

INTERNATIONAL STANDARD



**Medical electrical equipment –
Part 2-46: Particular requirements for the basic safety and essential performance
of operating tables**

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COMMENTED VERSION

INTERNATIONAL STANDARD



**Medical electrical equipment –
Part 2-46: Particular requirements for the basic safety and essential performance
of operating tables**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-46: Particular requirements for the basic safety and essential performance of operating tables

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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This commented version (CMV) of the official standard IEC 60601-2-46:2023 edition 4.0 allows the user to identify the changes made to the previous IEC 60601-2-46:2016 edition 3.0. Furthermore, comments from IEC SC 62D experts are provided to explain the reasons of the most relevant changes, or to clarify any part of the content.

A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text. Experts' comments are identified by a blue-background number. Mouse over a number to display a pop-up note with the comment.

This publication contains the CMV and the official standard. The full list of comments is available at the end of the CMV.

IEC 60601-2-46 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 fourth edition cancels and replaces the third edition published in 2016. This edition constitutes a technical revision **2**.

This edition includes the following significant technical change with respect to the previous edition: structural alignment with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

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

Draft	Report on voting
62D/1939/CDV	62D/1989/RVC

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 PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

- "clause" means one of the 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 particular standard 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,
- replaced by a revised edition, or
- amended.

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INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of OPERATING TABLES.

It amends and supplements IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

The aim of this document is to update it with reference to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 through reformatting and technical changes.

The requirements of this particular standard take priority over those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

A "general guidance and rationale" for the more important requirements of this particular standard 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 standard 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.

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-46: Particular requirements for the basic safety and essential performance of operating tables

201.1 Scope, object and related standards

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

201.1.1 Scope

Replacement:

This part of IEC 60601 specifies safety requirements for OPERATING TABLES, whether or not having electrical parts, including TRANSPORTERS, used for the transportation of the OPERATING TABLE top to or from the base or pedestal of an OPERATING TABLE with detachable OPERATING TABLE top.

NOTE See also IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 4.2.

This particular standard does not apply to **3**

- dental PATIENT chairs (see ISO 7494-1),
- examination chairs and couches,
- PATIENT-supporting systems of diagnostic, interventional and therapeutic ~~devices~~ equipment (see IEC 60601-2-54 or IEC 60601-2-43),
- OPERATING TABLE heating blankets (see ~~IEC 80601-2-35~~ IEC 60601-2-35),
- PATIENT transfer equipment,
- delivery tables and delivery beds,
- medical beds (see IEC 60601-2-52 and EN 50637), and
- field tables.

~~If OPERATING TABLES will be used in combination with diagnostic and/or therapeutic devices the relevant requirements of each related particular standard are also applicable.~~

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for OPERATING TABLES as defined in 201.3. ~~204~~203.

201.1.3 Collateral standards

Addition:

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

IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clauses 202 and 203 respectively. IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 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 particular standard 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 1) 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 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard 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 and applicable collateral standards 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 particular standard.

"Addition" means that the text of this particular standard 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 particular standard.

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, 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, e.g. 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 particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, 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 particular standard.

201.2 Normative references ⁴

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

Replacement:

~~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 60601-1-3:2008, Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment

Amendment 1:2013⁴

Amendment 2:2021

ISO 2878:2017, Rubber, vulcanized or thermoplastic – Antistatic and conductive products – Determination of electrical resistance

Addition:

IEC 60601-2-2:2017, 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 60601-2-43:2022, Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures

IEC 60601-2-54:2022, Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

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 and the following 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 on page 29.

⁴ ~~There exists a consolidated edition 2-1, which includes IEC 60601-1-3:2008 and its Amendment 1 (2013).~~

Addition:

201.3.201

MOBILE OPERATING TABLE

OPERATING TABLE intended to be relocated from one location to another while supported by its own wheels or equivalent means

201.3.202

NORMAL POSITION

position of the OPERATING TABLE top with all sections set in the horizontal position

201.3.203

OPERATING TABLE

device with the INTENDED USE of supporting and positioning a PATIENT during surgical procedures for not more than 24 h

Note 1 to entry: This includes pre- and post-operative phases in general, surgical/medical procedures under medical supervision.

Note 2 to entry: The device may serve as a PATIENT-supporting systems during diagnostic, interventional and therapeutic procedures but still considered to be a separate ME EQUIPMENT. **5**

201.3.204

TRANSPORTER

device intended for the transportation of an OPERATING TABLE top to or from the base or pedestal of an OPERATING TABLE, or the transportation of the OPERATING TABLE top complete with the base

Note 1 to entry: This definition does not include devices intended to simplify the transport of the PATIENT from one location to another without the transfer of parts associated with an OPERATING TABLE.

Note 2 to entry: The transportation can be done with or without a PATIENT in place.

201.3.205

TRENDELENBURG POSITION

supine PATIENT position where the body is in a single plane, with that plane inclined so that the head is lower than the pelvis

201.4 General requirements

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

201.4.3 Essential performance

Addition:

Besides the definition of the MANUFACTURER, the following shall be considered ESSENTIAL PERFORMANCE ~~is required from~~ for OPERATING TABLES: supporting a PATIENT without ~~unwanted~~ unintended movement (motorized or not) leading to an unacceptable risk **6** in a SINGLE FAULT CONDITION.

201.4.7 SINGLE FAULT CONDITION for ~~OPERATING TABLES~~ ME EQUIPMENT

Addition:

~~Additional SINGLE FAULT CONDITIONS to be regarded with OPERATING TABLES:~~

- ~~• flaw (impairment) in the transmission of commands from/to input devices.~~

The MANUFACTURER should provide means, where practical, to ensure that, in a SINGLE FAULT CONDITION, the PATIENT support platform of the OPERATING TABLE can return to a position for emergency treatment.

NOTE 101 Examples of positions for emergency treatment are TRENDLENBURG or positions for cardiopulmonary resuscitation (CPR), emergency back flattening.

201.5 General requirements for testing ~~OPERATING TABLES~~ ME EQUIPMENT

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

201.6 Classification of ~~OPERATING TABLES~~ ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 6, applies.

201.7 ~~OPERATING TABLES~~ ME EQUIPMENT identification, marking and documents

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

201.7.2 Marking on the outside of ~~OPERATING TABLES~~ ME EQUIPMENT or ~~OPERATING TABLES~~ ME EQUIPMENT parts

~~201.7.2.10~~ — Applied parts

~~Amendment:~~

~~The APPLIED PART marking symbol according to Table D.1 (symbol 19, 20 or 21) shall be located in a prominent place. Compliance is checked by inspection.~~ 7

201.7.2.21 Mass of MOBILE ~~OPERATING TABLES~~ ME EQUIPMENT

IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 7.2.21, does not apply.

201.7.9.2 Instructions for use

201.7.9.2.1 General

Addition:

Instructions for use shall include information regarding potential HAZARDS related to HIGH FREQUENCY SURGICAL EQUIPMENT 8, cardiac defibrillators and cardiac defibrillator-monitors.

NOTE 101 Potential HAZARDS which ~~have~~ need to be considered include but are not limited to: PATIENT burns, explosion HAZARDS or electrical shock of the PATIENT or OPERATOR.

201.8 Protection against electrical HAZARDS from ~~OPERATING TABLES~~ ME EQUIPMENT

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

201.8.6.7 POTENTIAL EQUALIZATION CONDUCTOR

Addition:

Where potential equalization is required, the APPLIED PARTS of OPERATING TABLES with ACCESSIBLE PARTS which are not PROTECTIVELY EARTHED shall be provided with a potential equalization terminal or a potential equalization connector. **9**

For OPERATING TABLES with a POTENTIAL EQUALIZATION terminal, the impedance between the potential equalization terminal or connector and any ACCESSIBLE PART shall not exceed 200 mΩ.

Compliance is checked by using the test method of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 8.6.4.

201.9 Protection against MECHANICAL HAZARDS of ~~OPERATING TABLES~~ ME EQUIPMENT and ME SYSTEMS

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

201.9.2.3 Other MECHANICAL HAZARDS associated with moving parts

201.9.2.3.1 *Unintended movement

Addition:

Wireless remote control devices of OPERATING TABLES shall be clearly assigned by internal means to the individual ~~items of~~ OPERATING TABLES.

Compliance is checked by inspection.

201.9.4 Instability HAZARDS

201.9.4.2.2 *Instability excluding transport position

Item a)

Addition:

OPERATING TABLES shall be subjected to SAFE WORKING LOAD.

NOTE See Figure AA.1 and Table AA.1 for guidance regarding mass distribution.

Additional requirement:

OPERATING TABLES with transferable OPERATING TABLE tops shall be designed and manufactured so as to minimize the RISK of physical injuries and of accidental separation of the OPERATING TABLE tops when being transferred.

Specifications concerning OPERATING TABLE top transfer operations shall indicate in the instructions for use the safety elements inherent in the transfer operation.

Compliance is checked by inspection and the following tests.

Having transferred the OPERATING TABLE top to the TRANSPORTER, the stability in NORMAL USE test of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 9.4.2.2, shall be carried out. The OPERATING TABLE top shall not disengage from the TRANSPORTER.

The test is then repeated with the OPERATING TABLE top being placed on the base and the stability test is carried out on the base immediately after transfer.

201.9.4.2.4.3 *Movement over a threshold

Addition:

If MOBILE OPERATING TABLES and TRANSPORTERS are not able to negotiate such obstacles safely, the MANUFACTURER shall include a warning in the instructions for use or determine which threshold can be negotiated safely and inform the OPERATOR accordingly.

201.9.4.3.1 Instability in transport position

Replacement of items b) and c) of the test procedure:

The MOBILE OPERATING TABLE or TRANSPORTER is placed with the SAFE WORKING LOAD in place, and the locking device (e.g. brakes) activated, on a plane covered with 2 mm to 4 mm thick vinyl flooring material and inclined at 6° from the horizontal plane on a concrete floor. Following initial elastic movement, initial creepage, and initial pivoting of castors, there shall be no movement of the MOBILE OPERATING TABLE or TRANSPORTER greater than 50 mm (in relation to the inclined plane). Any initial movement shall not result in an unacceptable RISK, taking into account the NORMAL USE of the MOBILE OPERATING TABLE or TRANSPORTER.

NOTE See Figure AA.1 and Table AA.1 for guidance regarding mass distribution.

201.9.8 MECHANICAL HAZARDS associated with support systems

201.9.8.1 General

Replacement of first dash:

- The construction of the support, suspension or actuation system shall be designed based upon Table 201.101 and the SAFE WORKING LOAD.

201.9.8.2 *TENSILE SAFETY FACTOR

Replacement:

Support systems shall maintain structural integrity during the EXPECTED SERVICE LIFE of the OPERATING TABLE or TRANSPORTER. TENSILE SAFETY FACTORS shall not be less than those shown in Table 201.101 unless an alternative method demonstrates structural integrity throughout the EXPECTED SERVICE LIFE of the OPERATING TABLE or TRANSPORTER.

Due to the fact that it is not always possible to determine in general whether a specific component or construction is impaired by wear, the decision shall be based on experience, tests and/or RISK MANAGEMENT and shall be documented accordingly. However, the MANUFACTURER is responsible for choosing the adequate TENSILE SAFETY FACTOR.

The OPERATING TABLE or TRANSPORTER shall be tested with the SAFE WORKING LOAD (required PATIENT mass according to Figure AA.1 and Table AA.1) and a TENSILE SAFETY FACTOR according to Table 201.101.

Table 201.101 – Determination of TENSILE SAFETY FACTOR

Situation			Minimum TENSILE SAFETY FACTOR
No.	System part	Elongation	
1	Support system not impaired by wear	Material having a specific elongation at break equal to or greater than 5 %	2,5
2	Support system not impaired by wear	Material having a specific elongation at break of less than 5 %	4
3	Support system impaired by wear	Material having a specific elongation at break equal to or greater than 5 %	5
4	Support system impaired by wear	Material having a specific elongation at break of less than 5 %	8
The material tensile strength and all external forces to be expected are quantifiable and known accurately.			

