(Technically equivalent to IEC 601-2-18:1990)
Under Revision see DR 97014

AS 3200.2.18—1992
IEC 601-2-18:1990

Australian Standard®

Approval and test specification—Medical electrical equipment

Part 2.18: Particular requirements for safety—Endoscopic equipment

[IEC title: Medical electrical equipment—
Part 2: Particular requirements for the safety of endoscopic equipment]

STANDARDS AUSTRALIA

This Australian Standard was prepared by Committee HT/16, High Frequency Surgical and Therapy Equipment. It was approved on behalf of the Council of Standards Australia on 29 April 1992 and published on 13 July 1992.

The following interests are represented on Committee HT/16:

Australian Dental Association

Australian Physiotherapy Association

Department of Health, Housing and Community Services

Department of Health, New South Wales

Institute of Biomedical Engineering (Australia)

Medical Industry Association of Australia

South Australian Health Commission

Urological Society of Australasia

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AS 3200.2.18—1992

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PREFACE

This Standard was prepared on behalf of the Standards Australia Multi-technics Board. It is technically equivalent to IEC 601-2-18—*Medical electrical equipment*, Part 2: *Particular requirements for the safety of endoscopic equipment.*

The Standard is one of a series of Approval and Test Specifications issued by Standards Australia for individual items of medical electrical equipment. It is supplementary to AS 3200.1—1990, *Approval and test specification—Medical electrical equipment*, Part 1: *General requirements for safety*. Only safety matters and closely aligned conditions are covered by this series. In some instances, however, these are more stringent than for most electrical appliances because of the additional requirements necessary to ensure the safety of the patient and because of the environmental conditions, e.g. high humidity and hazardous locations, in which some equipment is likely to be used.

The International Standard IEC 601-2-18 modifies and supplements the corresponding clauses of IEC 601-1 (1977), *Safety of medical electrical equipment*, Part 1: *General requirements*, first edition. This has since been revised and published as IEC 601-1 (1988), *Medical electrical equipment*, Part 1: *General requirements for safety*, second edition. The second edition has been adopted as the Australian Standard AS 3200.1—1990, *Approval and test specification—Medical electrical equipment*—Part 1: *General requirements for safety*, hereinafter referred to as the General Standard.

In order that IEC 601-2-18 and the General Standard are compatible the following editorial amendments have been made to IEC 601-2-18:

(a) The section and clause titles have been reworded.

(b) The following clauses have been renumbered:
6.1 p): Items 'a)' and 'b)' to dashes '—'
14.6: 'Amendment' to become 'Addition aa)'
19.3: Item d) to aa)
20.4: Item 'a)' to item 'aa)'
Item 'c)' to item 'bb)' and
Item 'd)' to item 'cc)'
42.3: Item 'a)' to item 'aa)'.

(c) Clauses 5.2 and 17 aa) d) have been reworded.

(d) The requirements of Clauses 5.1, 14.3, 14.4, 14.5 and 20.4 have been incorporated in the General Standard, therefore these clauses have been deleted.

The clauses of this Particular Standard supplement or modify the corresponding clauses in AS 3200.1—1990. As stated in Clause 1.3 of AS 3200.1—1990, the requirements of a Particular Standard take priority, where appropriate, over those of AS 3200.1—1990. Where the reference in the text of this Standard indicates an 'amendment', 'addition' or 'replacement' of the relevant requirements, tests or explanatory notes of AS 3200.1—1990, these changes are made to the relevant text which then becomes part of the Standard.

Subclauses and figures which are additional to the General Standard are numbered starting from 101; additional appendices are indicated by a sequence of double capitals e.g., AA), BB), ... and additional items are denoted by an aa), bb), ... sequence.

In some parts of this series Australian requirements differ from the IEC specifications. To accommodate Australian conditions and well-accepted safety practices, a marginal bar is placed alongside the IEC text, and Appendix ZZ details the Australian specifications and rationale for the deviations.

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

- Requirements, compliance with which can be tested and definitions: .... in roman type.
- Explanations, advice, introductions, general statements, exceptions and references ..... in smaller roman type.
- Headings of subclauses and test specifications ..... *in italic type.*
- 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.

This Standard requires reference to International Standards which are detailed in Appendix LL.

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SECTION ONE — GENERAL

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 integrated instrumentation used for medical diagnosis and for treatment in body cavities.

Requirements for particular applications of ENDOSCOPES are subdivided and identified as follows:

a) ENDOSCOPES for direct visual observation, using visible light as the transmitting means;

b) ENDOSCOPES integrated with GLOWCAUTERY DEVICE or THERMOCAUTERY DEVICE;

c) ENDOSCOPES for ELECTROSURGERY;

d) ENDOSCOPES integrated with ELECTROHYDRAULIC LITHOTRITE;

**e)* other specialized ENDOSCOPES.

1.2 *Object*

Replacement:

The object of this Particular Standard is the assurance of the safety of the entirety of the ENDOSCOPIC EQUIPMENT together with its ACCESSORIES.

The object is also to enable component parts of ENDOSCOPIC EQUIPMENT to be tested and certified separately and individually.

Additional sub-clause:

1.101 *References to International Standards*

This Particular Standard makes reference to IEC Publications 417G, 536, 601-1, 601-2-2 and 878.

2. Terminology and definitions

This clause of the General Standard applies except as follows:

2.1 *EQUIPMENT parts, auxiliaries and ACCESSORIES*

Additional definitions:

2.1.101 *ENDOSCOPIC EQUIPMENT*

As MEDICAL ELECTRICAL EQUIPMENT, the combination of an ENDOSCOPE, its ACCESSORIES and its supply unit (see Sub-clause 6.1 p) first dash).

NOTE. — The electrically heated elements of cryoprobes are regarded as ENDOSCOPIC EQUIPMENT.