AS/NZS 3200.2.39:2001
IEC 60601-2-39:1999

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.39: Particular requirements for safety—Peritoneal dialysis equipment

[IEC title: Medical electrical equipment, Part 2-39: Particular requirements for the safety of peritoneal dialysis equipment]

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This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 13 April 2001 and on behalf of the Council of Standards New Zealand on 16 February 2001. It was published on 6 August 2001.

The following interests are represented on Committee HE-003:
Australasian College of Physical Scientists and Engineers in Medicine
Australasian Society for Ultrasound in Medicine
Australian Dental Association
Australian Institute of Radiography
Australian Radiation Protection and Nuclear Safety Agency
Austalian Society of Anaesthetists
Australian and New Zealand College of Anaesthetists
College of Biomedical Engineering Institution of Engineers Australia
Commonwealth Department of Health and Aged Care
Medical Industry Association of Australia
Ministry of Economic Development, New Zealand
Royal Australasian College of Radiologists

Additional interests participating in the preparation of this Standard:
Repatriation General Hospital, N.S.W.
Royal Brisbane Hospital, Qld
Royal Melbourne Hospital, Vic.
Royal North Shore Hospital, N.S.W.
The Queen Elizabeth Hospital, S.A.
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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Subcommittee HE-003-08, Dialysis Equipment, under the responsibility of Committee HE-003, Medical Electrical Equipment.

This Particular Standard is identical with and has been reproduced from IEC 60601-2-39:1999, *Medical electrical equipment*, Part 2-39: *Particular requirements for the safety of peritoneal dialysis 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, *Medical electrical equipment*, Part 1.0: *General requirements for safety—Parent Standard* and is hereinafter referred to as the General Standard.

The General Standard details electrical safety requirements for the design and manufacture of medical electrical equipment which makes physical or electrical contact with the patient. A Particular Standard details additional safety requirements for a medical device, or related group of medical 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.

It is recommended that, to interpret a Particular Standard or a Collateral Standard, a copy of the General Standard should be readily available.

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, introduction, 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

As this Standard is reproduced from an International Standard, the following applies:

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

(ii) In the source text ‘this International Standard’ should read ‘this Australian/New Zealand Standard’

(iii) A full point should be substituted for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to equivalent Australian or Australian/New Zealand Standards, as follows:

Reference to International Standard		*Australian/New Zealand Standard*	
ISO/IEC		AS/NZS	
60601	Medical electrical equipment	3200*	Medical electrical equipment
60601-1	Part 1: General requirements for safety	3200.1.0	Part 1.0: General requirements for safety—Parent Standard

* This edition includes all three IEC Amendments.

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SECTION ONE – 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 PERITONEAL DIALYSIS EQUIPMENT as defined in 2.1.102, hereinafter referred to as EQUIPMENT. It applies to EQUIPMENT intended for use either by medical staff or under the supervision of medical experts, including EQUIPMENT operated by the PATIENT, regardless of whether the equipment is used in a hospital or domestic environment.

These particular requirements do not apply to the DIALYSING SOLUTION, the DIALYSING SOLUTION circuit, or to EQUIPMENT solely intended for use as continuous ambulatory PERITONEAL DIALYSIS EQUIPMENT.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of EQUIPMENT as defined in 2.1.102.

1.3 Particular Standards

Addition:

This Particular Standard amends and supplements a set of IEC publications consisting of IEC 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*, amendment 1 (1991), amendment 2 (1995); IEC 60601-1-1, amendment 1 (1995), IEC 60601-1-2 (1993) and IEC 60601-1-4 (1996).

For brevity, IEC 60601-1 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)”, and IEC 60601-1-1, 60601-1-2, and 60601-1-4 as the "Collateral Standards".

The term “this standard” covers the Particular Standard used together with the General Standard and any Collateral Standards.

The numbering of sections, clauses and subclauses of this 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: