IEC 60601-2-40

Edition 3.0 2024-12
REDLINE VERSION

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Medical electrical equipment –
Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment

Appareils électromédicaux –
Partie 2-40: Exigences particulières pour la sécurité de base et les performances essentielles des électromyographes et des appareils à potentiel évoqué

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Appareils électromédicaux – Partie 2-40: Exigences particulières pour la sécurité de base et les performances essentielles des électromyographes et des appareils à potentiel évoqué

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment

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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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at https://patents.iec.ch. IEC shall not be held responsible for identifying any or all such patent rights.

This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition IEC 60601-2-40:2016. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

IEC 60601-2-40 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This third edition cancels and replaces the second edition published in 2016. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) added requirements for constant voltage stimulators;

b) clarified requirements for VISUAL STIMULATORS.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62D/2168/FDIS	62D/2191/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, the following print types are used:

– requirements and definitions: roman type.

– *test specifications: 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 DEFINED IN CLAUSE 3 OF IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, AND IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

– "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 AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

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

INTRODUCTION

This document concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROMYOGRAPHS and EVOKED RESPONSE EQUIPMENT. It amends and supplements IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* (IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020).

The aim of this revision is to bring this document up to date with reference to ~~the latest edition of the general standard~~ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020.

The requirements of this document take priority over those of IEC 60601-1.

A "General guidance and rationale" for the more important requirements of this document is included in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the document but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, Annex AA does not form part of the requirements of this document.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment

201.1 Scope, object and related standards

Clause 1 of ~~the general standard~~[1] IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.1.1 Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROMYOGRAPHS and EVOKED RESPONSE EQUIPMENT, hereafter referred to as ME EQUIPMENT.

NOTE 1 Myofeedback equipment, where the capturing of muscle contraction is based on electromyography, is within the scope of this document.

NOTE 2 ELECTROMYOGRAPHS and EVOKED RESPONSE EQUIPMENT is intended for diagnostic and monitoring applications.

NOTE 3 If the ME EQUIPMENT supports both ELECTROMYOGRAPHY and EVOKED RESPONSE STIMULATION, clauses for electrical, auditory, and visual stimulators are applicable. In case the equipment supports ELECTROMYOGRAPHY, but not EVOKED RESPONSE STIMULATION, clauses concerning solely requirements for stimulators are NOT within the scope of this document.

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.

The following ME EQUIPMENT are excluded:

- ME EQUIPMENT intended for therapeutic application;
- ME EQUIPMENT intended for transcutaneous electrical nerve stimulators and electrical muscle stimulators (ME EQUIPMENT covered by IEC 60601-2-10).

201.1.2 Object

Replacement:

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ELECTROMYOGRAPHS and EVOKED RESPONSE EQUIPMENT [as defined in 201.3.201 and 201.3.202.]

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[1] ~~The general standard is IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*~~

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and Clause 201.2 of this document.

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply as modified in Clause 202. IEC 60601-1-3, IEC 60601-1-8 and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

~~For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.~~

The numbering of clauses and subclauses of this document corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is replaced completely by the text of this document.

"*Addition*" means that the text of this document is additional to the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"*Amendment*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.~~147~~154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, for example 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, any applicable collateral standards and this document taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

NOTE Informative references are listed in the bibliography.

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*
IEC 60601-1-2:2014/AMD1:2020

IEC 60318 (all parts), *Electroacoustics – Simulators of human head and ear*

ISO 15004-2, *Ophthalmic instruments – Fundamental requirements and test methods – Part 2: Light hazard protection*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 apply, except as follows:

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp

NOTE An index of defined terms is found beginning on page 30.

Additional terms and definitions:

201.3.201
ELECTROMYOGRAPH
ME EQUIPMENT for the detection or recording of biopotentials accompanying nerve and muscle action, either spontaneously, intentionally or evoked by electrical or other stimulation

201.3.202
EVOKED RESPONSE EQUIPMENT
ME EQUIPMENT for the detection or recording of biopotentials resulting from an evoking stimulus

Note 1 to entry: The stimulus ~~may~~ can be electrical, tactile, auditory, visual, olfactory, etc.

201.3.203
ELECTRICAL STIMULATOR
part of ~~ELECTROMYOGRAPHS and EVOKED RESPONSE~~ ME EQUIPMENT for the application of electric currents via ELECTRODES in direct contact with the PATIENT, for the evoking of biopotentials

201.3.204
PULSE DURATION
duration of the electrical stimulus pulse WAVEFORM at 50 % of the peak amplitude

201.3.205
WAVEFORM
variations in magnitude of an electrical stimulus output (either voltage or current) as a function of time appearing in the APPLIED PART(S) of the ELECTRICAL STIMULATOR or the collected biopotentials by the BIOPOTENTIALS INPUT PART

201.3.206
AUDITORY STIMULATOR
part of ~~ELECTROMYOGRAPHS and EVOKED RESPONSE~~ ME EQUIPMENT for the application of sound pressure from a transducer (headphone, bone conductor or free-field) to the ear(s) of the PATIENT, for the evoking of biopotentials

201.3.207
VISUAL STIMULATOR
part of ~~ELECTROMYOGRAPHS and EVOKED RESPONSE~~ ME EQUIPMENT for the application of pulsed electromagnetic radiation in the visible spectrum from a transducer to the eyes of the PATIENT, for the evoking of biopotentials

201.3.208
BIOPOTENTIAL INPUT PART
APPLIED PART(S) of ELECTROMYOGRAPHS and EVOKED RESPONSE EQUIPMENT for the collection of biopotentials

201.3.209
ELECTRODE
conductive portion that is applied to the PATIENT to detect electrical activity ~~and/~~or to apply the stimulus from the ELECTRICAL STIMULATOR to the PATIENT

201.3.210
PATIENT LEAD
cable connected between an ELECTRODE and either a PATIENT CABLE or the ME EQUIPMENT

201.3.211
PATIENT CABLE
multiwire cable used to connect PATIENT LEADS to ME EQUIPMENT

201.4 General requirements

Clause 4 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.4.2 *RISK MANAGEMENT PROCESS for ME EQUIPMENT ~~and~~ or ME SYSTEMS

Addition:

MANUFACTURERS shall include, within their RISK MANAGEMENT FILE, the RISK associated with the potential use of their STIMULATORS and accessories to deliver current exceeding 10 mA RMS or current densities for any ELECTRODE exceeding 2 mA/cm^2.

201.4.3 ESSENTIAL PERFORMANCE

Addition:

~~NOTE~~ Because of the variety of clinical applications for ELECTROMYOGRAPHS and EVOKED RESPONSE, no additional ESSENTIAL PERFORMANCE is specified in this document. However, ESSENTIAL PERFORMANCE ~~shall be~~ is determined by the manufacturer in accordance with the requirements of 4.3 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

201.4.11 Power input

Replacement:

The power input is measured with a load resistance of the lowest value specified in the technical description (see 201.7.9.3.101 a)), and with any output controls set to result in maximum power input.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows.

201.5.4 Other conditions

Addition:

Where values of voltage and current are used in this document, they mean the RMS values of an alternating, direct or composite voltage or current averaged over 1 s unless stated otherwise.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.6.2 * Protection against electric shock

Amendment:

Delete TYPE B APPLIED PART.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.3 * Consult ACCOMPANYING DOCUMENTS

Replacement:

Safety sign ISO 7010-M002 shall be used (see Table D.2, safety sign 10 in Annex D of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020).

201.7.2.7 Electrical input power from the SUPPLY MAINS

Replacement:

The RATED power input of MAINS operated ME EQUIPMENT shall be the maximum power input averaged over any period of 5 s under the specified operating conditions set out by the manufacturer.

201.7.2.8 Output connectors

201.7.2.8.2 Other power sources

Addition:

See also 201.12.4.102.

201.7.2.13 * Physiological effects (SAFETY SIGNS and warning statements)

Addition:

ME EQUIPMENT capable of delivering electrical stimulus outputs into a load resistance of 1 000 Ω in excess of 10 mA RMS or 10 V RMS averaged over any period of 5 s shall be marked near the ELECTRODE connections with the safety sign ISO 7010-M002 (see safety sign 10 in Table D.2 of Annex D of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020).

201.7.4 Marking of controls and instruments

201.7.4.2 * Control devices

Replacement:

~~An output control for the ELECTRICAL STIMULATOR shall be incorporated which will control the ELECTRICAL STIMULATOR output from minimum to maximum of the range continuously, or in discrete increments of not more than 1 mA peak amplitude or 5 V peak amplitude per increment. At its minimum setting, the output shall not exceed 2 % of that available at the maximum setting of the control.~~

~~The type of stimulator output, constant voltage and/or constant current shall be described and specified in the ACCOMPANYING DOCUMENTS. *Compliance is checked by inspection and measurement, using the load impedance which is the least favourable within the range specified in the ACCOMPANYING DOCUMENTS.*~~

~~*Or, as an alternate method of compliance, the following may be chosen:*~~

~~An output control for the ELECTRICAL STIMULATOR shall be incorporated which will control the ELECTRICAL STIMULATOR output from minimum to maximum of the range, continuously or in discrete increments as specified in the ACCOMPANYING DOCUMENTS or indicated on the ME EQUIPMENT (see 201.7.9.2.101).~~

~~*The following shall be addressed in the RISK MANAGEMENT FILE:*~~

~~*Voltage range, current range, increment, accuracy.*~~

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

The following information shall be provided in the instructions for use:

a) electrical stimulator output range: specify minimum and maximum values;

b) type of control used: specify if the output control is continuous or in discrete increments;

c) if discrete increments are used, the minimum increment shall be specified;

d) load impedance range: specify minimum and maximum load.

Compliance is checked by inspection of ACCOMPANYING DOCUMENTS.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.2 Instructions for use

Additional subclause:

201.7.9.2.101 Additional information in instructions for use

The instructions for use shall contain additionally:

a) * Information on the output WAVEFORM(s), including any DC component, PULSE DURATIONS, pulse repetition frequencies, maximum amplitude of output voltage ~~and/~~or current, and the effect of load impedance on the demanded parameters.

b) * Advice on the size of ELECTRODES to be used and the method of application for each particular type of examination for which the ELECTRICAL STIMULATOR is intended.

c) Advice on any necessary precautions to be taken when the output contains a DC component larger than 10 µA when averaged over 1 s.

d) * Advice that a PATIENT with an implanted electronic device (for example a cardiac pacemaker) should not be subjected to electrical stimulation unless specialist medical opinion has first been obtained.

e) Advice to avoid trans-thoracic stimulation.

f) A warning on the following potential HAZARDS:

- Connection of a PATIENT to a high frequency (HF) surgical equipment and to an ELECTROMYOGRAPH or EVOKED RESPONSE EQUIPMENT simultaneously ~~may~~ can result in burns at the site of the ELECTRODES and possible damage to the APPLIED PARTS;
- Operation in close proximity to a shortwave or microwave therapy equipment ~~may~~ can produce instability in the APPLIED PARTS.

g) * For ME EQUIPMENT capable of delivering output values in excess of 10 mA RMS or 10 V RMS into the specified load impedance (see 201.7.9.3.101a)), averaged over 1 s, or having an energy greater than 10 mJ per pulse into the specified load impedance:

- a list of recommended ELECTRODES that can be used with the ME EQUIPMENT.

h) * Advice to avoid accidental contact between connected but unapplied APPLIED PARTS and other conductive parts including those connected to protective earth.

i) * Any known susceptibilities to electromagnetic phenomena.

201.7.9.3 Technical description

Additional subclause:

201.7.9.3.101 Additional information in the technical description

The technical description shall additionally contain the following:

a) The technical description shall specify the parameters mentioned in 201.7.9.2.101 along with the range of load impedances for which these parameters are valid.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.8.3 * Classification of APPLIED PARTS

Replacement:

The APPLIED PARTS of ELECTRICAL STIMULATORS, VISUAL STIMULATORS, AUDITORY STIMULATORS and BIOPOTENTIAL INPUT PARTS shall be TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.

201.8.5.2.3 PATIENT LEADS or PATIENT CABLES

Addition:

PATIENT LEADS of ELECTROMYOGRAPHS are usually kept short (30 cm or less) and tied together; therefore, any PATIENT LEAD which falls off will stay in the vicinity of the PATIENT and thus there are no additional requirements for the ELECTRODE.

Where the PATIENT LEADS are long (longer than 30 cm) or not tied together, compliance is verified by inspection of the RISK MANAGEMENT FILE.

201.8.8.3 * Dielectric strength

Addition to item a):

Where the voltage to which the relevant insulation is subjected in NORMAL USE is non-sinusoidal AC, the test ~~may~~ can be performed using a sinusoidal 50 Hz or 60 Hz test voltage. Where this method is used, the value of test voltage shall be determined from Table 6 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 using a reference voltage (U) V DC equal to the measured peak-to peak voltage divided by $2\sqrt{2}$.

This reduction is only allowed for non-sinusoidal working voltages equal to or greater than 700 V peak.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies except as follows:

~~*Addition:*~~

201.9.6.2.1 Audible acoustic energy

Addition:

The limits specified in 9.6.2.1 do not apply to auditory stimulation delivered to the PATIENT for the purpose of evoking a physiological response during NORMAL USE of the ME EQUIPMENT or ME SYSTEM. Requirements for diagnostic acoustic pressure are found in 201.12.4.6.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.11.1 Excessive temperatures in ME EQUIPMENT

201.11.1.1 Maximum temperature during NORMAL USE

Addition:

Compliance with the requirements for maximum temperatures specified in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 shall be checked under the condition specified in 201.4.11.