Compliance with 201.9.8.1 and 201.9.8.2 is checked by inspection of the OPERATING TABLE or TRANSPORTER, the RISK MANAGEMENT FILE, the specifications of materials used and the processing specifications for these materials.

When test results are part of relevant information, testing consists of gradually applying a test load to the support assembly under test equal to the SAFE WORKING LOAD times the required TENSILE SAFETY FACTOR. The support assembly under test ~~is to~~ shall be in equilibrium after 1 min, or otherwise not result in an unacceptable RISK.

NOTE The 1 min time period might need to be longer for materials which might have creep type problems, such as plastics or other non-metallic materials.

201.9.8.3.2 *Static forces due to loading from persons

Replacement of item b):

- b) OPERATING TABLES and TRANSPORTERS shall be designed so that failure or permanent deformation shall not occur when subjected to 2,2 times SAFE WORKING LOAD in NORMAL POSITION. **10**

NOTE 101 See Figure AA.1 and Table AA.1 for guidance regarding mass distribution.

Compliance is checked by the following test.

- 1) In NORMAL POSITION and at maximum height, the OPERATING TABLES shall be statically loaded with 2,2 times SAFE WORKING LOAD. The deformation after 5 min is recorded. The OPERATING TABLES shall not be operated or moved during this part of the test.*
- 2) The load is removed and replaced as soon as practical with SAFE WORKING LOAD.*
- 3) After waiting 5 min in NORMAL POSITION and at maximum height, the OPERATING TABLES shall be statically loaded with 2,2 times SAFE WORKING LOAD. The deformation after 5 min is recorded.*

The deflections are compared to the values measured under 1) and shall be within $\pm 2,5$ mm of the original readings.

- 4) The load is removed and replaced with SAFE WORKING LOAD and the OPERATING TABLES shall operate over the full range of movements. The deformation/deflection shall be measured at the end of the head- and leg-section of the OPERATING TABLE. For ACCESSORIES, the measuring point shall be determined according the intended use.*

201.9.8.3.3 *Dynamic forces due to loading from persons

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 9.8.3.3, does not apply.

201.10 Protection against unwanted and excessive radiation HAZARDS

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

NOTE The collateral standard IEC 60601-1-3 is referenced in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and is covered under Clause 203 of this document. **11**

201.11 Protection against excessive temperatures and other HAZARDS

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

201.11.6 Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ~~OPERATING TABLES~~ ME EQUIPMENT

201.11.6.5 Ingress of water or particulate matter into ~~OPERATING TABLES~~ ME EQUIPMENT and ME SYSTEMS

Addition:

OPERATING TABLES shall be at least IPX4.

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

Addition:

In the event of interruption of the SUPPLY MAINS, whether or not the SUPPLY MAINS is restored, the height and configuration of the OPERATING TABLE top shall not alter. Movement into NORMAL POSITION and/or TRENDLENBURG POSITION shall remain possible.

Compliance is checked as follows.

- a) *By test after interruption of the SUPPLY MAINS with the OPERATING TABLE top in any position, other than the NORMAL POSITION, midway between its maximum and minimum heights, subjected to SAFE WORKING LOAD with mass distributed according to Figure AA.1 and Table AA.1. Movement into and out of the NORMAL POSITION shall be obtainable using the methods described by the MANUFACTURER.*
- b) *By observation after restoration of the SUPPLY MAINS.*

201.12 Accuracy of controls and instruments and protection against hazardous outputs

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 12, applies.

201.13 HAZARDOUS SITUATIONS and fault conditions for ~~OPERATING TABLES~~ ME EQUIPMENT

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

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

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

201.15 Construction of ~~OPERATING TABLES~~ ME EQUIPMENT

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

~~201.15.3.5~~ — ~~Rough handling test~~

~~Amendment:~~

~~Subclause 15.3.5 of the general standard applies to TRANSPORTERS and MOBILE OPERATING TABLES only.~~ 12

201.15.4 ME EQUIPMENT components and general assembly

Additional subclause:

201.15.4.101 *Pads for OPERATING TABLES 13

The MANUFACTURER shall provide evidence of durability and pressure distribution and demonstrate that the pads are designed to their intended purpose. The methodology used shall be based on experience and/or RISK MANAGEMENT and shall be documented accordingly.

Compliance is checked by inspection of documentation.

201.15.4.7.2 Accidental operation of ~~OPERATING TABLES~~ ME EQUIPMENT

Additional subclause:

201.15.4.7.2.101 Inadvertent operation

The actuating force for foot-operated control devices shall not be smaller than 10 N.

Compliance is checked by inspection.

201.16 ME SYSTEMS

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 16, applies.

201.17 Electromagnetic compatibility of ~~OPERATING TABLES~~ ME EQUIPMENT and ME SYSTEMS

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

202 Electromagnetic disturbances – Requirements and tests

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

202.8 Electromagnetic IMMUNITY requirements for ~~OPERATING TABLES~~ ME EQUIPMENT and ME SYSTEMS

Additional subclauses:

202.8.101 IMMUNITY pass/fail criteria

At least the following IMMUNITY pass/fail criteria associated with BASIC SAFETY and ESSENTIAL PERFORMANCE shall apply at all immunity test levels:

- no permanent degradation or loss of function or OPERATOR settings which are not recoverable shall be observed;
- no movement without activation of the OPERATOR shall occur;
- no movement, other than intended by the OPERATOR, shall occur;
- the OPERATING TABLE shall maintain ESSENTIAL PERFORMANCE within the limits specified by the MANUFACTURER (e.g. temporary degradation of functionality);
- within 15 s after the immunity test, the OPERATING TABLE shall resume normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data, and shall continue to perform its intended function as described in the ACCOMPANYING DOCUMENTS.

202.8.102 IMMUNITY to HF SURGICAL EQUIPMENT EMISSIONS

Electrical OPERATING TABLES intended for use within 2 m of active HF SURGICAL EQUIPMENT or to have a connection to a PATIENT undergoing treatment with HF SURGICAL EQUIPMENT shall be tested for IMMUNITY to HF SURGICAL EQUIPMENT EMISSIONS.

The IMMUNITY pass/fail criteria of 202.8.101 shall apply.

All tests ~~have to~~ shall be performed in two conditions:

- without activating a movement of the OPERATING TABLE;
- with activating any movement of the OPERATING TABLE (e.g. height movement).

In order to accommodate the huge variety of HF SURGICAL EQUIPMENT, all the tests described in 202.8.102 ~~have to~~ shall be applied with two different HF SURGICAL EQUIPMENT:

- HF SURGICAL EQUIPMENT complying with IEC 60601-2-2 and having a minimum power cut mode capability of 300 W, a minimum coagulation mode of 100 W and working frequencies to include at least 400 kHz $\pm$ 100 kHz; the HF SURGICAL EQUIPMENT used shall be specified in the test report;
- HF SURGICAL EQUIPMENT, ~~should have~~ with an argon plasma coagulation mode with a minimum 14 peak-to-peak voltage of 4 000 V_p (open circuit voltage) and 120 W power capability; the HF SURGICAL EQUIPMENT used shall be specified in the test report.

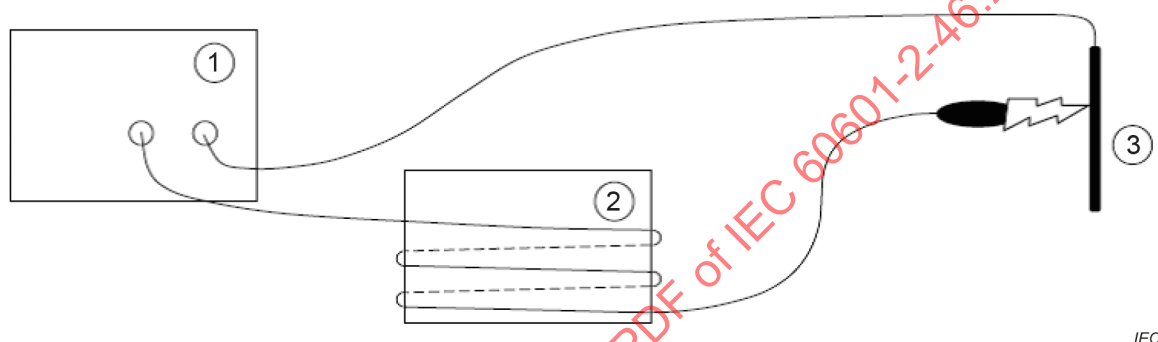
NOTE 1 The EM environment for OPERATING TABLES is a special environment (medical treatment areas with high-powered OPERATING TABLES). Besides the immunity tests required for the professional healthcare facility environment (according to IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, Table 4 to Table 9), at least immunity to HF SURGICAL EQUIPMENT emissions as described in 202.8.102 is applicable to OPERATING TABLES.

Compliance is checked by the following tests.

- a) For parts of OPERATING TABLES that are not PATIENT-COUPLED (e.g. remote control devices, foot-switches), wrap the cable of a MONOPOLAR HF SURGICAL ACCESSORY around the ENCLOSURE of such parts so that at least two full loops of the cable are present, as shown in Figure 202.101. No more than three loops are needed. If the part of the OPERATING TABLE is too large to accommodate two loops, wrap as much as possible or drape the cable over the portion of the parts of the OPERATING TABLE that is most likely to come in contact with HF SURGICAL EQUIPMENT ACCESSORY cables.

Attach one end of a cable to the NEUTRAL ELECTRODE connector of the HF SURGICAL EQUIPMENT and the other end to a metal plate. Using the MONOPOLAR HF SURGICAL ACCESSORY, activate the HF SURGICAL EQUIPMENT in each possible output mode and arc the ACCESSORY to the metal plate. For each mode, adjust the HF SURGICAL EQUIPMENT to the setting that will create the highest peak output voltage.

NOTE 2 This test generates high E-fields and high H-fields with the greatest possible spread of frequencies.



Key

- 1 HF SURGICAL EQUIPMENT
- 2 part of OPERATING TABLE (e.g. remote control devices, foot switches)
- 3 metal plate (typical size of a neutral electrode, specified by the MANUFACTURER of the used HF SURGICAL EQUIPMENT)

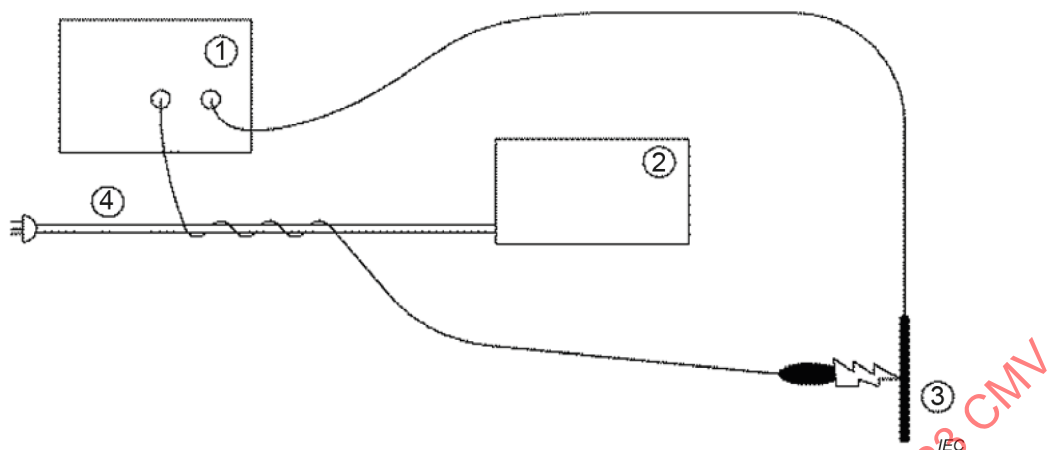
Figure 202.101 – ENCLOSURE ad hoc test

- b) Repeat the test of a) with the MONOPOLAR HF SURGICAL ACCESSORY short-circuiting to the metal plate. The HF SURGICAL EQUIPMENT should be adjusted to obtain the maximum output power for each output mode.

NOTE 3 This test generates the highest output currents and thus the greatest H-fields. It also creates high E-fields at the fundamental output frequency.

