SLOVENSKI STANDARD
oSIST prEN IEC 60601-2-46:2022

01-maj-2022

Medicinska električna oprema - 2-46. del: Posebne zahteve za osnovno varnost in bistvene lastnosti operacijskih miz

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

Medizinische elektrische Geräte - Teil 2-46: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Operationstischen

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

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Ta slovenski standard je istoveten z: prEN IEC 60601-2-46:2022

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ICS:

11.140	Oprema bolnišnic	Hospital equipment

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62D/1939/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER:	
IEC 60601-2-46 ED4	
DATE OF CIRCULATION:	CLOSING DATE FOR VOTING:
2022-03-25	**2022-06-17**
SUPERSEDES DOCUMENTS:	
62D/1866/CD, 62D/1935/CC	

IEC SC 62D : ELECTROMEDICAL EQUIPMENT

SECRETARIAT:	SECRETARY:
United States of America	Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐
	Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.

FUNCTIONS CONCERNED:

☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY

☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING
Attention IEC-CENELEC parallel voting The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	

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This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

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

PROPOSED STABILITY DATE: 2027

NOTE FROM TC/SC OFFICERS:

This revision project is to align with the Amendment projects of the IEC 60601-1 series and to address some technical updates to ED3. NCs are invited to submit their votes and comments at the CDV stage.

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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

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

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

FDIS	Report on voting
62D/XXXX/FDIS	62D/XXXX/RVD

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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.

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INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of OPERATING TABLES. It amends and supplements IEC 60601-1:2005, IEC 60601-2:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 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

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.

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This particular standard does not apply to

– dental PATIENT chairs;: Dentistry-Stationary dental units and dental patient chair – Part 1 general requirements (see ISO 7494-1)
– examination chairs and couches;
– PATIENT-supporting systems of diagnostic, interventional and therapeutic equipment; (see IEC 60601-2-54 or IEC 60601-2-43)
– OPERATING TABLE heating blankets; (see IEC 60601-2-35)
– PATIENT transfer equipment;
– delivery tables and delivery beds;
– medical beds; (see IEC 60601-2-52 and EN 50637)
– field tables.

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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, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

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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 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:

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"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.

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"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 3.154, 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, 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*
Amendment 1:2020

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

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*

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IEC 60601-2-43:2010, *Medical electrical equipment – Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures*
Amendment 1:2017
Amendment 2:2019

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IEC 60601-2-54:2009, *Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*
Amendment 1:2015
Amendment 2:2018

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ISO 20342-1:2019 *Assistive products for tissue integrity when lying down — Part 1: General requirements does not apply*

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 60601-2:2005/AMD2:2020 apply, except as follows:

NOTE An index of defined terms is found on page 26.

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

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

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

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

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

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

201.3.205
TRENDELENBURG POSITION
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.

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201.4.3 Essential performance

Addition:

Besides the definition of the MANUFACTURER, the following shall be considered ESSENTIAL PERFORMANCE for OPERATING TABLES:

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– Supporting a PATIENT without unintended movement (motorized or not) leading to an unacceptable risk in a SINGLE FAULT CONDITION.

201.4.7 SINGLE FAULT CONDITION for OPERATING TABLES

Addition:

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

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

201.5 General requirements for testing ME EQUIPMENT

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: