

Medical electrical equipment —

Part 2: Particular requirements for safety —

Section 2.35: Specification for blankets, pads and mattresses intended for heating in medical use

The European Standard EN 60601-2-35:1996 has the status of a
British Standard

ICS 11.140

Committees responsible for this British Standard

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- Association of British Health-care Industries
- Association of Manufacturers of Domestic Electrical Appliances
- British Anaesthetic and Respiratory Equipment Manufacturers Association
- British Surgical Trades Association
- Department of Health
- Institution of Physics and Engineering in Medicine and Biology
- Royal College of Midwives
- Royal College of Paediatrics and Child Health

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National foreword

This Section of BS EN 60601 has been prepared by Technical Committee CH/91 and is the English language version of EN 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* published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 601-2-35:1996 published by the International Electrotechnical Commission (IEC).

This Particular Standard amends and supplements BS EN 60601-1¹⁾ hereinafter called the General Standard. As stated in 1.3 of the General Standard, the requirements of the Particular Standard take precedence over those of the General Standard.

A rationale for the most important requirements is given in Annex AA. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of the standard, but will expedite any subsequent revision. Annex AA does not form part of the requirements of the standard.

In this Particular Standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: in roman type.
- notes, explanations, advice, introductions, general statements, exceptions and references: in smaller type.
- *test specifications: in italic type.*
- TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AND IN IEC 601-1: SMALL CAPITALS

Cross-references

Publication referred to	Corresponding British Standard
IEC 320 series	BS EN 60320 series <i>Appliance couplers for household and similar general purposes</i>
IEC 384-14:1993	BS 6201 <i>Fixed capacitors for use in electronic equipment</i> Part 3:1982 <i>Specification for fixed capacitors for radio interference suppression. Selection of methods of test and general requirements</i>
IEC 601-1:1988	BS 5724 <i>Medical electrical equipment</i> Part 1:1989 <i>General requirements for safety</i> BS EN 60601 <i>Medical electrical equipment</i> BS EN 60601-1 <i>General requirements for safety</i>
IEC 601-1-1:1992	BS EN 60601-1-1:1993 <i>Collateral standard. Safety requirements for medical electrical systems</i>
IEC 601-1-2:1993	BS EN 60601-1-2:1993 <i>Collateral standard. Electromagnetic compatibility. Requirements and tests</i>
IEC 601-2-19:1990	BS EN 60601-2-19:1997 <i>Specification for baby incubators</i>
IEC 601-2-20:1990	BS EN 60601-2-20:1997 <i>Specification for transport incubators</i>
IEC 601-2-21:1994	BS EN 60601-2-21:1995 <i>Specification for infant radiant warmers</i>
ISO 3743-2:1994	BS ISO 3743 <i>Acoustics. Determination of sound power levels of noise sources. Engineering methods for small movable sources in reverberant fields</i> BS EN ISO 3743-2:1994 <i>Methods for special reverberation test rooms</i>

¹⁾ Also numbered BS 5724-1.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, the EN title page, pages 2 to 34, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

ICS 11.140

Descriptors: Medical electrical equipment, heating blankets, heating pads, heating mattresses, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

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

(IEC 601-2-35:1996)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité
des couvertures, coussins et matelas
chauffants destinés au réchauffage des
patients en usage médical
(CEI 601-2-35:1996)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die
Sicherheit von Matten, Unterlagen und
Matratzen zur Erwärmung von Patienten
in der medizinische Anwendung
(IEC 601-2-35:1996)

This European Standard was approved by CENELEC on 1996-10-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B-1050 Brussels

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Foreword

The text of document 62D/196/FDIS, future edition 1 of IEC 601-2-35, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-35 on 1996-10-01.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1997-07-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1998-06-13

Annexes designated “normative” are part of the body of the standard.

Annexes designated “informative” are given for information only.

In this standard, Annex BB, Annex CC, Annex DD, Annex EE and Annex ZA are normative and Annex AA and Annex ZB are informative.

Annex ZA and Annex ZB have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 601-2-35:1996 was approved by CENELEC as a European Standard without any modification.

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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.

Section 1. 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 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 *MATRESS*

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 Figure 101a and Figure 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 3).

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);