- c) Repeat the tests of a) and b) with the cable of the MONOPOLAR HF SURGICAL ACCESSORY wrapped around the POWER SUPPLY CORD of the OPERATING TABLE (unit under test) as shown in Figure 202.102. This test does not need to be performed for PERMANENTLY INSTALLED OPERATING TABLES or for OPERATING TABLES without a mains POWER SUPPLY CORD. Three windings of the MONOPOLAR HF SURGICAL ACCESSORY cable around the POWER SUPPLY CORD are sufficient.

NOTE 4 This test simulates the noise that can be coupled into the operating cables or ME SYSTEM through the mains power cable.

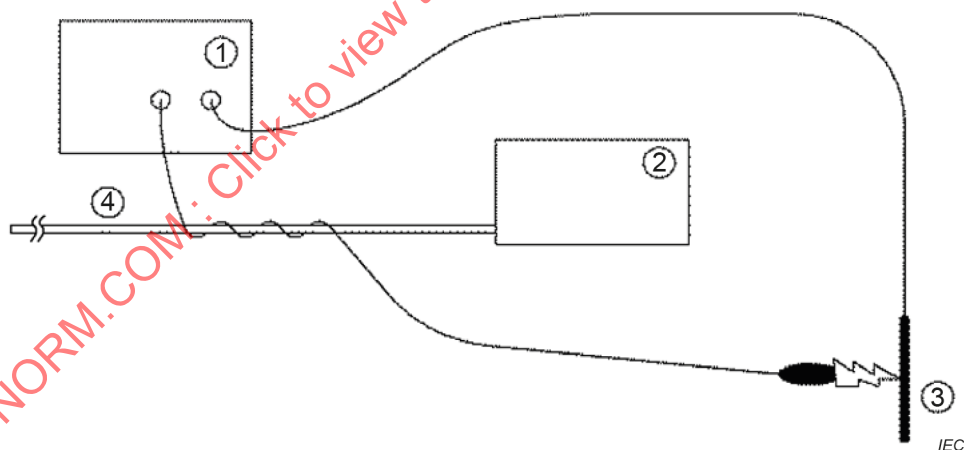


Key

- 1 HF SURGICAL EQUIPMENT
- 2 unit under test
- 3 metal plate (typical size of a neutral electrode, specified by the MANUFACTURER of the used HF SURGICAL EQUIPMENT)
- 4 MAINS POWER SUPPLY CORD of unit under test

Figure 202.102 – POWER SUPPLY CORD ad hoc test

- d) If the OPERATING TABLE has cables that enter the sterile field (e.g. cables from a remote control), coupling can also occur between those cables and the MONOPOLAR HF SURGICAL ACCESSORY cable. To test for this possibility, repeat the tests of a) and b) with the cable of the MONOPOLAR HF SURGICAL ACCESSORY wrapped around the ACCESSORY cable of the OPERATING TABLE under test, as shown in Figure 202.103. Three windings of the MONOPOLAR HF SURGICAL ACCESSORY CABLE around the OPERATING TABLE ACCESSORY CABLE are sufficient.



Key

- 1 HF SURGICAL EQUIPMENT
- 2 unit under test
- 3 metal plate (typical size of a neutral electrode, specified by the MANUFACTURER of the used HF SURGICAL EQUIPMENT)
- 4 ACCESSORY cable of unit under test

Figure 202.103 – ACCESSORY cable ad hoc test

The following tests shall be applied for the OPERATING TABLE itself. For OPERATING TABLES with detachable OPERATING TABLE tops, the combination of the base together with the OPERATING TABLE top ~~has to~~ shall be tested.

In all cases, leads of the active and neutral electrodes shall be draped along the side rails and/or the exposed metal parts of the OPERATING TABLE top.

During these tests, the HF SURGICAL EQUIPMENT shall be operated in each available mode with the maximum output power and/or the maximum peak voltage.

- e) The HF SURGICAL EQUIPMENT shall be operated at open circuit.*
- f) The HF SURGICAL EQUIPMENT shall be operated while short-circuiting the active and neutral electrodes and sparking with the active electrodes at the side rails and/or the exposed metal parts of the OPERATING TABLE top.*

203 *Radiation protection in diagnostic X-ray equipment

IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021 applies, except as follows:

~~Addition:~~

~~if the OPERATING TABLE is used as a PATIENT supporting system of a radiological diagnostic and interventional ME EQUIPMENT as described in IEC 60601-2-43, the aluminium equivalence requirements of IEC 60601-1-3 has to be met.~~

203.10.1 General

Replacement:

If the OPERATING TABLE shall serve as both a PATIENT supporting system of a radiological diagnostic or interventional ME EQUIPMENT as described in IEC 60601-2-54, or in IEC 60601-2-43, and as a PATIENT supporting system for surgical procedures, the requirements for the ATTENUATION of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR according to IEC 60601-2-54:2022, as well as IEC 60601-2-43:2022 shall be met or shall be determined in the RISK MANAGEMENT FILE. **15**

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:

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Annex G (normative)

Protection against hazards of ignition of flammable anaesthetic mixtures

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

201.G.4.3 Prevention of electrostatic charges

Addition:

Provision of electrically conductive paths from MOBILE OPERATING TABLES to a conductive floor or the protective earth system or the potential equalization system or via wheels to an antistatic floor of the medically used room shall exist, whether or not the table is connected to a SUPPLY MAINS.

The electrical resistance limits of all mattresses and pads ~~for~~ or castor tyres for OPERATING TABLES and other antistatic material shall be ~~at~~ in a ~~minimum~~ range of $10^4 \Omega$ and ~~at a maximum~~ $10^7 \Omega$.

Compliance is checked by the following measurement ~~of the electrical resistance according to ISO 2878.~~ **16**

The electrical resistance measured according to ISO 2878:2017 between the following parts of the OPERATING TABLE shall be in a range of $10^4 \Omega$ and $10^7 \Omega$.

- 1) measured between the surface of the pads on the main section of the OPERATING TABLE and the contact point of the castors on the floor, and*
- 2) measured between the surface of the pads on the main section of the OPERATING TABLE and the POTENTIAL EQUALIZATION terminal of the OPERATING TABLE if applicable.*

NOTE 1 The electrical resistance responsible for the prevention of electrostatic charges does not prevent burns caused by the use of high-frequency surgical ME EQUIPMENT and is no protection against electric shock HAZARDS.

NOTE 2 The main section of the OPERATING TABLE corresponds to the section that is permanently fixed to the table structure and cannot be detached from it.

In general, each pad should have a conductive path to the floor apart from pads of smaller support sections.

Annex AA (informative)

Particular guidance and rationale

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

Subclause 201.9.2.3.1 – Unintended movement

The requirement has been added in order to avoid unintended operation because of mixing up of remote controls in the department.

In addition to the internal mean, it should be possible to identify, for example by marking, which remote control is assigned to which OPERATING TABLE. 17

Subclause 201.9.4.2.2 – Instability excluding transport position

Human bodies do not gain mass at the same rate in all body parts, thus IEC 60601-1:2005, Figure A.19, is not representative for morbidly obese PATIENTS. Figure AA.1, in combination with Table AA.1, is recommended for use for higher mass PATIENTS. Figure AA.1 represents a 135 kg "baseline" PATIENT mass. For SAFE WORKING LOADS greater than 135 kg, the additional mass should be added to each body part in the proportions given in Table AA.1.

Figure AA.1 contains an example of human body mass distribution for a 135 kg PATIENT and body part labels for use in conjunction with Table AA.1.

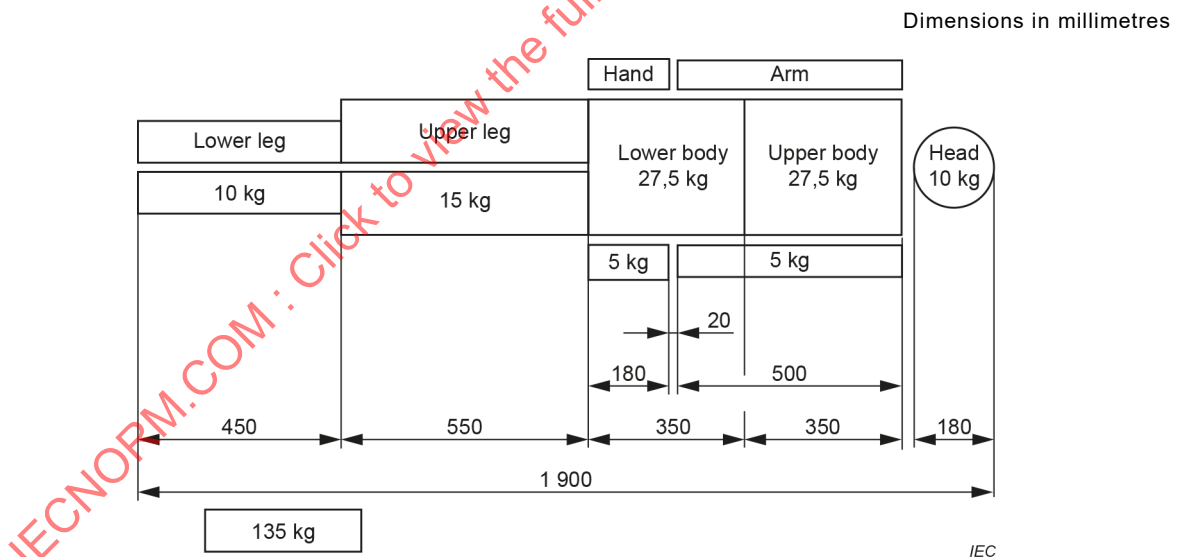


Figure AA.1 – Recommended distribution of mass in excess of 135 kg and examples of application

Table AA.1 – Recommended distribution of mass in excess of 135 kg and examples of application

	Lower leg	Upper leg	Lower body	Upper body	Hand	Upper arm	Head
Percentage of added mass (over 135 kg) to be applied to each part	10 % total (5 % each)	32 % total (16 % each)	32 %	14 %	3,0 % total (1,5 % each)	7 % total (3,5 % each)	2,0 %
Examples of application of additional mass for PATIENTS over 135 kg							
135 kg PATIENT (reference)	10 kg each	15 kg each	27,5 kg	27,5 kg	5 kg each	5 kg each	10 kg
250 kg PATIENT	15,8 kg each	33,4 kg each	64,3 kg	43,6 kg	6,7 kg each	9 kg each	12,3 kg
360 kg PATIENT	21,3 kg each	51 kg each	99,5 kg	59 kg	8,4 kg each	12,9 kg each	14,5 kg

Subclause 201.9.4.2.4.3 – Movement over a threshold

Occurrence of such threshold is not likely in the operating theatre environment.

Subclause 201.9.8.2 – TENSILE SAFETY FACTOR

Support systems are not necessarily made of metallic materials. Therefore, the considerations according the TENSILE SAFETY FACTOR shall be referenced to the term "material" only.

For example, PATIENT tables of X-ray/CT/MR systems are often designed with plastic materials laminated or reinforced by carbon fibres/cloths or glass fibres/cloths, since these PATIENT tables shall be optimised for low absorption of X-ray radiation (aluminium equivalence), MR compatibility (low proton signal), as well as structural stability. Although these plastic materials reinforced by carbon fibres/cloths can have elongation at break of less than 5 %, many years knowledge, acquired expertise, and post-market surveillance can provide sufficient evidence that suitable structural stability of PATIENT tables is achieved by applying a TENSILE SAFETY FACTOR from Table 201.101, situation 1 (rather than situation 2).

Further, it is not always possible to determine in general whether a specific component or construction is impaired by wear.

Therefore, the choice of the applicable TENSILE SAFETY FACTOR may be based on experience, tests and/or RISK MANAGEMENT and ~~has to~~ shall be documented accordingly.

Subclause 201.9.8.3.2 – Static forces due to loading from persons

The TENSILE SAFETY FACTOR requirements in 201.9.8.2 are still applicable. They are not overridden by the performance requirements in 201.9.8.3.2.

