

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]



Standards Australia



AS/NZS 3200.2.23:2001

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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
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We also welcome suggestions for improvement in our Standards, and especially encourage readers to notify us immediately of any apparent inaccuracies or ambiguities. Please address your comments to the Chief Executive of either Standards Australia International or Standards New Zealand at the address shown on the back cover.

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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:

<i>Reference to International Standards</i>		<i>Australian/New Zealand Standard</i>	
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.

CONTENTS

	<i>Page</i>
SECTION ONE – GENERAL	
1 Scope and object.....	1
2 Terminology and definitions.....	2
3 General requirements.....	4
4 General requirements for tests	4
5 Classification.....	4
6 Identification, marking and documents.....	5
SECTION TWO – ENVIRONMENTAL CONDITIONS	
SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS	
14 Requirements related to classification	6
17 Separation.....	6
20 Dielectric strength	6
SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS	
21 Mechanical strength	6
SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION	
*36 Electromagnetic compatibility	7
SECTION SIX – PROTECTION AGAINST THE HAZARDS OF IGNITION OF FLAMMABLE ANAESTHETIC MIXTURES	
SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS	
42 Excessive temperatures	10
44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility.....	11
49 Interruption of the power supply.....	11
SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT	
51 Protection against hazardous output.....	12
SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS	
52 Abnormal operation and fault conditions	18
SECTION TEN – CONSTRUCTIONAL REQUIREMENTS	
56 Components and general assembly	18
57 MAINS PARTS, components and layout	19

	<i>Page</i>
Figure 101 – TRANSDUCER cable strain relief test	19
Figure 102 – Foam block test	20
Figure 103a – Linearity and hysteresis test set-up – Gas mix chamber, assembled	21
Figure 103b – Linearity and hysteresis test set-up – Gas mix chamber, manufacturing dimensions.....	22
Figure 103c – Linearity and hysteresis test set-up – Gas mix chamber, dimensions of hose connector.....	23
Figure 104 – EMC test set-up for conducted and radiated emission, and radiated immunity test	24
Appendix L (normative) References – Publications mentioned in this standard	25
Annex AA (informative) General guidance and rationale	26

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment

Part 2.23:

Particular requirements for safety—Transcutaneous partial pressure monitoring equipment

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*.

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

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 Particular Standard corresponds with 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 text 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 any additional items aa), bb), etc.

Clauses and subclauses for which there is a rationale are marked with an asterisk*. These rationales can be found in an informative annex AA. Annex AA should be used in determining the relevance of the requirements addressed, but should never be used to establish additional test requirements.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard or Collateral Standard applies without modification.

Where it is intended that any part of the General Standard or Collateral Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard or Collateral Standard takes precedence over the corresponding General Requirement(s).

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5

APPLIED PART

Replacement:

TRANSDUCER and its connecting lead.

Additional definitions:

2.101

TRANSCUTANEOUS PARTIAL PRESSURE MONITORING EQUIPMENT (EQUIPMENT)

device and associated TRANSDUCERS for the monitoring of partial pressures of oxygen and/or carbon dioxide at the skin surface

2.102**TRANSDUCER**

device for converting the partial pressure of a gas into a signal for monitoring or recording

2.103**TEMPERATURE LIMITER**

means of limiting the temperature of the APPLIED PART INTERFACE

2.104**SET TEMPERATURE**

desired applied part interface temperature

2.105**WARNING SIGNAL**

means of signalling a predetermined state of a physiological parameter or EQUIPMENT

2.106**APPLIED PART INTERFACE**

that portion of the APPLIED PART intended to come into contact with the PATIENT's skin

2.2.102**MULTIFUNCTION PATIENT MONITORING EQUIPMENT**

stationary or mobile EQUIPMENT powered by an electrical power source and including one or more physiological monitoring units designed to collect information from a PATIENT, process it and generate ALARMS

2.12.101**ALARM**

signal which indicates abnormal events occurring to the PATIENT or EQUIPMENT

2.12.102**PHYSIOLOGICAL ALARM**

signal which either indicates that a monitored physiological parameter is out of the specified limits or indicates an abnormal PATIENT condition

