IEC 60601-2-46

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REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

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

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INTERNATIONAL
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

International standard IEC 60601-2-46 has been prepared by IEC subcommittee 62D Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 2010 and constitutes a technical revision. This edition of IEC 60601-2-46 was revised to align structurally with the 2005 edition of IEC 60601-1 and with IEC 60601-1:2005/AMD1:2012.

The text of this standard is based on the following documents:

FDIS	Report on voting
62D/1365/FDIS	62D/1371/RVD

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

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

In this standard, the following print types are used:

– Requirements and definitions: 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 THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, 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 standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

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

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

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex 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 publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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

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

INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of OPERATING TABLES. It amends and supplements IEC 60601-1 (third edition, 2005) ~~*: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance)*~~ and its Amendment 1 (IEC 60601-1:2005/AMD1:2012), hereinafter referred to as the general standard.

The aim of this third edition is to bring this particular standard up to date with reference to the third edition of the general standard through reformatting and technical changes.

The requirements of this particular standard take priority over those of the general standard.

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 Standard.

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

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 Scope

Replacement:

This particular standard 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 4.2 of the General Standard.

This particular standard does not apply to

– dental PATIENT chairs;
– examination chairs and couches;
– PATIENT-supporting systems of diagnostic and therapeutic devices; (see IEC 60601-2-43)
– OPERATING TABLE heating blankets; (see IEC 80601-2-35)
– PATIENT transfer equipment;
– delivery tables and beds;
– medical beds; (see IEC 60601-2-52)
– field tables.

~~NOTE~~ If OPERATING TABLES will be used in combination with diagnostic and/or therapeutic devices the relevant requirements of each related particular standard ~~have to be considered~~ 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 201.3.201 ~~and hereinafter also referred to as ME EQUIPMENT~~.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

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

IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clauses 202 and 203 respectively. ~~IEC 60601-1-3,~~ IEC 60601-1-8, 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 the general standard 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 the general standard.

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 the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where × 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 the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard 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 the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard 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 the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this standard 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 standard" is used to make reference to the general standard, 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 the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard 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

Clause 2 of the general standard applies, except as follows:

Replacement:

IEC 60601-1-2:~~2007~~ 2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic ~~compatibility~~ 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*
IEC 60601-1-3:2008/AMD1:2013[2]

Addition:

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

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

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1~~:2005~~ apply, except as follows:

NOTE An index of defined terms is found beginning on page 24.

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 ~~(hereinafter also referred to as ME EQUIPMENT)~~
device ~~for TEMPORARY USE,~~ 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.

~~**201.3.204**~~
~~**TEMPORARY USE**~~
~~normally intended for continuous use for not more than 24 hours~~

2 There exists a consolidated edition 2.1, which includes IEC 60601-1-3:2008 and its Amendment 1 (2013).

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
a 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

Clause 4 of the general standard applies, except as follows.

201.4.3 Essential performance

Addition:

Besides the definition of the MANUFACTURER, the following ESSENTIAL PERFORMANCE is required from OPERATING TABLES:

~~– no unwanted movement in any SINGLE FAULT CONDITION and any combined fault conditions as derived from RISK MANAGEMENT specified by the MANUFACTURER.~~

– supporting a PATIENT without unwanted movement in a SINGLE FAULT CONDITION.

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

Addition:

Additional SINGLE FAULT CONDITIONS to be regarded with OPERATING TABLES:

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

~~NOTE 101~~ 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~~ OPERATING TABLES

Clause 5 of the general standard applies.

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

Clause 6 of the general standard applies.

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

Clause 7 of the general standard applies, except as follows:

201.7.2 Marking on the outside of OPERATING TABLES or OPERATING TABLES 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.

201.7.2.21 Mass of MOBILE OPERATING TABLES

This subclause of the general standard 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 have 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~~ OPERATING TABLES

Clause 8 of the general standard 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.

For ~~ME EQUIPMENT~~ OPERATING TABLES with a POTENTIAL EQUALIZATION terminal the impedance between the potential equalization terminal and any ACCESSIBLE PART shall not exceed 200 mΩ,

Compliance is checked by using the test method of 8.6.4 of the general standard.

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

Clause 9 of the general standard 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 ~~ME EQUIPMENT~~ OPERATING TABLES.

Compliance is checked by inspection.

201.9.4 Instability hazards

201.9.4.2.2 *Instability excluding transport position

Item a)

Addition:

~~ME EQUIPMENT~~ OPERATING TABLES shall be subjected to SAFE WORKING LOAD.

NOTE See Figure AA.1 and Table AA.1 for guidance regarding ~~weight~~ 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 9.4.2.2 of the general standard 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 ~~weight~~ 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 ~~weight~~ 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 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.

