AS/NZS 3200.2.16:1999
IEC 60601-2-16:1998

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.16: Particular requirements for safety—Haemodialysis, haemodiafiltration and haemofiltration equipment

[IEC title: Medical electrical equipment-Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment]

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 1 March 1999 and on behalf of the Council of Standards New Zealand on 1 April 1999. It was published on 5 June 1999.

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 & New Zealand College of Anaesthetists
Australian Chamber of Commerce and Industry
Australian Dental Association
Australian Institute of Radiography
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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE/3, Medical Electrical Equipment to supersede AS 3200.2.16—1992.

This Particular Standard is identical with and has been reproduced from IEC 60601-2-16:1998, *Medical electrical equipment*, Part 2-16: *Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment* which modifies and supplements the corresponding Clauses of IEC 60601-1:1988, *Medical electrical equipment*, Part 1: *General requirements for safety* which has been adopted as AS/NZS 3200.1.0:1998, hereinafter referred to as the General Standard.

The General Standard details electrical safety requirements for all types of medical electrical equipment. A Particular Standard details additional safety requirements for a related group of medical electrical devices. A Collateral Standard 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 Annex AA.

As this publication has been reproduced from an international Standard, the following modifications apply:

(i) Its number does not appear on each page of text and its identity is shown on the cover and title page.

(ii) The words ‘this Australia/New Zealand Standard’ should replace the words ‘this International Standard’ wherever they appear.

(iii) Substitute a full point for a comma where it appears as a decimal marker.

The references to international Standards should be replaced by references to the following Australian or Australian/New Zealand Standards:

Reference to International Standard or other publication		*Australian or Joint Australian/New Zealand Standard*	
IEC		AS/NZS	
60513	Fundamental aspects of safety standards for medical electrical equipment	4513	Medical electrical equipment—Fundamental aspects of safety Standards
60529	Degrees of protection provided by enclosures (IP Code)	AS 1939	Degrees of protection provided by enclosures for electrical equipment (IP Code)

IEC		AS/NZS	
60601	Medical electrical equipment	3200	Medical electrical equipment
60601-1	Part 1: General requirements for safety Amendment 1 (1991) Amendment 2 (1995)	3200.1.0	Part 1.0: General requirements for safety— Parent Standard
60601-1-2	Collateral standard: Electromagnetic compatibility—Requirements and tests	3200.1.2	Part 1.2: General requirements for safety Collateral Standard: Electromagnetic compatibility— Requirements and tests
		AS	
60651	Sound level meters Amendment 1 (1993)	1259	Acoustics—Sound level meters
		1259.1	Part 1: Non-integrating.
60801	Electromagnetic compatibility for industrial-process measurement and control equipment	—	
60801-3	Part 3: Radiated electromagnetic field requirements		
60804	Integrating-averaging sound level meters Amendment 1 (1989) Amendment 2 (1993)	1259.2	Part 2: Integrating—Averaging
ISO			
594	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment	—	
594-2	Part 2: Lock fittings		
3744	Acoustics—Determination of sound power levels of noise sources using sound pressure—Engineering method in an essentially free field over a reflecting plane	—	

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