

STN	Zdravotnícke elektrické prístroje Časť 2-45: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti mamografických röntgenových prístrojov a mamografických stereotaktických zariadení Zmena A2	STN EN 60601-2-45/A2 36 4800
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Medical electrical equipment. Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices

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 60601-2-45 z apríla 2012 sa bez tejto zmeny A2 môže používať do 20. 9. 2027.

Obsahuje: EN 60601-2-45:2011/A2:2024, IEC 60601-2-45:2011/AMD2:2022

139570

Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, 2024
Slovenská technická norma a technická normalizačná informácia je chránená zákonom č. 60/2018 Z. z. o technickej normalizácii v znení neskorších predpisov.

EUROPEAN STANDARD

EN 60601-2-45:2011/A2

NORME EUROPÉENNE

EUROPÄISCHE NORM

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.

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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

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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.

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	-	-



IEC 60601-2-45

Edition 3.0 2022-08

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 2
AMENDEMENT 2

**Medical electrical equipment –
Part 2-45: Particular requirements for the basic safety and essential
performance of mammographic X-ray equipment and mammographic
stereotactic devices**

**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**



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IEC 60601-2-45

Edition 3.0 2022-08

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 2
AMENDEMENT 2

**Medical electrical equipment –
Part 2-45: Particular requirements for the basic safety and essential
performance of mammographic X-ray equipment and mammographic
stereotactic devices**

**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**

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices****AMENDMENT 2****FOREWORD**

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Amendment 2 to IEC 60601-2-45:2011 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

Draft	Report on voting
62B/1271/CDV	62B/1282/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 Amendment is English.

IEC 60601-2-45:2011/AMD2:2022

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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/standardsdev/publications/.

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- withdrawn,
- replaced by a revised edition, or
- amended.

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INTRODUCTION to Amendment 2

This second amendment to the third edition of this particular standard has been prepared to provide a complete set of safety requirements for MAMMOGRAPHIC X-RAY EQUIPMENT, based on the second amendment (2020) to IEC 60601-1:2005 and associated collateral standards. Moreover, in Annex AA the description of the term for ESSENTIAL PERFORMANCE is modified to better reflect the clarification published as interpretation sheet 1 of IEC 60601-1:2005/AMD1:2012. This particular standard addresses the system level of MAMMOGRAPHIC X-RAY EQUIPMENT including the equipment for MAMMOGRAPHIC TOMOSYNTHESIS.

FOREWORD

Replace, in the second paragraph, “IEC 60601-1-3 (2008)”, modified by Amendment 1, with “IEC 60601-1-3 (2008), Amendment 1 of IEC 60601-1-3 (2013) and Amendment 2 of IEC 60601-1-3 (2021)”.

201.1 Scope, object and related standards

Replace, in footnote 1), “IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012”, modified by Amendment 1, 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 first sentence of the second paragraph with:

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-3:2008, IEC 60601-1-3:2008/AMD1:2013 and IEC 60601-1-3:2008/AMD2:2021 apply as modified in Clauses 202 and 203, respectively.

Replace, at the end of the second sentence of the second paragraph, modified by Amendment 1, the existing footnote with:

2).

201.2 Normative references

Replace the existing reference to IEC 60601-1-2:2014, modified by Amendment 1, with:

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*
IEC 60601-1-2:2014/AMD1:2020

Replace the existing reference to IEC 60601-1-3:2008, modified by Amendment 1, with:

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*
IEC 60601-1-3:2008/AMD1:2013
IEC 60601-1-3:2008/AMD2:2021

2) IEC 60601-1-8, *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*. IEC 60601-1-9, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design*. IEC 60601-1-10, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*. IEC 60601-1-11, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*. IEC 60601-1-12, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*.

IEC 60601-2-45:2011/AMD2:2022 – 5 –
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Add, under "Addition:", the following reference:

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

Replace the existing reference "IEC 60788:2004" with "IEC TR 60788:2004".

201.3 Terms and definitions

Replace the first paragraph of this subclause, modified by Amendment 1, with the following:

For the purposes of this document, the terms and definitions given in IEC 60601-1, IEC 60601-1-3 and IEC TR 60788 apply, except as follows:

201.4.3.101 *Additional ESSENTIAL PERFORMANCE requirements

Replace the title of this subclause with the following new title:

201.4.3.101 *Additional potential ESSENTIAL PERFORMANCE requirements

Replace the first paragraph of this subclause with the following:

Additional potential ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Replace the existing title of the table with the following new title:

Table 201.101 – Distributed potential ESSENTIAL PERFORMANCE requirements

Add, after the existing Subclause 201.7.8.102, the following new subclause:

koniec náhľadu – text ďalej pokračuje v platenej verzii STN