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

Compliance is checked by the following test:

1) *In NORMAL POSITION and at maximum height the ~~ME EQUIPMENT~~ OPERATING TABLES shall be statically loaded with 2,2 times SAFE WORKING LOAD. The deformation after 5 min is recorded. The ~~ME EQUIPMENT~~ 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 ~~ME EQUIPMENT~~ 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 ± 2,5 mm of the original readings.
4) *The load is removed and replaced with SAFE WORKING LOAD and the ~~ME EQUIPMENT~~ 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

This subclause of the general standard does not apply.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard 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~~ OPERATING TABLES

~~*Additional subclause:*~~

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

Addition:

OPERATING TABLES shall be at least IPX4.

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

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 TRENDELENBURG 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 ~~weight~~ 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

Clause 12 of the general standard applies.

201.13 HAZARDOUS SITUATIONS and fault conditions for OPERATING TABLES

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ~~ME EQUIPMENT~~ OPERATING TABLES

Clause 15 of the general standard 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.

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

Addition:

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

Clause 16 of the general standard applies.

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

Clause 17 of the general standard applies.

202 Electromagnetic ~~compatibility~~ disturbances – Requirements and tests

IEC 60601-1-2~~:2007~~ applies, except as follows:

~~**202.6.2.2.1 Requirements**~~

~~*Replacement:*~~

~~ME EQUIPMENT shall comply with the requirements of 6.2.1.10 [of IEC 60601-1-2:2007] as modified below. For this requirement, the following conditions associated with BASIC SAFETY and ESSENTIAL PERFORMANCE shall apply:~~

~~No permanent DEGRADATION or loss of function or OPERATOR settings which are not recoverable shall be observed at any immunity test level.~~

~~No inappropriate movement shall occur at all immunity test levels.~~

~~At all immunity test levels the ME EQUIPMENT shall maintain ESSENTIAL PERFORMANCE within the specification limits.~~

~~At all immunity test levels the temporary DEGRADATION or loss of function or performance is acceptable.~~

~~Within 10 s or after OPERATOR intervention without requiring the use of a tool, the ME EQUIPMENT 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.~~

~~Check compliance by application of the tests in 6.2.2.2. Evaluate the response of the ME EQUIPMENT or ME SYSTEM during and after these tests in accordance with 6.2.1.10 [of IEC 60601-1-2:2007] as modified in above, considering each discharge individually.~~

~~*Additional subclause:*~~

~~**202.6.2.2.1.101 Interference with high-frequency surgical equipment**~~

~~OPERATING TABLES and remote control devices for OPERATING TABLES shall not present a HAZARDOUS SITUATION when used together with high-frequency surgical equipment.~~

~~*Compliance is checked by the following tests:*~~

~~NOTE 1 To accommodate the huge variety of high-frequency surgical equipment, two different test scenarios have been created.~~

~~a) The high-frequency surgical equipment which is used for this test shall comply with IEC 60601-2-2, shall have a rated output power of 300 W at least for an impedance between 200 Ohms and 500 Ohms, a quasi-square wave output frequency characteristic and shall operate in the frequency range of 400 kHz to 1 MHz.~~

~~b) The high-frequency surgical equipment which is used for this test shall comply with IEC 60601-2-2, shall have an argon plasma coagulation mode with a peak voltage of 4 000 Vp (open circuit voltage) and 120 W power capability~~

~~NOTE 2 For details, see Annex A.~~

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

~~The high frequency surgical equipment shall then be operated in a mode which generates an output power of 300 W ("conventional") or 4 000 Vp/120 W (argon plasma coagulation).~~

~~c) Compliance~~

~~1) Operating the high frequency surgical equipment at open circuit shall cause no movement of the OPERATING TABLE.~~

~~2) Operating the high-frequency surgical equipment 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, shall cause no movement of the OPERATING TABLE.~~

~~NOTE 3 If operating tables will be used in combination with diagnostic X-ray equipment, the relevant requirements of the collateral standard have to be considered.~~

202.8 Electromagnetic IMMUNITY requirements for OPERATING TABLES 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 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 this subclause have to be applied with two different HF SURGICAL EQUIPMENTS:

– 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 ± 100 kHz. The HF SURGICAL EQUIPMENT used shall be specified in the test report;

– HF SURGICAL EQUIPMENT, should have an argon plasma coagulation mode with a peak voltage of 4 000 Vp (open circuit voltage) and 120 W power capability. The HF SURGICAL EQUIPMENT used shall be specified in the test report.

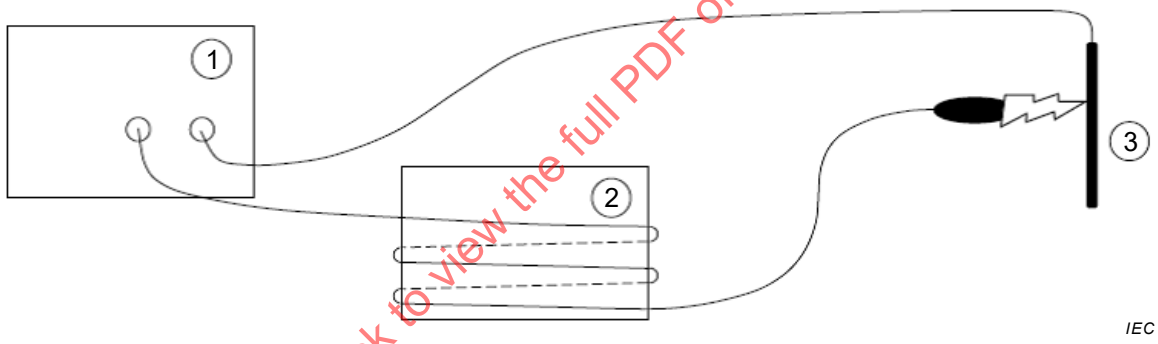
NOTE 1 The EM environment for OPERATING TABLES is a special environment (medical treatment areas with high-powered OPERATING TABLES). Besides the immunity tests required for the professional healthcare facility environment (according to Table 4 to Table 9 of IEC 60601-1-2:2014) at least immunity to HF surgical equipment emissions as described in this subclause 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)

