SLOVENSKI STANDARD

SIST EN 60601-2-35:1998

prva izdaja
september 1998

Medical electrical equipment - Part 2: Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use (IEC 60601-2-35:1996)

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ICS 11.140

Referenčna številka
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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-35

December 1996

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, annexes BB, CC, DD, EE and ZA are normative and annexes AA and ZB are informative.
Annexes ZA and 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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Annex ZA (normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE: When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
Addition to (replacement in) annex ZA of EN 60601-1:1990/A2:1995:				
IEC 83	1975	Plugs and socket-outlets for domestic and similar general use - Standards	-	-
IEC 320	series	Appliance couplers for household and similar general purposes	EN 60320	series
IEC 384-14	1993	Fixed capacitors for use in electronic equipment Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains	-	-
IEC 601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July	1990 1994
A1	1991		A1 + corr. July	1993 1994
A2	1995		A2 A13	1995 1996
IEC 601-1-1	1992	1. Collateral standard: Safety requirements for medical electrical systems	EN 60601-1-1	1993
A1	1995		A1	1996
IEC 601-1-2	1993	2. Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	1993
IEC 601-2-19	1990	Part 2: Particular requirements for the safety of baby incubators	EN 60601-2-19	1996
IEC 601-2-20	1990	Part 2: Particular requirements for safety of transport incubators	EN 60601-2-20	1996
IEC 601-2-21	1994	Part 2: Particular requirements for the safety of infant radiant warmers	EN 60601-2-21	1994

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Publication	Year	Title	EN/HD	Year
ISO 2439	1980	Cellular flexible polymeric materials Determination of hardness (indentation technique)	-	-
ISO 3743-2	1994	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	-	-

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Annex ZB (informative)

Normative references to international publications with their corresponding European publications

Publication	Year	Title	EN/HD	Year
Addition to annex ZB of EN 60601-1:1990/A2:1995:				
IEC 1000-4-6	1996	Electromagnetic compatibility (EMC) Part 4: Testing and measurement techniques Section 6: Immunity to conducted disturbances, induced by radio-frequency fields	EN 61000-4-6	1996

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NORME INTERNATIONALE

INTERNATIONAL STANDARD

CEI
IEC
601-2-35

Première édition
First edition
1996-10

Appareils électromédicaux –

Partie 2:
Règles particulières de sécurité pour couvertures, coussins et matelas chauffants destinés au réchauffage des patients en usage médical

Medical electrical equipment –

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

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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 601-2-35 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this standard is based on the following documents:

FDIS	Report on voting
62D/196/FDIS	62D/220/RVD

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Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

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Annex AA is for information only.

Annexes BB, CC, DD and EE form an integral part of this Particular 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.

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.

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2: Particular requirements for the safety of 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 *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:

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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).

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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:

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2.2 *EQUIPMENT types (classification)*

Additional definitions:

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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.