AS/NZS 3200.2.23:2001
IEC 60601-2-23:1999

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.23: Particular requirements for safety—Transcutaneous partial pressure monitoring equipment

[IEC title: Medical electrical equipment—Part 2.23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring 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 28 June 2001 and on behalf of the Council of Standards New Zealand on 19 October 2001. It was published on 12 November 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
Australian 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:

Canterbury Health, New Zealand
Monash Medical Centre, Vic.
N.S.W. Department of Public Works and Services
Prince Henry Hospital, N.S.W.
Royal Prince Alfred Hospital, N.S.W.
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Australian/New Zealand Standard™

Medical electrical equipment

Part 2.23: Particular requirements for safety— Transcutaneous partial pressure monitoring equipment

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Subcommittee HE-003-07, Patient Monitoring Equipment, under the responsibility of Committee HE-003, Medical Electrical Equipment to supersede AS/NZS 3200.2.23:1994, *Medical electrical equipment,* Part 2.23: *Particular requirements for safety—Transcutaneous partial pressure monitoring equipment.*

This Particular Standard has been reproduced from, and is identical to, IEC 6061-2-23:1999, *Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring system* 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: *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 fonts are used:

(a) Requirements, compliance with which can be tested, and definitions
……in large roman type

(b) Explanations , advice, introductions, general statements, exceptions, references
……in smaller roman type

(c) Headings, of sub-clauses and test specifications
……*in italic type*

(d) Terms used throughout the Standard, which have been defined in Clause 2
……IN SMALL CAPITALS

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

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

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

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

An asterisk (*) is placed before each Clause for which rationale is included in Annex AA.

The term ‘informative’ has been used in this Standard to define the application of the annex to which it applies. An ‘informative’ annex is only for information or guidance.

Some pages of the original IEC Standard, which relate to IEC administrative matters, do not appear in this version.

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

Reference to International Standards		*Australian/New Zealand Standard*	
IEC		AS/NZS	
60601	Medical electrical equipment	3200*	Medical electrical equipment
60601-1	Part 1: General requirements for safety Amendment 1 Amendment 2	3200.1.0	Part 1.0: General requirements for safety—Parent Standard
60601-1-2	Part 1: General requirements for safety 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
60601-1-4	Part 1: General requirements for safety 4. Collateral Standard: Programmable electrical medical systems	3200.1.4	Part 1.4: General requirements for safety Collateral Standard: Programmable electrical medical systems

* This edition incorporates the IEC amendments.

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SECTION ONE – GENERAL

The clauses and subclauses 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 requirements for the safety, including essential performance, of TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT, as defined in 2.101 and hereinafter referred to as EQUIPMENT, whether this EQUIPMENT is stand alone or part of a system.

It applies to transcutaneous monitors used with adults, children and neonates, and it includes the use of these devices in foetal monitoring during birth.

It does not apply to haemoglobin saturation oximeters or to devices applied to surfaces of the body other than the skin (for example conjunctiva, mucosa).

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety, including essential performance, of TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT as defined in 2.101.

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, amendment 2,

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests* and

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems.*

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