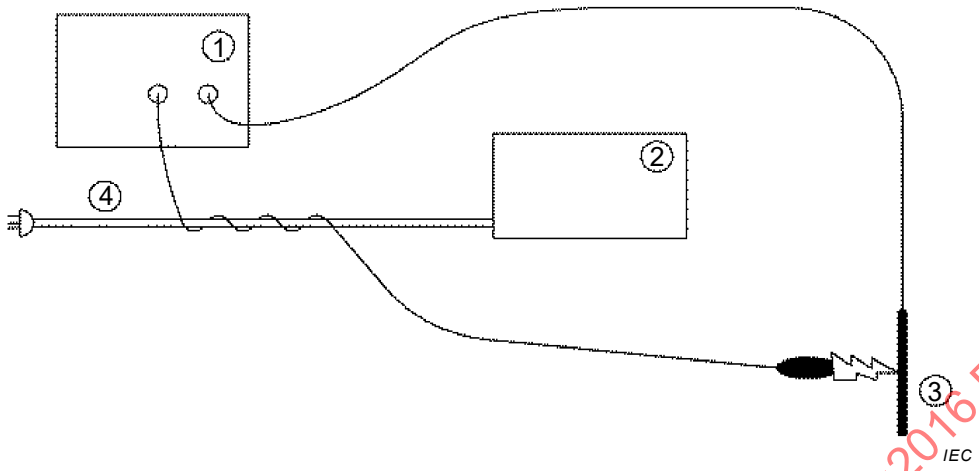
Figure 202.101 – ENCLOSURE ad hoc test

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

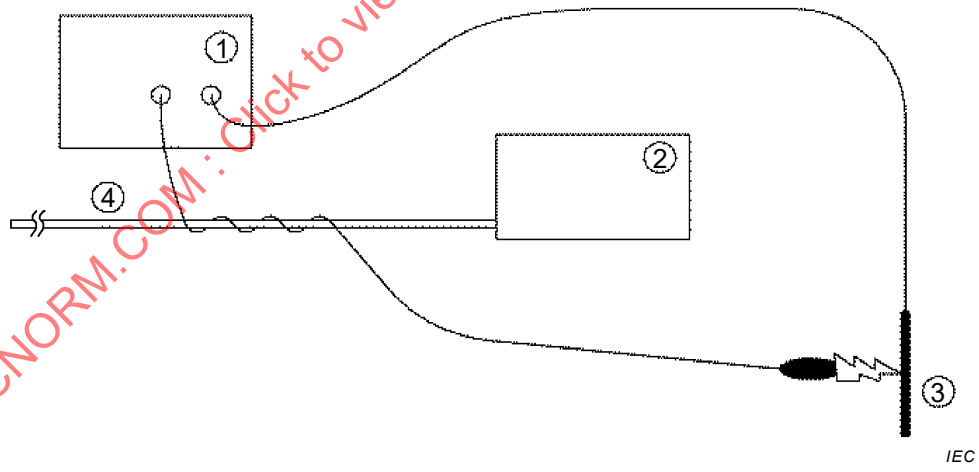
2 Unit under test

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 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 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.

Annexes

The annexes of the general standard apply, except as follows:

Annex G
(normative)

Protection against HAZARDS of ignition of flammable anaesthetic mixtures

Annex G of the general standard 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 mattresses and pads for castor tyres OPERATING TABLES and other antistatic material shall be at a minimum 10^4 Ω and at a maximum 10^7 Ω.

Compliance is checked by measurement of the electrical resistance according ISO 2878.

NOTE 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.

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.

