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 (IEC 60601-2-45:2011 + IEC 60601-2-45:2011/A1:2015 + IEC 60601-2-45:2011/A2:2022)

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-2-45:2011+A1 +A2:2025 sisaldab Euroopa standardi EN 60601-2-45:2011 ja selle muudatuste A1:2015 ja A2:2024 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-45:2011+A1+A2:2025 consists of the English text of the European standard EN 60601-2-45:2011 and its amendments A1:2015 and A2:2024.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 18.03.2011, muudatused A1 18.09.2015 ja A2 20.09.2024.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. Date of Availability of the European standard is 18.03.2011, for A1 18.09.2015 and A2 20.09.2024.
Muudatusega A1 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega [A1⟩ ⟨A1]. Muudatusega A2 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega [A2⟩ ⟨A2]. Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The start and finish of text introduced or altered by amendment A1 is indicated in the text by tags [A1⟩ ⟨A1]. The start and finish of text introduced or altered by amendment A2 is indicated in the text by tags [A2⟩ ⟨A2]. The standard is available from the Estonian Centre for Standardisation and Accreditation.

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

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-45 + A1 + A2

March 2011, September 2015, September 2024

ICS 11.040.50

Supersedes EN 60601-2-45:2001

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 + IEC 60601-2-45:2011/A1:2015 + IEC 60601-2-45:2011/A2:2022)

Appareils électromédicaux - Partie 2-45: Exigences particulières pour la sécurite de base et les performances essentielles des appareils de mammographie à rayonnement X et des appareils mammographiques stéréotaxiques
(CEI 60601-2-45:2011 + IEC 60601-2-45:2011/A1:2015 + 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 + IEC 60601-2-45:2011/A1:2015 + IEC 60601-2-45:2011/A2:2022)

This European Standard was approved by CENELEC on 2011-03-17. Amendment A1 was approved by CENELEC on 2015-07-23. Amendment A2 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 European Standard and its amendments the status of a national standard without any alteration.

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Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Ref. No. EN 60601-2-45:2011 E + EN 60601-2-45:2011/A1:2015 E + EN 60601-2-45:2011/A2:2024 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).

A1 Amendment A1 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

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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).

A1

A2 Amendment A2 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 level by publication of an identical national standard or by endorsement (dop) 2025-03-20
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Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

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. A2

IEC 60601-2-45

Edition 3.2 2022-08
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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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

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 60601-2-45:2011-02+AMD1:2015-06+AMD2:2022-08 CSV(en-fr)

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IEC 60601-2-45

Edition 3.2 2022-08
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

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colour inside

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 11.040.50

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International standard IEC 60601-2-45 has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This third edition cancels and replaces the second edition published in 2001. This edition constitutes a technical revision. The document has been aligned to the 3rd edition of IEC 60601-1 (2005) and to ▌A2⟩ IEC 60601-1-3 (2008), Amendment 1 of IEC 60601-1-3 (2013) and Amendment 2 of IEC 60601-1-3 (2021) ⟨A2▐. Further modifications have been made with respect to the current technology of MAMMOGRAPHIC X-RAY EQUIPMENT.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62B/817/FDIS	62B/821/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

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.

A list of all parts of the IEC 60601 series, published under the general title: *Medical electrical equipment*, can be found on the IEC website

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,
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- amended.

A1 Amendment A1 FOREWORD

This amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This bilingual version (2015-07) corresponds to the English version, published in 2015-06.

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 French version of this amendment has not been voted upon.

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

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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.

A1

Amendment A2 FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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.

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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- replaced by a revised edition, or
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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.

A2

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.

⟨A1⟩ 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 IEC 60601-1-3:2008 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. ⟨A1⟩

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.

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 ⟦A1⟩ including equipment for MAMMOGRAPHIC TOMOSYNTHESIS, ⟨A1⟧ 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 ⟦A1⟩ other than MAMMOGRAPHIC TOMOSYNTHESIS ⟨A1⟧;
– ⟦A1⟩ CT SCANNERS covered by IEC 60601-2-44; ⟨A1⟧
– 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.

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1) The general standard is ⟦A2⟩ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 ⟨A2⟧, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

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.

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.

〚A2〛 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 〈A2〉. 〚A1〛 IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply[2]. 〈A1〉. 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:

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2 〚A2〛 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.* 〈A2〉

"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.

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 55.

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

Replacement:

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

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

Addition:

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

〖A2〗 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 〖A2〗

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

〖A2〗 IEC TR 60788:2004 〖A2〗, *Medical electrical equipment – Glossary of defined terms*

〖A1〗 *deleted text* 〖A1〗

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*

201.3 Terms and definitions

〖A2〗 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: 〖A2〗

NOTE An index of defined terms is found beginning on page 49.

Addition:

201.3.201
APPARENT RESISTANCE OF SUPPLY MAINS
resistance of the SUPPLY MAINS determined under specific load conditions

201.3.202
AVERAGE GLANDULAR DOSE
AGD
<X-ray mammography> average absorbed dose in the glandular tissue (excluding skin) in a uniformly compressed breast of known tissue composition, using a specified calculation method

[IEC 61223-3-2:2007, definition 3.7]

NOTE The terms "AVERAGE GLANDULAR DOSE" and "mean glandular dose" are interchangeable according to literature use.

201.3.203
BREAST COMPRESSION DEVICE
device used to exert pressure upon the breast of a PATIENT during either examination or treatment

201.3.204
DEFECTIVE DETECTOR ELEMENT
element of an X-RAY IMAGE RECEPTOR whose response is out of acceptable tolerance, such as when output is independent of the entrance AIR KERMA, or there is an excessive NOISE level