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Elektrisk utrustning för medicinskt bruk - Säkerhet - Del 2: Särskilda fordringar på värmefiltar, värmedynor och värmemadrasser

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

Elektrisk utrustning för medicinskt bruk -

Säkerhet -

Del 2: Särskilda fordringar på värmefiltar, värmedynor och värmemadrasser

Medical electrical equipment -

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

Som svensk standard gäller europastandarden EN 60601-2-35:1996. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-35:1996.

Nationellt förord

Europastandarden EN 60601-2-35:1996

består av:

- **europastandardens ikraftsättningsdokument, utarbetat inom CENELEC**
- **IEC 601-2-35, First edition, 1996- Medical electrical equipment -**
Part 2: Particular requirements for the safety of
blankets, pads and mattresses, intended for heating
in medical use

utarbetad inom International Electrotechnical Commission, IEC.

Standarden skall användas tillsammans med SS-EN 60601-1, Elektromedicinsk utrustning - Säkerhet - Del 1: Allmänna fordringar, och dess separat utgivna ändringar och tillägg.

Till SS-EN 60601-1 utges en serie tilläggsstandarder som anger allmänna fordringar på säkerhet som är tillämpliga på

- en grupp av elektrisk utrustning för medicinskt bruk, t ex radiologisk utrustning
- särskilda egenskaper hos all elektrisk utrustning för medicinskt bruk, ej särskilt behandlade i SS-EN 60601-1, t ex elektromagnetisk kompatibilitet.

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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Foreword

The text of document 62 D/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.

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 Duplication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
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		A 1 + 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
A 1	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

<u>Publication</u>	Year	Title	EN/HD	<u>Year</u>
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		

Annex ZB (informative)

Normative references to international publications with their corresponding European publications

<u>Publication</u>	Year	Title	<u>EN/HD</u>	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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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 MAURESSES 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).