AS/NZS 3200.1.0:1998

Australian/New Zealand Standard™

Medical electrical equipment

Part 1.0: General requirements for safety—Parent Standard

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE/3, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 2 October 1998 and on behalf of the Council of Standards New Zealand on 11 November 1998. It was published on 5 December 1998.

The following interests are represented on Committee HE/3:

Australasian College of Physical Scientists and Engineers in Medicine
Australasian Society for Ultrasound in Medicine
Australian Dental Association
Australian Institute of Radiography
Australian Society of Anaesthetists
College of Biomedical Engineering Institution of Engineers Australia
Commonwealth Department of Health and Family Services
Department of Defence (Australia)
Medical Industry Association of Australia
Ministry of Commerce, New Zealand
Royal Australasian College of Surgeons
Royal Australasian College of Radiologists

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which subscribing members receive, and which give details of new publications, new editions and amendments, and of withdrawn Standards.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.

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PREFACE

This Standard is issued by Committee HE/3, Medical Electrical Equipment as a Joint Australian/New Zealand Standard to supersede AS 3200.1.0—1990/NZS 6150:1990, which now becomes AS/NZS 3200.1.0, *Medical electrical equipment,* Part 1.0: *Particular requirements for safety—Parent Standard.*

This General Standard is based on and reproduced from IEC 60601-1:1988, *Medical electrical equipment,* Part 1: *General requirements for safety,* including Amendment 1:1991, Amendment 2:1995 and Corrigendum:1995, and also includes a ZZ appendix for variations applicable in Australia and New Zealand. The amendments to IEC 60601-1 are indicated with a marginal bar against the relevant clause, note, table or figure. The General Standard is the Parent Standard for a series of Standards on the safety of electrical equipment.

This General Standard (AS/NZS 3200.1.0) details electrical safety requirements for all types of medical electrical equipment. A Particular Standard (the AS/NZS 3200.2.XX series) details additional safety requirements for a related group of medical electrical devices. A Collateral Standard (the AS/NZS 3200.1.XX series) details additional safety requirements for a range of devices within the scope of the General Standard which may not be related but share common problems.

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 Appendix A.

The objective of this revision is to incorporate AS 3200.1.0, Amendment 1:1992, Amendment 2:1995 and Amendment 3:1998 as a consolidated Joint Australian/ New Zealand Standard. The title has been changed but the requirements are unchanged apart from being presented differently for the convenience of the reader.

This Standard requires reference to IEC, ISO and Australian/New Zealand Standards. These are listed in Appendix L.

IEC has decided to apply a new numbering system, the 60000 series, to all its existing and future publications, including amendments to existing Standards. As a consequence, IEC has modified the bibliographic references in its databases to accord with the new numbering system. All IEC publications issued since the beginning of 1997 will carry references in terms of the 60000 series numbering. Publications printed earlier than 1997 will continue to carry the old series of numbers. For example, a reference to the IEC 60598 series of Standards will be to IEC 598 if the current edition of the Standard was printed prior to 1997.

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