201.11.8 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Addition:

When ME EQUIPMENT is switched off and on again or when the SUPPLY MAINS is interrupted and re-established, the subsequent operation shall be as follows:

All stimulators (electrical, visual, auditory) shall be disabled upon power reset. Manual intervention shall be required to re-start any stimulation.

Compliance is checked by interruption and restoration of relevant power supplies.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.12.1 * Accuracy of controls and instruments

Replacement:

201.12.1.101 * ELECTRICAL STIMULATOR accuracy

The accuracy of PULSE DURATION, pulse repetition frequencies and pulse amplitudes shall comply with one of the following:

a) The values of PULSE DURATION, pulse repetition frequencies and amplitudes, as described in the ACCOMPANYING DOCUMENTS or indicated on the ME EQUIPMENT (see 201.7.9.2.101), shall

not deviate by more than ±30 %, when measured with an error not exceeding ±10 % into a load resistance within the range specified in the ACCOMPANYING DOCUMENTS (see 201.7.9.3.101).

Compliance is checked by measurement.

b) The accuracy of the PULSE DURATION, pulse repetition frequencies and amplitudes, as described in the ACCOMPANYING DOCUMENTS or indicated on the ME EQUIPMENT (see 201.7.9.2.101), shall not exceed the tolerances established by the RISK MANAGEMENT PROCESS for acceptable values, when measured with an error not exceeding ±10 % into a load resistance within the range specified in the ACCOMPANYING DOCUMENTS (see 201.7.9.3.101).

Compliance is checked by measurement and by inspection of ACCOMPANYING DOCUMENTS and the RISK MANAGEMENT FILE.

201.12.1.102 Output control of ELECTRICAL STIMULATOR

An output control for the ELECTRICAL STIMULATOR shall be incorporated which will continuously control the ELECTRICAL STIMULATOR output range from minimum to maximum, or in discrete increments of not more than 1 mA peak amplitude or 5 V peak amplitude per increment.

Either the type of stimulator output, the constant voltage or the constant current, or one of these, shall be described and specified in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection and measurement, using the load impedance which is the least favourable within the range specified in the ACCOMPANYING DOCUMENTS.

Or, as an alternate method of compliance, the following can be chosen:

An output control for the ELECTRICAL STIMULATOR shall be incorporated which will continuously control the ELECTRICAL STIMULATOR output from minimum to maximum of the range, or in discrete increments as specified in the ACCOMPANYING DOCUMENTS or indicated on the ME EQUIPMENT (see 201.7.9.2.101).

The following shall be addressed in the RISK MANAGEMENT FILE:

Voltage range, current range, increment, accuracy.

Compliance is checked by inspection of ACCOMPANYING DOCUMENTS and the RISK MANAGEMENT FILE.

201.12.1.103 * Constant voltage stimulator limit

For constant voltage stimulators, the maximum output current shall be limited. The manufacturer shall state the maximum output current over the range of load impedances specified in the ACCOMPANYING DOCUMENTS.

Compliance is checked by measurement and by inspection of ACCOMPANYING DOCUMENTS.

201.12.2 USABILITY of ME EQUIPMENT

Additional subclause:

201.12.2.201 * Additional USABILITY requirement

The ELECTRICAL STIMULATOR shall not become unsafe if the output is switched on inadvertently with open circuited or short circuited ELECTRODES, even if such an operation is considered to be misuse.

Compliance is checked by operating the ELECTRICAL STIMULATOR at maximum output settings for 5 min, with the ELECTRODES open circuited and for 5 min with the ELECTRODES short circuited. After these tests all safety requirements of this document shall be satisfied.

201.12.3 ALARM SYSTEMS

Addition:

Audible and visible indicators of the ME EQUIPMENT that are not intended to meet the definition of an ALARM SIGNAL in IEC 60601-1-8 are allowed.

201.12.4 Protection against hazardous output

201.12.4.6 * Diagnostic or therapeutic acoustic pressure

Replacement:

If a continuous masking output is available, the maximum continuous masking sound level shall not exceed 100 dB SPL(A) when the sound pressure level is measured at the minimum distance from the PATIENT as specified by the manufacturer from the source of acoustic energy (masking noise) in NORMAL USE.

NOTE SPL(A): A-Weighted Sound Pressure Level.

Measurement shall be performed with an ear simulator that conforms to applicable part(s) of IEC 60318 (all parts). Sound level meter used in the measurement shall conform to IEC 61672-1, Class 1.

Applications which need an output value beyond the 100 dB SPL(A) shall not exceed 125 dB SPL(A). To enable this extended output limit the OPERATOR shall be informed and confirm a warning statement before continuing. The manufacturer shall provide the following information in the instructions for use:

Where applicable, warning(s) regarding the possibility of hearing damage

Compliance is checked by measurement and inspection of ACCOMPANYING DOCUMENTS.

Additional subclauses:

201.12.4.101 * Supply voltage variations

Supply voltage fluctuations of ±10 % of the nominal voltage shall not affect the ELECTRICAL STIMULATOR output amplitude, PULSE DURATION or pulse repetition frequencies by more than ±10 %.

Compliance is checked by measurement.

201.12.4.102 * ELECTRICAL STIMULATOR output indicator

ME EQUIPMENT which can deliver into a load resistance of 1 000 Ω an output in excess of 10 mA RMS or 10 V RMS or pulses having an energy exceeding 10 mJ per pulse, shall provide visual indication that the ELECTRICAL STIMULATOR is delivering stimuli, or is primed to deliver stimuli. ~~The colour of~~ The visual indicator shall be a yellow flashing light.

Compliance is checked by inspection and by a functional test.

201.12.4.103 * Limitation of ELECTRICAL STIMULATOR output parameters

The pulse energy with load resistance of 1 000 Ω shall not exceed 50 mJ per pulse.

Compliance is checked by measurement.

201.12.4.104 Limitation of VISUAL STIMULATOR output parameters

When the transducer of the VISUAL STIMULATOR consists of light emitting diodes and the intended use includes stimulation with open eyelids, the optical radiation shall not exceed the EMISSION limits specified by ISO 15004-2.

~~*Compliance is checked by measurement.*~~

~~Displays that are compliant with applicable IT requirements such as IEC 60950-1 (ITE Standard), or, IEC 62368-1 and are used at normal operating distances from the PATIENT shall not be required to be tested to ISO 15004-2.~~

Compliance is checked by measurement of the light output and inspection of ACCOMPANYING DOCUMENTS.

Without evidence of compliance with ISO 15004-2, any radiation into the patient's open eyelids is not allowed. In this case, MANUFACTURERS shall include, within their RISK MANAGEMENT FILE, the associated RISK with the potential use of their VISUAL STIMULATOR.

Compliance is checked by inspection of ACCOMPANYING DOCUMENTS and the RISK MANAGEMENT FILE.

Video monitors used to provide stimulus for Visual Evoked Potentials that are used at normal operating distances from the PATIENT and are compliant with applicable standards (IEC 60950-1 or IEC 62368-1) shall not be required to comply with ISO 15004-2.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.16 ME SYSTEMS

Clause 16 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies except as follows:

201.16.8 Interruption of the power supply to parts of an ME SYSTEM

Addition:

When a ME SYSTEM is switched off and on again or when any part of the ME SYSTEM SUPPLY MAINS is interrupted and re-established, the subsequent operation shall be as follows:

All stimulators (electrical, visual, auditory) shall be disabled upon power reset. A manual intervention shall be required to re-start any stimulation.

Compliance is checked by interruption and restoration of relevant power supplies.

201.17 ELECTROMAGNETIC compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

202 * ELECTROMAGNETIC DISTURBANCES – Requirements and tests

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply, except as follows:

202.8 Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS

202.8.1 General

Additional subclause:

202.8.1.101 * IMMUNITY pass/fail criteria

The IMMUNITY pass/fail criteria of the ME EQUIPMENT or ME SYSTEMS shall be one or more of the following as determined by the manufacturer.

A) The ME EQUIPMENT or ME SYSTEMS shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE during and after the IMMUNITY test. No DEGRADATION of ESSENTIAL PERFORMANCE is allowed below a level specified by the manufacturer.

B) The ME EQUIPMENT or ME SYSTEMS shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE during and after the IMMUNITY test. However, temporary loss of ESSENTIAL PERFORMANCE is allowed, provided it can be restored without manual intervention. No DEGRADATION of ESSENTIAL PERFORMANCE is allowed below a level specified by the manufacturer.

C) The ME EQUIPMENT or ME SYSTEMS shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE during and after the IMMUNITY test. However, temporary loss of ESSENTIAL PERFORMANCE is allowed, provided it can be restored with manual intervention. No DEGRADATION of ESSENTIAL PERFORMANCE is allowed below a level specified by the manufacturer.

Compliance is determined as follows:

The manufacturer shall define a method for determining whether ESSENTIAL PERFORMANCE has been maintained during and~~/or~~ after IMMUNITY tests as appropriate based on the manufacturer's RISK ASSESSMENT. Where manual intervention is required to restore ESSENTIAL PERFORMANCE, the method shall be provided in the instructions for use.

Where automatic recovery or manual intervention is allowed (criteria B, C) to restore ESSENTIAL PERFORMANCE, the time necessary to achieve restoration shall be justified in the RISK MANAGEMENT FILE.

Maintenance of BASIC SAFETY shall be determined by inspection of the equipment after completion of the IMMUNITY tests and if ~~necessary~~ applicable by performing the appropriate tests of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

Automatic re-start of electrical, visual, or auditory stimulation shall not occur. See also subclauses 201.11.8 and 201.16.8 of this document.

NOTE 1 Disturbance of the display during any test does not constitute a non-compliance with the requirements of this document.

NOTE 2 Where the manufacturer has determined there is no ESSENTIAL PERFORMANCE, the ME EQUIPMENT or ME SYSTEMS can cease to function during ~~and/~~or after the IMMUNITY test.

202.8.9 IMMUNITY TEST LEVELS

Addition:

The pass/fail criteria of 202.8.1.101 for tests specified in Table 4 of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 are as described in Table 202.101.

Table 202.101 – Pass/fail criteria for Table 4 of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020

Phenomenon	IMMUNITY test level	IMMUNITY pass/fail criteria	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE	±8 kV contact	A or B or C	A or B
	±2 kV air	A	A
	±4 kV air	A	A
	±8 kV air	A or B	A or B
	±15 kV air	A or B or C	A or B
Radiated RF EM fields	3 V/m 80 MHz to 2,7 GHz 80 % AM at 1 kHz	A	X [a]
	10 V/m 80 MHz to 2,7 GHz 80 % AM at 1 kHz	X [a]	A
Proximity fields from RF wireless communications equipment	See 8.10 of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020	A	A
RATED power frequency magnetic fields	30 A/m 50 Hz or 60 Hz	A or B or C	A or B
Proximity magnetic fields	65 A/m 134,2 kHz 7,5 A/m 13,56 MHz	A or B or C	X [a]
	8 A/m 30 kHz 65 A/m 134,2 kHz 7,5 A/m 13,56 MHz	X [a]	A or B

[a] X means not applicable

~~The pass/fail criteria of 202.8.1.101 for the tests specified in Table 5 of IEC 60601-1-2:2014, are as follows:~~

~~Pass/fail criterion A or B or C apply to the professional health care environment;~~

~~Pass/fail criterion A or B apply to the HOME HEALTHCARE ENVIRONMENT.~~

~~The pass/fail criteria of 202.8.1.101 for the tests specified in Table 6 of IEC 60601-1-2:2014, are as follows:~~

~~Pass/fail criterion A or B or C apply to the professional health care environment;~~

~~Pass/fail criterion A or B apply to the HOME HEALTHCARE ENVIRONMENT.~~

~~The pass/fail criteria of 202.8.1.101 for tests specified in Table 7 of IEC 60601-1-2:2014 are as described in Table 202.102.~~

The pass/fail criteria of 202.8.1.101 for tests specified in Table 7 of IEC 60601-1-2:2014, are as described in Table 202.102.

Table 202.102 – Pass/fail criteria for Table 7 of IEC 60601-1-2:2014

Phenomenon	IMMUNITY test level	IMMUNITY pass/fail criteria	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE	±8 kV contact	A or B or C	A or B
	±2 kV air	A	A
	±4 kV air	A	A
	±8 kV air	A or B	A or B
	±15 kV air	A or B or C	A or B
Conducted disturbances induced by RF fields	3 V 0,15 MHz to 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	A or B	X [a]
	3 V 0,15 MHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	X [a]	A or B

[a] X means not applicable

The pass/fail criteria of 202.8.1.101 for tests specified in Table 8 of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 are as described in Table 202.103.

Table 202.103 – Pass/fail criteria for Table 8 of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020

Phenomenon	IMMUNITY test level	IMMUNITY pass/fail criteria	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE	±8 kV contact	A or B or C	A or B
	±2 kV air	A or B or C	A or B
	±4 kV air	A or B or C	A or B
	±8 kV air	A or B or C	A or B
	±15 kV air	A or B or C	A or B
Electrical fast transients / bursts	±1 kV 100 kHz repetition rate	A or B or C	A or B
Surges line-to-ground	±2 kV	A or B or C	A or B
Conducted disturbances induced by RF fields	3 V 0,15 MHz to 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	A	X [a)]
	3 V 0,15 MHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	X [a)]	A

[a)] X means not applicable

~~The pass/fail criteria of 202.8.1.101 for tests specified in Table 9 of IEC 60601-1-2:2014 are as follows:~~

~~Pass/fail criterion A or B or C apply to the professional health care environment;~~

~~Pass/fail criterion A or B apply to the HOME HEALTHCARE ENVIRONMENT.~~

The pass/fail criteria of 202.8.1.101 for tests specified in Table 5, Table 6, and Table 9 of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 are as described in Table 202.104.

