AS/NZS 3200.2.22:1997
ISO/IEC 601-2-22:1995

Australian/New Zealand Standard®

Approval and test specification—Medical electrical equipment

Part 2.22: Particular requirements for safety—Diagnostic and therapeutic laser equipment

[IEC title: Medical electrical equipment,
Part 2-22: Particular requirements for the safety of diagnostic and therapeutic laser equipment]

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HT/28, Lasers in Medical Procedures. It was approved on behalf of the Council of Standards Australia on 31 November 1996 and on behalf of the Council of Standards New Zealand on 7 February 1997. It was published on 5 June 1997.

The following interests are represented on Committee HT/28:

Australasian College of Dermatologists
Australasian College of Physical Scientists and Engineers in Medicine
Australasian College of Physical Scientists, New Zealand
Australasian Faculty of Occupational Medicine
Australian and New Zealand College of Anaesthetists
Australian Confederation of Operating Room Nurses
Australian Radiation Laboratory
College of Biomedical Engineering, Australia
Commonwealth Department of Health & Family Services
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Ministry of Commerce, New Zealand
National Health and Medical Research Council, Australia
New South Wales Health Department
Royal Australasian College of Physicians
Royal Australian College of Obstetricians and Gynaecologists
Royal Australian College of Opthalmologists
University of Waikato, New Zealand

Additional interests participating in preparation of Standard:
Equipment manufacturers/suppliers

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.

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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.

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PREFACE

This Joint Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HT/28, Lasers in Medical Procedures, to supersede AS/NZS 3200.2.22:1993.

This Particular Standard is technically equivalent to and has been reproduced from IEC 601-2-22:1995, *Medical electrical equipment*, Part 2: *Particular requirements for the safety of diagnostic and therapeutic laser equipment*, which 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 3200.1/NZS 6150, hereinafter referred to as the General Standard.

This Particular 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 3200.1/NZS 6150:1990, *Approval and test specification—Medical electrical equipment*, Part 1: *General requirements for safety*. 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:

(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 type.*

(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 Annex AA.

Under arrangements made between Standards Australia/Standards New Zealand and the 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.

Appendix ZZ, which details additional requirements for Australia and New Zealand, is included in this Standard.

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

(i) *Terminology* The words ‘this Australian/New Zealand Standard’ should replace the words ‘this International Standard’ wherever they appear.

(ii) *Decimal marker* Substitute a full point for a comma where it appears as a decimal marker.

(iii) *References* The references to international Standards should be replaced by references to the following Australian or Joint Australian/New Zealand Standards:

Reference to International Standard or other publication		*Australian or Australian/New Zealand Standard*	
IEC		AS	
601	Medical electrical equipment	3200	Approval and test specification—Medical electrical equipment
		3200.1 (NZS 6150)	—General requirements for safety
601-1-1	Part 1: General requirements for safety—1. Collateral standard: Safety requirements for medical electrical systems	3200.1.1	Part 1.1: Collateral Standard—Safety requirements for medical electrical systems

IEC		AS	
601-1-1/Amd 1	Amendment 1	3200.1.1/Amd 1	Amendment 1
601-1-1/Amd 2	Amendment 2	—	
601-1-2	Part 1: General requirements for safety—2. Collateral standard: Electromagnetic compatibility—Requirements and tests	3200.1.2	Part 1.2: Collateral Standard—Electromagnetic compatibility—Requirements and tests
664	Insulation coordination for equipment within low-voltage systems	—	
664-1	Part 1: Principles, requirements and tests	—	
664-3	Part 3: Use of coatings to achieve insulation coordination of printed board assemblies	—	
825	Safety of laser products	2211	Laser safety
825-1	Part 1: Equipment classification, requirements and user's guide	—	
947	Low-voltage switchgear and controlgear	3947	Low voltage switchgear and controlgear
947-3	Part 3: Switches, disconnectors, switch-disconnectors and fuse-combination units	3947.3	Part 3: Switches, disconnectors, switch-disconnectors and fuse-combination units

The terms 'normative' and 'informative' have been used in this Standard to define the application of the appendix or annex to which they apply. A 'normative' appendix or annex is an integral part of a Standard, whereas an 'informative' appendix or annex is for information only.