ICS 11.040.30 SLOVENSKÁ TECHNICKÁ NORMA December 2024

STN	**Zdravotnícke elektrické prístroje Časť 2-2: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti vysokofrekvenčných chirurgických prístrojov a vysokofrekvenčných chirurgických príslušenstiev Zmena A1**	**STN EN IEC 60601-2-2/A1** 36 4800

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

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

STN EN IEC 60601-2-2 zo septembra 2018 sa bez tejto zmeny A1 môže používať do 31. 7. 2027.

Obsahuje: EN IEC 60601-2-2:2018/A1:2024, IEC 60601-2-2:2017/AMD1:2023

139569

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60601-2-2:2018/A1

September 2024

ICS 11.040.30

English Version

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 60601-2-2:2017/AMD1:2023)

Appareils électromédicaux - Partie 2-2: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'électrochirurgie à courant haute fréquence et des accessoires d'électrochirurgie à courant haute fréquence
(IEC 60601-2-2:2017/AMD1:2023)

Medizinische elektrische Geräte - Teil 2-2: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Hochfrequenz-Chirurgiegeräten
(IEC 60601-2-2:2017/AMD1:2023)

This amendment A1 modifies the European Standard EN IEC 60601-2-2:2018; it 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 amendment 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 CEN-CENELEC Management Centre or to any CENELEC member.

This amendment 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

Ref. No. EN IEC 60601-2-2:2018/A1:2024 E

European foreword

The text of document 62D/2010/FDIS, future edition 6 of IEC 60601-2-2/AMD1, 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 60601-2-2:2018/A1:2024.

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

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 60601-2-2:2017/AMD1:2023 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 60601-1-3	NOTE	Approved as EN 60601-1-3
IEC 60601-1-10	NOTE	Approved as EN 60601-1-10
IEC 60601-1-11	NOTE	Approved as EN 60601-1-11
IEC 60601-1-2	NOTE	Approved as EN 60601-1-2

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.

Replace EN 60601-1-2:2015 with:

Publication	Year	Title	EN/HD	Year
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	EN 60601-1-2	2015
+ A1	2020		+ A1	2021

Replace EN 60601-1-8:2006 with:

Publication	Year	Title	EN/HD	Year
IEC 60601-1-8	2006	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 60601-1-8	2007
-	-		+ AC	2010
+ A1	2012		+ A1	2013
-	-		+ AC	2014
-	-		+ A11	2017
+ A2	2020		+ A2	2021

EN IEC 60601-2-2:2018/A1:2024 (E)

Delete:

Publication	Year	Title	EN/HD	Year
IEC 61000-4-3	2006	Electromagnetic compatibility (EMC) - Part 4-3 : Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	-	-
IEC 61000-4-6	2013	Electromagnetic compatibility (EMC) - Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	EN 61000-4-6	2014

Replace EN 55011:2016 with:

Publication	Year	Title	EN/HD	Year
CISPR 11 (mod)	2015	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	EN 55011	2016
+ A1	2016		+ A1	2017
-	-		+ A11	2020
+ A2	2019		+ A2	2021

IEC 60601-2-2

Edition 6.0 2023-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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

Appareils électromédicaux –
Partie 2-2: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'électrochirurgie à courant haute fréquence et des accessoires d'électrochirurgie à courant haute fréquence

IEC 60601-2-2:2017-03/AMD1:2023-02(en-fr)

IEC 60601-2-2

Edition 6.0 2023-02

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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

Appareils électromédicaux – Partie 2-2: Exigences particulières pour la sécurité de base et les performances essentielles des appareils d'électrochirurgie à courant haute fréquence et des accessoires d'électrochirurgie à courant haute fréquence

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.30 ISBN 978-2-8322-6466-9

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

AMENDMENT 1

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 document may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to IEC 60601-2-2:2017 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems.

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

Draft	Report on voting
62D/2010/FDIS	62D/2021/RVD

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 Amendment 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/.

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.

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INTRODUCTION to Amendment 1

The 6th Edition of IEC 60601-2-2 was published in 2017. This amendment is intended to align the standard to IEC 60601-1:2005/AMD2:2020. Additionally, this amendment is intended to address several issues reported from the national committees, including but not limited to:

- requirement for including the length of an accessory in the instructions for use;
- clarification of test setup for HF LEAKAGE CURRENTS;
- considering modes with high DUTY CYCLES above 45 % in the risk management;
- including text of the interpretation sheet 62D/1703/INF regarding the HIGH CURRENT MODE to Annex AA.

201.1 Scope, object and related standards

Replace, in footnote 1 to the first sentence, "IEC 60601-1:2005/AMD1:2012" *with* "IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020".

201.1.3 Collateral standards

Replace the existing second paragraph with the following:

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 and IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, apply as modified in Clauses 202 and 208 respectively. IEC 60601-1-3, 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.