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 Figure A.19 of the general standard 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

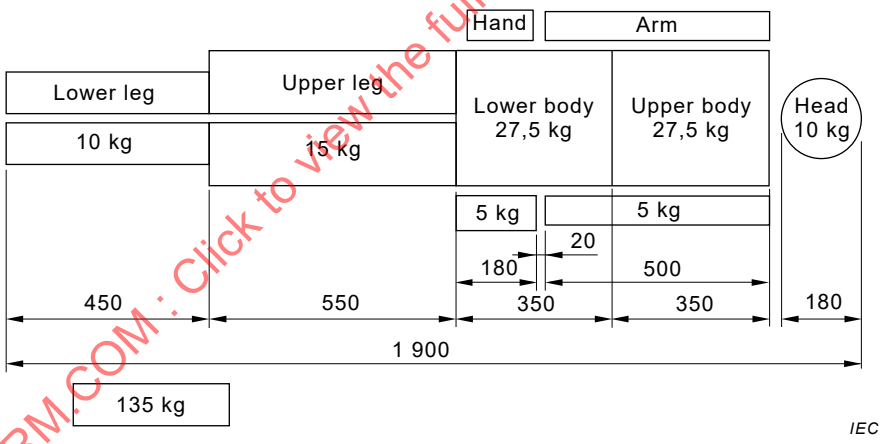


Figure AA.1 – Recommended distribution of mass in excess of 135 kg and examples of application

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 ~~to occur~~ 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 ~~must~~ 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 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.

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.

Bibliography

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

IEC 60601-1-10:2007, *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 60601-1-11:2015, *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 60601-1-12:2014, *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 60601-2-52, *Medical electrical equipment – Part 2-52: Particular requirements for the basic safety and essential performance of medical beds*

IEC 80601-2-35, *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*

Index of defined terms used in this particular standard

IEC 60601-2-46

Edition 3.0 2016-08

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

IEC 60601-2-46:2016-08(en-fr)

CONTENTS

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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9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 60601-2-46 has been prepared by IEC subcommittee 62D Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 2010 and constitutes a technical revision. This edition of IEC 60601-2-46 was revised to align structurally with the 2005 edition of IEC 60601-1 and with IEC 60601-1:2005/AMD1:2012.

The text of this standard is based on the following documents:

FDIS	Report on voting
62D/1365/FDIS	62D/1371/RVD

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

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

In this standard, the following print types are used:

– Requirements and definitions: 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 THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, 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 standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

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

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

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

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex 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 publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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

INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of OPERATING TABLES. It amends and supplements IEC 60601-1 (third edition, 2005) and its Amendment 1 (IEC 60601-1:2005/AMD1:2012), hereinafter referred to as the general standard.

The aim of this third edition is to bring this particular standard up to date with reference to the third edition of the general standard through reformatting and technical changes.

The requirements of this particular standard take priority over those of the general standard.

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 Standard.

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

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 Scope

Replacement:

This particular standard 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 4.2 of the General Standard.

This particular standard does not apply to

– dental PATIENT chairs;
– examination chairs and couches;
– PATIENT-supporting systems of diagnostic and therapeutic devices; (see IEC 60601-2-43)
– OPERATING TABLE heating blankets; (see IEC 80601-2-35)
– PATIENT transfer equipment;
– delivery tables and beds;
– medical beds; (see IEC 60601-2-52)
– 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 201.3.201.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

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

IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clauses 202 and 203 respectively. IEC 60601-1-8, IEC 60601-1-10, 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 the general standard 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 the general standard.

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 the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where × 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 the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard 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 the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard 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 the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this standard 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 standard" is used to make reference to the general standard, 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 the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard 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

Clause 2 of the general standard 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*
IEC 60601-1-3:2008/AMD1:2013[2]

Addition:

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

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

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1 apply, except as follows:

NOTE An index of defined terms is found beginning on page 24.

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.

2 There exists a consolidated edition 2.1, which includes IEC 60601-1-3:2008 and its Amendment 1 (2013).

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
a 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

Clause 4 of the general standard applies, except as follows.

201.4.3 Essential performance

Addition:

Besides the definition of the MANUFACTURER, the following ESSENTIAL PERFORMANCE is required from OPERATING TABLES:

– supporting a PATIENT without unwanted movement in a SINGLE FAULT CONDITION.

201.4.7 SINGLE FAULT CONDITION for OPERATING TABLES

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 TRENDELENBURG or positions for cardiopulmonary resuscitation (CPR), emergency back flattening.

201.5 General requirements for testing OPERATING TABLES

Clause 5 of the general standard applies.

201.6 Classification of OPERATING TABLES and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 OPERATING TABLES identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2 Marking on the outside of OPERATING TABLES or OPERATING TABLES 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.

201.7.2.21 Mass of MOBILE OPERATING TABLES

This subclause of the general standard 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 cardiac defibrillators and cardiac defibrillator-monitors.

NOTE 101 Potential HAZARDS which have 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

Clause 8 of the general standard 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.

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

Compliance is checked by using the test method of 8.6.4 of the general standard.

201.9 Protection against MECHANICAL HAZARDS of OPERATING TABLES and ME SYSTEMS

Clause 9 of the general standard 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 9.4.2.2 of the general standard 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 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.

NOTE 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 ± 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

This subclause of the general standard does not apply.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard 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

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

Addition:

OPERATING TABLES shall be at least IPX4.

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

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 TRENDELENBURG 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

Clause 12 of the general standard applies.

201.13 HAZARDOUS SITUATIONS and fault conditions for OPERATING TABLES

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of OPERATING TABLES

Clause 15 of the general standard 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.

201.15.4.7.2 Accidental operation of OPERATING TABLES

Addition:

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

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of OPERATING TABLES and ME SYSTEMS

Clause 17 of the general standard applies.

