

AS/NZS 3200.2.35:1999
IEC 60601-2-35:1996

AS/NZS 3200.2.35

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.35: Particular requirements for safety—Blankets, pads and mattresses intended for heating in medical use

[IEC title: Medical electrical equipment—Part 2: Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use]

AS/NZS 3200.2.35:1999

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PREFACE

This Standard was prepared by the Joint Standards Australian/Standards New Zealand Committee HE/3, Medical Electrical Equipment as a Joint Standard.

This particular Standard is identical with and has been reproduced from IEC 60601-2-35:1996 *Medical electrical equipment, Part 2: Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use* 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.

IEC has decided to apply a new numbering system, the 60000 series, to all its existing and future publications, including amendments to existing Standards. As a consequence, IEC has modified the bibliographic references in its databases to accord with the new numbering system. All IEC publications issued since the beginning of 1997 will carry references in terms of the 60000 series numbering. Publications printed earlier than 1997 will continue to carry the old series of numbers. For example, a reference to the IEC 60598 series of Standards will be to IEC 598 if the current edition of the Standard was printed prior to 1997.

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.

The even numbered pages of the original publication are in French and are omitted from this version.

Some other pages of the original, which relate to IEC administrative matters, are also omitted from this edition.

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 Australian/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 Joint Australian/New Zealand Standards:

*Reference to International Standard
or other Publication**Australian/New Zealand Standard*

IEC		AS/NZS	
83	Plugs and socket-outlets for domestic and similar general use—Standards	—	
	Fixed capacitors for use in electronic equipment	—	
384-14	Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connect to the supply mains		
601	Medical electrical equipment	3200	Medical electrical equipment
601-1	Part 1: General requirements for safety Amendment 1: 1991 Amendment 2: 1995	3200.1.0	Part 1.0: General requirements for safety—Parent Standard
601	Medical electrical equipment	3200	Approval and test specification—Medical electrical equipment
601-1-1	Part 1: General requirements for safety—1. Collateral standard: Safety requirements for medical electrical systems Amendment 1: 1995	3200.1.1	Part 1.1: General requirements for safety—Collateral Standard: Safety requirements for medical electrical systems
601-1-2	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
601-1-3	Part 1: General requirements for safety—3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment	3200.1.3	Part 1.3: General requirements for safety—Collateral Standard: Requirements for radiation protection in diagnostic X-ray equipment
1000	Electromagnetic compatibility (EMC)	—	
1000.4.6	Part 4: Testing and measurement techniques—Section 6: Immunity to conducted disturbances, induced by radio-frequency fields		
967	Safety of electrically heated blankets, pads and similar flexible heating appliances for household use	3164	Approval and test specification—Safety of electrically heated blankets, pads and similar flexible heating appliances for household use
ISO			
2439	Cellular flexible polymeric materials—Determination of hardness (indentation technique)	—	

ISO		AS/NZS
3743-2	Acoustics—Determination of sound power levels of noise sources using sound pressure—Engineering methods for small, movable sources in reverberant fields—Part 2: Methods for special reverberation test rooms	—

The terms 'normative' and 'informative' have been used in this Standard to define the application of the Annexes to which they apply. A 'normative' Annex is an integral part of a Standard, whereas an 'informative' Annex is only for information and guidance.

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INTRODUCTION

This particular International Standard amends and supplements IEC 601-1 (second edition, 1988): *Medical electrical equipment – Part 1: General requirements for safety*, as amended by its amendment 1 (1991) and its amendment 2 (1995), hereinafter referred to as the General Standard (see 1.3).

This Particular Standard is necessary because of the special attention which has to be given to features of HEATING DEVICES, which are frequently used for PATIENTS in operating theatres, intensive care units, and other situations when the PATIENT may be unable to react if excessive temperatures were to be produced.

Additional requirements for safety, beyond those stated in the General Standard are specified.

Figure 108 provides an overall summary of the main requirements of this Particular Standard.

While K (degree Kelvin) is the recognized unit and symbol for absolute temperature and temperature difference, nevertheless the °C has been used throughout this Particular Standard because all measurements will commonly be made using equipment marked with the Celsius temperature scale.

