AS 3200.2.200—1992

Australian Standard®

Approval and test specification—Medical electrical equipment

Part 2.200: Particular requirements for safety—Oxygen concentrators for individual patient use

This Australian Standard was prepared by Committee HT/15, Medical Electrical Equipment—General Safety Aspects. It was approved on behalf of the Council of Standards Australia on 1 July 1992 and published on 19 October 1992.

The following interests are represented on Committee HT/15:

Australasian College of Physical Scientists and Engineers in Medicine
Australian & New Zealand Intensive Care Society
Australian Federation for Medical and Biological Engineering
Australian Private Hospitals Association
Department of Defence
Department of Health, Housing and Community Services
Department of Health, N.S.W.
Department of Veterans Affairs
Health Department Victoria
Health Department, Western Australia
Institute of Biomedical Engineering
Medical Industry Association of Australia
Ministry of Commerce, NZ, Energy and Resources Division
Monash Medical Centre
Public Works Department, N.S.W.
Queensland Health
Royal Australasian College of Physicians
Royal Australasian College of Surgeons
Royal North Shore Hospital, Electromedical Standards Laboratory
Society for Medical and Biological Engineering
Standards Association of New Zealand

Additional interests participating in preparation of Standard:

Australian and New Zealand Society for Respiratory Science
Australian Society of Anaesthetists
Flinders Medical Centre
Medical Gases Australia
Thoracic Society of Australia and New Zealand

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Approval and test specification—Medical electrical equipment

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PREFACE

This Standard was prepared on behalf of the Standards Australia Multitechnics Standards Policy Board by Committee HT/15, Medical electrical equipment—General safety aspects. It is technically equivalent to ISO 8359: 1988, *Oxygen concentrators for medical use—Safety requirements*, but the opportunity has been taken to revise the format to include this International Standard in a series of Approval and Test Specifications issued by Standards Australia for individual items of medical electrical equipment. Only safety matters and closely aligned conditions are covered by this series of Standards. 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 in which some equipment is likely to be used.

The International Standard ISO 8359 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 ISO 8359 and the General Standard are compatible the following editorial amendments have been made to ISO 8359 (1988):

(a) Rewording of section and clause titles.

(b) Renumbering of additional clauses.

(c) Rewording of standard statements, i.e. 'This clause of the General Standard applies'.

(d) Transferring of clauses (with reference to Clauses 11, 26, 27, 30-36, 46, 47, 48). The terms 'under consideration' and 'not used' refer to the second edition of IEC 601-1 and are not a contradiction of any original text in the first edition.

(e) Decimal places are designated by a full stop.

The clauses of this Particular Standard either supplement or modify the corresponding clauses in AS 3200.1—1990. As stated in Clause 1.3 of the General Standard, 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, these changes are made to the relevant text which then becomes part of the Standard.

Where the Australian requirements differ from the international specifications, a marginal bar is placed alongside the altered text to accommodate Australian conditions and well-accepted safety practices. Appendix ZZ details the rationale for the deviation.

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

- Requirements, compliance with which can be tested and definitions: . . . . . in 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.

For the purposes of this Standard replace references to other publications with references to Australian Standards as follows:

Reference to International Standard		*Australian Standard*	
IEC		AS	
34-9	Rotating electric machines Part 9: Noise limits	1359	Rotating electrical machines—General requirements
		1359.51	Part 51: Noise level limits
601-1	Medical electrical equipment Part 1: General requirements for safety	3200	Approval and test specification—Medical electrical equipment
		3200.1	Part 1: General requirements for safety
651	Sound level meters	1259	Acoustics—Sound level metres
ISO			
3744	Acoustics—Determination of sound power levels of noise sources—Engineering methods for free-field conditions over a reflecting plane	1217	Acoustics—Determination of sound power levels of noise sources
		1217.5	Part 5: Engineering methods for free-field conditions over a reflecting plane

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