BS EN 60601-2-46:2011

BSI Standards Publication

Medical electrical equipment

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

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National foreword

This British Standard is the UK implementation of EN 60601-2-46:2011. It is idenitical to IEC 60601-2-46:2010. It supersedes BS EN 60601-2-46:1998 which is will be withdrawn on 20 January 2014.

The UK participation in its preparation was entrusted to Technical Committee CH/62/4, Electromedical equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 September 2011.

Amendments issued since publication

Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-46

August 2011

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Supersedes EN 60601-2-46:1998

English version

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

(IEC 60601-2-46:2010)

Appareils électromédicaux -
Partie 2-46: Exigences particulières pour la sécurité de base et les performances essentielles des tables d'opération
(CEI 60601-2-46:2010)

Medizinische elektrische Geräte -
Teil 2-46: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Operationstischen
(IEC 60601-2-46:2010)

This European Standard was approved by CENELEC on 2011-01-20. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Foreword

The text of document 62D/870/FDIS, future edition 2 of IEC 60601-2-46, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-46 on 2011-01-20.

This European Standard supersedes EN 60601-2-46:1998.

EN 60601-2-46:1998 was revised to align structurally with EN 60601-1:2006.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN and CENELEC shall not be held responsible for identifying any or all such patent rights.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2012-02-20
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2014-01-20

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

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

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

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/42/EEC). See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-46:2010 was approved by CENELEC as a European Standard without any modification.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Annex ZA of EN 60601-1:2006 applies except as follows:

Publication	Year	Title	EN/HD	Year
***Replace** IEC 60601-1-2 by:*				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corr. March	2007 2010
***Add**:*				
IEC 60601-2-2	-	Medical electrical equipment - Part 2-2: Particular requirements for basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	EN 60601-2-2	-

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
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7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) 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 second edition cancels and replaces the first edition published in 1998 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.

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

FDIS	Report on voting
62D/870/FDIS	62D/888/RVD

Full information on the voting for the approval of this particular 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.
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In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
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– “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 web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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

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)*, 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 table top to or from the base or pedestal of an OPERATING TABLE with detachable 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;
– OPERATING TABLE heating blankets;
– patient transfer equipment;
– delivery tables and beds;
– medical beds;
– field tables.

NOTE If OPERATING TABLES will be used in combination with diagnostic and/or therapeutic devices the relevant requirements of each particular standard have to be considered.

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

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

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in 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 x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 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 3.139, 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, with the following exception*:*

Replacement:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

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*

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 19.

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

NOTE 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

201.3.205
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 table top complete with the base

NOTE 1 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 The transportation can be done with or without a patient in place.

201.3.206
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.

201.4.7 SINGLE FAULT CONDITION for ME EQUIPMENT

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 102 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

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

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

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.

201.7.9.2 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 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

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 with 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 and ME SYSTEMS

Clause 9 of the general standard applies, except as follows:

201.9.2.3 Other 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.

Compliance is checked by inspection.

201.9.4.2.2 *Instability excluding transport

Item a)

Addition:

ME EQUIPMENT shall be subjected to SAFE WORKING LOAD.

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

Additional requirement:

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

Specifications concerning 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 table top to the TRANSPORTER, the stability in NORMAL USE test of 9.4.2.2 shall be carried out. The table top shall not disengage from the TRANSPORTER.

The test is then repeated with the 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

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 distribution.

201.9.8.1 General

Replacement of first dash:

– The construction of the support, suspension or actuation system shall be designed based upon Table 201.21 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 201.21 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 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 distribution.

Compliance is checked by the following test:

1) *In NORMAL POSITION and at maximum height the ME EQUIPMENT shall be statically loaded with 2,2 times SAFE WORKING LOAD. The deformation after 5 min is recorded. The ME EQUIPMENT 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 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 a) 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 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

Additional subclause:

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

Addition:

OPERATING TABLES shall be at least IPX4.

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

Addition:

In the event of interruption of the SUPPLY MAINS, whether or not the SUPPLY MAINS is restored, the height and configuration of the 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 table top in any position, other than the NORMAL POSITION, midway between its maximum and minimum heights, subjected to SAFE WORKING LOAD with weight 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

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

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

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 and ME SYSTEMS

Clause 17 of the general standard applies.

202 Electromagnetic compatibility – 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.

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

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

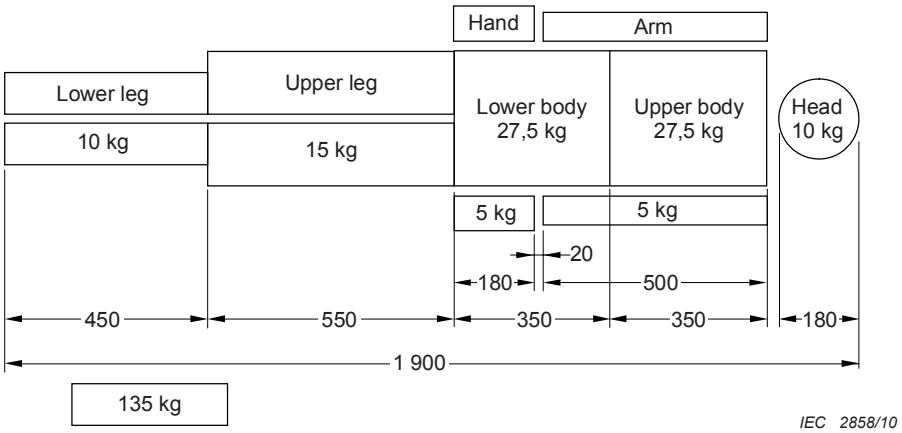

Figure AA.1 – Recommended distribution of mass in excess of 135 kg and examples of application

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 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.

Index of defined terms used in this particular standard

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