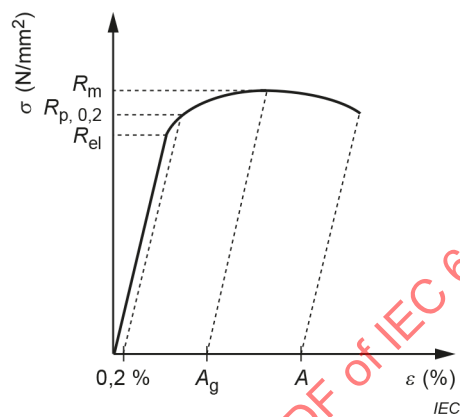
In 201.9.8.2, the compliance of structural integrity is checked regarding stress. This test does not define a limit for the permanent deformation. The support assembly under test shall be in equilibrium after 1 min, or otherwise not result in an unacceptable RISK.

In contrast, the test according to 201.9.8.3.2 b) using safety factor 2,2 allows only a specific value for the permanent deformation.

Related to the stress-strain behaviour of the material used, the support system can be designed considering the elastic limit or the ultimate tensile strength. A construction design based on the ultimate tensile strength needs to consider load factors to take into account with nonlinearities above of the elastic limit. This should be avoided if there is a big difference between the elastic limit and the ultimate tensile strength. In such a case, the test according to 201.9.8.3.2 will probably fail.

On the other hand, it can be expected that the test will be successful in case the design is based on the elastic limit.

The rationale is explained in Figure AA.2, which shows a typical stress-strain curve for materials with a continuous change from the elastic to the plastic behaviour.



Key	
R_m	ultimate tensile strength
$R_{p, 0,2}$	0,2 % elastic limit
R_{el}	elastic limit/yealding point
A_g	uniform strain
A	strain at break

Figure AA.2 – Typical stress-strain curve

Assuming an OPERATING TABLE as a single bending beam (see Figure AA.3), the self-supporting length L_0 is much higher than the deformation d_y at the end of the OPERATING TABLE.

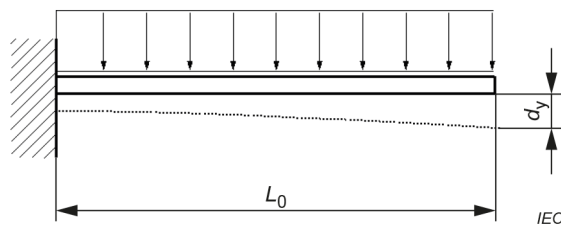


Figure AA.3 – Typical bending line along the length L_0 of a beam

According to 201.9.8.3.2, it is required that the 2,2 times SAFE WORKING LOAD does not result in a permanent deformation more than 2,5 mm. Using this value for an OPERATING TABLE with an unsupported length of 1 200 mm, which is a typical unsupported length, this will result to the following value for the strain:

$$\varepsilon = d_y/L_0$$

$$\varepsilon = 2,5 \text{ mm}/1\,200 \text{ mm}$$

$$\varepsilon = 0,208 \text{ \%}.$$

A remaining strain of around 0,2 % is equivalent to what the elastic limit load indicates.

Typically, the table top of an OPERATING TABLE consists of several detachable parts such as leg plates, head plates, back plates and so on. Depending on the surgical procedure, different configurations are possible. The test according to 201.9.8.3.2 should be performed with the OPERATING TABLE in the most unfavourable configuration. Detachable parts can be tested together with the OPERATING TABLE or separately using the applicable SAFE WORKING LOAD with a safety factor of 2,2 and the correct load distribution. **18**

Subclause 201.9.8.3.3 – Dynamic forces due to loading from persons

The loading of the PATIENT onto the OPERATING TABLE is performed in a controlled environment by professionals familiar with proper technique.

Subclause 201.15.4.101 – Pads for OPERATING TABLES **19**

OPERATING TABLES are used for different surgeries and different PATIENT weights in a wide combination of possibilities. Related HAZARDS, RISK reducing measures and corresponding methods showing evidence of RISK reduction should be documented in the RISK MANAGEMENT FILE.

Clause 203 – Radiation protection in diagnostic X-ray equipment **20**

When OPERATING TABLES are used as PATIENT supporting system for surgical procedures and not as a radiological PATIENT supporting system of diagnostical and/or interventional X-ray equipment, the requirements of Clause 203 are not applicable.

Bibliography 21

IEC 60601-1-8:2006, *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 60601-1-8:2006/AMD1:2012

IEC 60601-1-8:2006/AMD2:2020

IEC 60601-1-9:2007, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design*

IEC 60601-1-9:2007/AMD1:2013

IEC 60601-1-9:2007/AMD2:2020

IEC 60601-1-10:2007, *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 60601-1-10:2007/AMD1:2013

IEC 60601-1-10:2007/AMD2:2020

IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 60601-1-11:2015/AMD1:2020

IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

IEC 60601-1-12:2012/AMD1:2020

IEC ~~60601-2-35~~ 60601-2-35:2020, *Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use*

IEC 60601-2-52:2009, *Medical electrical equipment – Part 2-52: Particular requirements for the basic safety and essential performance of medical beds*

IEC 60601-2-52:2009/AMD1:2015

IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*

IEC 62366-1:2015/AMD1:2020

ISO 7494-1:2018, *Dentistry – Stationary dental units and dental patient chairs – Part 1: General requirements*

ISO 20342-1:2022, *Assistive products for tissue integrity when lying down – Part 1: General requirements*

EN 50637:2017, *Medical electrical equipment – Particular requirements for the basic safety and essential performance of medical beds for children*

Index of defined terms used in this particular standard **22**

ACCESSIBLE PART	IEC 60601-1:2005, 3.2
ACCESSORY	IEC 60601-1:2005, 3.3
APPLIED PART	IEC 60601-1:2005, 3.8
BASIC SAFETY	IEC 60601-1:2005, 3.10
ENCLOSURE	IEC 60601-1:2005, 3.26
ESSENTIAL PERFORMANCE	IEC 60601-1 and IEC 60601-1:2005/AMD1:2012, 3.27
~~GUARD~~	~~IEC 60601-1, 3.36~~
HAZARD	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.39
MANUFACTURER	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.55
ME EQUIPMENT (MEDICAL ELECTRICAL EQUIPMENT)	IEC 60601-1:2005, 3.63
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MEDICAL ELECTRICAL EQUIPMENT (ME EQUIPMENT)	IEC 60601-1:2005, 3.63
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PROGRAMMABLE ELECTRICAL MEDICAL SYSTEM (PEMS)	IEC 60601-1:2005, 3.90
PROTECTIVELY EARTHED	IEC 60601-1:2005, 3.96
RISK	IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.102
RISK MANAGEMENT	IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.107
SAFE WORKING LOAD	IEC 60601-1:2005, 3.109
SINGLE FAULT CONDITION	IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 3.116
SUPPLY MAINS	IEC 60601-1:2005, 3.120
TOOL	IEC 60601-1:2005, 3.127
TRANSPORTER	201.3.204
TRENDELENBURG POSITION	201.3.205
~~TYPE B APPLIED PART~~	~~IEC 60601-1, 3.132~~
USABILITY	IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.136
USABILITY ENGINEERING	IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.137

List of comments

- 1 Some titles have been aligned with the general standard.
- 2 The primary purpose of this new edition is to bring editorial and technical clarifications to the original text for the sake of a better understanding of the requirements. No major update is introduced in the text, as the OPERATING TABLES did not change drastically during the past 10 years.
- 3 There are no significant changes in the scope. The exclusions are now described more clearly and the relevant standards are added or updated.
- 4 Normative references are updated and non-used references removed. IEC 60601-2-54 is added since Subclause 203.10.1 refers to it.
- 5 Another clarification is given to explain that image-guided interventional systems and OPERATING TABLES are separate equipment with separated standards and separate requirements.
- 6 This is a clarification that only unintended movements leading to an unacceptable risk need to be considered. On the other hand, each unintended movement (motorized or not) needs to be considered.
- 7 This amendment is not needed. Marking of type B, type BF or type CF applied part is adequately described in the general standard.
- 8 High frequency surgical equipment are added here. This was already included in Edition 2.0 and accidentally deleted in Edition 3.0 of the standard.
- 9 The previous edition of the standard was design restrictive as it only mentioned “potential equalization terminals” and not the “potential equalization connectors”.
- 10 This clarification helps to understand in which position the OR Table is to be configured for the static load tests. This responds to repeated misunderstandings during verifications.
- 11 A note is added for clarification and additional information.
- 12 Amendment to Subclause 15.3.5 is not needed since rough handling test is only required for mobile equipment, according to the general standard.
- 13 A complete subclause is added because the OR Table pads are an important part of an OR Table as they are the interface between the OR Table and the patient.
- 14 This amendment introduces the possibility to test the immunity with higher peak voltage and gives a possible range to the requirement from a required minimum level.
- 15 This subclause is updated to make sure that the attenuation of the X-ray beam meets the requirements of the correct standard in case the OR Table is part of an X-ray imaging system (as described in IEC 60601-2-43 and IEC 60601-2-54).
- 16 This subclause is amended substantially in order to describe in detail the parts of the OR Tables where the tests are to be conducted. ISO 2878 would not give enough details for this specific equipment.
- 17 Additional precision is given here regarding the marking of the remote controls in order to facilitate the identification of these devices.
- 18 A complete description of the mechanical constraint context for OR Tables is added in this subclause in order to explain that OR Tables should be tested in the most unfavourable configuration along. This gives precisions on what part of the OR Table is to be tested (detachable parts can be tested together with the OPERATING TABLE or separately).
- 19 Rationale for new Subclause 201.15.4.101 is added.

- 20 Rationale for Clause 203 is added to give additional guidance.
 - 21 References are updated and completed.
 - 22 Non-used terms are removed.
-

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –

Part 2-46: Particular requirements for the basic safety and essential performance of operating tables

Appareils électromédicaux –

Partie 2-46: Exigences particulières pour la sécurité de base et les performances essentielles des tables d'opération

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-46: Particular requirements for the basic safety
and essential performance of operating tables****FOREWORD**

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IEC 60601-2-46 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 fourth edition cancels and replaces the third edition published in 2016. This edition constitutes a technical revision.

This edition includes the following significant technical change with respect to the previous edition: structural alignment with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

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

Draft	Report on voting
62D/1939/CDV	62D/1989/RVC

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 PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

- "clause" means one of the 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 particular standard 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,
- replaced by a revised edition, or
- amended.

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INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of OPERATING TABLES.

It amends and supplements IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

The aim of this document is to update it with reference to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 through reformatting and technical changes.

The requirements of this particular standard take priority over those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

A "general guidance and rationale" for the more important requirements of this particular standard 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 standard 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.

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-46: Particular requirements for the basic safety and essential performance of operating tables

201.1 Scope, object and related standards

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

201.1.1 Scope

Replacement:

This part of IEC 60601 specifies safety requirements for OPERATING TABLES, whether or not having electrical parts, including TRANSPORTERS, used for the transportation of the OPERATING TABLE top to or from the base or pedestal of an OPERATING TABLE with detachable OPERATING TABLE top.

NOTE See also IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 4.2.

This particular standard does not apply to

- dental PATIENT chairs (see ISO 7494-1),
- examination chairs and couches,
- PATIENT-supporting systems of diagnostic, interventional and therapeutic equipment (see IEC 60601-2-54 or IEC 60601-2-43),
- OPERATING TABLE heating blankets (see IEC 60601-2-35),
- PATIENT transfer equipment,
- delivery tables and delivery beds,
- medical beds (see IEC 60601-2-52 and EN 50637), and
- field tables.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for OPERATING TABLES as defined in 201.3.203.

201.1.3 Collateral standards

Addition:

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

IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clauses 202 and 203 respectively. IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 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 particular standard 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 1) 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 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard 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 and applicable collateral standards 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 particular standard.

"Addition" means that the text of this particular standard 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 particular standard.

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, e.g. 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 particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, 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 particular standard.

201.2 Normative references

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

Replacement:

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment*

Amendment 1:2013

Amendment 2:2021

ISO 2878:2017, *Rubber, vulcanized or thermoplastic – Antistatic and conductive products – Determination of electrical resistance*

Addition:

IEC 60601-2-2:2017, *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 60601-2-43:2022, *Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures*

IEC 60601-2-54:2022, *Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*

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 and the following apply.

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 on page 28.

