ICS 11.140 SLOVENSKÁ TECHNICKÁ NORMA December 2024

STN	**Zdravotnícke elektrické prístroje Časť 2-46: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti operačných stolov**	**STN EN IEC 60601-2-46** 36 4800

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 11/24

Obsahuje: EN IEC 60601-2-46:2024, IEC 60601-2-46:2023

Oznámením tejto normy sa od 31.07.2027 ruší
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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60601-2-46

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Supersedes EN IEC 60601-2-46:2019

English Version

Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables (IEC 60601-2-46:2023)

Appareils électromédicaux - Partie 2-46: Exigences particulières pour la sécurité de base et les performances essentielles des tables d'opération (IEC 60601-2-46:2023)

Medizinische elektrische Geräte - Teil 2-46: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Operationstischen (IEC 60601-2-46:2023)

This European Standard was approved by CENELEC on 2024-07-31. 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.

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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 CEN-CENELEC Management Centre 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, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of document 62D/1939/CDV, future edition 4 of IEC 60601-2-46, prepared by SC 62D "Particular medical equipment, software, and systems" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-46:2024.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2025-05-01
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2027-07-31

This document supersedes EN IEC 60601-2-46:2019 and all of its amendments and corrigenda (if any).

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

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 60601-2-46:2023 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standard indicated:

IEC 60601-1-8:2006	NOTE	Approved as EN 60601-1-8:2007 (not modified) +A11:2017
IEC 60601-1-8:2006/A1:2012	NOTE	Approved as EN 60601-1-8:2007/A1:2013 (not modified)
IEC 60601-1-8:2006/A2:2020	NOTE	Approved as EN 60601-1-8:2007/A2:2021 (not modified)
IEC 60601-1-9:2007	NOTE	Approved as EN 60601-1-9:2008 (not modified)
IEC 60601-1-9:2007/A1:2013	NOTE	Approved as EN 60601-1-9:2008/A1:2013 (not modified)
IEC 60601-1-9:2007/A2:2020	NOTE	Approved as EN 60601-1-9:2008/A2:2020 (not modified)
IEC 60601-1-10:2007	NOTE	Approved as EN 60601-1-10:2008 (not modified)
IEC 60601-1-10:2007/A1:2013	NOTE	Approved as EN 60601-1-10:2008/A1:2015 (not modified)
IEC 60601-1-10:2007/A2:2020	NOTE	Approved as EN 60601-1-10:2008/A2:2021 (not modified)
IEC 60601-1-11:2015	NOTE	Approved as EN 60601-1-11:2015 (not modified)
IEC 60601-1-11:2015/A1:2020	NOTE	Approved as EN 60601-1-11:2015/A1:2021 (not modified)
IEC 60601-1-12:2014	NOTE	Approved as EN 60601-1-12:2015 (not modified)

IEC 60601-1-12:2014/A1:2020	NOTE	Approved as EN 60601-1-12:2015/A1:2020 (not modified)
IEC 60601-2-35:2020	NOTE	Approved as EN IEC 60601-2-35:2021 (not modified)
IEC 60601-2-52:2009/A1:2015	NOTE	Approved as EN 60601-2-52:2010/A1:2015 (not modified)
IEC 62366-1:2015	NOTE	Approved as EN 62366-1:2015 (not modified)
IEC 62366-1:2015/A1:2020	NOTE	Approved as EN 62366-1:2015/A1:2020 (not modified)
ISO 7494-1:2018	NOTE	Approved as EN ISO 7494-1:2018 (not modified)
ISO 20342-1:2022	NOTE	Approved as EN ISO 20342-1:2022 (not modified)

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cencenelec.eu.

Annex ZA of EN 60601-1:2006[1]*, applies, except as follows:*

Replace:

Publication	Year	Title	EN/HD	Year
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	EN 60601-1-3	2008
-	-		+ AC	2010
+ A1	2013		+ A1	2013
-	-		+ AC	2014
-	-		+ A11	2016
+ A2	2021		+ A2	2021
ISO 2878	2017	Rubber, vulcanized or thermoplastic - Antistatic and conductive products - Determination of electrical resistance	-	-

[1] As impacted by EN 60601-1:2006/AC:2010, EN 60601-1:2006/A1:2013, EN 60601-1:2006/A1:2013/AC:2014, EN 60601-1:2006/A12:2014, EN 60601-1:2006/A2:2021, EN 60601-1:2006/AC:2022-12 and EN 60601-1:2006/A13:2024.

Add:

Publication	Year	Title	EN/HD	Year
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	EN IEC 60601-2-2	2018
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	EN IEC 60601-2-43	2023
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	EN IEC 60601-2-54	2024

IEC 60601-2-46

Edition 4.0 2023-05

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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

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

IEC 60601-2-46

Edition 4.0 2023-05

INTERNATIONAL STANDARD

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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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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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.

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.

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.

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

– dental PATIENT chairs (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), and
– field tables.

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 201.3.203.