ICS 11.040.01 SLOVENSKÁ TECHNICKÁ NORMA December 2024

STN	**Zdravotnícke elektrické prístroje Časť 2-75: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti fotodynamických terapeutických a fotodynamických diagnostických prístrojov Zmena A1**	**STN EN IEC 60601-2-75/A1** 36 4800

Medical Electrical Equipment - Part 2-75: Particular requirements for the basic safety and essential performance of photodynamic therapy and photodynamic diagnosis equipment

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 60601-2-75 z februára 2020 sa bez tejto zmeny A1 môže používať do 31. 7. 2027.

Obsahuje: EN IEC 60601-2-75:2019/A1:2024, IEC 60601-2-75:2017/AMD1:2023

139567

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 60601-2-75:2019/A1

September 2024

ICS 11.040.01

English Version

Medical electrical equipment - Part 2-75: Particular requirements for the basic safety and essential performance of photodynamic therapy and photodynamic diagnosis equipment (IEC 60601-2-75:2017/AMD1:2023)

Appareils électromédicaux - Partie 2-75: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de thérapie photodynamique et de diagnostic photodynamique (IEC 60601-2-75:2017/AMD1:2023)

Medizinische elektrische Geräte - Teil 2-75: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von photodynamischen Therapie- und photodynamischen Diagnosegeräten (IEC 60601-2-75:2017/AMD1:2023)

This amendment A1 modifies the European Standard EN IEC 60601-2-75:2019; 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 60601-2-75:2019/A1:2024 E

European foreword

The text of document 62D/2006/FDIS, future edition 1 of IEC 60601-2-75/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 60601-2-75:2019/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 60601-2-75:2017/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:

ISO 13694:2018	NOTE	Approved as EN ISO 13694:2018 (not modified)
ISO 14971:2019	NOTE	Approved as EN ISO 14971:2019 (not modified) +A11:2021
ISO 11554:2017	NOTE	Approved as EN ISO 11554:2017 (not modified)
ISO 11145:2018	NOTE	Approved as EN ISO 11145:2018 (not modified)
IEC 62304:2006/A1:2015	NOTE	Approved as EN 62304:2006/A1:2015 (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.

Replace EN 60601-1, EN 60601-2-22 and their amendments with :

Publication	Year	Title	EN/HD	Year
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ AC	2010
+ A1	2012		+ A1	2013
-	-		+ AC	2014
-	-		+ A12	2014
+ A2	2020		+ A2	2021
-	-		+ AC	2022
-	-		+ A13	2024
IEC 60601-2-22	2019	Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	EN IEC 60601-2-22	2020

IEC 60601-2-75

Edition 1.0 2023-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment – Part 2-75: Particular requirements for the basic safety and essential performance of photodynamic therapy and photodynamic diagnosis equipment

Appareils électromédicaux – Partie 2-75: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de thérapie photodynamique et de diagnostic photodynamique

IEC 60601-2-75:2017-05/AMD1:2023-01(en-fr)

IEC 60601-2-75

Edition 1.0 2023-01

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AMENDMENT 1
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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 2-75: Particular requirements for the basic safety and essential performance of photodynamic therapy and photodynamic diagnosis equipment

AMENDMENT 1

FOREWORD

This amendment 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/2006/FDIS	62D/2017/RVD

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

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://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.

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

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INTRODUCTION to Amendment 1

At the October 2019 meeting of IEC SC 62D in Shanghai, China, the subcommittee discussed the need for administrative/technical changes to most 62D standards after completion of the amendment projects within the IEC 60601-1 series. Those projects were all completed and the amendments published in 2020.

The full list of IEC SC 62D documents that will be amended or revised may be found within the IEC document 62D/1792/DC. The results and comments on the DC may be found within 62D/1808/INF. The review report for this amendment is 62D/1812/RR.

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201.1.1 Scope

Replace the existing footnote 1 with the following:

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.*

201.1.4 Particular standards

Replace the first three paragraphs of this subclause with the following:

In the IEC 60601 series, particular standards specify BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for the particular ME EQUIPMENT and ME SYSTEMS. Particular standards may modify, replace or delete requirements contained in the general standard and applicable collateral standards as appropriate for the particular ME EQUIPMENT and ME SYSTEMS under consideration.

A requirement of a particular standard takes priority over the general standard and applicable collateral standards.

For brevity, IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

201.2 Normative references

Replace the existing references to IEC 60601-1 and IEC 60601-2-22 and their amendments with the following new references:

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

IEC 60601-2-22:2019, *Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment*