

AS/NZS 3200.2.28:1994
IEC 601-2-28:1993

AS/NZS 3200.2.28

Australian/New Zealand Standard

Approval and test specification— Medical electrical equipment

Part 2.28: Particular requirements for safety—X-ray source assemblies and X-ray tube assemblies for medical diagnosis generators

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AS/NZS 3200.2.28:1994

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HT/23, Medical Diagnostic Imaging Equipment. It was approved on behalf of the Council of Standards Australia on 28 June 1994 and on behalf of the Council of Standards New Zealand on 27 June 1994. It was published on 19 September 1994.

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Australian Academy of Dento-Maxillo-Facial Radiologists
Australian and New Zealand Society of Nuclear Medicine
Australian Chamber of Commerce and Industry
Australian College of Physical Scientists and Engineers in Medicine
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Part 2.28: Particular requirements for safety—X-ray source assemblies and X-ray tube assemblies for medical diagnosis generators

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HT/23 on Medical Diagnostic Imaging Equipment and is issued as a Joint Standard under the terms of the Active Cooperation Agreement between Standards Australia and Standards New Zealand.

This Standard is identical with and has been reproduced from IEC 601-2-28:1993, *Medical electrical equipment, Part 2: Particular requirements for safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis*.

This Standard is one of a series of Approval and Test Specifications issued by Standards Australia and Standards New Zealand for various categories of medical equipment. It is supplementary to AS/NZS 3200.1:1990, *Approval and test specification—Medical electrical equipment, Part 1: General requirements for safety*.

The international Standard IEC 601-2-28 modifies 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, hereinafter referred to as the General Standard. The requirements of a Particular Standard take priority, where appropriate, over those of the General Standard.

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

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

Under arrangements made between Standards Australia/Standards New Zealand and ISO/IEC, as well as certain other Standards organizations, users of this Standard are advised that the number of this Standard is not reproduced on each page; its identity is shown only on the cover, inside cover and title page.

For the purpose of this Standard, the IEC text should be modified as follows:

- (a) *Terminology* The words ‘this Australian/New Zealand Standard’ should replace the words ‘this International Standard’ wherever they appear.
- (b) *Decimal marker* Substitute a full point for a comma where it appears as a decimal marker.

<i>Reference to International Standard or other Publication</i>	<i>Australian/New Zealand Standard</i>
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IEC		AS/NZS
336	Characteristics of focal spots in diagnostic X-ray tube assemblies for medical use	—
522	Inherent filtration of an X-ray tube assembly	—
526	High-voltage cable plug and socket connections for medical X-ray equipment	—

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IEC		AS/NZS	
601	Medical electrical equipment	3200	Approval and test specification—Medical electrical equipment
601-1-3	Part 1-3: General requirements for safety—3. Collateral Standard: General requirements for protection against ionizing radiation	—	
601-2-7	Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators	3200.2.7	Part 2.7: Particular requirements for safety—High-voltage generators of diagnostic X-ray generators
601-2-15	Part 2-15: Particular requirements for the safety of capacitor discharge X-ray generators	3200.2.15	Part 2.15: Particular requirements for safety—Capacitor discharge X-ray generators
613	Electrical, thermal and loading characteristics of rotating anode X-ray tubes for medical diagnosis	—	
788	Medical radiology—Terminology	—	
806	Determination of the maximum symmetrical radiation field from a rotating anode X-ray tube for medical diagnosis	—	

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AUSTRALIAN/NEW ZEALAND STANDARD

Approval and test specification—Medical electrical equipment

Part 2.28:

Particular requirements for safety—X-ray source assemblies and X-ray tube assemblies for medical diagnosis generators

SECTION ONE – 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*Replacement:*

This Standard applies to X-RAY SOURCE ASSEMBLIES and X-RAY TUBE ASSEMBLIES for medical diagnosis, and to components thereof, specified for use in medical X-RAY EQUIPMENT including equipment for COMPUTED TOMOGRAPHY, that incorporates a specified HIGH-VOLTAGE GENERATOR complying with IEC 601-2-7 or IEC 601-2-15.

1.2 Object*Replacement:*

The object of this Particular Standard is to establish particular requirements for design and manufacture, to ensure safety and to specify methods for demonstrating compliance.

1.3 Particular Standards*Addition:*

This Particular Standard refers to IEC 601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety*, and to IEC 601-1-3: *Medical electrical equipment – Part 1: General requirements for safety – 3. Collateral Standard: General requirements for protection against ionizing radiation* (under consideration).

For brevity, IEC 601-1 is referred to in this Particular Standard either as the General Standard or as the General Requirement(s), and IEC 601-1-3 as the Collateral Standard.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with 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.