Table 202.104 – Pass/fail criteria for Table 5, Table 6, Table 9 of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020

Table	IMMUNITY pass/fail criteria	
	Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
Table 5 of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020	A or B or C	A or B
Table 6 of IEC 60601-1-2:2014	A or B or C	A or B
Table 9 of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020	A or B or C	A or B

Annexes

The annexes of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 apply except as follows:

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Addition:

Additional requirements for marking on the outside of ELECTROMYOGRAPHS and EVOKED RESPONSE EQUIPMENT are found in Table 201.C.101.

Table 201.C.101 – Marking on the outside of ELECTROMYOGRAPHS and EVOKED RESPONSE EQUIPMENT or its parts

Description of marking	Subclause
RATED power input	201.7.2.7
Symbol 10 of Table D.2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020	201.7.2.3 201.7.2.13

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This annex provides a concise rationale for the important requirements of the standard and is intended for those who are familiar with the subject of the standard but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for the proper application of the standard. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any revision of the standard necessitated by these developments.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this document, with clause and subclause numbers parallel to those in the body of the document.

Subclause 201.4.2 – RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

ELECTRICAL STIMULATORS for evoked response are used to stimulate different locations such as central nervous system or peripheral nerves, and for invasive or non-invasive applications. It is strongly recommended to take into consideration the maximum possible current densities (RMS) for the type of electrodes used. Clinical data or scientific literature are typical sources of information that can be used to justify maximum current densities (RMS) for a medical device, taking into consideration the recommended electrodes, as well as the type of application.

Subclause 201.6.2 – Protection against electric shock

APPLIED PARTS ~~need to~~ shall be isolated to avoid unwanted current paths through the PATIENT due to the capacitance or a possible conductive connection to earth.

Subclause 201.7.2.3 – Consult ACCOMPANYING DOCUMENTS

Since only ELECTRODES recommended by the manufacturer should be used, the OPERATOR is required to consult the instructions for use.

Subclause 201.7.2.13 – Physiological effects (SAFETY SIGNS and warning statements)

The OPERATOR is particularly alerted to consult the instructions for use, because of the higher output allowed.

~~**Subclause 201.7.4.2 – (Marking on) control devices**~~

~~A small increase in output amplitude may produce a disproportionate stimulus to the PATIENT. A control which enables the OPERATOR to adjust the output amplitude smoothly or in small increments is considered to be an important safety feature. Limitation of the output available at the minimum setting of the output control enables the OPERATOR to commence stimulation from a low output level.~~

Subclause 201.7.9.2.101 a) – additional instructions for use

Because of the danger of tissue necrosis, any DC components of the WAVEFORMS should be declared.

Subclause 201.7.9.2.101 b) – additional instructions for use

ELECTRODES of inadequate size or unsuitable application could provoke skin reactions or burns.

Subclause 201.7.9.2.101 d) – additional instructions for use

Potential interference with implanted devices by the stimulating current could create a HAZARD.

Subclause 201.7.9.2.101 g) – additional instructions for use

The OPERATOR should be warned that stimulation with excessive current densities ~~may~~ can be a HAZARD to the PATIENT.

Subclause 201.7.9.2.101 h) – additional instructions for use

APPLIED PARTS connected to a PATIENT CONNECTION, but not connected to the PATIENT, should be prevented from contacting other conductive parts in order to preserve the PATIENT CONNECTION electrical isolation.

Subclause 201.7.9.2.101 i) – additional instructions for use

It is recognized that biopotential signals are of very low amplitude and it is likely there ~~may~~ can be some remaining unavoidable electromagnetic interference. This ~~may~~ can be acceptable based on RISK MANAGEMENT and proper disclosure in the instructions for use.

Subclause 201.8.3 – Classification of APPLIED PARTS

See rationale for 201.6.2.

Subclause 201.8.8.3 a)

~~*Addition:*~~

The method of compliance added by this document was allowed in IEC 60601-1:2005 (see specifically Note 2 in Table 6 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012) and it has been safely used for many years, in the absence of evidence to the contrary, there is no reason for not using it going forward.

In addition, in Table 6 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 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.

~~**Subclause 201.12.1 – Accuracy of controls and instruments**~~

Subclause 201.12.1.101 – ELECTRICAL STIMULATOR accuracy

An accuracy of ±30 % is considered to provide adequate safety in many cases, since the values selected are mainly determined by the electrophysiological responses and the subjective reaction of the PATIENT. However, there ~~may~~ can be applications for which ±30 % is not adequate. For these applications, the acceptable accuracy ~~needs to~~ shall be addressed in the RISK MANAGEMENT FILE.

Subclause 201.12.1.103 – Constant voltage stimulator limit

For additional information related to maximum output determination, see IEC 60479-1.

Subclause 201.12.2.201 – Additional USABILITY requirement

Switching on the ELECTRICAL STIMULATOR inadvertently is considered to be a normal occurrence since the ELECTRICAL STIMULATOR is likely to be short-circuited or open-circuited accidentally during use due to movements of the ELECTRODES ~~and/~~or the PATIENT.

Subclause 201.12.4.6 – Diagnostic or therapeutic acoustic pressure

White noise masking limit. The 125 dB HTL, from the 1998 edition was taken from IEC 60645-3:1994, which is a withdrawn standard. The current version of IEC 60645-3 does not address this subject. Also, dB HTL is a rather unusual unit of measure for white noise, dB SPL(A) is the common unit used for this type of parameter.

NOTE HTL: Hearing Threshold Level.

Subclause 201.12.4.101 – Supply voltage variations

Supply voltage fluctuations not exceeding the limit of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 should not influence the output parameters excessively.

Subclause 201.12.4.102 – ELECTRICAL STIMULATOR output indicator

The indication should advise the USER that the ELECTRICAL STIMULATOR is delivering stimuli, or that the ELECTRICAL STIMULATOR is armed to deliver stimuli as a result of further action by the USER, for example, manual triggering.

Subclause 201.12.4.103 – Limitation of ELECTRICAL STIMULATOR output parameters

Experience shows that the limits specified allow all known diagnostic applications to be carried out without exceeding the allowable value.

Subclause 202.8.1.101 – IMMUNITY pass/fail criteria

Criterion C is not acceptable for the HOME HEALTHCARE ENVIRONMENT. It is expected that equipment for this application shall be able to recover without OPERATOR intervention since the PATIENT is not likely to have appropriate training to determine proper functionality of the ME EQUIPMENT or ME SYSTEM.

AA.3 EMISSION and IMMUNITY tests example

~~**Suggested test layout for ELECTROMAGNETIC DISTURBANCE tests**~~

Figure AA.1 provides an example of cable layout for EMISSION and IMMUNITY tests.

The setting ~~may~~ can change based on the intended use or composition of the ME EQUIPMENT.

Compliance is checked by examination of the RISK MANAGEMENT FILE.

All relevant ELECTRODES shall be connected to the content of a 1 000 ml capacity phantom filled with 0,9 % saline or connected in conductive gel or paste (glue), positioned within 1 000 mm of the ME EQUIPMENT as shown in Figure AA.1. The purpose of the gel/paste is to provide stable impedance and WAVEFORM.

Any SIGNAL INPUT PARTS, SIGNAL OUTPUT PARTS, cables and POWER SUPPLY CORD are arranged generally as in Figure AA.1. Maintain distance of ≥400 mm between SIP/SOP cables and ground plane on the floor.

ME EQUIPMENT shall be located (800 ± 80) mm above the reference ground plane on the floor.

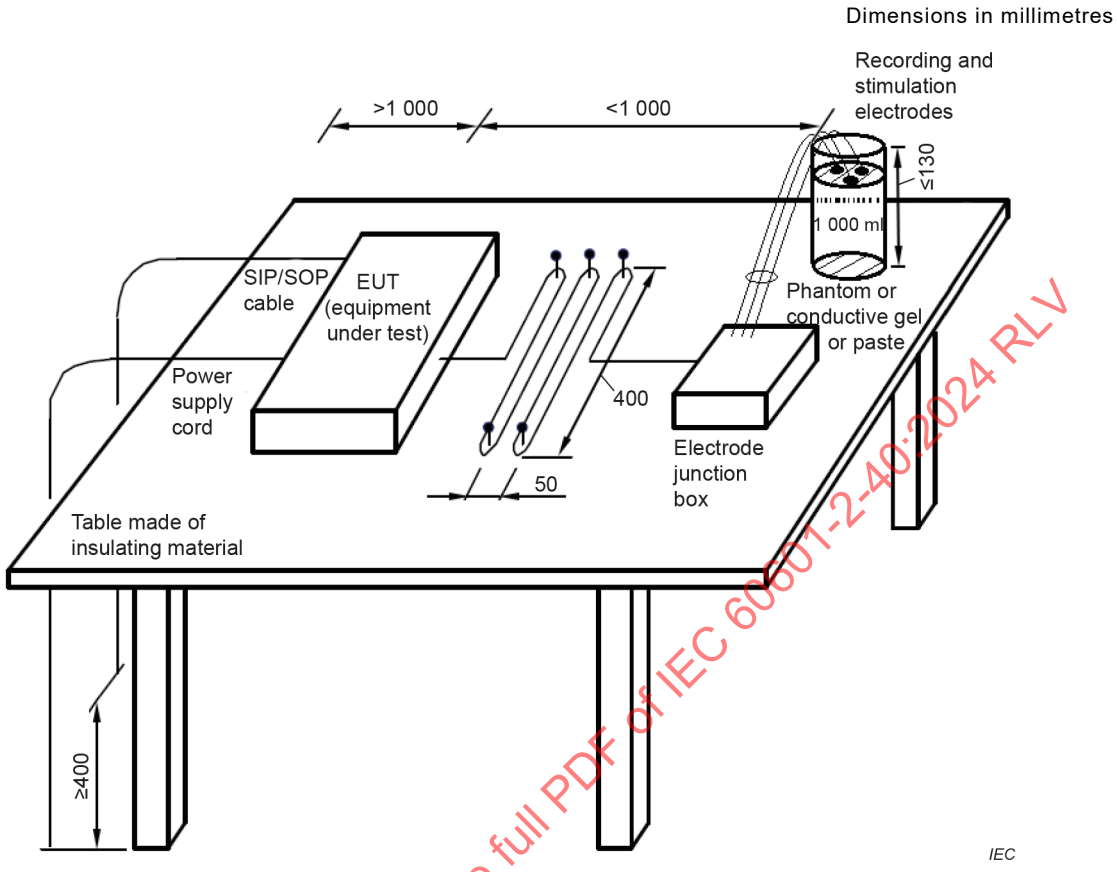


Figure AA.1 – Suggested ~~test~~ cable layout for EMISSION and radiated IMMUNITY testing

AA.4 Electrosurgery disturbances

~~*Addition:*~~

Test for protection against the effects of HF SURGICAL ME EQUIPMENT. If protection against the effects of HF SURGICAL ME EQUIPMENT is provided, the following is recommended for protection verification:

Perform the tests described below using PATIENT CABLES, LEAD WIRES, ACCESSORIES and settings recommended by the MANUFACTURER.

When the ME EQUIPMENT is used together with HF SURGICAL ME EQUIPMENT, it ~~may~~ can show DEGRADATION and shall return to previous operating mode within 30 s after exposure to the field produced by the HF SURGICAL ME EQUIPMENT. There shall be no loss of any OPERATOR settings or stored data.

Compliance evaluation is performed according to Figure AA.2 and Figure AA.3.

~~*Use*~~ *HF SURGICAL ME EQUIPMENT which complies with IEC 60601-2-2 and has a minimum power cut mode capability of 300 W, a minimum coagulation mode of 100 W and a working frequency ~~of 400 kHz ± 10 %~~ range of 300 kHz to 600 kHz should be used.*

a) Test in cut mode:

Set the output power of the HF SURGICAL EQUIPMENT to the 300 W position.

Touch the metal contact/block in the test set-up (see Figure AA.2 and Figure AA.3) with the active ELECTRODE and remove the ELECTRODE slowly to get an arc.

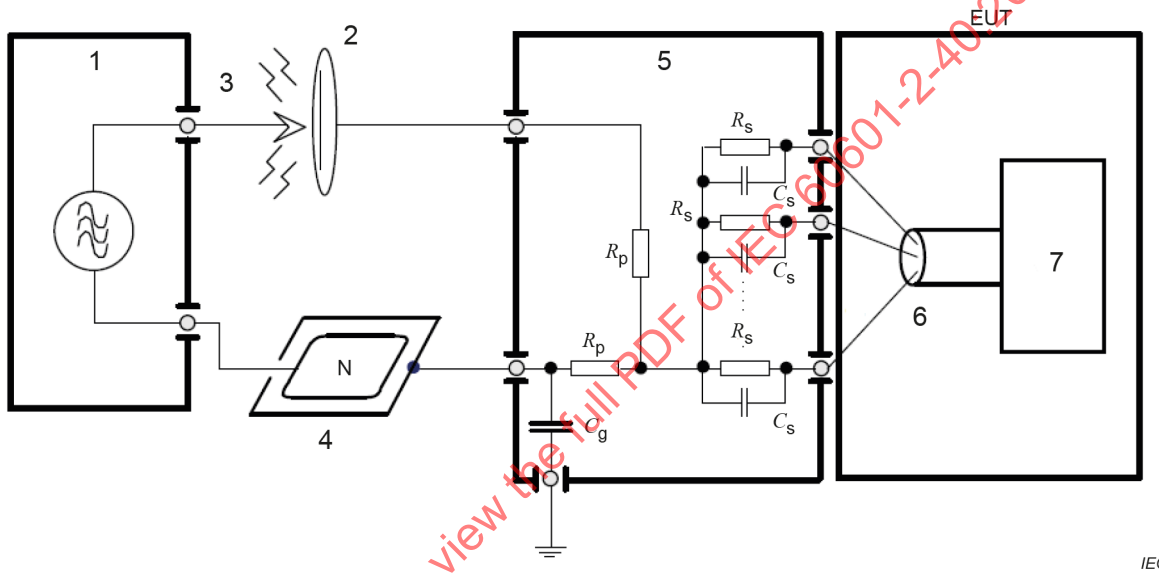
Verify whether the recorded/displayed EMG baseline returns ~~within 10 s~~ to its normal position and the ME EQUIPMENT returns to the previous operating mode within 30 s without loss of any stored data.

