AS/NZS 3200.1.1:1995
IEC 601-1-1:1992

Australian/New Zealand Standard

Approval and test specification—Medical electrical equipment

Part 1.1: General requirements for safety—Collateral Standard: Safety requirements for medical electrical systems

[IEC title: Medical electrical equipment
Part 1: General requirements for safety
1. Collateral Standard:
Safety requirements for medical electrical systems]

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HT/15, Medical Electrical Equipment—General Safety Systems. It was approved on behalf of the Council of Standards Australia on 17 March 1995 and on behalf of the Council of Standards New Zealand on 6 March 1995. It was published on 5 July 1995.

The following interests are represented on Committee HT/15:

Australasian College of Physical Scientists and Engineers
Australian and New Zealand College of Anaesthetists
Australian Federation for Medical and Biological Engineering
Australian Private Hospitals Association
Canterbury Area Health Board, New Zealand
Department of Defence, Australia
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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HT/15 on Medical Electrical Equipment—General Safety Aspects, as a Joint Standard.

It is based on and includes the full text of IEC 601-1-1:1992 *Medical electrical equipment* Part 1.1: *General requirements for safety—Collateral Standard—Safety requirements for medical electrical systems.*

This Standard includes IEC Amendment 1:1995. An Australian/New Zealand Appendix ZZ has been added to the Standard. Those Clauses affected by the Appendix are marked with marginal bars.

This 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 international Standard IEC 601-1-1 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. The requirements of a Particular Standard take priority, where appropriate, over those of the General Standard.

IEC 601-1-1 is a Collateral Standard. Collateral Standards specify safety requirements for groups of equipment (for example, radiology equipment) or for a characteristic common to all medical electrical equipment not covered by the General Standard.

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

(i) Requirements, compliance with which can be tested and definitions . . . . . in large roman type

(ii) Explanations, advice, introductions, general statements, exceptions and references . . . in smaller roman type

(iii) Headings of sub-clauses and text specifications . . . . . *in italic type*

(iv) 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 AAA.

Under arrangements made between Standards Australia/Standards New Zealand and ISO/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 and title page.

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

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

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

(c) *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/New Zealand Standard*	
IEC		AS/NZS	
50 (826)	International Electrotechnical Vocabulary Chapter 826: Electrical installations of buildings	1852.826	Electrical installation of buildings

IEC		AS/NZS	
65	Safety requirements for mains operated electronic and related apparatus for household and similar general use	3250	Approval and test specification—Mains operated electronic and related equipment for household and similar general use
335	Safety of household and similar electrical appliances	3300	Approval and test specification—General requirements for household and similar electrical appliances
348	Safety requirements for electronic measuring apparatus	—	
414	Safety requirements for indicating and recording electrical measuring instruments and their accessories	—	
820	Electrical safety of laser equipment and installations	—	
950	Safety of information technology equipment, including electrical business equipment	3260	Approval and test specification— Safety of information technology equipment including electrical business equipment
1010	Safety requirements for electrical equipment for measurement, control, and laboratory use	—	
1010-1	Part 1: General requirements		
ISO		—	
7767	Oxygen analyzers for monitoring patient breathing mixtures—Safety requirements		
8185	Humidifiers for medical use—Safety requirements	—	
8359	Oxygen concentrators for medical use—Safety requirements	3200.2.2000	Oxygen concentrators for individual patient use

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