

SLOVENSKI STANDARD
SIST EN 60601-2-45:2011/A2:2024**01-november-2024**

Medicinska električna oprema - 2-45. del: Posebne zahteve za osnovno varnost in bistvene lastnosti rentgenske opreme za mamografijo in stereotaktičnih naprav za mamografijo - Dopolnilo A2 (IEC 60601-2-45:2011/A2:2022)

Medical electrical equipment - Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices (IEC 60601-2-45:2011/A2:2022)

Medizinische elektrische Geräte - Teil 2-45: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Röntgen-Mammographiegeräten und mammographischen Stereotaxie-Einrichtungen (IEC 60601-2-45:2011/A2:2022)

Appareils électromédicaux - Partie 2-45: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de mammographie à rayonnement X et des appareils mammographiques stéréotaxiques (IEC 60601-2-45:2011/A2:2022)

Ta slovenski standard je istoveten z: EN 60601-2-45:2011/A2:2024

ICS:

11.040.50	Radiografska oprema	Radiographic equipment
13.280	Varstvo pred sevanjem	Radiation protection

SIST EN 60601-2-45:2011/A2:2024 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 60601-2-45:2011/A2

September 2024

ICS 11.040.50

English Version

**Medical electrical equipment - Part 2-45: Particular requirements
for the basic safety and essential performance of mammographic
X-ray equipment and mammographic stereotactic devices
(IEC 60601-2-45:2011/A2:2022)**

Appareils électromédicaux - Partie 2-45: Exigences
particulières pour la sécurité de base et les performances
essentiels des appareils de mammographie à
rayonnement X et des appareils mammographiques
stéréotaxiques
(IEC 60601-2-45:2011/A2:2022)

Medizinische elektrische Geräte - Teil 2-45: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von Röntgen-
Mammographiegeräten und mammographischen
Stereotaxie-Einrichtungen
(IEC 60601-2-45:2011/A2:2022)

This amendment A2 modifies the European Standard EN 60601-2-45:2011; it was approved by CENELEC on 2022-09-06. 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

EN 60601-2-45:2011/A2:2024 (E)**European foreword**

The text of document 62B/1271/CDV, future edition 3 of IEC 60601-2-45/A2, prepared by SC 62B "Medical imaging 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 60601-2-45:2011/A2:2024.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2025-03-20 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2027-09-20 document have to be withdrawn

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 60601-2-45:2011/A2:2022 was approved by CENELEC as a European Standard without any modification.

[SIST EN 60601-2-45:2011/A2:2024](https://standards.iteh.ai/catalog/standards/sist/bd2e5ee1-d779-4bf5-8b93-94508bac4597/sist-en-60601-2-45-2011-a2-2024)

<https://standards.iteh.ai/catalog/standards/sist/bd2e5ee1-d779-4bf5-8b93-94508bac4597/sist-en-60601-2-45-2011-a2-2024>

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:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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 60601-1-3:2008 with:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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

EN 60601-2-45:2011/A2:2024 (E)*Add:*

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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

Replace:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-

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<https://standards.iteh.ai/catalog/standards/sist/bd2e5ee1-d779-4bf5-8b93-94508bac4597/sist-en-60601-2-45-2011-a2-2024>