Repeat the procedure five times.

b) Test in coagulation mode:

Repeat the test in item a) except with an output power of 100 W.

Test of the spray coagulation mode is excluded.



IEC

Components

1 HF SURGICAL ME EQUIPMENT

2 Metal plate

3 ACTIVE ELECTRODE of the HF SURGICAL ME EQUIPMENT

4 Metal plate/neutral ELECTRODE (N) of HF SURGICAL ME EQUIPMENT

5 Coupling network

6 PATIENT CABLE

7 ME EQUIPMENT

R_p 500 Ω, 200 W (low-inductive, < 5 µH, simulates PATIENT impedance)

C_g 47 nF (to minimize the effect of different types of HF SURGICAL ME EQUIPMENT designs)

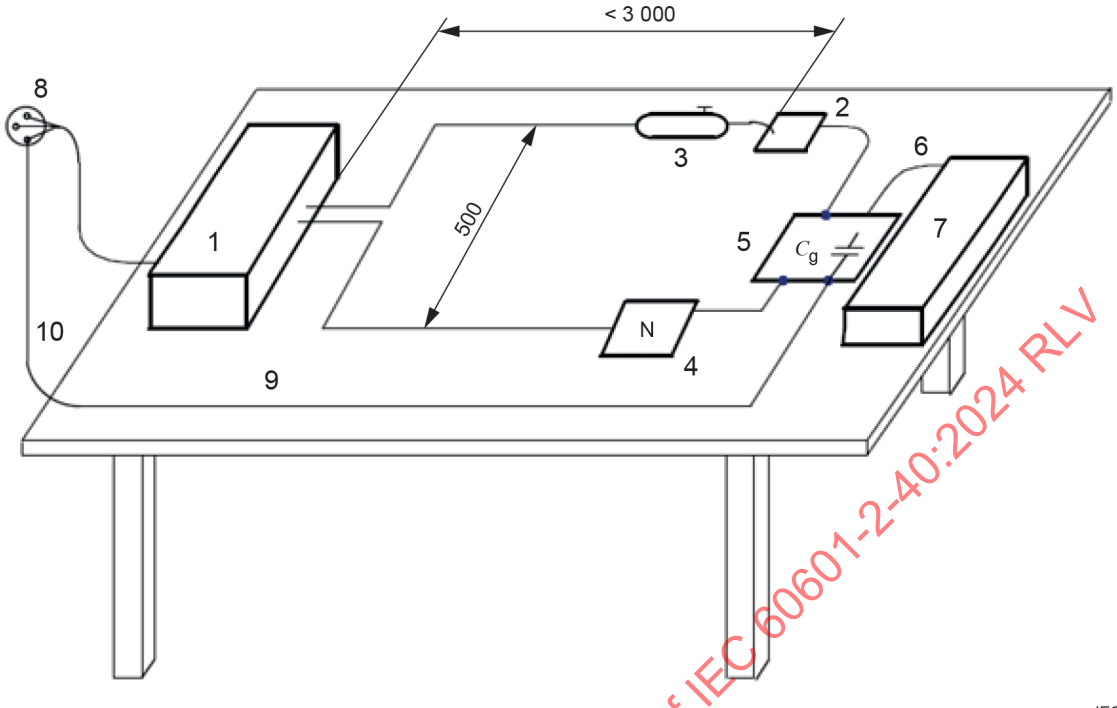
R_s ~~51 kΩ~~ 10 kΩ R_s//C_s simulate the skin impedance

C_s 47 nF

The test report should identify the HF SURGICAL EQUIPMENT that was used.

Figure AA.2 – Example of test setup for protection against the effects of HF SURGICAL ME EQUIPMENT

Dimensions in millimetres



IEC

Components

1 HF SURGICAL ME EQUIPMENT

2 Metal plate

3 ACTIVE ELECTRODE of the HF SURGICAL ME EQUIPMENT

4 NEUTRAL ELECTRODE of the HF SURGICAL ME EQUIPMENT

5 Coupling network – test set-up according to item 5 in Figure AA.2

6 PATIENT CABLE

7 ME EQUIPMENT under test

8 SUPPLY MAINS

9 Table made of insulating material

10 Connection to PROTECTIVE EARTH CONDUCTOR for grounding

The ME EQUIPMENT shall be located (800 ± 80) mm above the reference ground plane on the floor.

Figure AA.3 – Example of test setup for protection against the effects of HF SURGICAL ME EQUIPMENT

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IEC 60479-1, *Effects of current on human beings and livestock – Part 1: General aspects*

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

IEC 60601-1-10, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

IEC 60601-2-2, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

IEC 60601-2-10, *Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators*

IEC 60645-3, *Electroacoustics – Audiometric equipment – Part 3: Test signals of short duration*

IEC 60950-1[2], *Information technology equipment – Safety – Part 1: General requirements*

IEC 62368-1, *Audio/video, information and communication technology equipment – Part 1: Safety requirements*

[2] This publication was withdrawn.

Index of defined terms used in this particular standard

ACCOMPANYING DOCUMENT ..... IEC 60601-1:2005, 3.4

APPLIED PART ..... IEC 60601-1:2005, 3.8

AUDITORY STIMULATOR 201.3.206

BASIC SAFETY ..... IEC 60601-1:2005, 3.10

BIOPOTENTIAL INPUT PART 201.3.208

~~CONTINUOUS OPERATION ..... IEC 60601-1:2005, 3.18~~

~~EARTH LEAKAGE CURRENT ..... IEC 60601-1:2005/AMD1:2012, 3.25~~

ELECTRICAL STIMULATOR 201.3.203

ELECTRODE 201.3.209

ELECTROMAGNETIC COMPATIBILITY ..... IEC 60601-1-2:2014, 3.2

(ELECTROMAGNETIC) EMISSION ..... IEC 60601-1-2:2014, 3.4

ELECTROMYOGRAPH 201.3.201

ELECTROSTATIC DISCHARGE (ESD) ..... IEC 60601-1-2:2014, 3.6

ESSENTIAL PERFORMANCE ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.27

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OPERATOR ..... IEC 60601-1:2005, 3.73

PATIENT ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.76

~~PATIENT AUXILIARY CURRENT ..... IEC 60601-1:2005, 3.77~~

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~~PATIENT LEAKAGE CURRENT ..... IEC 60601-1:2005/AMD1:2012, 3.80~~

~~PORT ..... IEC 60601-1-2:2014, 3.17~~

PULSE DURATION 201.3.204

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TYPE BF APPLIED PART ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.133

TYPE CF APPLIED PART ..... IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.134

VISUAL STIMULATOR 201.3.207

WAVEFORM 201.3.205

IEC 60601-2-40

Edition 3.0 2024-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment

Appareils électromédicaux –
Partie 2-40: Exigences particulières pour la sécurité de base et les performances essentielles des électromyographes et des appareils à potentiel évoqué

IEC 60601-2-40:2024-12(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment

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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9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at https://patents.iec.ch. IEC shall not be held responsible for identifying any or all such patent rights.

IEC 60601-2-40 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This third edition cancels and replaces the second edition published in 2016. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) added requirements for constant voltage stimulators;
b) clarified requirements for VISUAL STIMULATORS.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62D/2168/FDIS	62D/2191/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, the following print types are used:

– requirements and definitions: roman type.
– *test specifications: 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 DEFINED IN CLAUSE 3 OF IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, AND IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
– "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 AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

INTRODUCTION

This document concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROMYOGRAPHS and EVOKED RESPONSE EQUIPMENT. It amends and supplements IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* (IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020).

The aim of this revision is to bring this document up to date with reference to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020.

The requirements of this document take priority over those of IEC 60601-1.

A "General guidance and rationale" for the more important requirements of this document is included in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the document but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, Annex AA does not form part of the requirements of this document.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment

201.1 Scope, object and related standards

Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.1.1 Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROMYOGRAPHS and EVOKED RESPONSE EQUIPMENT, hereafter referred to as ME EQUIPMENT.

NOTE 1 Myofeedback equipment, where the capturing of muscle contraction is based on electromyography, is within the scope of this document.

NOTE 2 ELECTROMYOGRAPHS and EVOKED RESPONSE EQUIPMENT is intended for diagnostic and monitoring applications.

NOTE 3 If the ME EQUIPMENT supports both ELECTROMYOGRAPHY and EVOKED RESPONSE STIMULATION, clauses for electrical, auditory, and visual stimulators are applicable. In case the equipment supports ELECTROMYOGRAPHY, but not EVOKED RESPONSE STIMULATION, clauses concerning solely requirements for stimulators are NOT within the scope of this document.

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.

The following ME EQUIPMENT are excluded:

- ME EQUIPMENT intended for therapeutic application;
- ME EQUIPMENT intended for transcutaneous electrical nerve stimulators and electrical muscle stimulators (ME EQUIPMENT covered by IEC 60601-2-10).

201.1.2 Object

Replacement:

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ELECTROMYOGRAPHS and EVOKED RESPONSE EQUIPMENT [as defined in 201.3.201 and 201.3.202.]

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and Clause 201.2 of this document.

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply as modified in Clause 202. IEC 60601-1-3, IEC 60601-1-8 and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

The numbering of clauses and subclauses of this document corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is replaced completely by the text of this document.

"*Addition*" means that the text of this document is additional to the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"*Amendment*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, for example 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, any applicable collateral standards and this document taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

NOTE Informative references are listed in the bibliography.

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*
IEC 60601-1-2:2014/AMD1:2020

IEC 60318 (all parts), *Electroacoustics – Simulators of human head and ear*

ISO 15004-2, *Ophthalmic instruments – Fundamental requirements and test methods – Part 2: Light hazard protection*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 apply, except as follows:

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp

NOTE An index of defined terms is found beginning on page 30.

Additional terms and definitions:

201.3.201
ELECTROMYOGRAPH
ME EQUIPMENT for the detection or recording of biopotentials accompanying nerve and muscle action, either spontaneously, intentionally or evoked by electrical or other stimulation

201.3.202
EVOKED RESPONSE EQUIPMENT
ME EQUIPMENT for the detection or recording of biopotentials resulting from an evoking stimulus

Note 1 to entry: The stimulus can be electrical, tactile, auditory, visual, olfactory, etc.

201.3.203
ELECTRICAL STIMULATOR
part of ME EQUIPMENT for the application of electric currents via ELECTRODES in direct contact with the PATIENT, for the evoking of biopotentials

201.3.204
PULSE DURATION
duration of the electrical stimulus pulse WAVEFORM at 50 % of the peak amplitude

201.3.205
WAVEFORM
variations in magnitude of an electrical stimulus output (either voltage or current) as a function of time appearing in the APPLIED PART(S) of the ELECTRICAL STIMULATOR or the collected biopotentials by the BIOPOTENTIALS INPUT PART

201.3.206
AUDITORY STIMULATOR
part of ME EQUIPMENT for the application of sound pressure from a transducer (headphone, bone conductor or free-field) to the ear(s) of the PATIENT, for the evoking of biopotentials

201.3.207
VISUAL STIMULATOR
part of ME EQUIPMENT for the application of pulsed electromagnetic radiation in the visible spectrum from a transducer to the eyes of the PATIENT, for the evoking of biopotentials

201.3.208
BIOPOTENTIAL INPUT PART
APPLIED PART(S) of ELECTROMYOGRAPHS and EVOKED RESPONSE EQUIPMENT for the collection of biopotentials

201.3.209
ELECTRODE
conductive portion that is applied to the PATIENT to detect electrical activity or to apply the stimulus from the ELECTRICAL STIMULATOR to the PATIENT

201.3.210
PATIENT LEAD
cable connected between an ELECTRODE and either a PATIENT CABLE or the ME EQUIPMENT

201.3.211
PATIENT CABLE
multiwire cable used to connect PATIENT LEADS to ME EQUIPMENT

201.4 General requirements

Clause 4 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.4.2 *RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

Addition:

MANUFACTURERS shall include, within their RISK MANAGEMENT FILE, the RISK associated with the potential use of their STIMULATORS and accessories to deliver current exceeding 10 mA RMS or current densities for any ELECTRODE exceeding 2 mA/cm^2.

201.4.3 ESSENTIAL PERFORMANCE

Addition:

Because of the variety of clinical applications for ELECTROMYOGRAPHS and EVOKED RESPONSE, no additional ESSENTIAL PERFORMANCE is specified in this document. However, ESSENTIAL PERFORMANCE is determined by the manufacturer in accordance with the requirements of 4.3 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

201.4.11 Power input

Replacement:

The power input is measured with a load resistance of the lowest value specified in the technical description (see 201.7.9.3.101 a)), and with any output controls set to result in maximum power input.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows.

201.5.4 Other conditions

Addition:

Where values of voltage and current are used in this document, they mean the RMS values of an alternating, direct or composite voltage or current averaged over 1 s unless stated otherwise.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.6.2 * Protection against electric shock

Amendment:

Delete TYPE B APPLIED PART.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.3 * Consult ACCOMPANYING DOCUMENTS

Replacement:

Safety sign ISO 7010-M002 shall be used (see Table D.2, safety sign 10 in Annex D of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020).

