et la fréquence recommandée.

NOTE 2 Ces informations sont directement dérivées des PERFORMANCES ESSENTIELLES identifiées par le FABRICANT en 4.3.

Si la description technique est séparable des instructions d'utilisation, elle doit contenir:

– toutes les classifications applicables spécifiées à l'Article 6, tout avertissement et toute consigne de sécurité ainsi que l'explication des signes de sécurité (marqués sur l'APPAREIL EM);

– une brève description de l'APPAREIL EM, de la manière dont l'APPAREIL EM fonctionne ainsi que ses caractéristiques physiques et de performances significatives; et

– un identifiant unique tel que la date de publication.

NOTE 3 La description technique est destinée à l'ORGANISME RESPONSABLE et au PERSONNEL D'ENTRETIEN.

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Le FABRICANT peut donner les qualifications minimales pour le PERSONNEL D'ENTRETIEN. Dans ce cas, ces exigences doivent être documentées dans la description technique.

NOTE 4 Certaines autorités de tutelle imposent des exigences supplémentaires pour la qualification du PERSONNEL D'ENTRETIEN.

7.9.3.2 Remplacement des fusibles, des CABLES D'ALIMENTATION et d'autres parties

La description technique doit contenir les éléments suivants, lorsque applicables:

– le type exigé et le calibre précis des fusibles utilisés dans le circuit d'alimentation externe d'un APPAREIL EM INSTALLE DE FAÇON PERMANENTE si le type et le calibre de ces fusibles ne se déduisent pas du courant ASSIGNE et du mode de fonctionnement de l'APPAREIL EM;

– une mention indiquant, pour les APPAREILS EM équipés d'un CABLE D'ALIMENTATION FIXE A DEMEURE, si le CABLE D'ALIMENTATION peut être ou non remplacé par le PERSONNEL D'ENTRETIEN, et, s'il peut l'être, les instructions pour un raccordement et une fixation corrects qui assurent que les exigences de 8.11.3 sont toujours satisfaites;

– des instructions pour le remplacement correct des parties interchangeables ou amovibles spécifiées par le FABRICANT comme remplaçables par le PERSONNEL D'ENTRETIEN; et

– lorsque le remplacement d'un composant pourrait engendrer un RISQUE inacceptable, des avertissements appropriés identifiant la nature du danger et, si le FABRICANT spécifie que le composant est remplacé par le PERSONNEL D'ENTRETIEN, toutes les informations nécessaires au remplacement en toute sécurité du composant concerné.

7.9.3.3 Schémas des circuits, listes de composants, etc.

La description technique doit comporter une mention indiquant que le FABRICANT met à disposition, sur demande, les schémas de circuits, les listes de composants, les descriptions, les consignes d'étalonnage ou toute autre information utile au PERSONNEL D'ENTRETIEN pour réparer les parties des APPAREILS EM que le FABRICANT a désignées comme réparables par le PERSONNEL D'ENTRETIEN.

7.9.3.4 * Interrupteur d'isolation réseau

La description technique doit identifier clairement tout dispositif utilisé pour être conforme aux exigences de 8.11.1.

La conformité aux exigences de 7.9.3 est vérifiée par inspection de la description technique.

8 * Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM

8.1 Règle fondamentale de protection contre les chocs électriques

Les limites spécifiées en 8.4 ne doivent pas être dépassées pour les PARTIES ACCESSIBLES, y compris les PARTIES APPLIQUEES, en CONDITION NORMALE ou en CONDITION DE PREMIER DEFAUT. Pour les autres SITUATIONS DANGEREUSES en CONDITION DE PREMIER DEFAUT, voir 13.1.

a) * La CONDITION NORMALE comprend simultanément toutes les situations suivantes:

– la présence de toute ENTREE/SORTIE DE SIGNAL quels que soient la tension et le courant provenant d'un autre appareil électrique qu'il est permis de raccorder d'après les DOCUMENTS D'ACCOMPAGNEMENT comme spécifié en 7.9 ou, si les DOCUMENTS D'ACCOMPAGNEMENT ne prévoient aucune restriction concernant un tel autre appareil électrique, la présence de la TENSION RESEAU MAXIMALE telle qu'elle est spécifiée en 8.5.3;

– la transposition des connexions d'alimentation, pour APPAREIL EM destinées à être raccordées au RESEAU D'ALIMENTATION au moyen d'une FICHE RESEAU ;

– le court-circuit de toute ou partie de l'isolation qui n'est pas conforme aux exigences de 8.8;

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– le court-circuit d'une ou de toutes les LIGNES DE FUITE ou DISTANCES DANS L'AIR qui ne sont pas conformes aux exigences de 8.9;

– la rupture d'une ou de toutes les liaisons à la terre qui ne sont pas conformes aux exigences de 8.6, y compris la liaison de terre fonctionnelle.

b) * Les CONDITIONS DE PREMIER DEFAUT comprennent:

– le court-circuit de toute isolation qui est conforme aux exigences pour un MOYEN DE PROTECTION comme spécifié en 8.8;

NOTE Cela comprend le court-circuit de tout élément constituant d'une DOUBLE ISOLATION conforme à 8.8.

– le court-circuit de toute LIGNE DE FUITE ou de toute DISTANCE DANS L'AIR qui est conforme aux exigences pour un MOYEN DE PROTECTION comme spécifié en 8.9;

– le court-circuit et l'ouverture du circuit de tout composant, autre qu'un COMPOSANT AUX CARACTERISTIQUES A HAUTE FIABILITE, connecté en parallèle avec l'isolation avec une DISTANCE DANS L'AIR ou avec une LIGNE DE FUITE à moins qu'il puisse être montré que le court-circuit n'est pas un mode de défaillance pour le composant (voir aussi 4.8 et 4.9);

– la rupture de tout CONDUCTEUR DE TERRE DE PROTECTION ou de toute CONNEXION DE TERRE DE PROTECTION qui est conforme aux exigences de 8.6: cela ne s'applique pas au CONDUCTEUR DE TERRE DE PROTECTION des APPAREILS EM INSTALLES DE FAÇON PERMANENTE, considéré comme peu susceptible d'être déconnecté;

– l'interruption de tout conducteur d'alimentation, à l'exception du conducteur neutre d'un APPAREIL EM polyphasé ou INSTALLE DE FAÇON PERMANENTE;

– l'interruption de tout conducteur d'alimentation entre des parties de l'APPAREIL EM situées dans des ENVELOPPES séparées, si cette condition peut causer le dépassement des limites autorisées;

– le mouvement non désiré d'un composant (voir 8.10.1);

– le détachement accidentel de conducteurs et de connecteurs lorsqu'il pourrait donner lieu à une SITUATION DANGEREUSE. Voir aussi 8.10.2.

La détermination des PARTIES ACCESSIBLES est réalisée conformément à 5.9.

Les COURANTS DE FUITE sont mesurés conformément à 8.7.

8.2 Exigences liées aux sources d'énergie électrique

8.2.1 Connexion à une source électrique séparée

Si l'APPAREIL EM est spécifié pour être connecté à une source électrique séparée, autre que le RESEAU, soit la source électrique séparée doit être considérée comme une partie de l'APPAREIL EM et toutes les exigences de la présente norme doivent s'appliquer, soit la combinaison doit être considérée comme un SYSTEME EM. Voir aussi 7.2.5, 7.9.2.14, 5.5 f) et l'Article 16.

NOTE Ce qui était désigné dans la première et dans la deuxième édition de la présente norme comme une "alimentation spécifiée" est désormais considéré soit comme une autre partie du même APPAREIL EM soit comme un autre appareil dans un SYSTEME EM.