Addition:

201.3.201

MOBILE OPERATING TABLE

OPERATING TABLE intended to be relocated from one location to another while supported by its own wheels or equivalent means

201.3.202

NORMAL POSITION

position of the OPERATING TABLE top with all sections set in the horizontal position

201.3.203

OPERATING TABLE

device with the INTENDED USE of supporting and positioning a PATIENT during surgical procedures for not more than 24 h

Note 1 to entry: This includes pre- and post-operative phases in general, surgical/medical procedures under medical supervision.

Note 2 to entry: The device may serve as a PATIENT-supporting systems during diagnostic, interventional and therapeutic procedures but still considered to be a separate ME EQUIPMENT.

201.3.204

TRANSPORTER

device intended for the transportation of an OPERATING TABLE top to or from the base or pedestal of an OPERATING TABLE, or the transportation of the OPERATING TABLE top complete with the base

Note 1 to entry: This definition does not include devices intended to simplify the transport of the PATIENT from one location to another without the transfer of parts associated with an OPERATING TABLE.

Note 2 to entry: The transportation can be done with or without a PATIENT in place.

201.3.205

TRENDELENBURG POSITION

supine PATIENT position where the body is in a single plane, with that plane inclined so that the head is lower than the pelvis

201.4 General requirements

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

201.4.3 Essential performance

Addition:

Besides the definition of the MANUFACTURER, the following shall be considered ESSENTIAL PERFORMANCE for OPERATING TABLES: supporting a PATIENT without unintended movement (motorized or not) leading to an unacceptable RISK in a SINGLE FAULT CONDITION.

201.4.7 SINGLE FAULT CONDITION for ME EQUIPMENT

Addition:

The MANUFACTURER should provide means, where practical, to ensure that, in a SINGLE FAULT CONDITION, the PATIENT support platform of the OPERATING TABLE can return to a position for emergency treatment.

NOTE 101 Examples of positions for emergency treatment are TRENDELENBURG or positions for cardiopulmonary resuscitation (CPR), emergency back flattening.

201.5 General requirements for testing ME EQUIPMENT

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

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 6, applies.

201.7 ME EQUIPMENT identification, marking and documents

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

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

201.7.2.21 Mass of MOBILE ME EQUIPMENT

IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 7.2.21, does not apply.

201.7.9.2 Instructions for use

201.7.9.2.1 General

Addition:

Instructions for use shall include information regarding potential HAZARDS related to HIGH FREQUENCY SURGICAL EQUIPMENT, cardiac defibrillators and cardiac defibrillator-monitors.

NOTE 101 Potential HAZARDS which need to be considered include but are not limited to: PATIENT burns, explosion HAZARDS or electrical shock of the PATIENT or OPERATOR.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

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

201.8.6.7 POTENTIAL EQUALIZATION CONDUCTOR

Addition:

Where potential equalization is required, the APPLIED PARTS of OPERATING TABLES with ACCESSIBLE PARTS which are not PROTECTIVELY EARTHED shall be provided with a potential equalization terminal or a potential equalization connector.

For OPERATING TABLES with a POTENTIAL EQUALIZATION terminal, the impedance between the potential equalization terminal or connector and any ACCESSIBLE PART shall not exceed 200 mΩ.

Compliance is checked by using the test method of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 8.6.4.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

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

201.9.2.3 Other MECHANICAL HAZARDS associated with moving parts

201.9.2.3.1 *Unintended movement

Addition:

Wireless remote control devices of OPERATING TABLES shall be clearly assigned by internal means to the individual OPERATING TABLES.

Compliance is checked by inspection.

201.9.4 Instability HAZARDS

201.9.4.2.2 *Instability excluding transport position

Item a)

Addition:

OPERATING TABLES shall be subjected to SAFE WORKING LOAD.

NOTE See Figure AA.1 and Table AA.1 for guidance regarding mass distribution.

Additional requirement:

OPERATING TABLES with transferable OPERATING TABLE tops shall be designed and manufactured so as to minimize the RISK of physical injuries and of accidental separation of the OPERATING TABLE tops when being transferred.

Specifications concerning OPERATING TABLE top transfer operations shall indicate in the instructions for use the safety elements inherent in the transfer operation.

Compliance is checked by inspection and the following tests.

Having transferred the OPERATING TABLE top to the TRANSPORTER, the stability in NORMAL USE test of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 9.4.2.2, shall be carried out. The OPERATING TABLE top shall not disengage from the TRANSPORTER.

The test is then repeated with the OPERATING TABLE top being placed on the base and the stability test is carried out on the base immediately after transfer.

201.9.4.2.4.3 *Movement over a threshold

Addition:

If MOBILE OPERATING TABLES and TRANSPORTERS are not able to negotiate such obstacles safely, the MANUFACTURER shall include a warning in the instructions for use or determine which threshold can be negotiated safely and inform the OPERATOR accordingly.

201.9.4.3.1 Instability in transport position

Replacement of items b) and c) of the test procedure:

The MOBILE OPERATING TABLE or TRANSPORTER is placed with the SAFE WORKING LOAD in place, and the locking device (e.g. brakes) activated, on a plane covered with 2 mm to 4 mm thick vinyl flooring material and inclined at 6° from the horizontal plane on a concrete floor. Following initial elastic movement, initial creepage, and initial pivoting of castors, there shall be no movement of the MOBILE OPERATING TABLE or TRANSPORTER greater than 50 mm (in relation to the inclined plane). Any initial movement shall not result in an unacceptable RISK, taking into account the NORMAL USE of the MOBILE OPERATING TABLE or TRANSPORTER.

NOTE See Figure AA.1 and Table AA.1 for guidance regarding mass distribution.

201.9.8 MECHANICAL HAZARDS associated with support systems

201.9.8.1 General

Replacement of first dash:

- The construction of the support, suspension or actuation system shall be designed based upon Table 201.101 and the SAFE WORKING LOAD.

201.9.8.2 *TENSILE SAFETY FACTOR

Replacement:

Support systems shall maintain structural integrity during the EXPECTED SERVICE LIFE of the OPERATING TABLE or TRANSPORTER. TENSILE SAFETY FACTORS shall not be less than those shown in Table 201.101 unless an alternative method demonstrates structural integrity throughout the EXPECTED SERVICE LIFE of the OPERATING TABLE or TRANSPORTER.

Due to the fact that it is not always possible to determine in general whether a specific component or construction is impaired by wear, the decision shall be based on experience, tests and/or RISK MANAGEMENT and shall be documented accordingly. However, the MANUFACTURER is responsible for choosing the adequate TENSILE SAFETY FACTOR.

The OPERATING TABLE or TRANSPORTER shall be tested with the SAFE WORKING LOAD (required PATIENT mass according to Figure AA.1 and Table AA.1) and a TENSILE SAFETY FACTOR according to Table 201.101.

Table 201.101 – Determination of TENSILE SAFETY FACTOR

Situation			Minimum TENSILE SAFETY FACTOR
No.	System part	Elongation	
1	Support system not impaired by wear	Material having a specific elongation at break equal to or greater than 5 %	2,5
2	Support system not impaired by wear	Material having a specific elongation at break of less than 5 %	4
3	Support system impaired by wear	Material having a specific elongation at break equal to or greater than 5 %	5
4	Support system impaired by wear	Material having a specific elongation at break of less than 5 %	8
The material tensile strength and all external forces to be expected are quantifiable and known accurately.			

Compliance with 201.9.8.1 and 201.9.8.2 is checked by inspection of the OPERATING TABLE or TRANSPORTER, the RISK MANAGEMENT FILE, the specifications of materials used and the processing specifications for these materials.

When test results are part of relevant information, testing consists of gradually applying a test load to the support assembly under test equal to the SAFE WORKING LOAD times the required TENSILE SAFETY FACTOR. The support assembly under test shall be in equilibrium after 1 min, or otherwise not result in an unacceptable RISK.

NOTE The 1 min time period might need to be longer for materials which might have creep type problems, such as plastics or other non-metallic materials.

201.9.8.3.2 *Static forces due to loading from persons

Replacement of item b):

- b) OPERATING TABLES and TRANSPORTERS shall be designed so that failure or permanent deformation shall not occur when subjected to 2,2 times SAFE WORKING LOAD in NORMAL POSITION.

NOTE 101 See Figure AA.1 and Table AA.1 for guidance regarding mass distribution.

Compliance is checked by the following test.

- 1) *In NORMAL POSITION and at maximum height, the OPERATING TABLES shall be statically loaded with 2,2 times SAFE WORKING LOAD. The deformation after 5 min is recorded. The OPERATING TABLES shall not be operated or moved during this part of the test.*
- 2) *The load is removed and replaced as soon as practical with SAFE WORKING LOAD.*
- 3) *After waiting 5 min in NORMAL POSITION and at maximum height, the OPERATING TABLES shall be statically loaded with 2,2 times SAFE WORKING LOAD. The deformation after 5 min is recorded.*
The deflections are compared to the values measured under 1) and shall be within $\pm 2,5$ mm of the original readings.
- 4) *The load is removed and replaced with SAFE WORKING LOAD and the OPERATING TABLES shall operate over the full range of movements. The deformation/deflection shall be measured at the end of the head- and leg-section of the OPERATING TABLE. For ACCESSORIES, the measuring point shall be determined according the intended use.*

201.9.8.3.3 *Dynamic forces due to loading from persons

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 9.8.3.3, does not apply.

201.10 Protection against unwanted and excessive radiation HAZARDS

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

NOTE The collateral standard IEC 60601-1-3 is referenced in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and is covered under Clause 203 of this document.

201.11 Protection against excessive temperatures and other HAZARDS

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

201.11.6 Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT

201.11.6.5 Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

Addition:

OPERATING TABLES shall be at least IPX4.

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

Addition:

In the event of interruption of the SUPPLY MAINS, whether or not the SUPPLY MAINS is restored, the height and configuration of the OPERATING TABLE top shall not alter. Movement into NORMAL POSITION and/or TRENDLENBURG POSITION shall remain possible.

Compliance is checked as follows.

- a) *By test after interruption of the SUPPLY MAINS with the OPERATING TABLE top in any position, other than the NORMAL POSITION, midway between its maximum and minimum heights, subjected to SAFE WORKING LOAD with mass distributed according to Figure AA.1 and Table AA.1. Movement into and out of the NORMAL POSITION shall be obtainable using the methods described by the MANUFACTURER.*

b) *By observation after restoration of the SUPPLY MAINS.*

201.12 Accuracy of controls and instruments and protection against hazardous outputs

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 12, applies.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

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

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

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

201.15 Construction of ME EQUIPMENT

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

201.15.4 ME EQUIPMENT components and general assembly

Additional subclause:

201.15.4.101 *Pads for OPERATING TABLES

The MANUFACTURER shall provide evidence of durability and pressure distribution and demonstrate that the pads are designed to their intended purpose. The methodology used shall be based on experience and/or RISK MANAGEMENT and shall be documented accordingly.

Compliance is checked by inspection of documentation.

201.15.4.7.2 Accidental operation of ME EQUIPMENT

Additional subclause:

201.15.4.7.2.101 Inadvertent operation

The actuating force for foot-operated control devices shall not be smaller than 10 N.

Compliance is checked by inspection.

201.16 ME SYSTEMS

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 16, applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

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

202 Electromagnetic disturbances – Requirements and tests

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

202.8 Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS

Additional subclauses:

202.8.101 IMMUNITY pass/fail criteria

At least the following IMMUNITY pass/fail criteria associated with BASIC SAFETY and ESSENTIAL PERFORMANCE shall apply at all immunity test levels:

- no permanent degradation or loss of function or OPERATOR settings which are not recoverable shall be observed;
- no movement without activation of the OPERATOR shall occur;
- no movement, other than intended by the OPERATOR, shall occur;
- the OPERATING TABLE shall maintain ESSENTIAL PERFORMANCE within the limits specified by the MANUFACTURER (e.g. temporary degradation of functionality);
- within 15 s after the immunity test, the OPERATING TABLE shall resume normal operation in the previous operating mode, without loss of any OPERATOR settings or stored data, and shall continue to perform its intended function as described in the ACCOMPANYING DOCUMENTS.