201.7.2.7 Electrical input power from the SUPPLY MAINS

Replacement:

The RATED power input of MAINS operated ME EQUIPMENT shall be the maximum power input averaged over any period of 5 s under the specified operating conditions set out by the manufacturer.

201.7.2.8 Output connectors

201.7.2.8.2 Other power sources

Addition:

See also 201.12.4.102.

201.7.2.13 * Physiological effects (SAFETY SIGNS and warning statements)

Addition:

ME EQUIPMENT capable of delivering electrical stimulus outputs into a load resistance of 1 000 Ω in excess of 10 mA RMS or 10 V RMS averaged over any period of 5 s shall be marked near the ELECTRODE connections with the safety sign ISO 7010-M002 (see safety sign 10 in Table D.2 of Annex D of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020).

201.7.4 Marking of controls and instruments

201.7.4.2 Control devices

Replacement:

The following information shall be provided in the instructions for use:

a) electrical stimulator output range: specify minimum and maximum values;
b) type of control used: specify if the output control is continuous or in discrete increments;
c) if discrete increments are used, the minimum increment shall be specified;
d) load impedance range: specify minimum and maximum load.

Compliance is checked by inspection of ACCOMPANYING DOCUMENTS.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.2 Instructions for use

Additional subclause:

201.7.9.2.101 Additional information in instructions for use

The instructions for use shall contain additionally:

a) * Information on the output WAVEFORM(s), including any DC component, PULSE DURATIONS, pulse repetition frequencies, maximum amplitude of output voltage or current, and the effect of load impedance on the demanded parameters.
b) * Advice on the size of ELECTRODES to be used and the method of application for each particular type of examination for which the ELECTRICAL STIMULATOR is intended.
c) Advice on any necessary precautions to be taken when the output contains a DC component larger than 10 µA when averaged over 1 s.

d) * Advice that a PATIENT with an implanted electronic device (for example a cardiac pacemaker) should not be subjected to electrical stimulation unless specialist medical opinion has first been obtained.

e) Advice to avoid trans-thoracic stimulation.

f) A warning on the following potential HAZARDS:

- Connection of a PATIENT to a high frequency (HF) surgical equipment and to an ELECTROMYOGRAPH or EVOKED RESPONSE EQUIPMENT simultaneously can result in burns at the site of the ELECTRODES and possible damage to the APPLIED PARTS;
- Operation in close proximity to a shortwave or microwave therapy equipment can produce instability in the APPLIED PARTS.

g) * For ME EQUIPMENT capable of delivering output values in excess of 10 mA RMS or 10 V RMS into the specified load impedance (see 201.7.9.3.101a)), averaged over 1 s, or having an energy greater than 10 mJ per pulse into the specified load impedance:

- a list of recommended ELECTRODES that can be used with the ME EQUIPMENT.

h) * Advice to avoid accidental contact between connected but unapplied APPLIED PARTS and other conductive parts including those connected to protective earth.

i) * Any known susceptibilities to electromagnetic phenomena.

201.7.9.3 Technical description

Additional subclause:

201.7.9.3.101 Additional information in the technical description

The technical description shall additionally contain the following:

a) The technical description shall specify the parameters mentioned in 201.7.9.2.101 along with the range of load impedances for which these parameters are valid.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.8.3 * Classification of APPLIED PARTS

Replacement:

The APPLIED PARTS of ELECTRICAL STIMULATORS, VISUAL STIMULATORS, AUDITORY STIMULATORS and BIOPOTENTIAL INPUT PARTS shall be TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.

201.8.5.2.3 PATIENT LEADS or PATIENT CABLES

Addition:

PATIENT LEADS of ELECTROMYOGRAPHS are usually kept short (30 cm or less) and tied together; therefore, any PATIENT LEAD which falls off will stay in the vicinity of the PATIENT and thus there are no additional requirements for the ELECTRODE.

Where the PATIENT LEADS are long (longer than 30 cm) or not tied together, compliance is verified by inspection of the RISK MANAGEMENT FILE.

201.8.8.3 * Dielectric strength

Addition to item a):

Where the voltage to which the relevant insulation is subjected in NORMAL USE is non-sinusoidal AC, the test can be performed using a sinusoidal 50 Hz or 60 Hz test voltage. Where this method is used, the value of test voltage shall be determined from Table 6 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 using a reference voltage (U) V DC equal to the measured peak-to peak voltage divided by $2\sqrt{2}$.

This reduction is only allowed for non-sinusoidal working voltages equal to or greater than 700 V peak.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies except as follows:

201.9.6.2.1 Audible acoustic energy

Addition:

The limits specified in 9.6.2.1 do not apply to auditory stimulation delivered to the PATIENT for the purpose of evoking a physiological response during NORMAL USE of the ME EQUIPMENT or ME SYSTEM. Requirements for diagnostic acoustic pressure are found in 201.12.4.6.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.11.1 Excessive temperatures in ME EQUIPMENT

201.11.1.1 Maximum temperature during NORMAL USE

Addition:

Compliance with the requirements for maximum temperatures specified in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 shall be checked under the condition specified in 201.4.11.

201.11.8 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Addition:

When ME EQUIPMENT is switched off and on again or when the SUPPLY MAINS is interrupted and re-established, the subsequent operation shall be as follows:

All stimulators (electrical, visual, auditory) shall be disabled upon power reset. Manual intervention shall be required to re-start any stimulation.

Compliance is checked by interruption and restoration of relevant power supplies.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.12.1 Accuracy of controls and instruments

Replacement:

201.12.1.101 * ELECTRICAL STIMULATOR accuracy

The accuracy of PULSE DURATION, pulse repetition frequencies and pulse amplitudes shall comply with one of the following:

a) The values of PULSE DURATION, pulse repetition frequencies and amplitudes, as described in the ACCOMPANYING DOCUMENTS or indicated on the ME EQUIPMENT (see 201.7.9.2.101), shall not deviate by more than ±30 %, when measured with an error not exceeding ±10 % into a load resistance within the range specified in the ACCOMPANYING DOCUMENTS (see 201.7.9.3.101).

   Compliance is checked by measurement.

b) The accuracy of the PULSE DURATION, pulse repetition frequencies and amplitudes, as described in the ACCOMPANYING DOCUMENTS or indicated on the ME EQUIPMENT (see 201.7.9.2.101), shall not exceed the tolerances established by the RISK MANAGEMENT PROCESS for acceptable values, when measured with an error not exceeding ±10 % into a load resistance within the range specified in the ACCOMPANYING DOCUMENTS (see 201.7.9.3.101).

   Compliance is checked by measurement and by inspection of ACCOMPANYING DOCUMENTS and the RISK MANAGEMENT FILE.

201.12.1.102 Output control of ELECTRICAL STIMULATOR

An output control for the ELECTRICAL STIMULATOR shall be incorporated which will continuously control the ELECTRICAL STIMULATOR output range from minimum to maximum, or in discrete increments of not more than 1 mA peak amplitude or 5 V peak amplitude per increment.

Either the type of stimulator output, the constant voltage or the constant current, or one of these, shall be described and specified in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection and measurement, using the load impedance which is the least favourable within the range specified in the ACCOMPANYING DOCUMENTS.

Or, as an alternate method of compliance, the following can be chosen:

An output control for the ELECTRICAL STIMULATOR shall be incorporated which will continuously control the ELECTRICAL STIMULATOR output from minimum to maximum of the range, or in discrete increments as specified in the ACCOMPANYING DOCUMENTS or indicated on the ME EQUIPMENT (see 201.7.9.2.101).

The following shall be addressed in the RISK MANAGEMENT FILE:

Voltage range, current range, increment, accuracy.

Compliance is checked by inspection of ACCOMPANYING DOCUMENTS and the RISK MANAGEMENT FILE.

201.12.1.103 * Constant voltage stimulator limit

For constant voltage stimulators, the maximum output current shall be limited. The manufacturer shall state the maximum output current over the range of load impedances specified in the ACCOMPANYING DOCUMENTS.

Compliance is checked by measurement and by inspection of ACCOMPANYING DOCUMENTS.

201.12.2 USABILITY of ME EQUIPMENT

Additional subclause:

201.12.2.201 * Additional USABILITY requirement

The ELECTRICAL STIMULATOR shall not become unsafe if the output is switched on inadvertently with open circuited or short circuited ELECTRODES, even if such an operation is considered to be misuse.

Compliance is checked by operating the ELECTRICAL STIMULATOR at maximum output settings for 5 min, with the ELECTRODES open circuited and for 5 min with the ELECTRODES short circuited. After these tests all safety requirements of this document shall be satisfied.

201.12.3 ALARM SYSTEMS

Addition:

Audible and visible indicators of the ME EQUIPMENT that are not intended to meet the definition of an ALARM SIGNAL in IEC 60601-1-8 are allowed.

201.12.4 Protection against hazardous output

201.12.4.6 * Diagnostic or therapeutic acoustic pressure

Replacement:

If a continuous masking output is available, the maximum continuous masking sound level shall not exceed 100 dB SPL(A) when the sound pressure level is measured at the minimum distance from the PATIENT as specified by the manufacturer from the source of acoustic energy (masking noise) in NORMAL USE.

NOTE SPL(A): A-Weighted Sound Pressure Level.

Measurement shall be performed with an ear simulator that conforms to applicable part(s) of IEC 60318 (all parts). Sound level meter used in the measurement shall conform to IEC 61672-1, Class 1.

Applications which need an output value beyond the 100 dB SPL(A) shall not exceed 125 dB SPL(A). To enable this extended output limit the OPERATOR shall be informed and confirm a warning statement before continuing. The manufacturer shall provide the following information in the instructions for use:

Where applicable, warning(s) regarding the possibility of hearing damage

Compliance is checked by measurement and inspection of ACCOMPANYING DOCUMENTS.

Additional subclauses:

201.12.4.101 * Supply voltage variations

Supply voltage fluctuations of ±10 % of the nominal voltage shall not affect the ELECTRICAL STIMULATOR output amplitude, PULSE DURATION or pulse repetition frequencies by more than ±10 %.

Compliance is checked by measurement.

201.12.4.102 * ELECTRICAL STIMULATOR output indicator

ME EQUIPMENT which can deliver into a load resistance of 1 000 Ω an output in excess of 10 mA RMS or 10 V RMS or pulses having an energy exceeding 10 mJ per pulse, shall provide visual indication that the ELECTRICAL STIMULATOR is delivering stimuli, or is primed to deliver stimuli. The visual indicator shall be a yellow flashing light.

Compliance is checked by inspection and by a functional test.

201.12.4.103 * Limitation of ELECTRICAL STIMULATOR output parameters

The pulse energy with load resistance of 1 000 Ω shall not exceed 50 mJ per pulse.

Compliance is checked by measurement.

201.12.4.104 Limitation of VISUAL STIMULATOR output parameters

When the transducer of the VISUAL STIMULATOR consists of light emitting diodes and the intended use includes stimulation with open eyelids, the optical radiation shall not exceed the EMISSION limits specified by ISO 15004-2.

Compliance is checked by measurement of the light output and inspection of ACCOMPANYING DOCUMENTS.

Without evidence of compliance with ISO 15004-2, any radiation into the patient's open eyelids is not allowed. In this case, MANUFACTURERS shall include, within their RISK MANAGEMENT FILE, the associated RISK with the potential use of their VISUAL STIMULATOR.

Compliance is checked by inspection of ACCOMPANYING DOCUMENTS and the RISK MANAGEMENT FILE.

Video monitors used to provide stimulus for Visual Evoked Potentials that are used at normal operating distances from the PATIENT and are compliant with applicable standards (IEC 60950-1 or IEC 62368-1) shall not be required to comply with ISO 15004-2.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

201.16 ME SYSTEMS

Clause 16 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies except as follows:

201.16.8 Interruption of the power supply to parts of an ME SYSTEM

Addition:

When a ME SYSTEM is switched off and on again or when any part of the ME SYSTEM SUPPLY MAINS is interrupted and re-established, the subsequent operation shall be as follows:

All stimulators (electrical, visual, auditory) shall be disabled upon power reset. A manual intervention shall be required to re-start any stimulation.

Compliance is checked by interruption and restoration of relevant power supplies.

201.17 ELECTROMAGNETIC compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies.

202 ELECTROMAGNETIC DISTURBANCES – Requirements and tests

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply, except as follows:

202.8 Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS

202.8.1 General

Additional subclause:

202.8.1.101 * IMMUNITY pass/fail criteria

The IMMUNITY pass/fail criteria of the ME EQUIPMENT or ME SYSTEMS shall be one or more of the following as determined by the manufacturer.

A) The ME EQUIPMENT or ME SYSTEMS shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE during and after the IMMUNITY test. No DEGRADATION of ESSENTIAL PERFORMANCE is allowed below a level specified by the manufacturer.

B) The ME EQUIPMENT or ME SYSTEMS shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE during and after the IMMUNITY test. However, temporary loss of ESSENTIAL PERFORMANCE is allowed, provided it can be restored without manual intervention. No DEGRADATION of ESSENTIAL PERFORMANCE is allowed below a level specified by the manufacturer.

C) The ME EQUIPMENT or ME SYSTEMS shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE during and after the IMMUNITY test. However, temporary loss of ESSENTIAL PERFORMANCE is allowed, provided it can be restored with manual intervention. No DEGRADATION of ESSENTIAL PERFORMANCE is allowed below a level specified by the manufacturer.

Compliance is determined as follows:

The manufacturer shall define a method for determining whether ESSENTIAL PERFORMANCE has been maintained during and after IMMUNITY tests as appropriate based on the manufacturer's RISK ASSESSMENT. Where manual intervention is required to restore ESSENTIAL PERFORMANCE, the method shall be provided in the instructions for use.

