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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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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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This consolidated version of the official IEC Standard and its amendments has been prepared for user convenience.

IEC 60601-2-45 edition 3.2 contains the third edition (2011-02) [documents 62B/817/FDIS and 62B/821/RVD], its amendment 1 (2015-06) [documents 62B/917/CDV and 62B/954/RVC] and its amendment 2 (2022-08) [documents 62B/1271/CDV and 62B/1282/RVC].

This Final version does not show where the technical content is modified by amendments 1 and 2. A separate Redline version with all changes highlighted is available in this publication.

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 IEC 60601-1-3 (2008), Amendment 1 of IEC 60601-1-3 (2013) and Amendment 2 of IEC 60601-1-3 (2021). Further modifications have been made with respect to the current technology of MAMMOGRAPHIC X-RAY EQUIPMENT.

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 the base publication and its amendments 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.

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

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.

INTRODUCTION to Amendment 1

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.

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, including equipment for MAMMOGRAPHIC TOMOSYNTHESIS, 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 other than MAMMOGRAPHIC TOMOSYNTHESIS;
– CT SCANNERS covered by IEC 60601-2-44;
– 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

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

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.

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. 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)]. 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.

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2) 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.*