202.8.102 IMMUNITY to HF SURGICAL EQUIPMENT EMISSIONS

Electrical OPERATING TABLES intended for use within 2 m of active HF SURGICAL EQUIPMENT or to have a connection to a PATIENT undergoing treatment with HF SURGICAL EQUIPMENT shall be tested for IMMUNITY to HF SURGICAL EQUIPMENT EMISSIONS.

The IMMUNITY pass/fail criteria of 202.8.101 shall apply.

All tests shall be performed in two conditions:

- without activating a movement of the OPERATING TABLE;
- with activating any movement of the OPERATING TABLE (e.g. height movement).

In order to accommodate the huge variety of HF SURGICAL EQUIPMENT, all the tests described in 202.8.102 shall be applied with two different HF SURGICAL EQUIPMENT:

- HF SURGICAL EQUIPMENT complying with IEC 60601-2-2 and having a minimum power cut mode capability of 300 W, a minimum coagulation mode of 100 W and working frequencies to include at least 400 kHz $\pm$ 100 kHz; the HF SURGICAL EQUIPMENT used shall be specified in the test report;
- HF SURGICAL EQUIPMENT with an argon plasma coagulation mode with a minimum peak-to-peak voltage of 4 000 V (open circuit voltage) and 120 W power capability; the HF SURGICAL EQUIPMENT used shall be specified in the test report.

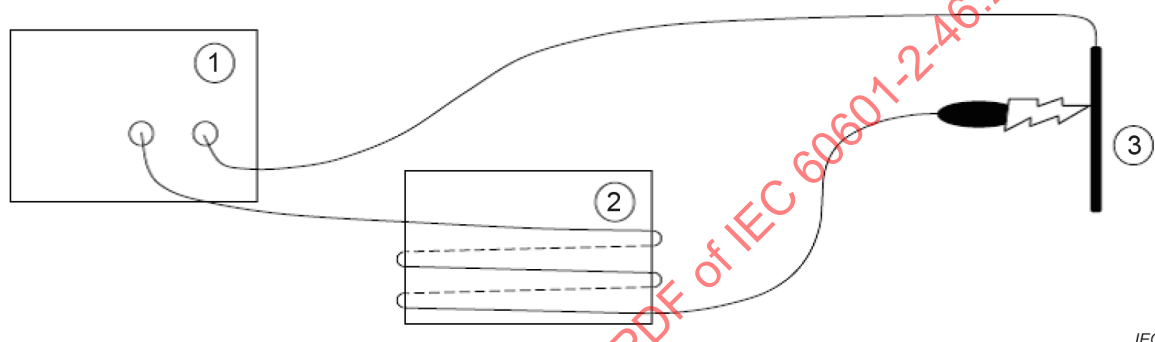
NOTE 1 The EM environment for OPERATING TABLES is a special environment (medical treatment areas with high-powered OPERATING TABLES). Besides the immunity tests required for the professional healthcare facility environment (according to IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, Table 4 to Table 9), at least immunity to HF SURGICAL EQUIPMENT emissions as described in 202.8.102 is applicable to OPERATING TABLES.

Compliance is checked by the following tests.

- a) For parts of OPERATING TABLES that are not PATIENT-COUPLED (e.g. remote control devices, foot-switches), wrap the cable of a MONOPOLAR HF SURGICAL ACCESSORY around the ENCLOSURE of such parts so that at least two full loops of the cable are present, as shown in Figure 202.101. No more than three loops are needed. If the part of the OPERATING TABLE is too large to accommodate two loops, wrap as much as possible or drape the cable over the portion of the parts of the OPERATING TABLE that is most likely to come in contact with HF SURGICAL EQUIPMENT ACCESSORY cables.

Attach one end of a cable to the NEUTRAL ELECTRODE connector of the HF SURGICAL EQUIPMENT and the other end to a metal plate. Using the MONOPOLAR HF SURGICAL ACCESSORY, activate the HF SURGICAL EQUIPMENT in each possible output mode and arc the ACCESSORY to the metal plate. For each mode, adjust the HF SURGICAL EQUIPMENT to the setting that will create the highest peak output voltage.

NOTE 2 This test generates high E-fields and high H-fields with the greatest possible spread of frequencies.



IEC

Key

- 1 HF SURGICAL EQUIPMENT
- 2 part of OPERATING TABLE (e.g. remote control devices, foot switches)
- 3 metal plate (typical size of a neutral electrode, specified by the MANUFACTURER of the used HF SURGICAL EQUIPMENT)

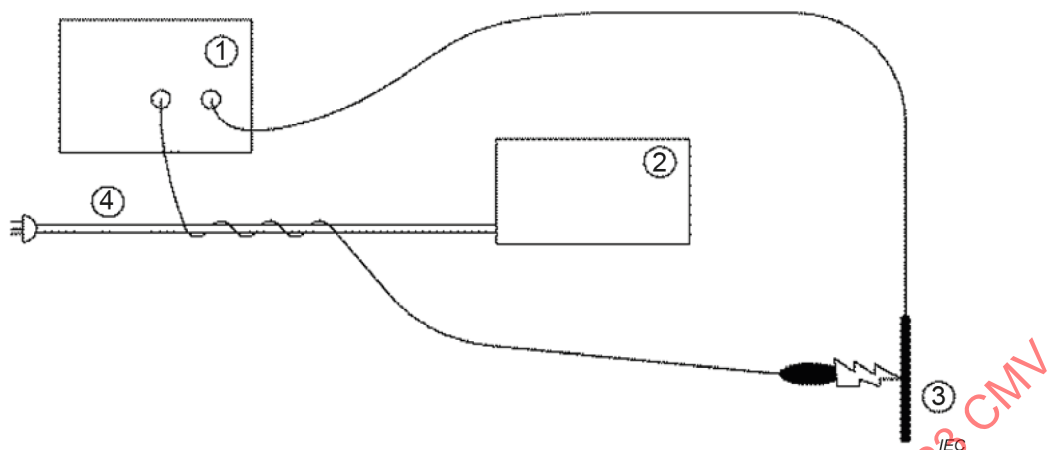
Figure 202.101 – ENCLOSURE ad hoc test

- b) Repeat the test of a) with the MONOPOLAR HF SURGICAL ACCESSORY short-circuiting to the metal plate. The HF SURGICAL EQUIPMENT should be adjusted to obtain the maximum output power for each output mode.

NOTE 3 This test generates the highest output currents and thus the greatest H-fields. It also creates high E-fields at the fundamental output frequency.

- c) Repeat the tests of a) and b) with the cable of the MONOPOLAR HF SURGICAL ACCESSORY wrapped around the POWER SUPPLY CORD of the OPERATING TABLE (unit under test) as shown in Figure 202.102. This test does not need to be performed for PERMANENTLY INSTALLED OPERATING TABLES or for OPERATING TABLES without a mains POWER SUPPLY CORD. Three windings of the MONOPOLAR HF SURGICAL ACCESSORY cable around the POWER SUPPLY CORD are sufficient.

NOTE 4 This test simulates the noise that can be coupled into the operating cables or ME SYSTEM through the mains power cable.

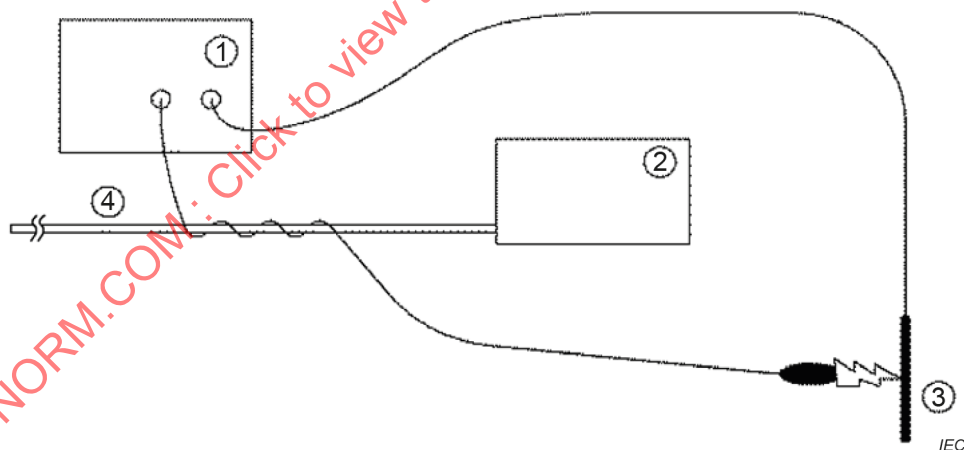


Key

- 1 HF SURGICAL EQUIPMENT
- 2 unit under test
- 3 metal plate (typical size of a neutral electrode, specified by the MANUFACTURER of the used HF SURGICAL EQUIPMENT)
- 4 MAINS POWER SUPPLY CORD of unit under test

Figure 202.102 – POWER SUPPLY CORD ad hoc test

- d) If the OPERATING TABLE has cables that enter the sterile field (e.g. cables from a remote control), coupling can also occur between those cables and the MONOPOLAR HF SURGICAL ACCESSORY cable. To test for this possibility, repeat the tests of a) and b) with the cable of the MONOPOLAR HF SURGICAL ACCESSORY wrapped around the ACCESSORY cable of the OPERATING TABLE under test, as shown in Figure 202.103. Three windings of the MONOPOLAR HF SURGICAL ACCESSORY CABLE around the OPERATING TABLE ACCESSORY CABLE are sufficient.



Key

- 1 HF SURGICAL EQUIPMENT
- 2 unit under test
- 3 metal plate (typical size of a neutral electrode, specified by the MANUFACTURER of the used HF SURGICAL EQUIPMENT)
- 4 ACCESSORY cable of unit under test

Figure 202.103 – ACCESSORY cable ad hoc test

The following tests shall be applied for the OPERATING TABLE itself. For OPERATING TABLES with detachable OPERATING TABLE tops, the combination of the base together with the OPERATING TABLE top shall be tested.

In all cases, leads of the active and neutral electrodes shall be draped along the side rails and/or the exposed metal parts of the OPERATING TABLE top.

During these tests, the HF SURGICAL EQUIPMENT shall be operated in each available mode with the maximum output power and/or the maximum peak voltage.

- e) The HF SURGICAL EQUIPMENT shall be operated at open circuit.*
- f) The HF SURGICAL EQUIPMENT shall be operated while short-circuiting the active and neutral electrodes and sparking with the active electrodes at the side rails and/or the exposed metal parts of the OPERATING TABLE top.*

203 *Radiation protection in diagnostic X-ray equipment

IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021 applies, except as follows:

203.10.1 General

Replacement:

If the OPERATING TABLE shall serve as both a PATIENT supporting system of a radiological diagnostic or interventional ME EQUIPMENT as described in IEC 60601-2-54, or in IEC 60601-2-43, and as a PATIENT supporting system for surgical procedures, the requirements for the ATTENUATION of the X-RAY BEAM between the PATIENT and the X-RAY IMAGE RECEPTOR according to IEC 60601-2-54:2022, as well as IEC 60601-2-43:2022 shall be met or shall be determined in the RISK MANAGEMENT FILE.

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:

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Annex G (normative)

Protection against HAZARDS of ignition of flammable anaesthetic mixtures

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

201.G.4.3 Prevention of electrostatic charges

Addition:

Provision of electrically conductive paths from MOBILE OPERATING TABLES to a conductive floor or the protective earth system or the potential equalization system or via wheels to an antistatic floor of the medically used room shall exist, whether or not the table is connected to a SUPPLY MAINS.

The electrical resistance limits of all mattresses and pads or castor tyres for OPERATING TABLES and other antistatic material shall be in a range of $10^4 \Omega$ and $10^7 \Omega$.

Compliance is checked by the following measurement.

The electrical resistance measured according to ISO 2878:2017 between the following parts of the OPERATING TABLE shall be in a range of $10^4 \Omega$ and $10^7 \Omega$.

- 1) measured between the surface of the pads on the main section of the OPERATING TABLE and the contact point of the castors on the floor, and*
- 2) measured between the surface of the pads on the main section of the OPERATING TABLE and the POTENTIAL EQUALIZATION terminal of the OPERATING TABLE if applicable.*

NOTE 1 The electrical resistance responsible for the prevention of electrostatic charges does not prevent burns caused by the use of high-frequency surgical ME EQUIPMENT and is no protection against electric shock HAZARDS.

