

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]

## **AS/NZS 3200.2.22:1997**

---

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  
Department of Human Services, Victoria  
Health Department of Western Australia  
Medical Industry Association of Australia  
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 Ophthalmologists  
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.

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.

---

AS/NZS 3200.2.22:1997

Australian/New Zealand Standard®

---

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

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

---

Originated in Australia as AS/NZS 3200.2.22:1993.  
Second edition 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 0892 7

## 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:

<i>Reference to International Standard or other publication</i>		<i>Australian or Australian/New Zealand Standard</i>	
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

## iii

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.

© 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.

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

- 
- Looking for additional Standards? Visit Intertek Inform Infostore
  - Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation
-