La conformité est vérifiée par inspection et par les essais spécifiés en 5.5 f). Si une alimentation séparée spécifique est indiquée, les essais applicables sont réalisés, l'APPAREIL EM étant connecté à celle-ci. Si une alimentation séparée générique est indiquée, la spécification dans les DOCUMENTS D'ACCOMPAGNEMENT fait l'objet d'un examen.

8.2.2 Connexion à une source externe en courant continu

Si l'APPAREIL EM est spécifié comme étant alimenté par une source externe en courant continu, alors une connexion sur la mauvaise polarité ne doit pas conduire aux SITUATIONS DANGEREUSES décrites en 13.1. L'APPAREIL EM, lorsque la connexion est ensuite effectuée sur la bonne polarité, doit maintenir la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES.

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Les dispositifs de protection qui peuvent être remis en service par quiconque sans utiliser un OUTIL sont acceptables, si l'APPAREIL EM retourne à la CONDITION NORMALE à la remise en service.

NOTE 1 Voir aussi 11.8.

NOTE 2 La source externe en courant continu peut être constituée par un RESEAU D'ALIMENTATION ou par un autre élément d'appareil électrique. Dans ce dernier cas, la combinaison est considérée comme étant un SYSTEME EM tel que spécifié en 8.2.1.

8.3 Classification des PARTIES APPLIQUEES

a) * Une PARTIE APPLIQUEE qui est spécifiée dans les DOCUMENTS D'ACCOMPAGNEMENT comme adaptée à une application cardiaque directe doit être une PARTIE APPLIQUEE DE TYPE CF.

NOTE Voir les justifications pour la définition de l'APPLICATION CARDIAQUE DIRECTE (3.22) concernant les PARTIES APPLIQUEES qui doivent être des PARTIES APPLIQUEES DE TYPE CF. D'autres restrictions peuvent exister pour les applications cardiaques.

La conformité est vérifiée par inspection.

b) * Une PARTIE APPLIQUEE qui comprend une CONNEXION PATIENT destinée à fournir de l'énergie électrique ou un signal électrophysiologique vers ou provenant du PATIENT doit être une PARTIE APPLIQUEE DE TYPE BF ou une PARTIE APPLIQUEE DE TYPE CF.

La vérification est effectuée par inspection.

c) Une PARTIE APPLIQUEE qui n'est pas couverte par a) ou b) doit être une PARTIE APPLIQUEE DE TYPE B , une PARTIE APPLIQUEE DE TYPE BF ou une PARTIE APPLIQUEE DE TYPE CF.

La conformité est vérifiée par inspection.

8.4 Limitation de la tension, du courant ou de l'énergie

8.4.1 * CONNEXIONS PATIENT destinées à fournir du courant

Les limites spécifiées en 8.4.2 ne s'appliquent pas aux courants qui sont destinés à traverser le corps du PATIENT pour produire un effet physiologique en UTILISATION NORMALE.

8.4.2 PARTIES ACCESSIBLES et PARTIES APPLIQUEES

a) Les courants en provenance, vers ou entre des CONNEXIONS PATIENT ne doivent pas dépasser les limites du COURANT DE FUITE PATIENT et du COURANT AUXILIAIRE PATIENT spécifiées au Tableau 3 et au Tableau 4 lorsqu'ils sont mesurés comme spécifié en 8.7.4.

La conformité est vérifiée par des mesures selon 8.7.4.

b) * Les COURANTS DE FUITE en provenance, vers ou entre des PARTIES ACCESSIBLES ne doivent pas dépasser les limites pour le COURANT DE CONTACT spécifiées en 8.7.3 c) lorsqu'ils sont mesurés comme spécifié en 8.7.4.