NOTE 2 The main section of the OPERATING TABLE corresponds to the section that is permanently fixed to the table structure and cannot be detached from it.

In general, each pad should have a conductive path to the floor apart from pads of smaller support sections.

Annex AA (informative)

Particular guidance and rationale

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

Subclause 201.9.2.3.1 – Unintended movement

The requirement has been added in order to avoid unintended operation because of mixing up of remote controls in the department.

In addition to the internal mean, it should be possible to identify, for example by marking, which remote control is assigned to which OPERATING TABLE.

Subclause 201.9.4.2.2 – Instability excluding transport position

Human bodies do not gain mass at the same rate in all body parts, thus IEC 60601-1:2005, Figure A.19, is not representative for morbidly obese PATIENTS. Figure AA.1, in combination with Table AA.1, is recommended for use for higher mass PATIENTS. Figure AA.1 represents a 135 kg "baseline" PATIENT mass. For SAFE WORKING LOADS greater than 135 kg, the additional mass should be added to each body part in the proportions given in Table AA.1.

Figure AA.1 contains an example of human body mass distribution for a 135 kg PATIENT and body part labels for use in conjunction with Table AA.1.

Dimensions in millimetres

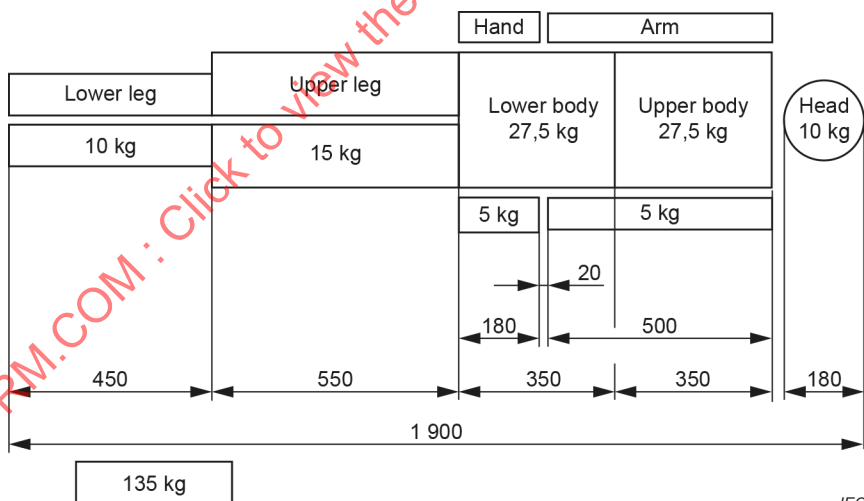


Figure AA.1 – Recommended distribution of mass in excess of 135 kg and examples of application

Table AA.1 – Recommended distribution of mass in excess of 135 kg and examples of application

	Lower leg	Upper leg	Lower body	Upper body	Hand	Upper arm	Head
Percentage of added mass (over 135 kg) to be applied to each part	10 % total (5 % each)	32 % total (16 % each)	32 %	14 %	3,0 % total (1,5 % each)	7 % total (3,5 % each)	2,0 %
Examples of application of additional mass for PATIENTS over 135 kg							
135 kg PATIENT (reference)	10 kg each	15 kg each	27,5 kg	27,5 kg	5 kg each	5 kg each	10 kg
250 kg PATIENT	15,8 kg each	33,4 kg each	64,3 kg	43,6 kg	6,7 kg each	9 kg each	12,3 kg
360 kg PATIENT	21,3 kg each	51 kg each	99,5 kg	59 kg	8,4 kg each	12,9 kg each	14,5 kg

Subclause 201.9.4.2.4.3 – Movement over a threshold

Occurrence of such threshold is not likely in the operating theatre environment.

Subclause 201.9.8.2 – TENSILE SAFETY FACTOR

Support systems are not necessarily made of metallic materials. Therefore, the considerations according the TENSILE SAFETY FACTOR shall be referenced to the term "material" only.

For example, PATIENT tables of X-ray/CT/MR systems are often designed with plastic materials laminated or reinforced by carbon fibres/cloths or glass fibres/cloths, since these PATIENT tables shall be optimised for low absorption of X-ray radiation (aluminium equivalence), MR compatibility (low proton signal), as well as structural stability. Although these plastic materials reinforced by carbon fibres/cloths can have elongation at break of less than 5 %, many years knowledge, acquired expertise, and post-market surveillance can provide sufficient evidence that suitable structural stability of PATIENT tables is achieved by applying a TENSILE SAFETY FACTOR from Table 201.101, situation 1 (rather than situation 2).

Further, it is not always possible to determine in general whether a specific component or construction is impaired by wear.

Therefore, the choice of the applicable TENSILE SAFETY FACTOR may be based on experience, tests and/or RISK MANAGEMENT and shall be documented accordingly.

Subclause 201.9.8.3.2 – Static forces due to loading from persons

The TENSILE SAFETY FACTOR requirements in 201.9.8.2 are still applicable. They are not overridden by the performance requirements in 201.9.8.3.2.

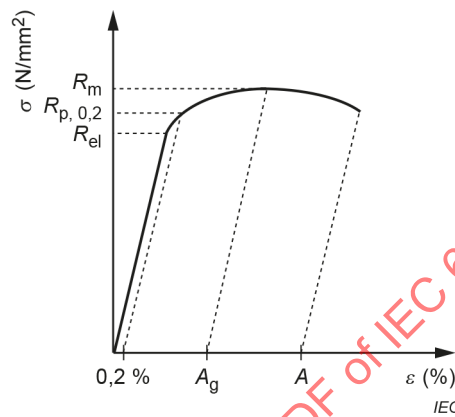
In 201.9.8.2, the compliance of structural integrity is checked regarding stress. This test does not define a limit for the permanent deformation. The support assembly under test shall be in equilibrium after 1 min, or otherwise not result in an unacceptable RISK.

In contrast, the test according to 201.9.8.3.2 b) using safety factor 2,2 allows only a specific value for the permanent deformation.

Related to the stress-strain behaviour of the material used, the support system can be designed considering the elastic limit or the ultimate tensile strength. A construction design based on the ultimate tensile strength needs to consider load factors to take into account with nonlinearities above of the elastic limit. This should be avoided if there is a big difference between the elastic limit and the ultimate tensile strength. In such a case, the test according to 201.9.8.3.2 will probably fail.

On the other hand, it can be expected that the test will be successful in case the design is based on the elastic limit.

The rationale is explained in Figure AA.2, which shows a typical stress-strain curve for materials with a continuous change from the elastic to the plastic behaviour.



Key

R_m	ultimate tensile strength
$R_{p, 0,2}$	0,2 % elastic limit
R_{el}	elastic limit/yealding point
A_g	uniform strain
A	strain at break

Figure AA.2 – Typical stress-strain curve

Assuming an OPERATING TABLE as a single bending beam (see Figure AA.3), the self-supporting length L_0 is much higher than the deformation d_y at the end of the OPERATING TABLE.

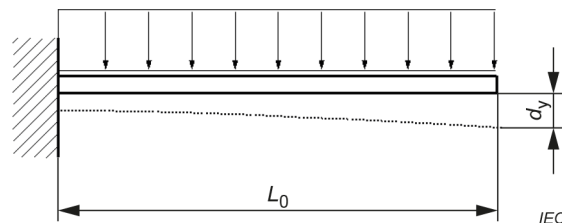


Figure AA.3 – Typical bending line along the length L_0 of a beam

According to 201.9.8.3.2, it is required that the 2,2 times SAFE WORKING LOAD does not result in a permanent deformation more than 2,5 mm. Using this value for an OPERATING TABLE with an unsupported length of 1 200 mm, which is a typical unsupported length, this will result to the following value for the strain:

$$\varepsilon = d_y/L_0$$

$$\varepsilon = 2,5 \text{ mm}/1\,200 \text{ mm}$$

$$\varepsilon = 0,208 \text{ \%}.$$

A remaining strain of around 0,2 % is equivalent to what the elastic limit load indicates.

Typically, the table top of an OPERATING TABLE consists of several detachable parts such as leg plates, head plates, back plates and so on. Depending on the surgical procedure, different configurations are possible. The test according to 201.9.8.3.2 should be performed with the OPERATING TABLE in the most unfavourable configuration. Detachable parts can be tested together with the OPERATING TABLE or separately using the applicable SAFE WORKING LOAD with a safety factor of 2,2 and the correct load distribution.

Subclause 201.9.8.3.3 – Dynamic forces due to loading from persons

The loading of the PATIENT onto the OPERATING TABLE is performed in a controlled environment by professionals familiar with proper technique.

Subclause 201.15.4.101 – Pads for OPERATING TABLES

OPERATING TABLES are used for different surgeries and different PATIENT weights in a wide combination of possibilities. Related HAZARDS, RISK reducing measures and corresponding methods showing evidence of RISK reduction should be documented in the RISK MANAGEMENT FILE.

Clause 203 – Radiation protection in diagnostic X-ray equipment

When OPERATING TABLES are used as PATIENT supporting system for surgical procedures and not as a radiological PATIENT supporting system of diagnostical and/or interventional X-ray equipment, the requirements of Clause 203 are not applicable.

Bibliography

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IEC 62366-1:2015/AMD1:2020

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

APPAREILS ÉLECTROMÉDICAUX –

**Partie 2-46: Exigences particulières pour la sécurité de base
et les performances essentielles des tables d'opération**

AVANT-PROPOS

- 1) La Commission Électrotechnique Internationale (IEC) est une organisation mondiale de normalisation composée de l'ensemble des comités électrotechniques nationaux (Comités nationaux de l'IEC). L'IEC a pour objet de favoriser la coopération internationale pour toutes les questions de normalisation dans les domaines de l'électricité et de l'électronique. À cet effet, l'IEC – entre autres activités – publie des Normes internationales, des Spécifications techniques, des Rapports techniques, des Spécifications accessibles au public (PAS) et des Guides (ci-après dénommés "Publication(s) de l'IEC"). Leur élaboration est confiée à des comités d'études, aux travaux desquels tout Comité national intéressé par le sujet traité peut participer. Les organisations internationales, gouvernementales et non gouvernementales, en liaison avec l'IEC, participent également aux travaux. L'IEC collabore étroitement avec l'Organisation Internationale de Normalisation (ISO), selon des conditions fixées par accord entre les deux organisations.
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- 8) L'attention est attirée sur les références normatives citées dans cette publication. L'utilisation de publications référencées est obligatoire pour une application correcte de la présente publication.
- 9) L'attention est attirée sur le fait que certains des éléments de la présente Publication de l'IEC peuvent faire l'objet de droits de brevet. L'IEC ne saurait être tenue pour responsable de ne pas avoir identifié de tels droits de brevets.

L'IEC 60601-2-46 a été établie par le sous-comité 62D de l'IEC: Équipements, logiciels et systèmes médicaux particuliers, du comité d'études 62 de l'IEC: Equipement médical, logiciels et systèmes médicaux. Il s'agit d'une Norme internationale.

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

La présente édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente: alignement de la structure sur l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020.

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

Projet	Rapport de vote
62D/1939/CDV	62D/1989/RVC

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 at 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 apparaissant hors des tableaux, comme les notes, les exemples et les références: petits caractères romains. Le texte normatif à l'intérieur des tableaux est également en petits caractères.
- TERMES DÉFINIS À 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 LA PRÉSENTE NORME PARTICULIÈRE OU COMME NOTÉS: PETITES MAJUSCULES.

Concernant la structure du présent document, le terme

- "article" désigne l'une des sections numérotées dans la table des matières, avec toutes ses subdivisions (par exemple, l'Article 7 inclut les Paragraphes 7.1, 7.2, etc.);
- "paragraphe" désigne une subdivision numérotée d'un article (par exemple, 7.1, 7.2 et 7.2.1 sont tous des paragraphes appartenant à l'Article 7).

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

Dans le présent document, la conjonction "ou" est utilisée avec la valeur d'un "ou inclusif", ainsi un énoncé est vrai si une combinaison des conditions, quelle qu'elle soit, est vraie.

