AS/NZS IEC 60601.2.18:2015
IEC 60601-2-18, Ed.3.0 (2009)

AS/NZS IEC 60601.2.18:2015

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.18: Particular requirements for basic safety and essential performance of endoscopic equipment

STANDARDS Australia

STANDARDS NEW ZEALAND
PAEREWA AOTEAROA

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 12 October 2015 and on behalf of the Council of Standards New Zealand on 2 October 2015.
This Standard was published on 16 November 2015.

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
College of Biomedical Engineering Engineers Australia
Department of Defence
Engineers Australia
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This Standard was issued in draft form for comment as DR AS/NZS IEC 60601.2.18:2015.

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Medical electrical equipment

Part 2.18: Particular requirements for basic safety and essential performance of endoscopic equipment

Originated in Australia as AS 3200.2.18—1992.
Previous and first joint edition AS/NZS 3200.2.18:1997.
Jointly revised and redesignated as AS/NZS IEC 60601.2.18:2015.

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Jointly published by SAI Global Limited under licence from Standards Australia Limited, GPO Box 476, Sydney, NSW 2001 and by Standards New Zealand, Private Bag 2439, Wellington 6140.

ISBN 978 1 76035 302 5

PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3200.2.18:1997, *Approval and test specification—Medical electrical equipment,* Part 2.18: *Particular requirements for safety—Endoscopic equipment*.

The objective of this Standard is to establish particular basic safety and essential performance requirements for endoscopic equipment. 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 an identical adoption of IEC 60601-1, Ed.3.1 (2012) and is referred to in the source text as 'the general standard'.

This Standard is identical with, and has been reproduced from IEC 60601-2-18, Ed.3.0 (2009), *Medical electrical equipment,* Part 2-18: *Particular requirements for basic safety and essential performance of endoscopic equipment*

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.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

Reference to International Standard		*Australian/New Zealand Standard*	
IEC		AS/NZS IEC	
60601	Medical electrical equipment	60601	Medical electrical equipment
60601-2-2	Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	60601.2.2	Part 2.2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Only normative references that have been adopted as Australian or Australian/New Zealand Standard have been listed.

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.

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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 collateral 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.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of endoscopic equipment.

This particular standard amends and supplements IEC 60601-1 (third edition, 2005): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as 'the general standard'.

The requirements are followed by specifications for the relevant tests.

NOTES

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment

Part 2.18:
Particular requirements for basic safety and essential performance of endoscopic equipment

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 ENDOSCOPIC EQUIPMENT together with its INTERCONNECTION CONDITIONS and INTERFACE CONDITIONS.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ENDOSCOPIC EQUIPMENT [as defined in 201.3.204].

NOTE This object includes endoscopic intense light source equipment which is part of the ENDOSCOPIC EQUIPMENT including its supply unit, therefore IEC 60601-2-57 does not apply.

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 60601-1-2 applies as modified in Clause 202. IEC 60601-1-3 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

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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.*

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