

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

122368

Úrad pre normalizáciu, metrológiu a skúšobníctvo SR, 2016
Podľa zákona č. 264/1999 Z. z. v znení neskorších predpisov sa môžu slovenské technické normy
rozmnžovať a rozširovať iba so súhlasom Úradu pre normalizáciu, metrológiu a skúšobníctvo SR.

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
essentielle 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

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:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Replace the existing references to IEC 60601-1-2:2007 and IEC 60601-1-3:2008 by the following:</i>				
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	2008	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance -	EN 60601-1-3	2008
+A1	2013	Collateral Standard: Radiation protection in diagnostic X-ray equipment	+ corr. March +A1 +A1/AC	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
---------------	------	--	--------------	------



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**





THIS PUBLICATION IS COPYRIGHT PROTECTED
Copyright © 2015 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

IEC Central Office
 3, rue de Varembe
 CH-1211 Geneva 20
 Switzerland

Tel.: +41 22 919 02 11
 Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

IEC Catalogue - webstore.iec.ch/catalogue

The stand-alone application for consulting the entire bibliographical information on IEC International Standards, Technical Specifications, Technical Reports and other documents. Available for PC, Mac OS, Android Tablets and iPad.

IEC publications search - www.iec.ch/searchpub

The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,...). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and also once a month by email.

Electropedia - www.electropedia.org

The world's leading online dictionary of electronic and electrical terms containing more than 30 000 terms and definitions in English and French, with equivalent terms in 15 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary

More than 60 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

IEC Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: csc@iec.ch.



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

Warning! Make sure that you obtained this publication from an authorized distributor.

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.

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 apply¹.

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

koniec náhľadu – text ďalej pokračuje v platenej verzii STN