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Elektrisk utrustning för medicinskt bruk – Säkerhet och väsentliga prestanda – Del 2-45: Särskilda fordringar på mammografiutrustning och utrustning för stereotaktisk mammografi

Medical electrical equipment –

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

Som svensk standard gäller europastandarden EN 60601-2-45:2011. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-45:2011.

Nationellt förord

Europastandarden EN 60601-2-45:2011

består av:

- **europastandardens ikraftsättningsdokument**, utarbetat inom CENELEC
- **IEC 60601-2-45, Third edition, 2011 - Medical electrical equipment - Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices**

utarbetad inom International Electrotechnical Commission, IEC.

Standarden ska användas tillsammans med SS-EN 60601-1.

Tidigare fastställd svensk standard SS-EN 60601-2-45, utgåva 2, 2001, gäller ej fr o m 2014-03-17.

ICS 11.040.50

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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
essentielle 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)

This European Standard was approved by CENELEC on 2011-03-17. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard 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 Central Secretariat or to any CENELEC member.

This European Standard 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 Central Secretariat 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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

Management Centre: Avenue Marnix 17, B - 1000 Brussels

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:

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

CONTENTS

INTRODUCTION.....	6
201.1 Scope, object and related standards	7
201.2 Normative references.....	9
201.3 Terms and definitions.....	10
201.4 General requirements	11
201.5 General requirements for testing of ME EQUIPMENT	12
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	12
201.7 ME EQUIPMENT identification, marking and documents	12
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	16
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	19
201.10 Protection against unwanted and excessive radiation HAZARDS	21
201.11 Protection against excessive temperatures and other HAZARDS	22
201.12 Accuracy of controls and instruments and protection against hazardous outputs	22
201.13 Hazardous situations and fault conditions	22
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	22
201.15 Construction of ME EQUIPMENT.....	22
201.16 ME SYSTEMS	22
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	23
202 Electromagnetic compatibility – Requirements and tests	23
203 Radiation protection in diagnostic X-ray equipment.....	23
Annex AA (informative) Particular guidance and rationale	46
Bibliography.....	48
Index of defined terms used in this particular standard.....	49
Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements	11
Table 203.101 – Minimum values of TOTAL FILTRATION and factors for determining the minimum AIR KERMA RATE	38

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 standard¹⁾ 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.

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

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2:2007 and IEC 60601-1-3:2008 apply as modified in Clauses 202 and 203, respectively. IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10, and IEC 60601-1-11 do not apply²⁾. All other published collateral standards in the IEC 60601-1-X series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard or a collateral standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g., 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g., 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

2) 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*

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g., 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding, clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 48.

Clause 2 of the general standard applies, except as follows:

Replacement:

IEC 60601-1-2:2007, *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*

Addition:

IEC 60336:2005, *Medical electrical equipment – X-ray tube assemblies for medical diagnosis – Characteristics of focal spots*

IEC 60613:2010, *Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis*

IEC 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*

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 used in mammography*

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*