202 Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2 applies, except as follows:

202.8 Electromagnetic IMMUNITY requirements for OPERATING TABLES 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 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 this subclause have to be applied with two different HF SURGICAL EQUIPMENTS:

– 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 ± 100 kHz. The HF SURGICAL EQUIPMENT used shall be specified in the test report;
– HF SURGICAL EQUIPMENT, should have an argon plasma coagulation mode with a peak voltage of 4 000 Vp (open circuit voltage) and 120 W power capability. The HF SURGICAL EQUIPMENT used shall be specified in the test report.

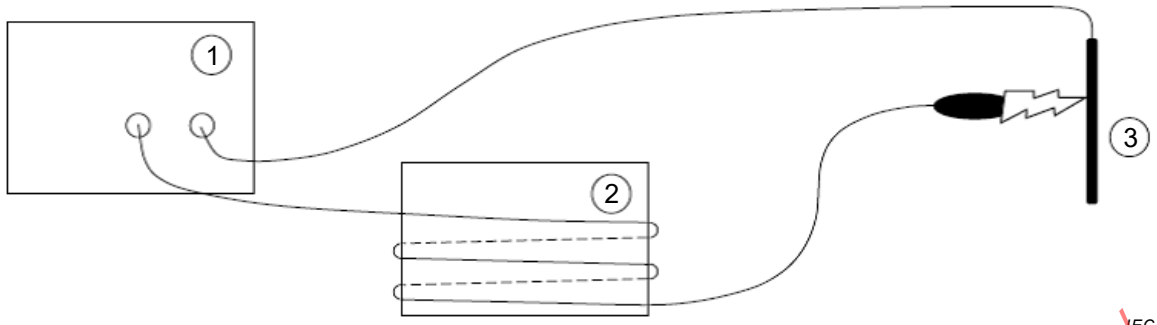
NOTE 1 The EM environment for OPERATING TABLES is a special environment (medical treatment areas with high-powered OPERATING TABLES). Besides the immunity tests required for the professional healthcare facility environment (according to Table 4 to Table 9 of IEC 60601-1-2:2014) at least immunity to HF surgical equipment emissions as described in this subclause 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)

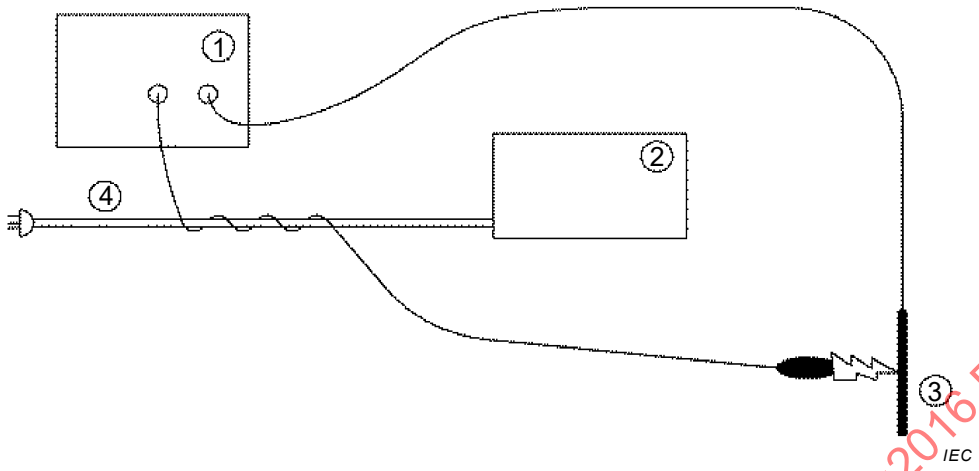
Figure 202.101 – ENCLOSURE ad hoc test

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

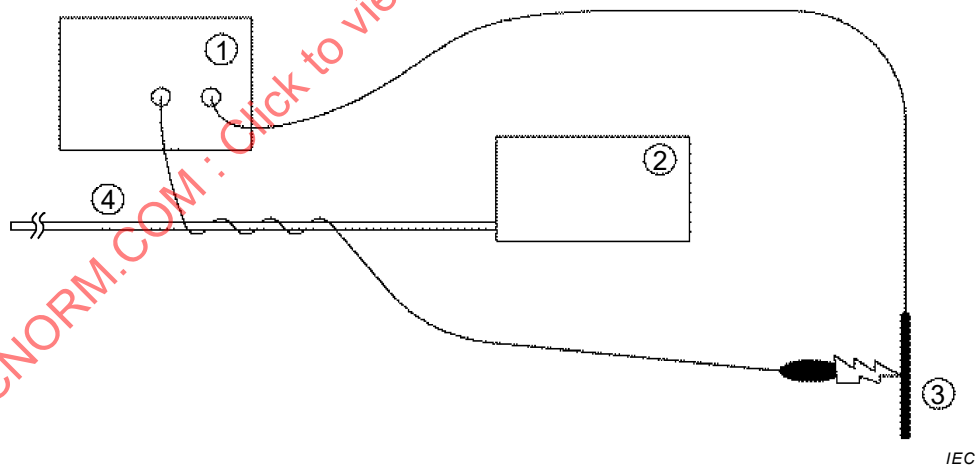
2 Unit under test

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 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 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.

