IEC 60601-2-46

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Withdrawn

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 60601-2-46:2010

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CONTENTS

FOREWORD 3
INTRODUCTION 5
201.1 Scope, object and related standards 6
201.2 Normative references 8
201.3 Terms and definitions 8
201.4 General requirements 9
201.5 General requirements for testing ME EQUIPMENT 9
201.6 Classification of ME EQUIPMENT and ME SYSTEMS 9
201.7 ME EQUIPMENT identification, marking and documents 9
201.8 Protection against electrical HAZARDS from ME EQUIPMENT 10
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS 10
201.10 Protection against unwanted and excessive radiation HAZARDS 13
201.11 Protection against excessive temperatures and other HAZARDS 13
201.12 Accuracy of controls and instruments and protection against hazardous outputs 13
201.13 Hazardous situations and fault conditions 13
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 13
201.15 Construction of ME EQUIPMENT 14
201.16 ME SYSTEMS 14
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 14
202 Electromagnetic compatibility – Requirements and tests 14
Annexes 16
Annex G (normative) Protection against HAZARDS of ignition of flammable anaesthetic mixtures 16
Annex AA (informative) Particular guidance and rationale 17
Index of defined terms used in this particular standard 19

Figure AA.1 – Recommended distribution of mass in excess of 135 kg and examples of application 17

Table 201.101 – Determination of TENSILE SAFETY FACTOR 12
Table AA.1 – Recommended distribution of mass in excess of 135 kg and examples of application: 18

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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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.

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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 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.

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.

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INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of OPERATING TABLES. It amends and supplements IEC 60601-1 (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.

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MEDICAL ELECTRICAL EQUIPMENT –

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

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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.*

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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.

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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.

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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:

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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:

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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:

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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.

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