An asterisk (*) by a clause or subclause number indicates that some explanatory notes are given in annex AA at the end of this Particular Standard.

AUSTRALIAN/NEW ZEALAND STANDARD

Medical electrical equipment

Part 2.35

Particular requirements for safety—Blankets, pads and mattresses intended for heating in medical use

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 ScopeAddition:*

This Particular Standard specifies requirements for BLANKETS, PADS, and MATTRESSES including air-flotation MATTRESSES and forced-air systems as defined in 2.2.102, 2.2.106 and 2.2.107.

NOTE – In this Particular Standard they are referred to separately as BLANKETS, PADS, or MATTRESSES, but when referred to collectively the term HEATING DEVICE is used.

HEATING DEVICES are intended for medical and paramedical use.

1.2 Object*Addition:*

The object of this Particular Standard is to establish requirements for HEATING DEVICES which minimize hazards to PATIENT and OPERATOR and to specify tests by which compliance can be verified.

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 amendments 1 (1991) and 2 (1995).

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 a 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.

1.101 *Equipment excluded

This Particular Standard does not apply to:

- HEATING DEVICES intended for physiotherapy;
- radiant warmers; for information, see IEC 601-2-21;
- incubators; for information, see IEC 601-2-19;
- transport incubators, (for information, see IEC 601-2-20).

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.2 *EQUIPMENT types (classification)*

Additional definitions:

2.2.101 *HEATING DEVICE*

EQUIPMENT intended to supply heat to the whole or part of the body of a PATIENT by means of heated BLANKETS, PADS, MATTRESSES, and fluid-filled MATTRESSES.

2.2.102 *BLANKET*

Flexible HEATING DEVICE, which may be folded, for use under or over a PATIENT.

2.2.103 OVER-BLANKET

BLANKET to be used over a PATIENT.

2.2.104 UNDER-BLANKET

BLANKET to be used under a PATIENT.

2.2.105 RUCK-RESISTANT BLANKET

BLANKET having a construction of such rigidity that rucking of the flexible part is unlikely.

2.2.106 MATTRESS

HEATING DEVICE providing resilient support to the whole body of a PATIENT.

2.2.107 PAD

HEATING DEVICE which can be bent but not folded.

2.2.108 HIGH HEAT TRANSFER

Thermal characteristic of a HEATING DEVICE as determined according to annex CC or annex DD.

2.2.109 LOW HEAT TRANSFER

Thermal characteristic of a HEATING DEVICE as determined according to annex CC or annex DD.

2.10 Operation of EQUIPMENT

Additional subclause:

2.10.101 CONDITIONS OF ADEQUATE HEAT DISCHARGE

The conditions achieved when a HEATING DEVICE is supported and covered as specified in annex EE.

2.12 Miscellaneous

Additional subclause:

2.12.101 CONTACT SURFACE TEMPERATURE

The temperature T_R at the reference point of the heated APPLIED PART (see figures 101a and 101b).

3 General requirements

This clause of the General Standard applies except as follows:

3.6 *Additional item:*

- aa) contact between a PATIENT and the heat-transfer fluid, caused by a leak from a fluid-filled MATTRESS (see Section Three).

Additional subclause:

3.101 *Combination of equipments*

For EQUIPMENT which combines several heat sources, for instance incubators with integrated radiant warmers, heated mattresses etc., safety requirements of other relevant particular standards shall be considered. Further the safety requirements of this Particular Standard shall be fulfilled with the combination of the other equipment, which is approved by the manufacturer stated in the instruction for use according to the IEC 601-1-1: *Medical electrical equipment – Part 1: General requirements for safety – 1. Collateral standard: Safety requirements for medical electrical systems.*

5 Classification

5.2 *Additional item:*

- aa) HEATING DEVICES shall have TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.