Annexes

The annexes of the general standard apply, except as follows:

Annex G
(normative)

Protection against HAZARDS of ignition of flammable anaesthetic mixtures

Annex G of the general standard 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 mattresses and pads for castor tyres OPERATING TABLES and other antistatic material shall be at a minimum 10^4 Ω and at a maximum 10^7 Ω.

Compliance is checked by measurement of the electrical resistance according ISO 2878.

NOTE 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.

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.

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 Figure A.19 of the general standard 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

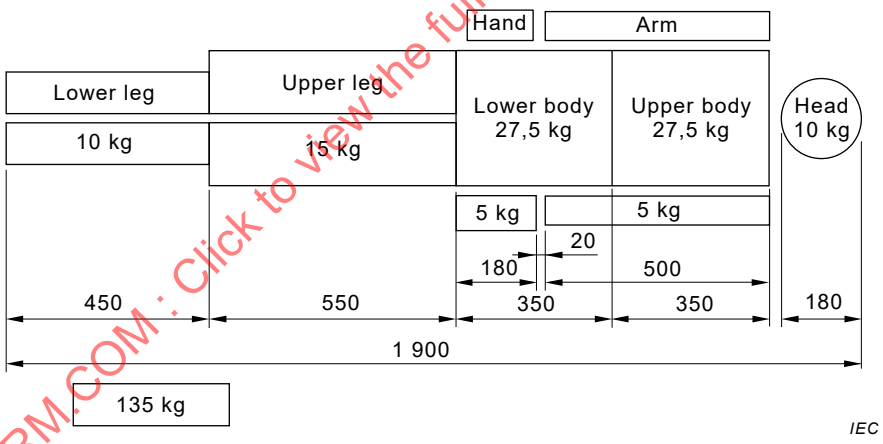


Figure AA.1 – Recommended distribution of mass in excess of 135 kg and examples of application

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 has to 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.

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.

Bibliography

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

IEC 60601-1-10:2007, *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 60601-1-11:2015, *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 60601-1-12:2014, *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 60601-2-52, *Medical electrical equipment – Part 2-52: Particular requirements for the basic safety and essential performance of medical beds*

IEC 80601-2-35, *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*

Index of defined terms used in this particular standard

SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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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 Electrotechnique 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. A 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 et de ne pas avoir signalé leur existence.

La Norme internationale IEC 60601-2-46 a été établie par le sous-comité 62D de l'IEC: Appareils électromédicaux, du comité d'études 62 de l'IEC: Équipements électriques dans la pratique médicale.

Cette troisième édition annule et remplace la deuxième édition parue en 2010. Cette édition constitue une révision technique. La présente édition de l'IEC 60601-2-46 a été révisée de façon à s'aligner sur la structure de l'édition 2005 de l'IEC 60601-1 et de l'IEC 60601-1:2005/AMD1:2012.

Le texte de cette norme est issu des documents suivants:

FDIS	Rapport de vote
62D/1365/FDIS	62D/1371/RVD

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

Cette publication a été rédigée selon les Directives ISO/IEC, Partie 2.

Dans la présente norme, 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 DEFINIS A L'ARTICLE 3 DE LA NORME GENERALE, DANS LA PRESENTE NORME PARTICULIERE OU COMME NOTES: PETITES MAJUSCULES.

Concernant la structure de la présente norme, 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 la présente norme, 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 la présente norme, la conjonction "ou" est utilisée avec la valeur d'un "ou inclusif", ainsi un énoncé est vrai si une combinaison des conditions quelle qu'elle soit est vraie.

Les formes verbales utilisées dans la présente norme sont conformes à l'usage donné à l'Annexe H des Directives ISO/IEC, Partie 2. Pour les besoins de la présente norme:

– "devoir" mis au présent de l'indicatif signifie que la satisfaction à une exigence ou à un essai est obligatoire pour la conformité à la présente norme;

– "il convient/il est recommandé" signifie que la satisfaction à une exigence ou à un essai est recommandée mais n'est pas obligatoire pour la conformité à la présente norme;

– "pouvoir" mis au présent de l'indicatif est utilisé pour décrire un moyen admissible pour satisfaire à une exigence ou à un essai.

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

Une liste de toutes les parties de la série IEC 60601, publiées sous le titre général *Appareils électromédicaux*, peut être consultée sur le site web de l'IEC.

Le comité a décidé que le contenu de cette publication ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "http://webstore.iec.ch" dans les données relatives à la publication recherchée. A cette date, la publication sera

- reconduite,
- supprimée,
- remplacée par une édition révisée, ou
- amendée.

INTRODUCTION

La présente norme particulière concerne la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES des TABLES D'OPERATION. Elle modifie et complète l'IEC 60601-1 (troisième édition, 2005) et son Amendement 1 (IEC 60601-1:2005/AMD1:2012), appelée norme générale dans la suite du texte.

