

AS/NZS 3200.2.45:1999

IEC 60601-2-45:1998

AS/NZS 3200.2.45

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.45: Particular requirements for safety—Mammographic X-ray equipment and mammographic stereotactic devices.

[IEC title: Medical electrical equipment - Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices]



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AS/NZS 3200.2.45:1999

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE/3, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 15 July 1999 and on behalf of the Council of Standards New Zealand on 1999. It was published on 5 September 1999.

The following interests are represented on Committee HE/3:

Australasian College of Physical Scientists and Engineers in Medicine
Australasian Society for Ultrasound in Medicine
Australian Dental Association
Australian Institute of Radiography
Australian Radiation Laboratory
Australian Society of Anaesthetists
College of Biomedical Engineering Institution of Engineers Australia
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Australian/New Zealand Standard™

Medical electrical equipment

Part 2.45: Particular requirements for safety—Mammographic X-ray equipment and mammographic stereotactic devices

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PREFACE

This Standard was prepared by the Joint Australian/New Zealand Standards Committee HE/3, Medical Electrical Equipment.

This Particular Standard is identical with and has been reproduced from IEC 60601-2-45:1998 and supplements the corresponding Clauses of IEC 601-1:1988, *Medical electrical equipment*, Part 1: *General requirements for safety* which has been adopted as AS/NZS 3200.1.0:1998 hereinafter referred to as the General Standard.

The General Standard details electrical safety requirements for all types of medical electrical equipment. A Particular Standard details additional safety requirements for a related group of medical electrical devices. A Collateral Standard details additional safety requirements for a range of devices within the scope of the General Standard which may not be related but share common problems.

In the text of this Standard, the following print types are used.

- (a) Requirements, compliance with which can be tested and definitions
..... in large roman type
- (b) Explanations, advice, introductions, general statements, exceptions and references
..... in smaller roman type
- (c) Headings of sub-clauses and text specifications in italic type
- (d) Terms used throughout the Standard, which have been defined in Clause 2 and which are also in the index IN SMALL CAPITALS

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- (i) its number does not appear on each page of text and its identity is shown on the cover and title page.
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<i>Reference to International Standard or other publication</i>		<i>Australian/New Zealand Standard</i>	
IEC		AS/NZS	
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-1	Part 1: General requirements for safety Amendment 1 (1991) Amendment 2 (1995)	3200.1.0*	Part 1.0: General requirements for safety— Parent Standard
60601-2-28	Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis	3200.2.28	Part 2.28: Particular requirements for safety— X-ray source assemblies and X-ray tube assemblies for medical diagnosis generators

* This edition incorporates Amendments 1 (1992), 2 (1995) and 3 (1998).

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IEC	AS/NZS	
60601-2-32	3200.2.32	Part 2.32: Particular requirements for safety— Associated equipment of X-ray equipment
60788		Medical radiology—Terminology —

The terms 'normative' and 'informative' have been used in this Standard to define the application of the annex to which they apply. A 'normative' annex is an integral part of a Standard, whereas an 'informative' annex is only for information and guidance.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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.
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- 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.