

AS/NZS 3200.2.34:1996
IEC 601-2-34:1994

AS/NZS 3200.2.34

Australian/New Zealand Standard®

**Approval and test specification—
Medical electrical equipment**

**Part 2.34: Particular requirements
for safety—Direct blood-pressure
monitoring equipment**

[IEC title: Medical electrical equipment, Part 2: Particular requirements
for the safety of direct blood-pressure monitoring equipment]

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This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HT/20, Cardiac Equipment and Patient Monitoring Equipment. It was approved on behalf of the Council of Standards Australia on 14 February 1996 and on behalf of the Council of Standards New Zealand on 28 February 1996. It was published on 5 May 1996.

The following interests are represented on Committee HT/20:

Australian and New Zealand College of Anaesthetists
 Australian Federation for Medical and Biological Engineering
 Australian Society of Anaesthetists
 Canterbury Health Ltd, New Zealand
 College of Biomedical Engineering
 Commonwealth Department of Human Services and Health, Australia
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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HT/20 on Cardiac Equipment and Patient Monitoring Equipment, as a Joint Standard.

This Standard is identical with and has been reproduced from IEC 601-2-34:1994 *Medical electrical equipment Part 2: Particular requirements for the safety of direct blood-pressure monitoring equipment*.

This Standard is one of a series of Approval and Test Specifications issued by Standards Australia and Standards New Zealand for various categories of medical equipment. It is supplementary to AS 3200.1: (NZS 6150: 1990), *Approval and test specification—Medical electrical equipment, Part 1: General requirements for safety*.

The international Standard IEC 601-2-34 modifies and supplements the corresponding Clauses of IEC 601-1:1988, *Medical electrical equipment, Part 1: General requirements for safety* which has been adopted as AS 3200.1 (NZS 6150) hereinafter referred to as the General Standard. The requirements of a Particular Standard take priority, where appropriate, over those of the General Standard.

In the text of this Standard, the following print types are used:

- (i) Requirements, compliance with which can be tested and definitions in large roman type
 - (ii) Explanations, advice, introductions, general statements, exceptions and references in smaller roman type
 - (iii) Headings of sub-clauses and text specifications in italic
 - (iv) 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.

Under arrangements made between Standards Australia/Standards New Zealand and the IEC, as well as certain other Standards organizations, users of this Standard are advised that the number of this Standard is not reproduced on each page; its identity is shown only on the cover.

For the purpose of this Standard, the IEC text should be modified as follows:

- (a) *Terminology* The words 'this Australian/New Zealand Standard' should replace the words 'this International Standard' wherever they appear.
- (b) *Decimal marker* Substitute a full point for a comma where it appears as a decimal marker.

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

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AUSTRALIAN/NEW ZEALAND STANDARD

Approval and test specification—Medical electrical equipment**Part 2.34:****Particular requirements for safety—Direct blood pressure monitoring equipment**

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 applies to DIRECT BLOOD-PRESSURE MONITORING EQUIPMENT as defined in 2.101, hereinafter referred to as EQUIPMENT.

This Particular Standard does not apply to catheter tubing, catheter needles, Luer locks, taps and taptables, etc.

This Particular Standard also does not apply to indirect blood-pressure monitoring equipment.

1.2 Object*Replacement:*

The object of this Particular Standard is to establish particular requirements for the safety of DIRECT BLOOD-PRESSURE MONITORING EQUIPMENT and the electrical safety requirements for CATHETER TIP TRANSDUCERS as defined in 2.103.

1.3 Particular Standards*Addition:*

This Particular Standard refers to IEC 601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety* as amended by its amendment 1 (1991).

For brevity, Part 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 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 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.

The requirements of this Particular Standard take priority over those of the General Standard.

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5 APPLIED PART

Replacement:

The TRANSDUCER, including any fluid-filled system up to the point at which the electrical isolation of the APPLIED PART is completed.

Additional definitions:

2.101 DIRECT BLOOD-PRESSURE MONITORING EQUIPMENT (EQUIPMENT)

MEDICAL ELECTRICAL EQUIPMENT including TRANSDUCERS for the monitoring and/or recording of the internal blood-pressure of PATIENTS.

2.102 TRANSDUCER

Part for converting pressure into a signal for monitoring or recording.

2.103 CATHETER TIP TRANSDUCER

TRANSDUCER intended for insertion into the cardiovascular system.

2.104 *DOME*

The means for hydraulically coupling the PATIENT's blood-pressure to the TRANSDUCER, where a TRANSDUCER external to the PATIENT is used.

4 General requirements for tests

This clause of the General Standard applies except as follows:

4.11* *Sequence*

Amendment:

Tests called for in 17.101, 45.101 and 51.101 of this Particular Standard shall be performed in that order prior to the LEAKAGE CURRENT and dielectric strength tests of C24 and C25 of appendix C 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 and BF EQUIPMENT.

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:

6.1 *Marking on the outside of EQUIPMENT or EQUIPMENT parts*

Additional item:

aa) EQUIPMENT and/or the TRANSDUCER as appropriate shall be marked with the symbol given in the addition to appendix D of this Particular Standard unless such parts are too small or otherwise have limitations on their ability to be marked (for example, disposable DOMES). Parts excepted from such markings shall contain information on the protection against the effects of defibrillation in the ACCOMPANYING DOCUMENTS.

6.8.2 Instructions for use

Additional item:

aa) Supplementary instructions for use

Advice shall be provided on the following:

- The connection of the TRANSDUCER and ACCESSORIES, the pressure calibration of the TRANSDUCER and suggested means for removing trapped air from the hydraulic system connected to the TRANSDUCER.
- The safe use of TRANSDUCERS and ACCESSORIES, and also on their choice where the use of other parts could degrade the safety of the EQUIPMENT. In particular, if fulfilment of TYPE CF depends on the TRANSDUCER then recommended types of TRANSDUCERS shall be mentioned in the ACCOMPANYING DOCUMENTS and the OPERATOR shall be alerted by appropriate marking on the EQUIPMENT.
- The need for the OPERATOR to avoid conductive connection to the APPLIED PART likely to degrade safety. (For example, by not contacting metal cocks if used.)
- The type of electrical installation to which the EQUIPMENT may be safely connected, including the connection to any POTENTIAL EQUALIZATION CONDUCTOR terminal on the EQUIPMENT if provided.
- If parts of the TRANSDUCERS and EQUIPMENT are provided with protective means against burns to the PATIENT when used with HF surgical equipment, such means shall be drawn to the attention of the OPERATOR. If such means are absent, notice shall be given in the ACCOMPANYING DOCUMENTS.
- In connection with the above, advice shall also be given on the use of the EQUIPMENT with HF surgical equipment, for example, to avoid burns to the PATIENT.
- The action to be taken following accidental wetting of the EQUIPMENT.
- Description of those parts of the EQUIPMENT that are protected against the effects of a discharge of a cardiac defibrillator.
- Any precautions specific to the EQUIPMENT to be taken when a defibrillator is used on a PATIENT and on any effects on the EQUIPMENT of a discharge of a cardiac defibrillator.
- A warning that single-use devices are not designed to be reused. (ISO 7000¹⁾ symbol 1051 may be used.)

SECTION TWO: ENVIRONMENTAL CONDITIONS

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

SECTION THREE: PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

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

¹⁾ ISO 7000: 1989, *Graphical symbols for use on equipment – Index and synopsis*