L'objectif de cette troisième édition est de mettre à jour la présente norme particulière par rapport à la troisième édition de la norme générale par une remise en forme et l'introduction de modifications techniques.

Les exigences de la présente norme particulière prévalent sur celles de la norme générale.

Des lignes directrices et les justifications relatives aux exigences les plus importantes de la présente norme particulière sont fournies dans l'Annexe AA. On considère que la connaissance des raisons qui ont conduit à énoncer ces exigences non seulement facilitera l'application correcte de la norme, mais accélérera 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 de la présente norme.

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'Article 1 de la norme générale[1)] s'applique, à l'exception de ce qui suit:

201.1.1 Domaine d'application

Remplacement:

La présente norme particulière spécifie les exigences de sécurité applicables aux TABLES D'OPERATION, 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'OPERATION vers ou depuis la base ou le socle d'une TABLE D'OPERATION à plateau mobile.

NOTE Voir également 4.2 de la norme générale.

La présente norme particulière ne concerne pas

– les fauteuils dentaires pour PATIENTS;
– les fauteuils et lits d'examen;
– les systèmes de support du PATIENT des appareils de diagnostic et de thérapie; (voir l'IEC 60601-2-43)
– les couvertures chauffantes des TABLES D'OPERATION; (voir l'IEC 80601-2-35)
– les dispositifs de transfert des PATIENTS;
– les tables et lits d'accouchement;
– les lits médicaux; (voir l'IEC 60601-2-52)
– les tables d'opération de campagne.

Si les TABLES D'OPERATION sont destinées à être utilisées en combinaison avec des appareils de diagnostic et/ou de thérapie, les exigences applicables de chaque norme particulière correspondante sont également applicables.

201.1.2 Objet

Remplacement:

L'objet de la présente norme particulière est d'établir des exigences particulières pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES applicables aux TABLES D'OPERATION, telles que définies en 201.3.201.

1) La norme générale est l'IEC 60601-1:2005/AMD1:2012, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*.

201.1.3 Normes collatérales

Addition:

La présente norme particulière fait référence aux normes collatérales applicables énumérées à l'Article 2 de la norme générale 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 60601-1-10, 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 la norme générale et dans les normes collatérales en fonction de ce qui est approprié à l'APPAREIL EM considéré, et elles peuvent ajouter d'autres exigences de SECURITE DE BASE et de PERFORMANCES ESSENTIELLES.

Une exigence d'une norme particulière prévaut sur l'exigence correspondante de la norme générale.

Par souci de concision, l'IEC 60601-1 est désignée dans la présente norme particulière, par le terme "norme générale". Les normes collatérales sont désignées par leur numéro de document.

La numérotation des articles et paragraphes de la présente norme particulière correspond à celle de la norme générale avec le préfixe "201" (par exemple, 201.1 dans la présente norme aborde le contenu de l'Article 1 de la norme générale) ou de la norme collatérale applicable avec le préfixe "20x", où × est (sont) le (les) dernier(s) chiffre(s) du numéro de document de la norme collatérale (par exemple, 202.4 dans la présente norme particulière aborde le contenu de l'Article 4 de la norme collatérale IEC 60601-1-2, 203.4 dans la présente norme particulière aborde le contenu de l'Article 4 de la norme collatérale IEC 60601-1-3, etc.). Les modifications apportées au texte de la norme générale sont spécifiées par l'utilisation des termes suivants:

"Remplacement" signifie que l'article ou le paragraphe de la norme générale 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 la norme générale ou de la norme collatérale applicable.

"Amendement" signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est modifié comme indiqué par le texte de la présente norme particulière.

Les paragraphes, figures ou tableaux qui sont ajoutés à ceux de la norme générale sont numérotés à partir de 201.101. Toutefois, en raison du fait que les définitions dans la norme générale sont numérotées 3.1 à 3.147, les définitions complémentaires dans la présente norme sont numérotées à partir de 201.3.201. Les annexes complémentaires sont notées AA, BB, etc., et les alinéas complémentaires aa), bb), etc.

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

L'expression “la présente norme” est utilisée pour faire référence à la norme générale, à toutes les normes collatérales applicables et à la présente norme particulière, considérées ensemble.

Lorsque la présente norme particulière ne comprend pas d'article ou de paragraphe correspondant, l'article ou le paragraphe de la norme générale 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 la norme générale 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'Article 2 de la norme générale s'applique, à l'exception de ce qui suit:

Remplacement:

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

IEC 60601-1-3:2008, *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*
IEC 60601-1-3:2008/AMD1:2013[2]

Addition:

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

201.3 Termes et définitions

Pour les besoins du présent document, les termes et définitions donnés dans l'IEC 60601-1 s'appliquent, à l'exception de ce qui suit:

NOTE Un index des termes définis est donné à partir de la page 50.

