INTERNATIONAL STANDARD

IEC 60601-2-45

First edition
1998-09

Medical electrical equipment –

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

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- **IEC web site***
- **Catalogue of IEC publications**
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- **IEC Bulletin**
  Available both at the IEC web site* and as a printed periodical

Terminology, graphical and letter symbols

For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams*.

* See web site address on title page.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

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.

The text of this Particular Standard is based on the following documents:

FDIS	Report on voting
62B/343/FDIS	62B/353/RVD

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

Annex AA forms an integral part of this standard.

Annex BB is for information only.

In this standard, the following print types are used:

– requirements, compliance with which can be tested, and definitions: roman type;
– explanations, advice, notes, general statements and exceptions: smaller roman type;

– *test specifications: italic type;*

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD, IN THIS STANDARD, IN IEC 60788 OR IN OTHER IEC STANDARDS REFERENCED IN ANNEX AA: SMALL CAPITALS.

NOTE – Attention is drawn to the existence of legislation in some countries concerning RADIATION safety which may not align with the provisions of this standard.

A bilingual version of this standard may be issued at a later date.

MEDICAL ELECTRICAL EQUIPMENT –

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

SECTION 1: GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Addition:

This Particular Standard contains requirements for the safety of X-RAY EQUIPMENT designed for mammography and MAMMOGRAPHIC STEREOTACTIC DEVICES.

1.2 Object

Replacement:

The object of this standard is to formulate appropriate design and manufacturing requirements for the safety of mammographic X-RAY EQUIPMENT and MAMMOGRAPHIC STEREOTACTIC DEVICES, reflecting the particular characteristics and circumstances of use of such equipment.

1.3 Particular Standards

Addition:

This Particular Standard, hereinafter referred to as "this standard", amends and supplements a set of IEC publications, hereinafter referred to as "General Standard", consisting of IEC 60601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*, its amendments 1 (1991) and 2 (1995) and all Collateral Standards. The numbering of sections, clauses and subclauses of this standard corresponds to that of the General Standard. 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 is replaced completely by the text of this standard.

"Addition" means that the text of this standard is additional to the requirements of the General Standard.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Where there is no corresponding section, clause or subclause in this standard, the section, clause or subclause of the General Standard applies without modification.

Where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this standard.

A requirement of this standard replacing or modifying requirements of the General Standard takes precedence over the original requirements concerned.

1.3.101 Related International Standards

IEC 60601-2-28:1993, *Medical electrical equipment – Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis*

IEC 60601-2-32:1994, *Medical electrical equipment – Part 2: Particular requirements for the safety of associated equipment of X-ray equipment*

IEC 60788:1984, *Medical radiology – Terminology*

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Addition:

2.101 Definitions

In this standard, terms printed in SMALL CAPITALS are used in accordance with their definitions either in the General Standard, in this standard, in IEC 60788 or in other IEC standards referenced in annex AA.

NOTE – Attention is drawn to the fact that, in cases where the concept addressed is not strongly confined to the definition given in one of the publications listed above, a corresponding term is printed in lower case letters.

An index of defined terms used in this standard is given in annex AA.

For the purpose of this standard, the following additional definitions apply.

2.101.1
MAMMOGRAPHIC STEREOTACTIC DEVICE
device for three-dimensional localization of a point within the breast, and for mechanically guided placement of a needle or position marker for such purposes as fine-needle aspiration, core biopsy and pre-surgical localization. The localization is based on radiographic images of an immobilized breast acquired at different known angles. Such a device may be a dedicated system or an ACCESSORY for mammographic X-RAY EQUIPMENT

2.101.2
CORE BIOPSY GUN
automatic needle device for performing core biopsy

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

Addition:

NOTE – For the purpose of this clause, EQUIPMENT or EQUIPMENT parts includes all items that are within the scope of this standard; see 1.1.

aa) Marking of compliance

If compliance with this standard is to be marked on an item, such marking shall be made on the outside of the item in combination with the MODEL OR TYPE REFERENCE as follows:

.... *) IEC 60601-2-45:1998 **).

*) Description of item and MODEL OR TYPE REFERENCE

**) Year of publication of this standard

6.8 ACCOMPANYING DOCUMENTS

6.8.1 General

Addition:

The ACCOMPANYING DOCUMENTS shall include a declaration of the dimensions of all available X-RAY FIELDS.

The ACCOMPANYING DOCUMENTS of any MAMMOGRAPHIC STEREOTACTIC DEVICE designed as an ACCESSORY for mammographic X-RAY EQUIPMENT shall contain:

– at least one MODEL OR TYPE REFERENCE to mammographic X-RAY EQUIPMENT with which it is designed to operate;

– a reference to the relevant standards with which the MAMMOGRAPHIC STEREOTACTIC DEVICE complies.

6.8.2 INSTRUCTIONS FOR USE

a) General information

Addition:

– The INSTRUCTIONS FOR USE shall contain instructions for the inspection and safe use of all compression plates used with the X-RAY EQUIPMENT.

– The INSTRUCTIONS FOR USE of MAMMOGRAPHIC STEREOTACTIC DEVICES shall contain:

  • instructions for the safe handling and use of needles and CORE BIOPSY GUNS;

  • the designation of the types of needles and CORE BIOPSY GUNS with which they are designed to be used and shall contain a warning against the use of any other types.

Addition:

aa) CONTROLLED AREA

The INSTRUCTIONS FOR USE shall draw the attention of the USER to the need to restrict access to the EQUIPMENT in accordance with local regulations for RADIOLOGICAL PROTECTION.

SECTION 2: ENVIRONMENTAL CONDITIONS

The clauses and subclauses of this section of the General Standard apply.

SECTION 3: PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

The clauses and subclauses of this section of the General Standard apply.

SECTION 4: PROTECTION AGAINST MECHANICAL HAZARDS

The clauses and subclauses of this section of the General Standard apply except as follows:

21 Mechanical strength

This clause of the General Standard applies except as follows:

Addition:

21.101 Application of maximum compression force

21.101.1 Motion of ANTI-SCATTER GRID

For mammographic X-RAY EQUIPMENT with a moving ANTI-SCATTER GRID, the application of the maximum force attainable for the COMPRESSION DEVICE shall not impede the motion of the ANTI-SCATTER GRID.

Compliance is determined by the following test:

a) Test equipment

The following test equipment is required:

- *appropriately sized objects, one for each image receptor format, leading to sufficiently realistic force distributions when under compression. The objects shall be sand filled bags or soft rubber blocks. Their thickness shall be in the range from 20 mm to 50 mm. For the smallest image receptor format, the object shall be 100 mm to 120 mm long and wide, and it shall be 120 mm to 150 mm long and wide for larger formats;*
- *an aluminium plate of 2 mm thickness and of dimensions sufficient to intercept the whole X-RAY BEAM when mounted as described below;*
- *if the X-RAY EQUIPMENT uses RADIOGRAPHIC FILMS:*
  - *a densitometer, covering the optical density range from 0 to 3,5;*
  - *RADIOGRAPHIC CASSETTES with INTENSIFYING SCREENS and RADIOGRAPHIC FILMS for each image format.*