

INTERNATIONAL STANDARD

NORME INTERNATIONALE

**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
essentielle des appareils de mammographie à rayonnement X et des appareils
mammographiques stéréotaxiques**



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IEC 60601-2-45

Edition 3.0 2011-02

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE **XA**
CODE PRIX

ICS 11.040.50

ISBN 978-2-88912-347-6

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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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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 (2010). 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,
- 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 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*.