

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.44: Particular requirements for safety—X-ray equipment for computed tomography

[IEC title; Medical electrical equipment—Particular requirements for the safety
of X-ray equipment for computed tomography]

AS/NZS 3200.2.44:2000

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 January 2000 and on behalf of the Council of Standards New Zealand on 20 March 1999. It was published on 3 April 2000.

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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First published as AS/NZS 3200.2.44:2000.

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Jointly published by Standards Australia International Ltd, PO Box 1055, Strathfield, NSW 2135 and Standards New Zealand, Private Bag 2439, Wellington 6020

ISBN 0 7337 3238 0

PREFACE

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

This Particular Standard is identical to and has been reproduced from IEC 60601-2-44:1999, which modifies and supplements the corresponding Clauses of IEC 60601-1:1988, *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

Some pages of the original, which relate to IEC administrative matters, are omitted from this edition.

As this publication has been reproduced from an international Standard, the following modifications apply:

- (i) Its number does not appear on each page of text and its identity is shown on the cover and title page.
- (ii) The words ‘this Australian/New Zealand Standard’ should replace the words ‘this International Standard’ wherever they appear.
- (iii) Substitute a full point for a comma where it appears as a decimal marker.

The references to international Standards should be replaced by references to the following Australian or Joint Australian/New Zealand Standards:

<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
60601-1-1	Part 1: General requirements for safety 1: Collateral Standard: Safety requirements for medical electrical systems	3200.1.1	Part 1:1: General requirements for safety Collateral Standard: Safety requirements for medical electrical systems
60601-1-2	Part 1: General requirements for safety 2. Collateral Standard: Electromagnetic compatibility—Requirements and tests	3200.1.2	Part 1.2: General requirements for safety Collateral Standard: Electromagnetic compatibility—Requirements and tests

IEC		AS/NZS	
60601-1-3	Part 1: General requirements for safety 3. Collateral Standard: General requirements for radiation protection in diagnostic X-ray equipment	3200.1.3	Part 1.3: General requirements for safety Collateral Standard: Requirements for radiation protection in diagnostic X-ray equipment
60601-1-4	Part 1: General requirements for the safety 4. Collateral Standard: Programmable electrical medical systems	3200.1.4	Part 1.4: General requirements for safety Collateral Standard: Programmable electrical medical systems
60601-2-32	Part 2: Particular requirements for the safety of associated equipment of X-ray equipment	3200.2.32	Part 2.32: Particular requirements for safety Associated equipment of X-ray equipment
60788	Medical radiology—Terminology	—	
ISO			
2092	Light metals and their alloys— Code of designation based on chemical symbols	—	

The term ‘normative’ has been used in this Standard to define the application of the annex to which it applies. A ‘normative’ annex is an integral part of a Standard.

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AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment

Part 2.44:

Particular requirements for safety—X-ray equipment for computed tomography

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 applies to X-RAY EQUIPMENT for COMPUTED TOMOGRAPHY (CT SCANNERS). It does not cover the safety requirements for HV-generators which will be the subject of another standard.

1.2 Object

Replacement:

The object of this standard is to establish requirements for safe operation of CT SCANNERS in as far as those requirements have not yet been specified in the General Standard, the Collateral Standards or other Particular Standards.

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 any Collateral Standard.

The numbering of sections, clauses and subclauses of this Particular 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 Particular Standard.
- "Addition" means that the text of this Particular 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 Particular Standard.

Subclauses, figures or tables 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 Particular Standard, the section, clause or subclause of the General Standard applies without modification.