Where automatic recovery or manual intervention is allowed (criteria B, C) to restore ESSENTIAL PERFORMANCE, the time necessary to achieve restoration shall be justified in the RISK MANAGEMENT FILE.

Maintenance of BASIC SAFETY shall be determined by inspection of the equipment after completion of the IMMUNITY tests and if applicable by performing the appropriate tests of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

Automatic re-start of electrical, visual, or auditory stimulation shall not occur. See also subclauses 201.11.8 and 201.16.8 of this document.

NOTE 1 Disturbance of the display during any test does not constitute a non-compliance with the requirements of this document.

NOTE 2 Where the manufacturer has determined there is no ESSENTIAL PERFORMANCE, the ME EQUIPMENT or ME SYSTEMS can cease to function during or after the IMMUNITY test.

202.8.9 IMMUNITY TEST LEVELS

Addition:

The pass/fail criteria of 202.8.1.101 for tests specified in Table 4 of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 are as described in Table 202.101.

Table 202.101 – Pass/fail criteria for Table 4 of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020

Phenomenon	IMMUNITY test level	IMMUNITY pass/fail criteria	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE	±8 kV contact	A or B or C	A or B
	±2 kV air	A	A
	±4 kV air	A	A
	±8 kV air	A or B	A or B
	±15 kV air	A or B or C	A or B
Radiated RF EM fields	3 V/m 80 MHz to 2,7 GHz 80 % AM at 1 kHz	A	X [a)]
	10 V/m 80 MHz to 2,7 GHz 80 % AM at 1 kHz	X [a)]	A
Proximity fields from RF wireless communications equipment	See 8.10 of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/ AMD1:2020	A	A
RATED power frequency magnetic fields	30 A/m 50 Hz or 60 Hz	A or B or C	A or B

Phenomenon	IMMUNITY test level	IMMUNITY pass/fail criteria	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
Proximity magnetic fields	65 A/m 134,2 kHz 7,5 A/m 13,56 MHz	A or B or C	X [a)]
	8 A/m 30 kHz 65 A/m 134,2 kHz 7,5 A/m 13,56 MHz	X [a)]	A or B
[a)] X means not applicable			

The pass/fail criteria of 202.8.1.101 for tests specified in Table 7 of IEC 60601-1-2:2014, are as described in Table 202.102.

Table 202.102 – Pass/fail criteria for Table 7 of IEC 60601-1-2:2014

Phenomenon	IMMUNITY test level	IMMUNITY pass/fail criteria	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE	±8 kV contact	A or B or C	A or B
	±2 kV air	A	A
	±4 kV air	A	A
	±8 kV air	A or B	A or B
	±15 kV air	A or B or C	A or B
Conducted disturbances induced by RF fields	3 V 0,15 MHz to 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	A or B	X [a)]
	3 V 0,15 MHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	X [a)]	A or B
[a)] X means not applicable			

The pass/fail criteria of 202.8.1.101 for tests specified in Table 8 of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 are as described in Table 202.103.

Table 202.103 – Pass/fail criteria for Table 8 of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020

Phenomenon	IMMUNITY test level	IMMUNITY pass/fail criteria	
		Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
ELECTROSTATIC DISCHARGE	±8 kV contact	A or B or C	A or B
	±2 kV air	A or B or C	A or B
	±4 kV air	A or B or C	A or B
	±8 kV air	A or B or C	A or B
	±15 kV air	A or B or C	A or B
Electrical fast transients / bursts	±1 kV 100 kHz repetition rate	A or B or C	A or B
Surges line-to-ground	±2 kV	A or B or C	A or B
Conducted disturbances induced by RF fields	3 V 0,15 MHz to 80 MHz 6 V in ISM bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	A	X [a]
	3 V 0,15 MHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	X [a]	A

[a] X means not applicable

The pass/fail criteria of 202.8.1.101 for tests specified in Table 5, Table 6, and Table 9 of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 are as described in Table 202.104.

Table 202.104 – Pass/fail criteria for Table 5, Table 6, Table 9 of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020

Table	IMMUNITY pass/fail criteria	
	Professional healthcare facility environment	HOME HEALTHCARE ENVIRONMENT
Table 5 of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020	A or B or C	A or B
Table 6 of IEC 60601-1-2:2014	A or B or C	A or B
Table 9 of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020	A or B or C	A or B

Annexes

The annexes of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 apply except as follows:

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Addition:

Additional requirements for marking on the outside of ELECTROMYOGRAPHS and EVOKED RESPONSE EQUIPMENT are found in Table 201.C.101.

Table 201.C.101 – Marking on the outside of ELECTROMYOGRAPHS and EVOKED RESPONSE EQUIPMENT or its parts

Description of marking	Subclause
RATED power input	201.7.2.7
Symbol 10 of Table D.2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020	201.7.2.3 201.7.2.13

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This annex provides a concise rationale for the important requirements of the standard and is intended for those who are familiar with the subject of the standard but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for the proper application of the standard. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate any revision of the standard necessitated by these developments.

AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this document, with clause and subclause numbers parallel to those in the body of the document.

Subclause 201.4.2 – RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

ELECTRICAL STIMULATORS for evoked response are used to stimulate different locations such as central nervous system or peripheral nerves, and for invasive or non-invasive applications. It is strongly recommended to take into consideration the maximum possible current densities (RMS) for the type of electrodes used. Clinical data or scientific literature are typical sources of information that can be used to justify maximum current densities (RMS) for a medical device, taking into consideration the recommended electrodes, as well as the type of application.

Subclause 201.6.2 – Protection against electric shock

APPLIED PARTS shall be isolated to avoid unwanted current paths through the PATIENT due to the capacitance or a possible conductive connection to earth.

Subclause 201.7.2.3 – Consult ACCOMPANYING DOCUMENTS

Since only ELECTRODES recommended by the manufacturer should be used, the OPERATOR is required to consult the instructions for use.

Subclause 201.7.2.13 – Physiological effects (SAFETY SIGNS and warning statements)

The OPERATOR is particularly alerted to consult the instructions for use, because of the higher output allowed.

Subclause 201.7.9.2.101 a) – additional instructions for use

Because of the danger of tissue necrosis, any DC components of the WAVEFORMS should be declared.

Subclause 201.7.9.2.101 b) – additional instructions for use

ELECTRODES of inadequate size or unsuitable application could provoke skin reactions or burns.

Subclause 201.7.9.2.101 d) – additional instructions for use

Potential interference with implanted devices by the stimulating current could create a HAZARD.

Subclause 201.7.9.2.101 g) – additional instructions for use

The OPERATOR should be warned that stimulation with excessive current densities can be a HAZARD to the PATIENT.

Subclause 201.7.9.2.101 h) – additional instructions for use

APPLIED PARTS connected to a PATIENT CONNECTION, but not connected to the PATIENT, should be prevented from contacting other conductive parts in order to preserve the PATIENT CONNECTION electrical isolation.

Subclause 201.7.9.2.101 i) – additional instructions for use

It is recognized that biopotential signals are of very low amplitude, and it is likely there can be some remaining unavoidable electromagnetic interference. This can be acceptable based on RISK MANAGEMENT and proper disclosure in the instructions for use.

Subclause 201.8.3 – Classification of APPLIED PARTS

See rationale for 201.6.2.

Subclause 201.8.8.3 a)

The method of compliance added by this document was allowed in IEC 60601-1:2005 (see specifically Note 2 in Table 6 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012) and it has been safely used for many years, in the absence of evidence to the contrary, there is no reason for not using it going forward.

In addition, in Table 6 of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 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.

Subclause 201.12.1.101 – ELECTRICAL STIMULATOR accuracy

An accuracy of ±30 % is considered to provide adequate safety in many cases, since the values selected are mainly determined by the electrophysiological responses and the subjective reaction of the PATIENT. However, there can be applications for which ±30 % is not adequate. For these applications, the acceptable accuracy shall be addressed in the RISK MANAGEMENT FILE.

Subclause 201.12.1.103 – Constant voltage stimulator limit

For additional information related to maximum output determination, see IEC 60479-1.

Subclause 201.12.2.201 – Additional USABILITY requirement

Switching on the ELECTRICAL STIMULATOR inadvertently is considered to be a normal occurrence since the ELECTRICAL STIMULATOR is likely to be short-circuited or open-circuited accidentally during use due to movements of the ELECTRODES or the PATIENT.

Subclause 201.12.4.6 – Diagnostic or therapeutic acoustic pressure

White noise masking limit. The 125 dB HTL, from the 1998 edition was taken from IEC 60645-3:1994, which is a withdrawn standard. The current version of IEC 60645-3 does not address this subject. Also, dB HTL is a rather unusual unit of measure for white noise, dB SPL(A) is the common unit used for this type of parameter.

NOTE HTL: Hearing Threshold Level.

Subclause 201.12.4.101 – Supply voltage variations

Supply voltage fluctuations not exceeding the limit of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 should not influence the output parameters excessively.

Subclause 201.12.4.102 – ELECTRICAL STIMULATOR output indicator

The indication should advise the USER that the ELECTRICAL STIMULATOR is delivering stimuli, or that the ELECTRICAL STIMULATOR is armed to deliver stimuli as a result of further action by the USER, for example, manual triggering.

Subclause 201.12.4.103 – Limitation of ELECTRICAL STIMULATOR output parameters

Experience shows that the limits specified allow all known diagnostic applications to be carried out without exceeding the allowable value.

Subclause 202.8.1.101 – IMMUNITY pass/fail criteria

Criterion C is not acceptable for the HOME HEALTHCARE ENVIRONMENT. It is expected that equipment for this application shall be able to recover without OPERATOR intervention since the PATIENT is not likely to have appropriate training to determine proper functionality of the ME EQUIPMENT or ME SYSTEM.

AA.3 EMISSION and IMMUNITY tests example

Figure AA.1 provides an example of cable layout for EMISSION and IMMUNITY tests.

The setting can change based on the intended use or composition of the ME EQUIPMENT.

Compliance is checked by examination of the RISK MANAGEMENT FILE.

All relevant ELECTRODES shall be connected to the content of a 1 000 ml capacity phantom filled with 0,9 % saline or connected in conductive gel or paste (glue), positioned within 1 000 mm of the ME EQUIPMENT as shown in Figure AA.1. The purpose of the gel/paste is to provide stable impedance and WAVEFORM.

Any SIGNAL INPUT PARTS, SIGNAL OUTPUT PARTS, cables and POWER SUPPLY CORD are arranged generally as in Figure AA.1. Maintain distance of ≥400 mm between SIP/SOP cables and ground plane on the floor.

ME EQUIPMENT shall be located (800 ± 80) mm above the reference ground plane on the floor.

Dimensions in millimetres

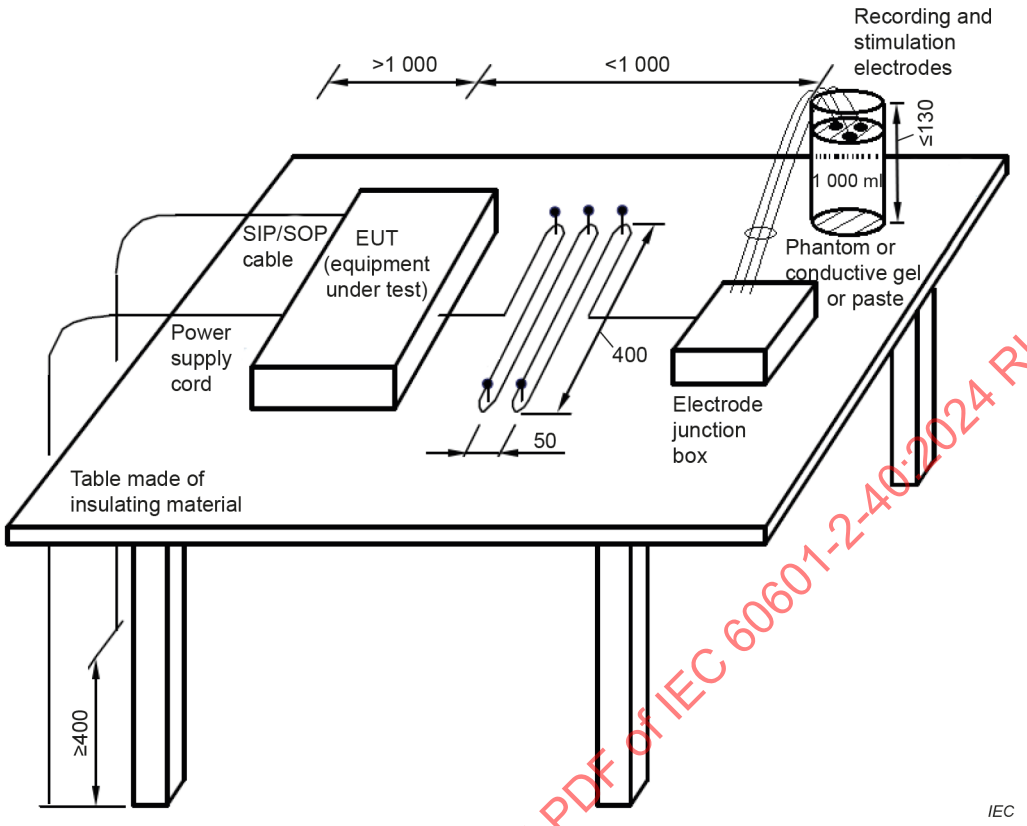


Figure AA.1 – Suggested cable layout for EMISSION and radiated IMMUNITY testing

AA.4 Electrosurgery disturbances

Test for protection against the effects of HF SURGICAL ME EQUIPMENT. If protection against the effects of HF SURGICAL ME EQUIPMENT is provided, the following is recommended for protection verification:

Perform the tests described below using PATIENT CABLES, LEAD WIRES, ACCESSORIES and settings recommended by the MANUFACTURER.

