IEC 60601-2-46

Edition 4.0 2023-05
COMMENTED VERSION

INTERNATIONAL STANDARD

colour inside

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

IEC 60601-2-46:2023-05 CMV(en)

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.140

ISBN 978-2-8322-7087-5

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

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

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

IEC 60601-2-46 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

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

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

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

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

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

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

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

In this document, the following print types are used:

– requirements and definitions: roman type;
– *test specifications: italic type*;
– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;
– TERMS DEFINED IN CLAUSE 3 OF IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

– "clause" means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes Subclauses 7.1, 7.2, etc.);
– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

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

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

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

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

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

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

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

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

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

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

INTRODUCTION

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

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

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

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

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

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

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

201.1.1 Scope

Replacement:

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

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

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

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

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

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for OPERATING TABLES as defined in 201.3.~~201~~203.

201.1.3 Collateral standards

Addition:

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

IEC 60601-1-2 and IEC 60601-1-3 apply as modified in Clauses 202 and 203 respectively. IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

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

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

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

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

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

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

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

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

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

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

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

201.2 Normative references 4

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

Replacement:

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

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment*
Amendment 1:2013~~[1]~~
Amendment 2:2021

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

Addition:

IEC 60601-2-2:2017, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

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

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

201.3 Terms and definitions

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

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

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

NOTE An index of defined terms is found on page 29.

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

Addition:

201.3.201
MOBILE OPERATING TABLE
OPERATING TABLE intended to be relocated from one location to another while supported by its own wheels or equivalent means

201.3.202
NORMAL POSITION
position of the OPERATING TABLE top with all sections set in the horizontal position

201.3.203
OPERATING TABLE
device with the INTENDED USE of supporting and positioning a PATIENT during surgical procedures for not more than 24 h

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

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

201.3.204
TRANSPORTER
device intended for the transportation of an OPERATING TABLE top to or from the base or pedestal of an OPERATING TABLE, or the transportation of the OPERATING TABLE top complete with the base

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

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

201.3.205
TRENDELENBURG POSITION
supine PATIENT position where the body is in a single plane, with that plane inclined so that the head is lower than the pelvis

201.4 General requirements

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

201.4.3 Essential performance

Addition:

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

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

Addition:

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

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

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

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

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

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

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

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

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

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

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

~~**201.7.2.10 Applied parts**~~

~~*Amendment:*~~

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

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

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

201.7.9.2 Instructions for use

201.7.9.2.1 General

Addition:

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

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

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

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

201.8.6.7 POTENTIAL EQUALIZATION CONDUCTOR

Addition:

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

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

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

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

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

201.9.2.3 Other MECHANICAL HAZARDS associated with moving parts

201.9.2.3.1 *Unintended movement

Addition:

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

Compliance is checked by inspection.

201.9.4 Instability HAZARDS

201.9.4.2.2 *Instability excluding transport position

Item a)

Addition:

OPERATING TABLES shall be subjected to SAFE WORKING LOAD.

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

Additional requirement:

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

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

Compliance is checked by inspection and the following tests.

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