ICS 11.040.50 SLOVENSKÁ TECHNICKÁ NORMA Marec 2016

STN	**Zdravotnícke elektrické prístroje. Časť 2-45: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti mamografických röntgenových prístrojov a mamografických stereotaktických zariadení. Zmena A1**	**STN EN 60601-2-45/A1** 36 4800

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. 02/16

STN EN 60601-2-45 z apríla 2012 sa bez zmeny A1 môže používať do 23. 07. 2018.

Obsahuje: EN 60601-2-45:2011/A1:2015, IEC 60601-2-45:2011/AMD1:2015

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-45:2011/A1

September 2015

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/A1:2015)

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/A1:2015)

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/A1:2015)

This amendment A1 modifies the European Standard EN 60601-2-45:2011; it was approved by CENELEC on 2015-07-23. 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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 60601-2-45:2011/A1:2015 E

EN 60601-2-45:2011/A1:2015

European foreword

The text of document 62B/917/CDV, future IEC 60601-2-45:2011/A1, prepared by SC 62B "Diagnostic imaging equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-45:2011/A1:2015.

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)	2016-04-23
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-07-23

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

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 60601-2-45:2011.

Endorsement notice

The text of the International Standard IEC 60601-2-45:2011/A1:2015 was approved by CENELEC as a European Standard without any modification.

In the Bibliography of EN 60601-2-45:2011, the following note has to be **added** for the standard indicated:

IEC 61223-3-2:2007	NOTE	Harmonized as EN 61223-3-2:2008 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When 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.cenelec.eu

Annex ZA of EN 60601-2-45:2011 applies, except as follows:

Publication	Year	Title	EN/HD	Year
Replace the existing references to IEC 60601-1-2:2007 and IEC 60601-1-3:2008 by the following:				
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
IEC 60601-1-3 +A1	2008 2013	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 + corr. March +A1 +A1/AC	2008 2010 2013 2014
Delete the following reference:				
IEC 61223-3-2	2007	Evaluation and routine testing in medical imaging departments - Part 3-2: Acceptance tests - Imaging performance of mammographic X-ray equipment	EN 61223-3-2	2008

IEC 60601-2-45

Edition 3.0 2015-06

INTERNATIONAL STANDARD

AMENDMENT 1

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 60601-2-45:2011-02/AMD1:2015-06(en)

IEC 60601-2-45

Edition 3.0 2015-06

INTERNATIONAL STANDARD

AMENDMENT 1

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.50

ISBN 978-2-8322-2727-5

FOREWORD

This amendment 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:

CDV	Report on voting
62B/917/CDV	62B/954/RVC

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

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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

A bilingual version of this publication may be issued at a later date.

NOTE The attention of National Committees 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 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 implementation nationally not earlier than 3 years from the date of publication.

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INTRODUCTION TO THE AMENDMENT

This first 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 IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-2:2014, and IEC60601-1-3:2008 and IEC60601-1-3:2008/AMD1:2013. This particular standard addresses the system level of MAMMOGRAPHIC X-RAY EQUIPMENT and introduces equipment for MAMMOGRAPHIC TOMOSYNTHESIS.

FOREWORD

Replace, in the second paragraph, the reference to “IEC 60601-1-3 (2010)" *by “*IEC 60601-1-3 (2008)”.

201.1 Scope, object and related standards

*Replace, in footnote 1, the reference to "*IEC 60601-1:2005" *by "*IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012".

201.1.1 Scope

*Add, in the first paragraph, after the term "*MAMMOGRAPHIC X-RAY EQUIPMENT*" the phrase "*including equipment for MAMMOGRAPHIC TOMOSYNTHESIS,*".*

*Replace, in the first dashed item of the third paragraph, the words "*modes of operation*" by "*other than MAMMOGRAPHIC TOMOSYNTHESIS*"*

Add, after this first dashed item, the following new dashed item:

– CT SCANNERS covered by IEC 60601-2-44;

201.1.3 Collateral standards

*Replace, in the first sentence of the second paragraph, the reference to "*IEC 60601-1-2:2007" *by* "IEC 60601-1-2:2014

*Replace the reference to "*IEC 60601-1-3:2008*" by "*IEC 60601-1-3:2008 and IEC 60601-1-3:2008/AMD1:2013*"*

Replace the second sentence of the second paragraph, including its footnote, with the following new sentence and footnote:

IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply[1].

1 IEC 60601-1-9:2007, *Medical electrical equipment – Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design.* IEC 60601-1-10:2007*, 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 60601-1-11:2010, *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 60601-1-12:2004, *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 used in the emergency medical services environment.*

201.2 Normative references

Replace the existing references to IEC 60601-1-2:2007 and IEC 60601-1-3:2008 by the following:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

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

Delete the following normative reference:

IEC 61223-3-2:2007, *Evaluation and routine testing in medical imaging departments – Part 3-2: Acceptance tests – Imaging performance of mammographic X-ray equipment*