2.12.103**TECHNICAL ALARM**

signal which indicates that an EQUIPMENT is not capable of accurately monitoring or no longer monitors the PATIENT's condition

2.12.104**SILENCING**

stopping an auditory ALARM manifestation by manual action

2.12.105**SILENCING/RESET**

stopping a visual and/or auditory ALARM manifestation and re-enabling the equipment response to an abnormal PATIENT condition

2.12.106**INHIBITION**

disabling, or SILENCING and disabling, an ALARM until intentionally revoked

2.12.107**SUSPENSION**

disabling, or SILENCING and disabling, an ALARM temporarily

2.12.108**LATCHED ALARM**

an ALARM, the visual and auditory manifestation of which does not stop when the parameter returns to a value which no longer exceeds the ALARM limit or when the abnormal PATIENT condition does not exist any longer

2.12.109**NON-LATCHED ALARM**

an ALARM, the visual and auditory manifestation of which stops when the parameter returns to a value which no longer exceeds the ALARM limit or when the abnormal PATIENT condition does not exist any longer

3 General requirements

This clause of the General Standard applies except as follows:

3.6 SINGLE FAULT CONDITION

Additional item:

- aa) Any single failure in the EQUIPMENT resulting in a transfer of energy to the APPLIED PART which is greater than that necessary to maintain the SET TEMPERATURE value.

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.11 Sequence

Amendment:

The tests called for in item h) of clause 17 shall be performed prior to the LEAKAGE CURRENT and dielectric strength tests of clauses C.24 and C.25 of the General Standard.

5 Classification

This clause of the General Standard applies except as follows:

***5.2** According to the degree of protection against electric shock:

Amendment:

Delete TYPE B APPLIED PART.

5.6 According to the mode of operation:

Amendment:

Delete all but CONTINUOUS OPERATION.

6 Identification, marking and documents

This clause of the General Standard applies except as follows:

6.8.2 Instructions for use

Additional item:

aa) Supplementary instructions for use

Advice shall be given on the following:

- 1) Procedures affecting the safety of operation, in particular the temperature selection and duration of monitoring time, on that particular site at that temperature, based upon clinical evaluation of the PATIENT, for example age, weight and physiological condition.
- 2) Choice of TRANSDUCERS and ACCESSORIES, where the use of other TRANSDUCERS and ACCESSORIES could degrade the safety of the EQUIPMENT.
- *3) Use of the EQUIPMENT with high frequency surgical EQUIPMENT, to avoid burns to the PATIENT and damage to the TRANSDUCER, including, if applicable, a statement that the TRANSDUCER shall be removed from the PATIENT during the high frequency surgical procedures.
- 4) The ACCOMPANYING DOCUMENTS shall contain information on protection against the effects of defibrillation.
- 5) Those parts of the EQUIPMENT which are protected against the effects of a discharge of a cardiac defibrillator.
- 6) Any precautions to be taken when a defibrillator is used on a PATIENT and information on any effects of a discharge of a cardiac defibrillator on the EQUIPMENT and the TRANSDUCER.
- 7) The ACCOMPANYING DOCUMENTS shall contain a statement to the effect: "This EQUIPMENT is not a blood gas device".
- *8) For TRANSDUCERS and cables, particularly disposable TRANSDUCERS, the manufacturer shall state the recommended usable safe life.
- *9) Proper handling of TRANSDUCERS and their ACCESSORIES to avoid damage to these delicate components, thereby extending their useful life. In addition, these instructions shall refer, in particular, to the TRANSDUCER to cable connection and provide information on the measures that the USER should adopt to prevent damage to this connection.
- 10) If the EQUIPMENT can be connected to other medical or non-medical EQUIPMENT, this combination shall comply with IEC 60601-1-1.
- 11) Information on the warm-up time for the TRANSDUCER and EQUIPMENT.

SECTION TWO – ENVIRONMENTAL CONDITIONS

The clauses and subclauses of this section of the General Standard apply.