

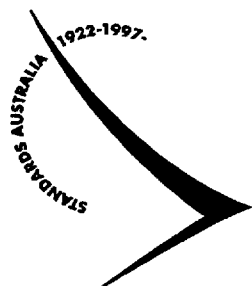
AS/NZS 3200.2.18:1997

Australian/New Zealand Standard[®]

**Approval and test specification—
Medical electrical equipment**

**Part 2.18: Particular requirements
for safety—Endoscopic equipment**

[Based on and including the full text of IEC 601-2-18:1996]



**LEADING AUSTRALIA
INTO THE FUTURE**



AVA Documents
Document Sharing Hub

AS/NZS 3200.2.18:1997

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 26 May 1997 and on behalf of the Council of Standards New Zealand on 23 June 1997. It was published on 5 July 1997.

The following interests are represented on Committee HE/3:

Australian Faculty of Occupational Medicine
Australian Dental Association
Canterbury Health, New Zealand
College of Biomedical Engineering, Australia
Health Department, N.S.W.
Medical Industry Association of Australia
Ministry of Commerce, New Zealand
Royal Australasian College of Surgeons
South Australian Health Commission
The Urological Society of Australasia
Wellington Area Health Board, New Zealand

Review of Standards. To keep abreast of progress in industry, Joint Australian/New Zealand Standards are subject to periodic review and are kept up to date by the issue of amendments or new editions as necessary. It is important therefore that Standards users ensure that they are in possession of the latest edition, and any amendments thereto.

Full details of all Joint Standards and related publications will be found in the Standards Australia and Standards New Zealand Catalogue of Publications; this information is supplemented each month by the magazines 'The Australian Standard' and 'Standards New Zealand', which subscribing members receive, and which give details of new publications, new editions and amendments, and of withdrawn Standards.

Suggestions for improvements to Joint Standards, addressed to the head office of either Standards Australia or Standards New Zealand, are welcomed. Notification of any inaccuracy or ambiguity found in a Joint Australian/New Zealand Standard should be made without delay in order that the matter may be investigated and appropriate action taken.

This Standard was issued in draft form for comment as DR 97014.

**Documents**

Document Sharing Hub

AS/NZS 3200.2.18:1997

Australian/New Zealand Standard[®]

**Approval and test specification—
Medical electrical equipment**

**Part 2.18: Particular requirements
for safety—Endoscopic equipment**

Originated as AS 3200.2.18—1992.
Second edition AS/NZS 3200.2.18:1997.

PUBLISHED JOINTLY BY:

STANDARDS AUSTRALIA
1 The Crescent,
Homebush NSW 2140 Australia

STANDARDS NEW ZEALAND
Level 10, Standards House,
155 The Terrace,
Wellington 6001 New Zealand

ISBN 0 7337 1244 4

 **Documents**
Document Sharing Hub

PREFACE

This Joint Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HT/16, High Frequency Surgical and Therapy Equipment.

This Particular Standard is based on and has been reproduced from IEC 601-2-18:1996, which modifies and supplements the corresponding Clauses of IEC 601-1:1988, *Safety of medical electrical equipment*, Part 1: *General requirements for safety*, which has been adopted as AS 3200.1.0 (NZS 6150), 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
- (d) Terms used throughout the Standard, which have been defined in Clause 2 and which are also in the index IN SMALL CAPITALS

An asterisk* is placed before each Clause for which rationale is included in Appendix AA.

The even numbered pages of the original publication are in French and are omitted from this edition. 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</i>		<i>Australian/New Zealand Standard</i>	
<i>or other publication</i>			
IEC		AS	
417	Graphical symbols for use on equipment—Index, survey and compilation of the single sheets	—	
601	Medical electrical equipment	3200	Approval and test specification—Medical electrical equipment

iii

IEC		AS	
601-1	Part 1: General requirements for safety	3200.1.0	Part 1.0: General requirements for safety Parent Standard (NZS 6150) Amendment 1
Amendment 1			
Amendment 2		—	
		AS/NZS	
601-1-1	Part 1-1: Collateral Standard: Safety requirements for medical electrical systems	3200.1.1	Part 1.1 Collateral Standard—Safety requirements for medical electrical systems
Amendment 1		—	
601-2-2	Part 2-2: Particular requirements for the safety of high frequency surgical equipment	3200.2.2	Part 2.2: Particular requirements for safety—High frequency surgical equipment
601-2-37	Part 2-37: Particular requirements for safety of ultrasonic diagnostic and monitoring equipment (in preparation)	—	
664	Insulation co-ordination for equipment within low-voltage systems	—	
664-1	Part 1: Principles, requirements and tests	—	
IEC			
CISPR 11	Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radiofrequency equipment	2064	Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment
		2064.1	Part 1: General requirements

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

Appendix D in the Parent standard is an informative appendix so Appendix D in this Standard is an informative appendix; Appendix L in the Parent Standard is a normative appendix, therefore Appendix L in this Standard is a normative appendix, i.e. an integral part of the Standard.

Appendix ZZ sets out Australia-only variations to IEC 601-2-18 and is therefore a normative appendix.