La conformité est vérifiée par des mesures selon 8.7.4.

c) * Les limites spécifiées en b) ci-dessus ne s'appliquent pas aux parties suivantes si la probabilité d'une connexion vers le PATIENT, soit directement soit par l'intermédiaire du corps de l'OPERATEUR, au travers duquel un courant dépassant le COURANT DE CONTACT admissible pourrait s'écouler, est négligeable en UTILISATION NORMALE, et que les instructions d'utilisation indiquent à l'OPERATEUR de ne pas toucher la partie correspondante et le PATIENT simultanément:

- contacts accessibles des connecteurs;
- contacts des portes fusibles qui sont accessibles au cours du remplacement du fusible;
- contacts des douilles qui sont accessibles après enlèvement de la lampe;
- parties sous un CAPOT D'ACCES qui peut être ouvert sans l'utilisation d'un OUTIL, ou lorsqu'un OUTIL est nécessaire mais que les instructions d'utilisation indiquent à tout OPERATEUR qui ne fait pas partie du PERSONNEL D'ENTRETIEN comment ouvrir le CAPOT D'ACCES.

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EXEMPLE 1 Boutons poussoirs lumineux.

EXEMPLE 2 Voyants lumineux.

EXEMPLE 3 Plumes d'enregistreur.

EXEMPLE 4 Parties de modules enfichables.

EXEMPLE 5 Batteries d'accumulateurs.

Pour de telles parties, la tension par rapport à la terre ou par rapport à d'autres PARTIES ACCESSIBLES ne doit pas dépasser 42,4 V en valeur de crête en courant alternatif ou 60 V en courant continu en CONDITION NORMALE ou en CONDITION DE PREMIER DEFAUT. La limite de 60 V en courant continu s'applique à un courant continu avec 10 % d'ondulation crête à crête au maximum. Si l'ondulation dépasse cette grandeur, la limite de 42,4 V de crête s'applique. L'énergie ne doit pas dépasser 240 VA pendant plus de 60 s ou l'énergie stockée disponible ne doit pas dépasser 20 J à une valeur de potentiel de 2 V ou plus.

NOTE En présence de tensions supérieures aux limites spécifiées en 8.4.2 c), les limites du COURANT DE FUITE données en 8.4.2 b) s'appliquent.

La conformité est vérifiée par l'inspection des instructions d'utilisation et par des mesures.

d) * Les limites de tension et d'énergie spécifiées en c) ci-dessus s'appliquent également:

– aux parties internes, autres que les contacts des fiches, des connecteurs et des socles qui peuvent être touchés par la broche d'essai représentée à la Figure 8, insérée par une ouverture dans une ENVELOPPE ; et

– aux parties internes qui peuvent être touchées par une tige d'essai métallique d'un diamètre de $4\ ^{0}_{-0,05}$ mm et d'une longueur de $100\ ^{+0,5}_{0}$ mm, insérée à travers une ouverture au sommet d'une ENVELOPPE ou à travers une ouverture prévue pour l'ajustement de commandes préréglées qui peuvent être ajustées par l'ORGANISME RESPONSABLE en UTILISATION NORMALE en utilisant un OUTIL.

Voir aussi 8.9.4 pour la mesure des LIGNES DE FUITE et des DISTANCES DANS L'AIR à travers les fentes ou les ouvertures dans les parties externes par rapport au doigt d'essai normalisé.

La conformité est vérifiée en insérant la broche d'essai ou la tige d'essai dans les ouvertures correspondantes. La broche d'essai est insérée dans chaque position possible avec une force minimale (1 N maximum).

La tige d'essai est insérée dans chaque position possible dans les ouvertures prévues pour l'ajustement des commandes préréglées qui peuvent être ajustées par l'ORGANISME RESPONSABLE en UTILISATION NORMALE, en cas de doute avec une force de 10 N.

Si les instructions d'utilisation spécifient qu'un OUTIL particulier doit être utilisé, l'essai est répété avec cet OUTIL.

La tige d'essai est également suspendue librement et verticalement à travers toute ouverture au sommet de l'ENVELOPPE.

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