INTERNATIONAL STANDARD

IEC 60601-2-45

Second edition
2001-05

Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-45:
Règles particulières de sécurité pour les appareils de radiographie mammaire et les appareils mammographiques stéréotaxiques

Reference number
IEC 60601-2-45:2001(E)

Publication numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series. For example, IEC 34-1 is now referred to as IEC 60034-1.

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE S

For price, see current catalogue

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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 specifications, 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.

This second edition cancels and replaces the first edition published in 1998 and constitutes a technical revision.

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

FDIS	Report of voting
62B/427/FDIS	62B/438/RVD

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

Annexes AA and CC form 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 and headings of subclauses: 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.

The committee has decided that the contents of this publication will remain unchanged until 2004-06. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

A bilingual version of this publication 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. The safety requirements for the X-RAY GENERATOR and its sub-assemblies form an integral part of this standard.

1.2 Object

Replacement:

The object of this standard is

1 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;

2 to establish particular requirements to ensure safety and to specify methods for demonstrating compliance with those requirements.

NOTE 1 Requirements for reproducibility, linearity, constancy and accuracy are given because of their relationship to the quality and quantity of the IONIZING RADIATION produced and are confined to those considered necessary for safety.

NOTE 2 Both the levels for compliance and the tests prescribed to determine compliance reflect the fact that the safety of HIGH-VOLTAGE GENERATORS is not sensitive to small differences in levels of performance. The combinations of LOADING FACTORS specified for the tests are therefore limited in number but chosen from experience as being appropriate in most cases. It is considered important to standardize the choice of combinations of LOADING FACTORS so that comparison can be made between tests performed in different places on different occasions. However, combinations other than those specified could be of equal technical validity.

NOTE 3 The safety philosophy on which this standard is based is described in the introduction to the General Standard and in IEC 60513.

NOTE 4 Concerning RADIOLOGICAL PROTECTION it has been assumed in the preparation of this standard that MANUFACTURERS and USERS do accept the general principles of the International Commission on Radiological Protection (ICRP) as stated in ICRP 60, 1990, paragraph 112,[1)] namely:

"(a) No practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes. (The justification of a practice.)

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1) ICRP Publication 60: *Recommendations of the International Commission on Radiological Protection (Annals of the ICRP Vol. 21 No 1-3, 1990)*. Published by Pergamon Press.

(b) In relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed and the likelihood of incurring exposures where these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account. This procedure should be constrained by restrictions on the doses to individuals (dose constraints), or the risks to individuals in the case of potential exposures (risk constraints), so as to limit the inequity likely to result from the inherent economic and social judgements. (The optimisation of protection.)

(c) The exposure of individuals resulting from the combination of all the relevant practices should be subject to dose limits, or to some control of risk in the case of potential exposures. These are aimed at ensuring that no individual is exposed to radiation risks that are judged to be unacceptable from these practices in any normal circumstances. Not all sources are susceptible of control by action at the source and it is necessary to specify the sources to be included as relevant before selecting a dose limit. (Individual dose and risk limits.)"

NOTE 5 Most of the requirements on X-RAY EQUIPMENT and its sub-assemblies for protection against IONIZING RADIATION are given in the Collateral Standard IEC 60601-1-3.

This standard does, however, deal with some aspects of RADIOLOGICAL PROTECTION, mainly those that depend upon the supply, control and indication of electrical energy from the HIGH-VOLTAGE GENERATOR.

NOTE 6 It is recognized that many of the judgements necessary to follow the ICRP general principles have to be made by the USER and not by the MANUFACTURER of the 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 60664-1:1992, *Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests*

IEC 60788:1984, *Medical radiology – Terminology*

IEC 61223-3-2:1996, *Evaluation and routine testing in medical imaging departments – Part 3-2: Acceptance tests – Imaging performance of mammographic X-RAY EQUIPMENT*

ISO 497:1973, *Guide to the choice of series of preferred numbers and of series containing more rounded values of preferred numbers*

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Associated conditions qualifying the usage of certain terms are given in 2.102.

a) In this standard unless otherwise indicated:
   - values of X-RAY TUBE VOLTAGE refer to peak values, transients being disregarded;
   - values of X-RAY TUBE CURRENT refer to average values.