© Copyright – STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Users of Standards are reminded that copyright subsists in all Standards Australia and Standards New Zealand publications and software. Except where the Copyright Act allows and except where provided for below no publications or software produced by Standards Australia or Standards New Zealand may be reproduced, stored in a retrieval system in any form or transmitted by any means without prior permission in writing from Standards Australia or Standards New Zealand. Permission may be conditional on an appropriate royalty payment. Australian requests for permission and information on commercial software royalties should be directed to the head office of Standards Australia. New Zealand requests should be directed to Standards New Zealand.

Up to 10 percent of the technical content pages of a Standard may be copied for use exclusively in-house by purchasers of the Standard without payment of a royalty or advice to Standards Australia or Standards New Zealand.

Inclusion of copyright material in computer software programs is also permitted without royalty payment provided such programs are used exclusively in-house by the creators of the programs.

Care should be taken to ensure that material used is from the current edition of the Standard and that it is updated whenever the Standard is amended or revised. The number and date of the Standard should therefore be clearly identified.

The use of material in print form or in computer software programs to be used commercially, with or without payment, or in commercial contracts is subject to the payment of a royalty. This policy may be varied by Standards Australia or Standards New Zealand at any time.

CONTENTS

Page

SECTION ONE – GENERAL

Clause		
1	Scope and object	1
2	Terminology and definitions	2
3	General requirements	4
4	General requirements for tests	4
5	Classification	4
6	Identification, marking and documents	4

SECTION TWO – ENVIRONMENTAL CONDITIONS

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

20	Dielectric strength	7
----	---------------------------	---

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

21	Mechanical strength	7
22	Moving parts	7
25	Expelled parts	7
26	Vibration and noise	8
27	Pneumatic and hydraulic power	8
28	Suspended masses	8

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED
OR EXCESSIVE RADIATION

36	Electromagnetic compatibility	8
----	-------------------------------------	---

SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION
OF FLAMMABLE ANAESTHETIC MIXTURES

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES
AND OTHER SAFETY HAZARDS

42	Excessive temperatures	9
44	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility	11

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION
AGAINST HAZARDOUS OUTPUT

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS;
ENVIRONMENTAL TESTS

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

57	MAINS PARTS, components and layout	12
Figures		
101	Identification of LIGHT EMISSION PART	13
102	Measurement of CAPACITIVELY COUPLED HF CURRENT through the eyepiece.....	13
Appendices/Annexes		
D	Symbols on marking.....	14
L	References – Publications mentioned in this standard.....	15
AA	Rationale.....	16
Appendix ZZ	Variations to IEC 601-2-18 for application in Australia only	21

AUSTRALIAN/NEW ZEALAND STANDARD

Approval and test specification— Medical electrical equipment**Part 2.18:****Particular requirements for safety—Endoscopic equipment**

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*Addition:*

This Particular Standard specifies requirements for the safety of ENDOSCOPIC EQUIPMENT and its INTERCONNECTION CONDITIONS with ENDOSCOPICALLY-USED ACCESSORIES.

NOTE – As the General Standard does not give requirements for the safety of APPLIED PARTS of different MEDICAL ELECTRICAL EQUIPMENT when used together, this standard gives requirements for specific INTERCONNECTION CONDITIONS commonly encountered during the use of ENDOSCOPES.

1.2 Object*Replacement:*

The object of this Particular Standard to establish particular requirements for the safety of ENDOSCOPIC EQUIPMENT and enable parts of ENDOSCOPIC EQUIPMENT to be tested together or individually.

1.3 Particular Standards*Addition:*

This Particular Standard amends and supplements a set of IEC publications, hereinafter referred to as “General Standard”, consisting of IEC 601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*, amendment 1, amendment 2, IEC 601-1-1: 1992, *Medical electrical equipment – Part 1: General requirements for safety, 1. Collateral Standard: Safety requirements for medical electrical systems*, amendment 1, and IEC 601-1-2: 1993, *Medical electrical equipment – Part 1: General requirements for safety, 2. Collateral standard: Electromagnetic compatibility – Requirements and tests*.

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 601-1-1 and IEC 601-1-2 as the “Collateral Standards”.

The term “this Standard” covers this Particular Standard, used together with the General Standard and Collateral Standards.

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.

“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 or figures 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.

Clauses and subclauses to which there is a rationale are marked with an asterisk *. These rationales can be found in an informative annex AA. Annex AA is not part of this Particular Standard and only gives additional information; it can never be the subject of testing.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard or Collateral Standard applies without modification.

Where it is intended that any part of the General Standard or Collateral Standards, although possibly irrelevant, is not to be applied, a statement to that effect is given in this Particular Standard.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard or Collateral Standards takes precedence over the corresponding General Requirement(s).

2 Terminology and definitions

This clause of the General Standard applies, except as follows:

2.1.4 APPLIED PART

Addition:

For some ENDOSCOPIC EQUIPMENT, the APPLIED PART extends, as seen from the PATIENT, into the SUPPLY UNIT(s) to the point(s) where the required separation is provided (see 17a) of the General Standard).

Additional definitions:

***2.1.101 ENDOSCOPE**

An APPLIED PART of MEDICAL ELECTRICAL EQUIPMENT introduced into a PATIENT to provide an internal view or image for examination, diagnosis and/or therapy.