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 items:

aa) *HEATING DEVICES*

A HEATING DEVICE shall be marked as follows:

- 1) to indicate how it is intended to be positioned in NORMAL USE, whether:
 - over the PATIENT;
 - under the PATIENT;
 - directly in contact with the PATIENT;
 - separated from the PATIENT by an intermediate layer, or layers, for example by a water-bed, other type of MATTRESS, or bedclothes;
 - it has to be used flat (that is without creases), or whether it can be used wrapped around the PATIENT.
- 2) to warn against possible SAFETY HAZARDS from penetration by sharp objects.
- 3) to warn against possible SAFETY HAZARDS from folding or methods of storage, other than those specified by the manufacturer.

4) to warn against the possibility of a SAFETY HAZARD if partial covering is caused by pillows or other items having good thermal insulation being laid over part of the HEATING DEVICE.

5) to specify, in the case of water-filled MATTRESSES intended to be used above a PAD, the minimum depth of water to which the MATTRESS shall be filled, and a warning that if this minimum depth is not present a PATIENT could suffer a burn.

6) to specify, in the case of HEATING DEVICES supplied or controlled by an external unit, that the HEATING DEVICE shall only be used with the external unit specified by the manufacturer of the HEATING DEVICE.

**bb) Temperature sensors*

Temperature sensors which are designed to be attached to or inserted into a PATIENT shall have their intended use identified clearly and unambiguously on or adjacent to the sensor (see 6.1 bb) of annex AA).

cc) HEATING DEVICES with a large unheated border

For HEATING DEVICES having an unheated border wider than 30 mm around the heated area, and where the requirements of 50.101 are not satisfied, the outer boundary of the heated area shall be marked on both sides of the HEATING DEVICE.

6.3 Marking of controls and instruments

Addition:

b) (see also 50.1).

Additional item:

aa) Where provided, a control for setting the CONTACT SURFACE TEMPERATURE of a HEATING DEVICE shall indicate temperature in intervals not greater than 1 °C (see also 50.104).

6.8 ACCOMPANYING DOCUMENTS

6.8.1 General

Addition:

The following shall be included in full in the ACCOMPANYING DOCUMENTS (see also 6.1 d) of the General Standard):

- all markings specified in 6.1 aa) and bb);
- other markings specified in 6.1 which have not been permanently affixed to the EQUIPMENT by the manufacturer.

6.8.2 Instructions for use

**6.8.2 d) Cleaning, disinfection and sterilization of parts in contact with the PATIENT*

Addition:

The following wording shall appear in the documentation:

"Users should not use cleaning or decontamination methods different from those recommended by the manufacturer without first checking with the manufacturer that the proposed methods will not damage the equipment."

"Users" and "equipment" are defined terms in the General Standard but are not in capitals in the paragraph above because it is shown as it would be printed in the documentation.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

Additional item:

6.8.2 aa) HEATING DEVICES

The instructions for use shall additionally contain the following:

- a strong recommendation that the surface of the HEATING DEVICE should be checked for freedom from mechanical damage prior to each application;
- an indication for the use of parts of HEATING DEVICES which are intended to be used together;
- if applicable, statements, details and warnings on the use of the HEATING DEVICE in combination with other heat sources;
- warning statements that the use of materials of good thermal conductivity, such as water, gel and similar substances, with the HEATING DEVICE not switched on may decrease the temperature of the body of a PATIENT;
- warning statements regarding the use of HF surgical instruments or endocardial catheters while a HEATING DEVICE is in use, for example in respect of potential equalization;
- the approximate time required for the HEATING DEVICE to heat up from 20 °C to 37 °C, when operated under CONDITIONS OF ADEQUATE HEAT DISCHARGE as specified in annex EE;
- particulars of any necessary calibration procedure;
- a statement that the OPERATOR should consider whether it is necessary to monitor the temperature of the body of the PATIENT at regular intervals;
- a warning statement that means for drainage of fluid leaking from a fluid-filled HEATING DEVICE is required (see also 44.4);
- a warning that means for retaining a PATIENT either on or under a HEATING DEVICE may need to be used;
- information as to how an alarm system is tested by the OPERATOR, either automatically or manually, according to 51.105;
- information as to how the OPERATOR can confirm that the independent SAFETY DEVICE is operational;
- if the HEATING DEVICE contains a mains failure alarm, a statement to that effect.