b) The electric power in the high-voltage circuit mentioned in 6.8.2 a) 3) and 6.8.2 a) 4) is calculated according to the formula:

$$P = f\,U\,I$$

where

P is the electric power;

f is the factor depending on the waveform of the X-RAY TUBE VOLTAGE, selected as below and is:

   a) 0,95 for SIX-PEAK HIGH-VOLTAGE GENERATORS; or

   b) 1,00 for TWELVE-PEAK HIGH-VOLTAGE GENERATORS and CONSTANT POTENTIAL high-voltage generators; or

   c) for other HIGH-VOLTAGE GENERATORS, the most appropriate value, 0,95 or 1,00, chosen according to the waveform of the X-RAY TUBE VOLTAGE, with a statement of the value selected;

U is the X-RAY TUBE VOLTAGE;

I is the X-RAY TUBE CURRENT.

2.101 Additional 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 purposes of this standard, the following additional definitions apply.

2.101.1 Not used.

2.101.2
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

2.101.3
CORE BIOPSY GUN
automatic needle device for performing core biopsy

2.101.4
DIRECT FOCAL DISTANCE
shortest distance from the X-RAY IMAGE RECEPTOR to the position of the FOCAL SPOT

2.102 Qualifying conditions for defined terms

2.102.1
operating conditions for NOMINAL X-RAY TUBE VOLTAGE
NOMINAL X-RAY TUBE VOLTAGE is defined in IEC 60788 (rm-36-03) as the highest permitted X-RAY TUBE VOLTAGE for specific operating conditions. In this standard, if specific operating conditions are not stated, it is to be assumed that the value referenced is unconditional and is thus the highest X-RAY TUBE VOLTAGE permitted for NORMAL USE of the item under consideration. Such a value cannot be higher, but is sometimes lower, than values permitted for certain separate sub-assemblies or parts of the item

2.102.2
PERCENTAGE RIPPLE in CONSTANT POTENTIAL HIGH-VOLTAGE GENERATORS
Unless otherwise stated, it is to be assumed that for a HIGH-VOLTAGE GENERATOR to be regarded as a CONSTANT POTENTIAL HIGH-VOLTAGE GENERATOR, the PERCENTAGE RIPPLE of its output voltage (under the relevant conditions) does not exceed 4

2.102.3
RADIATION QUANTITY for NOMINAL SHORTEST IRRADIATION TIME
The definition of NOMINAL SHORTEST IRRADIATION TIME refers to a required constancy of a RADIATION QUANTITY. In this standard the RADIATION QUANTITY concerned is AIR KERMA

2.102.4
IRRADIATION TIME
Generally the IRRADIATION TIME is measured in terms of LOADING TIME as the time interval between:

– the instant that the X-RAY TUBE VOLTAGE has risen for the first time to a value of 75 % of the peak value; and

– the instant at which it finally drops below the same value

3 General requirements

This clause of the General Standard applies except as follows:

Addition:

Mammographic X-RAY EQUIPMENT shall be designed so as not to deliver in NORMAL USE to any connected X-RAY TUBE ASSEMBLY a voltage greater than the NOMINAL X-RAY TUBE VOLTAGE for the X-RAY TUBE ASSEMBLY concerned.

5 Classification

This clause of the General Standard applies except as follows:

5.1 *Replacement:*

Mammographic X-RAY EQUIPMENT shall be CLASS I EQUIPMENT or INTERNALLY POWERED EQUIPMENT.

5.6 *Replacement:*

Unless otherwise specified, mammographic X-RAY EQUIPMENT or sub-assemblies thereof shall be classified as suitable for continuous connection to the SUPPLY MAINS in the STAND-BY STATE and for specified LOADINGS; see also 6.1 m) and 6.8.101.

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

g) Connection to the supply

Addition:

– For mammographic X-RAY EQUIPMENT that is specified to be permanently installed, the information required in 6.1 g) of the General Standard may be stated in the ACCOMPANYING DOCUMENTS only.

h) Supply frequency

Addition:

– For mammographic X-RAY EQUIPMENT that is specified to be permanently installed, the information required in 6.1 h) of the General Standard may be stated in the ACCOMPANYING DOCUMENTS only.

j) Power input

Addition:

For mammographic X-RAY EQUIPMENT that is specified to be permanently installed, the following information may be stated in the ACCOMPANYING DOCUMENTS only.