ELEKTRILISED MEDITSIINISEADMED. OSA 2-45: ERINÕUDED MAMMOGRAAFILISTE RÖNTGENSEADMETE JA MAMMOGRAAFILISTE STEREOTAKTILISTE SEADISTE ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-2-45:2011+A1:2015 sisaldab Euroopa standardi EN 60601-2-45:2011 ja selle muudatuse A1:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-45:2011+A1:2015 consists of the English text of the European standard EN 60601-2- 45:2011 and its amendment A1:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 18.03.2011, muudatus A1 18.09.2015.	Date of Availability of the European standard is 18.03.2011, for Amendment A1 18.09.2015
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.50

EUROPEAN STANDARD

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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)

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
(CEI 60601-2-45:2011)

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)

CENELEC

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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 60601-2-45:2011 E

Foreword

The text of document 62B/817/FDIS, future edition 3 of IEC 60601-2-45, 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 was approved by CENELEC as EN 60601-2-45 on 2011-03-17.

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

This European Standard supersedes EN 60601-2-45:2001.

EN 60601-2-45:2011 has been aligned to EN 60601-1:2006 and to EN 60601-1-3:2008 + corrigendum March 2010. Further modifications have been made with respect to the current technology of MAMMOGRAPHIC X-RAY EQUIPMENT.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2011-12-17
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2014-03-17

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– Test specifications: italic type.

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g., Clause 7 includes subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g., 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” , so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/423/EEC). See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-45:2011 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 standards indicated:

IEC 60601-2-7:1998	NOTE	Harmonized as EN 60601-2-7:1998 (not modified).
IEC 60601-2-28:2010	NOTE	Harmonized as EN 60601-2-28:2010 (not modified).
IEC 60601-2-32:1994	NOTE	Harmonized as EN 60601-2-32:1994 (not modified).
IEC 60664-1:2007	NOTE	Harmonized as EN 60664-1:2007 (not modified).
ISO 4090:2001	NOTE	Harmonized as EN ISO 4090:2004 (not modified).
ISO 12052	NOTE	Harmonized as EN ISO 12052 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Annex ZA of EN 60601-1:2006 applies, except as follows:

Publication	Year	Title	EN/HD	Year
Replace *IEC 60601-1-2 and IEC 60601-1-3 by:*				
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corr. March	2007 2010
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 + corr. March	2008 2010
Add:				
IEC 60336	2005	Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Characteristics of focal spots	EN 60336	2005
IEC 60613	2010	Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis	EN 60613	2010
IEC/TR 60788	2004	Medical electrical equipment - Glossary of defined terms	-	-
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 62220-1-2	2007	Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-2: Determination of the detective quantum efficiency - Detectors use in mammography	EN 62220-1-2	2007
ISO 9236-3	1999	Photography - Sensitometry of screen/film systems for medical radiography - Part 3: Determination of sensitometric curve shape, speed and average gradient for mammography	-	-

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

CONTENTS

The committee has decided that the contents of this 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.

INTRODUCTION

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 (3rd edition) and its collaterals. This particular standard addresses the system level of MAMMOGRAPHIC X-RAY EQUIPMENT, which consists of a combination of an X-RAY GENERATOR, associated equipment and ACCESSORIES. Components functions are addressed as far as necessary.

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of MAMMOGRAPHIC X-RAY EQUIPMENT.

Like the previous edition of this Part 2-45, the present third edition includes requirements on HIGH-VOLTAGE GENERATORS for mammography.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 Scope

Replacement:

This international standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MAMMOGRAPHIC X-RAY EQUIPMENT and MAMMOGRAPHIC STEREOTACTIC DEVICES, hereafter also referred to as ME EQUIPMENT.

NOTE 1 This includes MAMMOGRAPHIC X-RAY EQUIPMENT using integrated digital X-RAY IMAGE RECEPTORS or integrated storage phosphor subsystems.

Excluded from the scope of this document are:

– reconstructive tomography modes of operation;
– diagnostic consoles;
– picture archiving and communication systems (PACS);
– non-integrated storage phosphor readers;
– hard copy cameras;
– films, screens and cassettes;
– computer aided detection (CAD);
– devices for performing core biopsy and other biopsy instruments;
– modes of operation intended to demonstrate local contrast medium uptake (contrast enhanced digital mammography);

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

NOTE 2 IEC 60601-2-7:1998 and IEC 60601-2-32 are not part of the 3rd edition scheme for MAMMOGRAPHIC X-RAY EQUIPMENT and MAMMOGRAPHIC STEREOTACTIC DEVICES.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MAMMOGRAPHIC X-RAY EQUIPMENT and MAMMOGRAPHIC STEREOTACTIC DEVICES, to ensure safety, to specify methods for demonstrating compliance with those requirements and to provide guidance for RISK MANAGEMENT.

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1) The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.