AS/NZS IEC 60601.2.28:2015
IEC 60601-2-28, Ed.2.0 (2010)

AS/NZS IEC 60601.2.28:2015

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 19 November 2015 and on behalf of the Council of Standards New Zealand on 4 November 2015.
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The following are represented on Committee HE-003:

Australian and New Zealand College of Anaesthetists
Australian Dental Association
Australian Society of Anaesthetists
Canterbury District Health Board, New Zealand
College of Biomedical Engineering, Engineers Australia
Department of Defence, Australia
Engineers Australia
Medical Technology Association of Australia
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We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of either Standards Australia or Standards New Zealand at the address shown on the back cover.

This Standard was issued in draft form for comment as DR AS/NZS IEC 60601.2.28:2015.

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3200.2.28:1994, *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*.

The objective of this Standard is to establish particular basic safety and essential performance requirements for X-ray tube assemblies for medical diagnosis.

The requirements of this Standard supplement the general requirements specified in AS/NZS IEC 60601.1. This Standard is intended to be read in conjunction with AS/NZS IEC 60601.1:2015, which is referred to in the source text as 'the general standard'.

This Standard is identical with, and has been reproduced from IEC 60601-2-28, Ed.2.0 (2010), *Medical electrical equipment*, Part 2-28: *Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis*.

As this Standard is reproduced from an International Standard, the following applies:

(a) In the source text 'this International Standard' should read 'this Australian/New Zealand Standard'.

(b) A full point substitutes for a comma when referring to a decimal marker.

None of the normative references in the source document have been adopted as Australian or Australian/New Zealand Standards.

The term 'informative' has been used in this Standard to define the application of the annex to which it applies. An 'informative' annex is only for information and guidance.

CONTENTS

IEC FOREWORD

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment

Part 2.28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis

201.1 Scope, object and related standards

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of X-RAY TUBE ASSEMBLIES and to components thereof:

– hereafter referred to as ME EQUIPMENT;
– intended for medical diagnosis and imaging.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

NOTE This International Standard is also applicable to the X-RAY TUBE ASSEMBLY aspects of X-RAY SOURCE ASSEMBLIES and X-RAY TUBE HEADS.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for X-RAY TUBE ASSEMBLIES for medical diagnosis.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-3 applies as modified in Clause 203. IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8, IEC 60601-1-9, IEC 60601-1-10 and IEC 60601-1-11 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

NOTE 101 IEC 60601-1-2 does not apply because RISKS for the X-RAY TUBE ASSEMBLY outside the system may only be indicative of RISKS for the system due to the difference in electromagnetic environment.

NOTE 102 IEC 60601-1-6 and IEC 60601-1-8 do not apply because X-RAY TUBE ASSEMBLIES are not operated as a stand-alone device.

NOTE 103 X-RAY TUBE ASSEMBLIES are not in the scope of IEC 60601-1-10 and IEC 60601-1-11.

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1) The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*