

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]

AS/NZS 3200.2.16:1999

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
 Australian Radiation Laboratory
 Australian Society of Anaesthetists
 College of Biomedical Engineering Institution of Engineers Australia
 Commonwealth Department of Health and Family Services
 Department of Defence (Australia)
 Health Industry Suppliers Association of New Zealand
 Medical Industry Association of Australia
 Ministry of Commerce New Zealand
 Royal Australasian College of Surgeons
 Royal Australasian College of Physicians
 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which subscribing members receive, and which give details of new publications, new editions and amendments, and of withdrawn Standards.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.

This Standard was issued in draft form for comment as DR 98341.

AS/NZS 3200.2.16:1999

Australian/New Zealand Standard™

Medical electrical equipment

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

Originated in Australia as AS 3207 — 1981.
Final Australian edition AS 3200.2.16 — 1992.
Jointly revised and designated AS/NZS 3200.2.16:1999.

Published jointly by:

Standards Australia
1 The Crescent,
Homebush NSW 2140 Australia

Standards New Zealand
Level 10, Radio New Zealand House,
155 The Terrace,
Wellington 6001 New Zealand

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:

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

iii

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
60651	Sound level meters Amendment 1 (1993)	AS 1259 1259.1	Acoustics—Sound level meters 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.

© 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.

CONTENTS

	<i>Page</i>
INTRODUCTION	v
SECTION 1: GENERAL	
Clause	
1 Scope and object	1
2 Terminology and definitions	2
3 General requirements	4
6 Identification, marking and documents	4
SECTION 2: ENVIRONMENTAL CONDITIONS	
SECTION 3: PROTECTION AGAINST ELECTRIC SHOCK HAZARDS	
19 Continuous LEAKAGE CURRENT and PATIENT AUXILIARY CURRENTS	6
SECTION 4: PROTECTION AGAINST MECHANICAL HAZARDS	
SECTION 5: PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION	
36 Electromagnetic compatibility	7
SECTION 6: PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES	
SECTION 7: PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS	
44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection	7
49 Interruption of the power supply	8
SECTION 8: ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT	
51 Protection against hazardous output	8
SECTION 9: ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS	
SECTION 10: CONSTRUCTIONAL REQUIREMENTS	
54 General	14
56 Components and general assembly	15
57 MAINS PARTS, components and layout	15
ANNEXES	
L – References – Publications mentioned in this standard	16
AA (informative) General guidance and rationale	17

INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT.

This particular standard does not take into consideration the specific safety aspects of systems using regeneration of DIALYSING FLUID.

This particular standard amends and supplements IEC 60601-1 (second edition, 1988): *Medical electrical equipment – Part 1: General requirements for safety*, as amended by its amendment 1 (1991) and amendment 2 (1995), hereinafter referred to as the General Standard (see 1.3).

The requirements are followed by specifications for the relevant tests.

Following the decision taken by subcommittee 62D at the meeting in Washington in 1979, a "General guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in annex AA.

Clauses or subclauses for which there are explanatory notes in annex AA are marked with an asterisk (*).

It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this standard.

AUSTRALIAN/NEW ZEALAND STANDARD

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

SECTION 1: GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope*Addition:*

This particular standard specifies the minimum safety requirements for single PATIENT HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT (as defined in 2.101). These devices are intended for use either by medical staff or under the supervision of medical expertise, including HAEMODIALYSIS, HAEMODIAFILTRATION and HAEMOFILTRATION EQUIPMENT operated by the PATIENT. These particular requirements do not apply to

- EXTRACORPOREAL CIRCUITS,
- DIALYSERS,
- DIALYSING FLUID CONCENTRATES,
- water purification EQUIPMENT,
- EQUIPMENT used to perform peritoneal dialysis (see IEC 60601-2-39).

1.3 Particular standards*Addition:*

This particular standard refers to IEC 60601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety* as amended by its amendment 1 (1991) and amendment 2 (1995).

For brevity IEC 60601-1 is referred to in this particular standard either as the "General Standard" or as the "General Requirement(s)".

The numbering of sections, clauses and subclauses of this particular standard corresponds to that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the General Standard is replaced completely by the text of this particular standard.

"Addition" means that the clause or subclause of this particular standard is additional to the requirements of the General Standard.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this particular standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items *aa*), *bb*), etc.

The term "this standard" is used to make reference to the General Standard and this particular standard taken together.

Where there is no corresponding section, clause or subclause in this particular standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification; where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

1.5 Collateral standards

IEC 60601-1-2 applies (see clause 36).

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5 APPLIED PART

Replacement:

The EXTRACORPOREAL CIRCUIT and the DIALYSING FLUID circuit and/or all parts permanently and conductively connected to it.

2.2.15 MEDICAL ELECTRICAL EQUIPMENT (hereinafter referred to as EQUIPMENT)

Addition:

Under the scope of this particular standard EQUIPMENT means HAEMODIALYSIS, HAEMODIAFILTRATION and/or HAEMOFILTRATION EQUIPMENT.

Additional definitions:

2.101 HAEMODIALYSIS, HAEMODIAFILTRATION and/or HAEMOFILTRATION EQUIPMENT

A system or combination of units used to perform HAEMODIALYSIS, HAEMODIAFILTRATION and/or HAEMOFILTRATION (also refer to 2.2.15).

2.102 HAEMODIALYSIS (HD)

Process whereby solute imbalances in a PATIENT's blood are corrected mainly by diffusion across a semi-permeable membrane.

NOTE – This process normally includes fluid removal.

2.103 HAEMOFILTRATION (HF)

A process whereby solute imbalances of a PATIENT's blood are corrected mainly by filtration across a semi-permeable membrane.

NOTE – This process includes fluid exchange and normally fluid removal.