When the ME EQUIPMENT is used together with HF SURGICAL ME EQUIPMENT, it can show DEGRADATION and shall return to previous operating mode within 30 s after exposure to the field produced by the HF SURGICAL ME EQUIPMENT. There shall be no loss of any OPERATOR settings or stored data.

Compliance evaluation is performed according to Figure AA.2 and Figure AA.3.

HF SURGICAL ME EQUIPMENT which complies with IEC 60601-2-2 and has a minimum power cut mode capability of 300 W, a minimum coagulation mode of 100 W and a working frequency range of 300 kHz to 600 kHz should be used.

a) Test in cut mode:

Set the output power of the HF SURGICAL EQUIPMENT to the 300 W position.

Touch the metal contact/block in the test set-up (see Figure AA.2 and Figure AA.3) with the active ELECTRODE and remove the ELECTRODE slowly to get an arc.

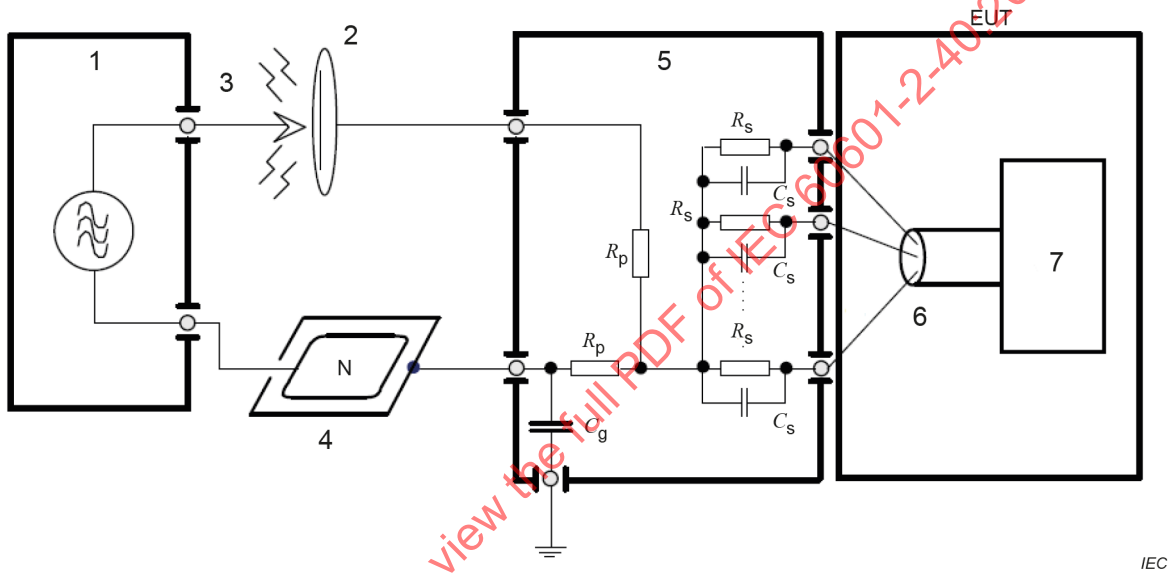
Verify whether the recorded/displayed EMG baseline returns to its normal position and the ME EQUIPMENT returns to the previous operating mode within 30 s without loss of any stored data.

Repeat the procedure five times.

b) Test in coagulation mode:

Repeat the test in item a) except with an output power of 100 W.

Test of the spray coagulation mode is excluded.



Components

1 HF SURGICAL ME EQUIPMENT

2 Metal plate

3 ACTIVE ELECTRODE of the HF SURGICAL ME EQUIPMENT

4 Metal plate/neutral ELECTRODE (N) of HF SURGICAL ME EQUIPMENT

5 Coupling network

6 PATIENT CABLE

7 ME EQUIPMENT

R_p 500 Ω, 200 W (low-inductive, < 5 µH, simulates PATIENT impedance)

C_g 47 nF (to minimize the effect of different types of HF SURGICAL ME EQUIPMENT designs)

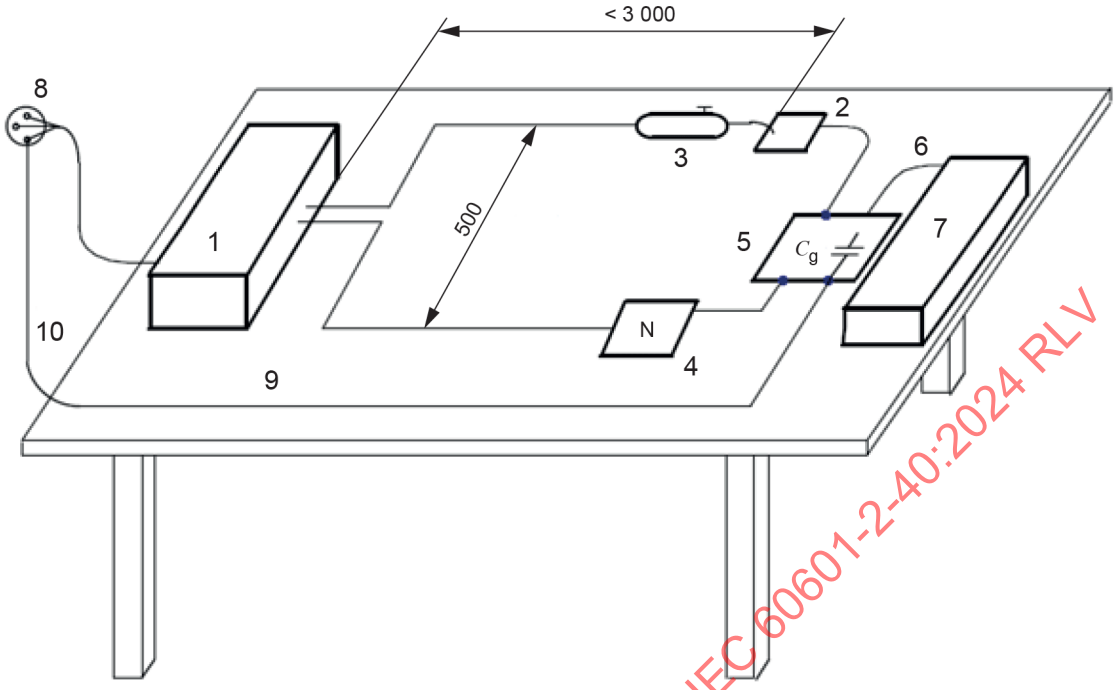
R_s 10 kΩ R_s//C_s simulate the skin impedance

C_s 47 nF

The test report should identify the HF SURGICAL EQUIPMENT that was used.

Figure AA.2 – Example of test setup for protection against the effects of HF SURGICAL ME EQUIPMENT

Dimensions in millimetres



Components

1 HF SURGICAL ME EQUIPMENT

2 Metal plate

3 ACTIVE ELECTRODE of the HF SURGICAL ME EQUIPMENT

4 NEUTRAL ELECTRODE of the HF SURGICAL ME EQUIPMENT

5 Coupling network – test set-up according to item 5 in Figure AA.2

6 PATIENT CABLE

7 ME EQUIPMENT under test

8 SUPPLY MAINS

9 Table made of insulating material

10 Connection to PROTECTIVE EARTH CONDUCTOR for grounding

The ME EQUIPMENT shall be located (800 ± 80) mm above the reference ground plane on the floor.

Figure AA.3 – Example of test setup for protection against the effects of HF SURGICAL ME EQUIPMENT

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IEC 60601-1-10, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

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IEC 60601-2-10, *Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators*

IEC 60645-3, *Electroacoustics – Audiometric equipment – Part 3: Test signals of short duration*

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

IEC 62368-1, *Audio/video, information and communication technology equipment – Part 1: Safety requirements*

[1] This publication was withdrawn.

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

_____

APPAREILS ÉLECTROMÉDICAUX –

Partie 2-40: Exigences particulières pour la sécurité de base et les performances essentielles des électromyographes et des appareils à potentiel évoqué

AVANT-PROPOS

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L'IEC 60601-2-40 a été établie par le sous-comité 62D: Équipements, logiciels et systèmes médicaux particuliers, du comité d'études 62 de l'IEC: Équipement médical, logiciels et systèmes médicaux. Il s'agit d'une Norme internationale.

Cette troisième édition annule et remplace la deuxième édition parue en 2016. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

a) des exigences relatives aux stimulateurs à tension constante ont été ajoutées;

b) des exigences relatives aux STIMULATEURS VISUELS ont été clarifiées.

Le texte de cette Norme internationale est issu des documents suivants:

Projet	Rapport de vote
62D/2168/FDIS	62D/2191/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à son approbation.

La langue employée pour l'élaboration de cette Norme internationale est l'anglais.

Ce document a été rédigé selon les Directives ISO/IEC, Partie 2, il a été développé selon les Directives ISO/IEC, Partie 1 et les Directives ISO/IEC, Supplément IEC, disponibles sous www.iec.ch/members_experts/refdocs. Les principaux types de documents développés par l'IEC sont décrits plus en détail sous www.iec.ch/publications.

Dans le présent document, les caractères d'imprimerie suivants sont utilisés:

– exigences et définitions: caractères romains;

– *modalités d'essais: caractères italiques;*

– indications de nature informative qui apparaissent 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 DEFINIS A L'ARTICLE 3 DE L'IEC 60601-1:2005, L'IEC 60601-1:2005/AMD1:2012 ET L'IEC 60601-1:2005/AMD2:2020, DANS LE PRESENT DOCUMENT OU COMME NOTES: PETITES MAJUSCULES.

Concernant la structure du présent document, 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, le 7.1, le 7.2 et le 7.2.1 sont tous des paragraphes de l'Article 7).

Dans le présent document, les références à des articles sont précédées du mot "Article" suivi du numéro de l'article concerné. Dans le présent document, les références aux paragraphes utilisent uniquement le numéro du paragraphe concerné.

Dans le présent document, la conjonction "ou" a 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 le présent document sont conformes à l'usage donné à l'Article 7 des Directives ISO/IEC, Partie 2. Pour les besoins du présent document:

– le verbe "devoir" signifie que la conformité à une exigence ou à un essai est obligatoire pour assurer la conformité au présent document;

– l'expression "il convient" signifie que la conformité à une exigence ou à un essai est recommandée, mais n'est pas obligatoire pour assurer la conformité au présent document;

– le verbe "pouvoir" est utilisé afin de décrire un moyen admissible pour assurer la conformité à une exigence ou à un essai.

Lorsqu'un astérisque (*) est utilisé comme premier caractère devant un titre ou au début d'un titre d'alinéa ou de tableau, il indique l'existence de recommandations ou d'une justification à consulter à l'Annexe AA.

Une liste de toutes les parties des séries IEC 60601 et IEC 80601, publiées sous le titre général *Appareils électromédicaux*, se trouve sur le site web de l'IEC.

Le comité a décidé que le contenu de ce document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous webstore.iec.ch dans les données relatives au document recherché. À cette date, le document sera

- reconduit,
- supprimé, ou
- révisé.

INTRODUCTION

Le présent document concerne la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES des ELECTROMYOGRAPHES et des APPAREILS A POTENTIEL EVOQUE. Il modifie et complète l'IEC 60601-1, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles* (IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 et IEC 60601-1:2005/AMD2:2020).

Cette révision a pour objectif d'actualiser le présent document par rapport à l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020.

Les exigences du présent document prévalent sur celles de l'IEC 60601-1.

L'Annexe AA fournit des "recommandations générales et des justifications" pour les exigences les plus importantes du présent document. Il est considéré que la connaissance des raisons qui ont conduit à énoncer ces exigences non seulement facilite l'application correcte du document, mais accélère en son temps toute révision rendue nécessaire par suite de changements dans la pratique clinique ou d'évolutions technologiques. Cependant, l'Annexe AA ne fait pas partie des exigences du présent document.

APPAREILS ÉLECTROMÉDICAUX –

Partie 2-40: Exigences particulières pour la sécurité de base et les performances essentielles des électromyographes et des appareils à potentiel évoqué

201.1 Domaine d'application, objet et normes connexes

L'Article 1 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.1.1 Domaine d'application

Remplacement:

La présente partie de l'IEC 60601 s'applique à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des ELECTROMYOGRAPHES et des APPAREILS A POTENTIEL EVOQUE, désignés ci-après sous le terme APPAREILS EM.

NOTE 1 Les appareils de type "Myofeedback" (rétroaction musculaire) pour lesquels le contrôle de la contraction musculaire est fondé sur l'électromyographie relèvent du domaine d'application du présent document.

NOTE 2 Les ELECTROMYOGRAPHES et les APPAREILS A POTENTIEL EVOQUE sont destinés aux applications de diagnostic et de surveillance.

NOTE 3 Lorsque les APPAREILS EM prennent en charge l'ELECTROMYOGRAPHIE et la STIMULATION A POTENTIEL EVOQUE, les articles relatifs aux stimulateurs électriques, auditifs et visuels s'appliquent. Lorsque les appareils prennent en charge l'ELECTROMYOGRAPHIE, mais pas la STIMULATION A POTENTIEL EVOQUE, les articles qui concernent uniquement les exigences relatives aux stimulateurs NE relèvent PAS du domaine d'application du présent document.

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 APPAREILS EM suivants sont exclus de la liste:

- APPAREILS EM destinés à une application thérapeutique;
- APPAREILS EM destinés à être utilisés avec les neurostimulateurs électriques transcutanés et les stimulateurs musculaires électriques (APPAREILS EM couverts par l'IEC 60601-2-10).

201.1.2 Objet

Remplacement:

L'objet du présent document est d'établir des exigences particulières pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES des ELECTROMYOGRAPHES et des APPAREILS A POTENTIEL EVOQUE [définis en 201.3.201 et 201.3.202].

201.1.3 Normes collatérales

Addition:

Le présent document fait référence aux normes collatérales applicables énumérées à l'Article 2 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 et à l'Article 201.2 du présent document.

L'IEC 60601-1-2:2014 et l'IEC 60601-1-2:2014/AMD1:2020 s'appliquent, avec les modifications apportées à l'Article 202. L'IEC 60601-1-3, l'IEC 60601-1-8 et l'IEC 60601-1-10 ne s'appliquent pas. Toutes les autres normes collatérales publiées de la série IEC 60601-1 s'appliquent, telles que publiées.

201.1.4 Normes particulières

Remplacement:

Dans la série IEC 60601, des normes particulières peuvent modifier, remplacer ou supprimer des exigences contenues dans l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 et dans les normes collatérales en fonction de l'APPAREIL EM concerné. Elles peuvent également ajouter des exigences supplémentaires pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES.

Une exigence d'une norme particulière prévaut sur l'exigence correspondante de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020.

La numérotation des articles et des paragraphes du présent document correspond à celle de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 avec le préfixe "201" (par exemple, le 201.1 du présent document concerne le contenu de l'Article 1 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020) ou à celle de la norme collatérale applicable avec le préfixe "20x" où x représente le ou les derniers chiffres du numéro de document de la norme collatérale (par exemple, le 202.4 du présent document concerne le contenu de l'Article 4 de la norme collatérale IEC 60601-1-2, le 203.4 du présent document concerne le contenu de l'Article 4 de la norme collatérale IEC 60601-1-3, etc.). Les modifications apportées au texte de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 sont précisées en utilisant les termes suivants:

"*Remplacement*" signifie que l'article ou le paragraphe de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable est remplacé complètement par le texte du présent document.

"*Addition*" signifie que le texte du présent document vient s'ajouter aux exigences de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable.

"*Amendement*" signifie que l'article ou le paragraphe de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable est modifié comme cela est indiqué par le texte du présent document.

Les paragraphes, figures ou tableaux qui sont ajoutés à ceux de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 sont numérotés à partir de 201.101. Toutefois, en raison du fait que les définitions dans l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 sont numérotées de 3.1 à 3.154, les définitions qui sont ajoutées dans le présent document sont numérotées à partir de 201.3.201. Les annexes qui sont ajoutées sont notées AA, BB, etc., et les éléments qui sont ajoutés aa), bb), etc.

Les paragraphes, figures ou tableaux qui s'ajoutent à ceux d'une norme collatérale sont numérotés à partir de 20x, où "x" est le chiffre de la norme collatérale, par exemple 202 pour l'IEC 60601-1-2, 203 pour l'IEC 60601-1-3, etc.

L'expression "le présent document" est utilisée pour se référer à l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, à toutes les normes collatérales applicables et au présent document, pris en compte ensemble.

Lorsque le présent document ne comprend pas d'article ou de paragraphe correspondant, l'article ou le paragraphe de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable, bien qu'il puisse être sans objet, s'applique sans modification; lorsqu'il est demandé qu'une partie quelconque de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 ou de la norme collatérale applicable, bien que potentiellement pertinente, ne s'applique pas, cela est expressément mentionné dans le présent document.

201.2 Références normatives

L'Article 2 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec l'exception suivante:

NOTE Une liste des références informatives est donnée dans la bibliographie.

Addition:

IEC 60601-1:2005, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-2:2014, *Appareils électromédicaux – Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Perturbations électromagnétiques – Exigences et essais*
IEC 60601-1-2:2014/AMD1:2020

IEC 60318 (toutes les parties), *Électroacoustique – Simulateurs de tête et d'oreille humaines*

ISO 15004-2, *Instruments ophtalmiques – Exigences fondamentales et méthodes d'essai – Partie 2: Protection contre les dangers de la lumière*

201.3 Termes et définitions

Pour les besoins du présent document, les termes et les définitions de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'appliquent, avec les exceptions suivantes:

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse https://www.electropedia.org/
- ISO Online browsing platform: disponible à l'adresse https://www.iso.org/obp

NOTE Un index des termes définis est fourni à partir de la page 62.

Termes et définitions supplémentaires:

201.3.201
ELECTROMYOGRAPHE
APPAREIL EM destiné à la détection ou à l'enregistrement des biopotentiels qui accompagnent le fonctionnement des nerfs et des muscles, qu'ils soient spontanés, volontaires ou provoqués par une stimulation électrique ou autre

201.3.202
APPAREIL A POTENTIEL EVOQUE
APPAREIL EM destiné à la détection ou à l'enregistrement des biopotentiels qui proviennent d'un stimulus évoqué

Note 1 à l'article: Le stimulus peut être électrique, tactile, auditif, visuel, olfactif, etc.

201.3.203
STIMULATEUR ELECTRIQUE
élément d'un APPAREIL EM destiné à appliquer des courants électriques au moyen d'ELECTRODES en contact direct avec le PATIENT, pour obtenir des biopotentiels évoqués

201.3.204
DUREE D'IMPULSION
durée de la FORME D'ONDE de l'impulsion du stimulus électrique à 50 % de l'amplitude de crête

201.3.205
FORME D'ONDE
variations en amplitude d'un stimulus électrique (tension ou courant) en fonction du temps dans la ou les PARTIES APPLIQUEES du STIMULATEUR ELECTRIQUE ou les biopotentiels collectés par l'ELEMENT D'ENTREE POUR BIOPOTENTIELS

201.3.206
STIMULATEUR AUDITIF
élément d'un APPAREIL EM destiné à appliquer à l'oreille ou aux oreilles du PATIENT, une pression acoustique qui provient d'un transducteur (écouteur, conducteur osseux ou champ libre), pour obtenir des biopotentiels évoqués

201.3.207
STIMULATEUR VISUEL
élément d'un APPAREIL EM destiné à appliquer aux yeux du PATIENT un rayonnement électromagnétique à impulsions du spectre visible qui provient d'un transducteur, pour obtenir des biopotentiels évoqués

201.3.208
ELEMENT D'ENTREE POUR BIOPOTENTIELS
PARTIE(S) APPLIQUEE(S) d'ELECTROMYOGRAPHES et d'APPAREILS A POTENTIEL EVOQUE pour la collecte des biopotentiels

201.3.209
ELECTRODE
partie conductrice en contact avec le PATIENT, qui est destinée à détecter l'activité électrique ou à appliquer au PATIENT le stimulus qui provient du STIMULATEUR ELECTRIQUE

201.3.210
CONDUCTEUR PATIENT
câble qui relie une ELECTRODE et un CABLE PATIENT ou l'APPAREIL EM

201.3.211
CABLE PATIENT
câble à plusieurs conducteurs utilisé pour relier les CONDUCTEURS PATIENT à l'APPAREIL EM

201.4 Exigences générales

L'Article 4 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.4.2 *PROCESSUS DE GESTION DES RISQUES pour les APPAREILS EM ou SYSTEMES EM

Addition:

Les FABRICANTS doivent inclure dans leur DOSSIER DE GESTION DES RISQUES le RISQUE associé à l'utilisation possible de leurs STIMULATEURS et accessoires pour fournir un courant supérieur à 10 mA en valeur efficace ou des densités de courant pour toute ELECTRODE supérieures à 2 mA/cm^2.

201.4.3 PERFORMANCES ESSENTIELLES

Addition:

En raison de la diversité des applications cliniques des ELECTROMYOGRAPHES et des APPAREILS A POTENTIEL EVOQUE, le présent document ne spécifie aucune PERFORMANCE ESSENTIELLE supplémentaire. Toutefois, les PERFORMANCES ESSENTIELLES sont spécifiées par le fabricant, conformément aux exigences du 4.3 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020.

201.4.11 Puissance absorbée

Remplacement:

La puissance absorbée est mesurée avec une résistance de charge ayant la plus faible valeur spécifiée dans la description technique (voir 201.7.9.3.101 a)), et avec toutes les commandes de sortie réglées pour fournir la puissance absorbée maximale.

201.5 Exigences générales relatives aux essais des APPAREILS EM

L'Article 5 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.5.4 Autres conditions

Addition:

Lorsque des valeurs de tension et de courant sont utilisées dans le présent document, elles correspondent aux valeurs efficaces d'une tension ou d'un courant alternatif, continu ou composite dont la moyenne est prise sur une période de 1 s, sauf indication contraire.

201.6 Classification des APPAREILS EM et des SYSTEMES EM

L'Article 6 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.6.2 * Protection contre les chocs électriques

Amendement:

Supprimer PARTIE APPLIQUEE DE TYPE B.

201.7 Identification, marquage et documentation des APPAREILS EM

L'Article 7 de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 s'applique, avec les exceptions suivantes:

201.7.2 Marquage sur l'extérieur des APPAREILS EM ou parties d'APPAREILS EM

201.7.2.3 * Consultation des DOCUMENTS D'ACCOMPAGNEMENT

Remplacement:

Le signe de sécurité ISO 7010-M002 doit être utilisé (voir Tableau D.2, signe de sécurité 10 de l'Annexe D de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020).

201.7.2.7 Puissance absorbée du RESEAU D'ALIMENTATION

Remplacement:

La puissance absorbée ASSIGNEE d'un APPAREIL EM alimenté par le RÉSEAU doit être la puissance absorbée maximale, dont la moyenne est prise sur une période de 5 s dans les conditions de fonctionnement spécifiées prévues par le fabricant.

201.7.2.8 Connecteurs de sortie

201.7.2.8.2 Autres sources de puissance

Addition:

Voir aussi le 201.12.4.102.

201.7.2.13 * Effets physiologiques (SIGNES DE SECURITE et avertissements)

Addition:

Un APPAREIL EM capable de fournir, dans une résistance de charge de 1 000 Ω, des valeurs de sortie pour le stimulus électrique supérieures à 10 mA en valeur efficace ou à 10 V en valeur efficace, dont la moyenne est prise sur une période de 5 s, doit être marqué, près des connexions d'ELECTRODES, du signe de sécurité ISO 7010-M002 (voir signe de sécurité 10 dans le Tableau D.2 de l'Annexe D de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020).

201.7.4 Marquage des organes de commande et des instruments

201.7.4.2 Dispositifs de commande

Remplacement:

Les informations suivantes doivent être fournies dans les instructions d'utilisation:

a) plage de sortie du stimulateur électrique: spécifier les valeurs minimales et maximales;

b) type de commande utilisé: spécifier si la commande de sortie est continue ou par incréments discrets;

c) si des incréments discrets sont utilisés, l'incrément minimal doit être spécifié;

d) plage d'impédances de charge: spécifier la charge minimale et maximale.

La conformité est vérifiée par examen des DOCUMENTS D'ACCOMPAGNEMENT.

201.7.9 DOCUMENTS D'ACCOMPAGNEMENT

201.7.9.2 Instructions d'utilisation

Paragraphe supplémentaire:

201.7.9.2.101 Informations complémentaires dans les instructions d'utilisation

Les instructions d'utilisation doivent, en plus, comprendre:

a) * Des informations sur la ou les FORMES D'ONDE de sortie, y compris toute composante continue, les DUREES D'IMPULSIONS, les fréquences de répétition des impulsions, l'amplitude maximale de la tension ou du courant de sortie et l'effet de l'impédance de charge sur les paramètres exigés.

b) * Une recommandation sur les dimensions des ELECTRODES à utiliser et sur la façon de les appliquer dans chaque cas particulier d'examen auquel le STIMULATEUR ELECTRIQUE est destiné.

c) Une recommandation sur l'ensemble des précautions nécessaires à prendre lorsqu'il existe à la sortie une composante continue supérieure à 10 µA dont la moyenne est prise sur une période de 1 s.

d) * Une recommandation signalant qu'il convient de ne pas soumettre un PATIENT ayant un dispositif électronique implanté (par exemple, un stimulateur cardiaque) à une stimulation électrique, sans avoir obtenu l'avis d'un médecin spécialiste.

e) Une recommandation d'éviter une stimulation transthoracique.

f) Un avertissement sur les DANGERS possibles suivants:

   – la connexion simultanée d'un PATIENT à un appareil chirurgical à haute fréquence (HF) et à un ELECTROMYOGRAPHE ou à un APPAREIL A POTENTIEL EVOQUE peut provoquer des brûlures à l'emplacement des ELECTRODES et des dégradations possibles des PARTIES APPLIQUEES;

   – le fonctionnement à proximité immédiate d'un appareil de thérapie à ondes courtes ou à micro-ondes peut provoquer une instabilité dans les PARTIES APPLIQUEES.

g) * Pour les APPAREILS EM capables de fournir, dans l'impédance de charge spécifiée (voir 201.7.9.3.101 a)), des valeurs de sortie supérieures à 10 mA en valeur efficace ou à 10 V en valeur efficace, dont la moyenne est prise sur une période de 1 s, ou des impulsions dont l'énergie dépasse 10 mJ par impulsion à l'impédance de charge spécifiée:

   – une liste des ELECTRODES recommandées qui peuvent être utilisées avec l'APPAREIL EM.

h) * Une recommandation d'éviter tout contact accidentel entre les PARTIES APPLIQUEES connectées, mais non appliquées, et d'autres parties conductrices, y compris celles reliées à la terre de protection.

i) * Toute susceptibilité connue aux phénomènes électromagnétiques.

201.7.9.3 Description technique

Paragraphe supplémentaire:

201.7.9.3.101 Informations complémentaires dans la description technique

La description technique doit, en plus, comprendre le point suivant:

a) La description technique doit spécifier les paramètres cités en 201.7.9.2.101, ainsi que la plage d'impédances de charge pour laquelle ces paramètres sont valables.