AS/NZS 4513:1995 IEC 513:1994

Australian/New Zealand Standard

Medical electrical equipment— Fundamental aspects of safety standards

[IEC title: Fundamental aspects of safety standards for medical electrical equipment]

AS/NZS 4513:1995

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HT/15, Medical Electrical Equipment—General Safety Aspects. It was approved on behalf of the Council of Standards Australia on 13 February 1995 and on behalf of the Council of Standards New Zealand on 13 March 1995. It was published on 5 June 1995.

The following interests are represented on Committee HT/15:

Australasian College of Physical Scientists and Engineers in Medicine 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 Department of Health, New South Wales Department of Health, Western Australia Department of Human Services and Health, Australia Department of Veterans Affairs, Australia Institute of Biomedical Engineering, Australia Medical Industry Association of Australia Ministry of Commerce, New Zealand Monash Medical Centre, Victoria Public Works Department, New South Wales Oueensland Health Society for Medical and Biological Engineering Wellington Area Health Board, New Zealand

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which subscribing members receive, and which give details of new publications, new editions and amendments, and of withdrawn Standards.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

AS/NZS 4513:1995

Australian/New Zealand Standard

Medical electrical equipment— Fundamental aspects of safety standards

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 ii

PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HT/15 on Medical Electrical Equipment—General Safety Aspects. This Standard is identical to and has been reproduced from IEC 513: Fundamental aspects of safety standards for medical electrical equipment.

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 and title page.

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

- (a) *Terminology* The words 'this Australian/New Zealand Standard' should replace the words '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		
50	International Electrotechnical Vocabulary—	1852	International Electrotechnical Vocabulary	
50.191	Chapter 191: Dependability and quality of service	_		
Guide 104	Guide to the drafting of s safety Standards	_		
601	Medical electrical equipment	3200	Approval and test specification— Medical electrical equipment	
601-1	Part 1: General requirements for safety	3200.1 NZS 6150	Part 1: General requirements for safety	
601-1-XX	Part 1.XX: Series of Collateral Standards		Part X.XX: Series of Collateral Standards	
601-2.XX	Part 2.XX: Series of particular Standards	3200-2	Part 2.XX: Series of particular Standards	
ISO/IEC				
Guide 51:	Guidelines for the inclusion of safety aspects	_		
ISO		AS/NZS		
8402	Quality management and quality assurance—Vocabulary	ISO 8402	Quality management and quality assurance—Vocabulary	
9001	Quality systems—Model for quality assurance in design, development, introduction, installation and servicing	AS/NZS ISO 9001	Quality systems—Model for quality assurance in design, development, introduction, installation and servicing	

iii

AS 9004

Quality management and quality systems elements

Part 1: Guidelines

AS/NZS

ISO 9004.1 Quality management and quality

system elements
Part 1: Guidelines

$@ \ Copyright - STANDARDS \ AUSTRALIA/STANDARDS \ NEW \ ZEALAND \\$

Users of Standards are reminded that copyright subsists in all Standards Australia and Standards New Zealand publications and software. Except where the Copyright Act allows and except where provided for below no publications or software produced by Standards Australia or Standards New Zealand may be reproduced, stored in a retrieval system in any form or transmitted by any means without prior permission in writing from Standards Australia or Standards New Zealand. Permission may be conditional on an appropriate royalty payment. Australian requests for permission and information on commercial software royalties should be directed to the head office of Standards Australia. New Zealand requests should be directed to Standards New Zealand.

Up to 10 percent of the technical content pages of a Standard may be copied for use exclusively in-house by purchasers of the Standard without payment of a royalty or advice to Standards Australia or Standards New Zealand.

Inclusion of copyright material in computer software programs is also permitted without royalty payment provided such programs are used exclusively in-house by the creators of the programs.

Care should be taken to ensure that material used is from the current edition of the Standard and that it is updated whenever the Standard is amended or revised. The number and date of the Standard should therefore be clearly identified.

The use of material in print form or in computer software programs to be used commercially, with or without payment, or in commercial contracts is subject to the payment of a royalty. This policy may be varied by Standards Australia or Standards New Zealand at any time.



The is a new provider i arenade and chare publication at the limit below	This is a free preview.	Purchase the	entire publication	at the link below:
--	-------------------------	--------------	--------------------	--------------------

Product Page

- Dooking for additional Standards? Visit Intertek Inform Infostore
- Dearn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation