

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]



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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

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This Standard was issued in draft form for comment as DR 96275.



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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



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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

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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.

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AUSTRALIAN STANDARD

Approval and test specification—Medical electrical equipment**Part 2.22:****Particular requirements for safety—Diagnostic and therapeutic laser 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 International Standard applies to LASER EQUIPMENT FOR MEDICAL APPLICATIONS, as defined in 2.1.111 classified as a CLASS 3B or CLASS 4 LASER PRODUCT according to 3.17 and 3.18 in IEC 825-1, hereinafter referred to as LASER EQUIPMENT.

NOTE – LASER EQUIPMENT for medical applications classified as a CLASS 1, 2 or CLASS 3A LASER PRODUCT, is covered by IEC 601-1 and IEC 825-1.

1.2 Object

The object of this Particular Standard is to specify particular requirements for the safety of LASER EQUIPMENT for medical applications classified as a CLASS 3B or CLASS 4 LASER PRODUCT.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 601-1, as amended by its amendment 1 (1991) and its amendment 2; it also refers to its Collateral Standards IEC 601-1-1 and IEC 601-1-2.

For brevity, Part 1 together with the Collateral Standards mentioned above are referred to in this Particular Standard either as the "General Standard" or as the "General Requirement(s)".

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to 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.

The term "this Standard" is used to make reference to the General Standard and this Particular Standard taken together.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification; where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

Concerning LASER RADIATION safety of LASER EQUIPMENT, IEC 825-1 applies, except that the relevant requirements are specified, changed or amended in this Particular Standard.

Clauses and subclauses of the General Standard and IEC 825-1, which are not applicable to LASER EQUIPMENT for medical applications, are not necessarily indicated as "not applicable".

1.5 Collateral Standards

Addition:

Collateral Standards IEC 601-1-1 and IEC 601-1-2 apply.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

Additional definitions:

2.1.101 ACCESSIBLE EMISSION LIMIT (AEL)

ACCESSIBLE EMISSION LIMIT for Class 1 (2, 3A, 3B) lasers. See 3.2 and tables 1 through 4 of IEC 825-1.

2.1.102 AIMING BEAM

Beam of optical radiation, producing a visible AIMING BEAM SPOT, intended for indication of the anticipated point of impact of the WORKING BEAM.

2.1.103 AIMING BEAM SPOT

Area of impact of the AIMING BEAM within the WORKING AREA.

2.1.104 AIMING LASER

LASER emitting an AIMING BEAM.

2.1.105 APERTURE

See 3.7 of IEC 825-1.

2.1.106 BEAM DELIVERY SYSTEM

Optical system which guides the LASER RADIATION from its origin to a LASER APERTURE.

2.1.107 CLASS 1 (2, 3A, 3B, 4) LASER PRODUCT

LASER EQUIPMENT for medical applications, incorporating a LASER as defined in 3.15 through 3.18 and 3.36 of IEC 825-1.

2.1.108 EMERGENCY LASER STOP

Hand- or foot-actuated device intended to stop the LASER OUTPUT immediately in case of emergency.

2.1.109 LASER EMISSION OCCURRING INDICATOR

Visible and/or audible signal which indicates that LASER OUTPUT of the WORKING LASER is being emitted through any APERTURE.

2.1.110 LASER ENERGY

LASER RADIANT ENERGY of the WORKING BEAM, incident on the WORKING AREA, see 3.63 of IEC 825-1.

2.1.111 LASER EQUIPMENT (FOR MEDICAL APPLICATION)

LASER EQUIPMENT for medical applications defined as a LASER PRODUCT in 3.41 of IEC 825-1, intended for application of LASER RADIATION to biological tissue for diagnostic or therapeutic purposes.

2.1.112 LASER OUTPUT

Either LASER POWER or LASER ENERGY.

2.1.113 LASER POWER

LASER RADIANT POWER of the WORKING BEAM, incident on the WORKING AREA, see 3.65 of IEC 825-1.

2.1.114 LASER READY INDICATOR

Visible means which indicates that the LASER EQUIPMENT is in the READY condition.

The purpose of the LASER READY INDICATOR is to make all persons present in the LASER area aware of the need to take precautions against hazardous LASER RADIATION, as detailed in the ACCOMPANYING DOCUMENTS (instructions for use). See 6.8.