Les formes verbales utilisées dans 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:

- "devoir" mis au présent de l'indicatif signifie que la satisfaction à une exigence ou à un essai est obligatoire pour la conformité au présent document;
- "il convient" signifie que la satisfaction à une exigence ou à un essai est recommandée mais n'est pas obligatoire pour la conformité au présent document;
- "pouvoir" mis au présent de l'indicatif est utilisé pour décrire un moyen admissible pour satisfaire à une exigence ou à un essai.

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

Une liste de toutes les parties de la série IEC 60601, 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 à la publication recherchée. À cette date, le document sera

- reconduit,
- supprimé,
- remplacé par une édition révisée, ou
- amendé.

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INTRODUCTION

La présente norme particulière concerne la SÉCURITÉ DE BASE et les PERFORMANCES ESSENTIELLES des TABLES D'OPÉRATION.

Elle modifie et complète l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020.

L'objectif du présent document est une mise à jour par rapport à l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020 par une remise en forme et l'introduction de modifications techniques.

Les exigences de la présente norme particulière prévalent sur celles de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020.

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

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APPAREILS ÉLECTROMÉDICAUX –

Partie 2-46: Exigences particulières pour la sécurité de base et les performances essentielles des tables d'opération

201.1 Domaine d'application, objet et normes connexes

L'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, Article 1, s'applique, à l'exception de ce qui suit:

201.1.1 Domaine d'application

Remplacement:

La présente partie de l'IEC 60601 spécifie les exigences de sécurité applicables aux TABLES D'OPÉRATION, que celles-ci comportent ou non des parties électriques, y compris les CHARIOTS DE TRANSFERT, utilisés pour le transport du plateau de la TABLE D'OPÉRATION vers ou depuis la base ou le socle d'une TABLE D'OPÉRATION à plateau amovible.

NOTE Voir également l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, 4.2.

La présente norme particulière ne s'applique pas

- aux fauteuils dentaires pour PATIENTS (voir l'ISO 7494-1),
- aux fauteuils et lits d'examen,
- aux systèmes de support du PATIENT des appareils de diagnostic, d'intervention et de thérapie (voir l'IEC 60601-2-54 ou l'IEC 60601-2-43),
- aux couvertures chauffantes des TABLES D'OPÉRATION (voir l'IEC 60601-2-35),
- aux appareils de transfert des PATIENTS,
- aux tables et lits d'accouchement,
- aux lits médicaux (voir l'IEC 60601-2-52 et l'EN 50637), et
- aux tables d'opération de campagne.

201.1.2 Objet

Remplacement:

La présente norme particulière a pour objet d'établir des exigences particulières pour la SÉCURITÉ DE BASE et les PERFORMANCES ESSENTIELLES applicables aux TABLES D'OPÉRATION, telles qu'elles sont définies en 201.3.203.

201.1.3 Normes collatérales

Addition:

La présente norme particulière fait référence aux normes collatérales applicables énumérées à l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, Article 2, et à l'Article 201.2 de la présente norme particulière.

L'IEC 60601-1-2 et l'IEC 60601-1-3 s'appliquent telles que modifiées respectivement par les Articles 202 et 203. L'IEC 60601-1-8, l'IEC 60601-1-9, l'IEC 60601-1-10, l'IEC 60601-1-11 et l'IEC 60601-1-12 ne s'appliquent pas. Toutes les autres normes collatérales publiées dans la série IEC 60601-1 s'appliquent, telles qu'elles sont 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 ce qui est approprié à l'APPAREIL EM particulier à l'étude, et elles peuvent ajouter d'autres exigences de SÉCURITÉ DE BASE et de 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 paragraphes de la présente norme particulière 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, 201.1 dans le présent document traite du contenu de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, Article 1) ou de la norme collatérale applicable avec le préfixe "20x", où x est le ou les derniers chiffres du numéro de document de la norme collatérale (par exemple, 202.4 dans la présente norme particulière traite du contenu de l'Article 4 de la norme collatérale IEC 60601-1-2, 203.4 dans la présente norme particulière traite du 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 et aux normes collatérales applicables sont spécifiées 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 de la présente norme particulière.

"Addition" signifie que le texte de la présente norme particulière 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.

"Modification" 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 de la présente norme particulière.

Les paragraphes, figures ou tableaux ajoutés à 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 3.1 à 3.154, les définitions complémentaires dans le présent document sont numérotées à partir de 201.3.201. Les annexes complémentaires sont désignées AA, BB, etc., et les points complémentaires aa), bb), etc.

Les paragraphes, figures ou tableaux ajoutés à une norme collatérale sont numérotés à partir de 20x, où "x" est le numéro 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 faire référence 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 à la présente norme particulière, prises en compte ensemble.

Lorsque la présente norme particulière 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 la présente norme particulière.

201.2 Références normatives

L'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, Article 2, s'applique, à l'exception de ce qui suit:

Remplacement:

IEC 60601-1-3:2008, *Appareils électromédicaux – Partie 1-3: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Radioprotection dans les appareils à rayonnement X de diagnostic*

Amendement 1:2013

Amendement 2:2021

ISO 2878:2017, *Caoutchouc vulcanisé ou thermoplastique – Produits antistatiques et conducteurs – Détermination de la résistance électrique*

Addition:

IEC 60601-2-2:2017, *Appareils électromédicaux – Partie 2-2: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'électrochirurgie à courant haute fréquence et des accessoires d'électrochirurgie à courant haute fréquence*

IEC 60601-2-43:2010, *Appareils électromédicaux – Partie 2-43: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X lors d'interventions*

Amendement 1:2017

Amendement 2:2019

IEC 60601-2-54:2009, *Appareils électromédicaux – Partie 2-54: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X utilisés pour la radiographie et la radioscopie*

Amendement 1:2015

Amendement 2:2018

201.3 Termes et définitions

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

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 donné à partir de la page 32.

Addition:

201.3.201

TABLE D'OPÉRATION MOBILE

TABLE D'OPÉRATION destinée à être déplacée d'un endroit à un autre tout en étant soutenue par ses propres roues ou un moyen équivalent

201.3.202

POSITION NORMALE

position du plateau d'une TABLE D'OPÉRATION, lorsque tous les éléments sont en position horizontale

201.3.203

TABLE D'OPÉRATION

dispositif dont l'UTILISATION PRÉVUE est de soutenir et positionner un PATIENT lors d'interventions chirurgicales pendant une durée maximale de 24 h

Note 1 à l'article: Sont incluses les phases pré et postopératoires en général, les interventions à caractère chirurgical/médical sous surveillance médicale.

Note 2 à l'article: Le dispositif peut être utilisé comme un système de support du PATIENT lors de diagnostics, d'interventions chirurgicales et de procédures thérapeutiques tout en continuant à être considéré comme un APPAREIL EM séparé.

201.3.204

CHARIOT DE TRANSFERT

dispositif destiné au transfert du plateau d'une TABLE D'OPÉRATION vers ou depuis la base ou le socle d'une TABLE D'OPÉRATION, ou au transfert du plateau complet de la TABLE D'OPÉRATION avec la base

Note 1 à l'article: Cette définition exclut les dispositifs destinés à faciliter le déplacement du PATIENT d'un endroit à un autre sans transfert des éléments liés à une TABLE D'OPÉRATION.

Note 2 à l'article: Le transfert peut s'effectuer avec ou sans PATIENT.

201.3.205

POSITION DE TREDELENBURG

position dans laquelle le PATIENT est allongé sur le dos, son corps étant à plat, incliné de telle sorte que la tête soit plus basse que le bassin

201.4 Exigences générales

L'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, Article 4, s'applique, à l'exception de ce qui suit:

201.4.3 Performance essentielle

Addition:

En plus de la définition du FABRICANT, l'élément suivant doit être considéré comme faisant partie des PERFORMANCES ESSENTIELLES pour les TABLES D'OPÉRATION: soutenir un PATIENT sans mouvement non désiré (motorisé ou non) qui mène à un RISQUE inacceptable en CONDITION DE PREMIER DÉFAUT.

201.4.7 CONDITION DE PREMIER DÉFAUT pour les APPAREILS EM

Addition:

Il convient que le FABRICANT fournisse un moyen qui assure que, dans toute la mesure du possible, dans une CONDITION DE PREMIER DÉFAUT, le plateau support PATIENT de la TABLE D'OPÉRATION peut revenir à une position permettant un traitement d'urgence.

NOTE 101 Des exemples de positions pour un traitement d'urgence sont la POSITION DE TRENDLENBURG ou les positions pour la réanimation cardio-pulmonaire (RCP), le couchage d'urgence sur le dos.

201.5 Exigences générales relatives aux essais des APPAREILS EM

L'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, Article 5, s'applique.

201.6 Classification des APPAREILS EM et des SYSTÈMES EM

L'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, Article 6, s'applique.

201.7 Identification, marquage et documentation des APPAREILS EM

L'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, Article 7, s'applique, à l'exception de ce qui suit:

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

201.7.2.21 Masse de l'APPAREIL EM MOBILE

L'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012, 7.2.21, ne s'applique pas.

201.7.9.2 Instructions d'utilisation

201.7.9.2.1 Généralités

Addition:

Les instructions d'utilisation doivent comporter des informations relatives aux DANGERS potentiels liés aux APPAREILS D'ÉLECTROCHIRURGIE À HAUTE FRÉQUENCE, aux défibrillateurs cardiaques et aux moniteurs de défibrillateurs cardiaques.

NOTE 101 Les DANGERS potentiels qui doivent être pris en considération incluent, entre autres: les brûlures des PATIENTS, les DANGERS d'explosion ou les chocs électriques concernant le PATIENT ou l'OPÉRATEUR.

201.8 Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM

L'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, Article 8, s'applique, à l'exception de ce qui suit:

201.8.6.7 CONDUCTEUR D'ÉGALISATION DES POTENTIELS

Addition:

Lorsque l'égalisation des potentiels est exigée, les PARTIES APPLIQUÉES des TABLES D'OPÉRATION avec des PARTIES ACCESSIBLES non PROTÉGÉES PAR MISE À LA TERRE doivent être équipées d'une borne d'égalisation des potentiels ou d'un connecteur d'égalisation des potentiels.

Pour les TABLES D'OPÉRATION qui comportent une borne d'ÉGALISATION DES POTENTIELS, l'impédance entre la borne ou le connecteur et toute PARTIE ACCESSIBLE ne doit pas dépasser 200 mΩ.

La vérification est effectuée au moyen de la méthode d'essai de l'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, 8.6.4.

201.9 Protection contre les DANGERS MÉCANIQUES des APPAREILS EM et SYSTÈMES EM

L'IEC 60601-1:2005, l'IEC 60601-1:2005/AMD1:2012 et l'IEC 60601-1:2005/AMD2:2020, Article 9, s'applique, à l'exception de ce qui suit:

201.9.2.3 Autres DANGERS MÉCANIQUES associés aux parties en mouvement

201.9.2.3.1 *Mouvement non désiré

Addition:

Les dispositifs de commande à distance sans fil des TABLES D'OPÉRATION doivent être clairement affectés à des TABLES D'OPÉRATION particulières par des moyens internes.

La vérification est effectuée par examen.

201.9.4 DANGERS d'instabilité

201.9.4.2.2 *Instabilité à l'exclusion de la position de transport

Point a)

Addition:

Les TABLES D'OPÉRATION doivent être soumises à une CHARGE DE FONCTIONNEMENT EN SÉCURITÉ.

NOTE Voir la Figure AA.1 et le Tableau AA.1 pour des recommandations relatives à la répartition de la masse.

Exigence supplémentaire:

Les TABLES D'OPÉRATION à plateaux transférables de TABLE D'OPÉRATION doivent être conçues et fabriquées de façon à réduire le plus possible le RISQUE de blessures physiques et de séparation accidentelle du plateau de la TABLE D'OPÉRATION en cours de transfert.

Des spécifications concernant les manœuvres de transfert du plateau de la TABLE D'OPÉRATION doivent préciser dans les instructions d'utilisation les éléments de sécurité relatifs à la manœuvre de transfert.

La vérification est effectuée par examen et par les essais suivants.