AS/NZS 3200.2.22:1993

Australian/New Zealand Standard

Approval and test specification—Medical electrical equipment

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

STANDARDS AUSTRALIA

STANDARDS NEW ZEALAND

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 21 December 1992 and on behalf of the Council of Standards New Zealand on 14 May 1993. It was published on 17 May 1993.

The following interests are represented on Committee HT/28:

Australasian College of Dermatologists
Australasian College of Physical Scientists and Engineers in Medicine
Australian Centre for Medical Laser Technology
Australian Confederation of Operating Room Nurses
Australian Radiation Protection Association
Department of Health, Housing and Community Services
Department of Health, N.S.W.
Health Department, Vic.
Health Department, W.A.
Institute of Biomedical Engineering
Medical Industry Association of Australia
Ministry of Commerce, New Zealand, Energy & Resources Division
National Health & Medical Research Council
Royal Australasian College of Physicians
Royal Australasian College of Surgeons
Royal Australian College of Obstetricians and Gynaecologists
Royal Australian College of Ophthalmologists
Standards New Zealand

Additional interests participating in preparation of Standard:

Equipment manufacturers/suppliers

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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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STANDARDS AUSTRALIA
1 The Crescent,
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PREFACE

This Standard is issued as a Joint Standard under the terms of the Active Cooperation Agreement between Standards Australia and Standards New Zealand. It was prepared by the Committee on Lasers in Medical Procedures on behalf of the Standards Australia Multitechnics Standards Policy Board. It is technically equivalent to IEC 601-2-22 (1992), *Medical electrical equipment*, Part 2: *Particular requirements for the safety of diagnostic and therapeutic laser equipment.*

The Standard is one of a series of Approval and Test Specifications issued by Standards Australia and Standards New Zealand for individual items of medical electrical equipment. It is supplementary to AS 3200.1—1990/NZS 6150:1990, *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 601-2-22 modifies and supplements the corresponding clauses of IEC 601-1 second edition (1988), *Medical electrical equipment*, Part 1: *General requirements for safety.* This second edition has been adopted as the Australian/New Zealand Standard AS 3200.1—1990/NZS 6150:1990, *Approval and test specification—Medical electrical equipment*, Part 1: *General requirements for safety*, hereinafter referred to as the General Standard.

The clauses of this Particular Standard supplement or modify the corresponding clauses in the General Standard. As stated in Clause 1.3 of AS 3200.1—1990/NZS 6150:1990, the requirements of a Particular Standard take priority, where appropriate, over those of the General Standard. 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/NZS 6150:1990, these changes are made to the relevant text which then becomes part of the Standard.

Sub-clauses or 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/New Zealand requirements differ from the IEC specifications. To accommodate Australian/New Zealand conditions and well-accepted safety practices, a marginal bar is placed alongside the IEC text, and Appendix ZZ details the Australian/New Zealand specifications and rationale for the deviations.

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

(a) Requirements, compliance with which can be tested and definitions: in roman type;

(b) Explanations, advice, introductions, general statements, exceptions and references: in smaller roman type;

(c) Headings of subclauses and test 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;

(e) An asterisk is located prior to each clause for which rationale is included in Appendix AA.

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

Decimal marker—substitute a full point for a comma as a decimal marker.

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

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