SECTION TWO – ENVIRONMENTAL CONDITIONS

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

9 Removable protective means (not used)

12 (not used)

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

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

17 Separation

This clause of the General Standard applies, except as follows:

Additional item:

**aa)* HEATING DEVICES, except those heated by circulation of fluid (liquid or gas) from a remote unit which is itself protected as CLASS I EQUIPMENT or CLASS II EQUIPMENT, shall be separated from the SUPPLY MAINS by an isolating transformer according to 57.9, excluding 57.9.4a) and complying with the following:

A transformer with an output-winding which is electrically separated from earth and the body of the transformer by at least BASIC INSULATION and which is electrically separated from the input-winding by an insulation at least equivalent to DOUBLE INSULATION or REINFORCED INSULATION

Compliance is checked by inspection of the HEATING DEVICES and examination of the circuit diagram.

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

This clause of the General Standard applies except as follows:

**19.2 SINGLE FAULT CONDITIONS*

Addition to 19.2 a):

- perforation of a liquid-filled MATTRESS heated by circulation of liquid from a remote unit. The liquid is replaced by isotonic water (0,9 g sodium chloride per litre of water). The PATIENT LEAKAGE CURRENT is measured using an electrode 5 mm × 5 mm positioned in the saline in contact with the surface which provides heat to the liquid.
- perforation of the ENCLOSURE of HEATING DEVICES separated from the SUPPLY MAINS by a transformer (see 17 aa)).

19.4 Tests

h) Measurement of the PATIENT LEAKAGE CURRENT

9) Replacement:

An APPLIED PART consisting of a surface of insulating material is tested using metal foil as mentioned in 19.4 g) 5).

- for HEATING DEVICES large enough for a PATIENT not to be in contact with the whole surface of the HEATING DEVICE, foil of area 100 cm × 30 cm is used;
- for HEATING DEVICES whose area is less than 100 cm × 30 cm, the whole HEATING DEVICE is covered by foil.

For HEATING DEVICES heated by circulation of liquid from a remote unit, measurement of LEAKAGE CURRENT is made from the surface of the APPLIED PART.

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

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

21 Mechanical strength

This clause of the General Standard applies except as follows:

Additional subclauses:

21.101 PADS are subjected to a test on a ramp as shown in figure 102, which is constructed of plywood or other smooth material, their POWER SUPPLY CORDS having been cut off at a distance of 100 mm from the point where the POWER SUPPLY CORD enters the PAD. The ramp is set up at an angle of 70° to the horizontal.

A stop-block, strong enough to withstand the impact of the PAD, is fixed at the lower end of the ramp. The ramp and stop-block are at least as wide as the longest dimension of the PAD under test.

The PAD is placed on the ramp, 1 m above the stop-block (measured along the ramp) and with the lower edge of the PAD parallel to the stop-block. The PAD is allowed to slide down the ramp so that its lower edge impacts against the stop-block. This test is repeated 100 times for each of the four edges of the PAD.

21.102 If separation could cause a SAFETY HAZARD, HEATING DEVICES using bonded construction, shall have sufficient strength and/or rigidity to withstand such rough handling as may be experienced in NORMAL USE, without separation of the layers which are bonded.

NOTE – Bonded means welded or glued.

Compliance is checked by cutting six samples of the bonded material, each having dimensions of 100 mm × 130 mm, from the flexible part. Three of the samples are cut in the direction of the runs of the heating elements and the other three samples are cut perpendicular to this direction.

From the sides measuring 100 mm, a strip of the enclosure material having a width of 25 mm is removed from one face at one end of each sample. Another similar strip is removed from the opposite face and at the opposite end of the sample, any heating element situated under the removed strips is cut away.

A clamp is attached along the full length of each single layer.

The sample is then suspended by one of the clamps and a mass of 1,25 kg is suspended from the other clamp. The test is carried out for 1 h at an ambient temperature of 20 °C, and then for 1 h at a temperature of 60 °C. The test is repeated on six samples taken from the flexible part of a new HEATING DEVICE.