Addition:

201.3.201
TABLE D'OPERATION MOBILE
TABLE D'OPERATION destinée à être déplacée d'un endroit à un autre tout en étant supportée par ses propres roues ou un moyen équivalent

201.3.202
POSITION NORMALE
position du plateau d'une TABLE D'OPERATION, lorsque tous les éléments sont en position horizontale

2 Il existe une édition consolidée 2.1 qui comprend l'IEC 60601-1-3:2008 et son Amendement 1 (2013).

201.3.203
TABLE D'OPERATION
dispositif dont l'UTILISATION PREVUE est de supporter 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.

201.3.204
CHARIOT DE TRANSFERT
dispositif destiné au transfert du plateau d'une TABLE D'OPERATION vers ou depuis la base ou le socle d'une TABLE D'OPERATION, ou au transfert du plateau complet de la TABLE D'OPERATION 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'OPERATION.

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

201.3.205
POSITION DE TRENDELENBURG
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'Article 4 de la norme générale s'applique, à l'exception de ce qui suit.

201.4.3 Performance essentielle

Addition:

En plus de la définition du FABRICANT, les PERFORMANCES ESSENTIELLES suivantes sont exigées pour les TABLES D'OPERATION:

– supporter un PATIENT sans mouvement intempestif en CONDITION DE PREMIER DEFAUT.

201.4.7 CONDITION DE PREMIER DEFAUT pour les TABLES D'OPERATION

Addition:

CONDITIONS DE PREMIER DEFAUT supplémentaires à prendre en compte avec les TABLES D'OPERATION:

- défaut (défaillance) dans la transmission de commandes depuis/vers des dispositifs d'entrée.

Il convient que le FABRICANT fournisse un moyen, dans toute la mesure du possible, permettant d'assurer que, dans une CONDITION DE PREMIER DEFAUT, la plateforme de la TABLE D'OPERATION supportant le PATIENT puisse revenir à une position permettant un traitement d'urgence.

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

201.5 Exigences générales relatives aux essais des TABLES D'OPERATION

L'Article 5 de la norme générale s'applique.

201.6 Classification des TABLES D'OPERATION et DES SYSTEMES EM

L'Article 6 de la norme générale s'applique.

201.7 Identification, marquage et documentation des TABLES D'OPERATION

L'Article 7 de la norme générale s'applique, à l'exception de ce qui suit:

201.7.2 Marquage sur l'extérieur des TABLES D'OPERATION ou des parties des TABLES D'OPERATION

201.7.2.10 Parties appliquées

Amendement:

Le symbole de marquage des PARTIES APPLIQUÉES conforme au Tableau D.1 (symbole 19, 20 ou 21) doit être apposé en un endroit bien visible. La conformité est vérifiée par examen.

201.7.2.21 Masse des TABLES D'OPERATION MOBILES

Le paragraphe de la norme générale 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 défibrillateurs cardiaques et aux moniteurs de défibrillateurs cardiaques.

NOTE 101 Les DANGERS potentiels qui doivent être pris en compte sont, sans caractère d'exhaustivité: les brûlures des PATIENTS, les DANGERS d'explosion ou les chocs électriques concernant le PATIENT ou l'OPERATEUR.

201.8 Protection contre les DANGERS d'origine électrique provenant des TABLES D'OPERATION

L'Article 8 de la norme générale s'applique, à l'exception de ce qui suit:

201.8.6.7 CONDUCTEUR D'EGALISATION DES POTENTIELS

Addition:

Lorsque l'EGALISATION DES POTENTIELS est exigée, les PARTIES APPLIQUEES des TABLES D'OPERATION avec des PARTIES ACCESSIBLES non PROTEGEES PAR MISE A LA TERRE doivent être équipées d'un connecteur d'EGALISATION DES POTENTIELS.

Pour les TABLES D'OPERATION munies d'un connecteur d'EGALISATION DES POTENTIELS, l'impédance entre ce dernier et toute PARTIE ACCESSIBLE ne doit pas dépasser 200 mΩ.

La conformité est vérifiée au moyen de la méthode d'essai de 8.6.4 de la norme générale.

201.9 Protection contre les DANGERS MECANIQUES des TABLES D'OPERATION et SYSTEMES EM

L'Article 9 de la norme générale s'applique, à l'exception de ce qui suit:

201.9.2.3 Autres DANGERS MECANIQUES 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'OPERATION doivent être clairement affectés par des moyens internes à des éléments particuliers des TABLES D'OPERATION.

La conformité est vérifiée 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'OPERATION doivent être soumises à une CHARGE DE FONCTIONNEMENT EN SECURITE.

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

Exigence supplémentaire:

Les TABLES D'OPERATION à plateaux transférables de TABLE D'OPERATION 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'OPERATION en cours de transfert.

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

La conformité est vérifiée par examen et par les essais suivants:

Après transfert du plateau de la TABLE D'OPERATION sur le CHARIOT DE TRANSFERT, l'essai de stabilité en UTILISATION NORMALE de 9.4.2.2 de la norme générale doit être effectué. Le plateau de la TABLE D'OPERATION ne doit pas se séparer du CHARIOT DE TRANSFERT.

L'essai est alors répété, le plateau de la TABLE D'OPERATION étant remis sur le socle, et l'essai de stabilité est effectué sur la base aussitôt après le transfert.