SLOVENSKI STANDARD
SIST EN 60601-2-38:1998

01-september-1998

Medicinska električna oprema - 2-38. del: Posebne varnostne zahteve za električno nastavljive bolnišnične postelje (IEC 60601-2-38:1996)

Medical electrical equipment - Part 2-38: Particular requirements for the safety of electrically operated hospital beds (IEC 60601-2-38:1996)

Medizinische elektrische Geräte - Teil 2-38: Besondere Festlegungen für die Sicherheit von elektrisch betriebenen Krankenhausbetten (IEC 60601-2-38:1996)

Appareils électromédicaux - Partie 2-38: Règles particulières de sécurité des lits d'hôpital électriques (CEI 60601-2-38:1996)

Ta slovenski standard je istoveten z: **EN 60601-2-38:1996**

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Descriptors: Medical electrical equipment, hospital beds, 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 electrically operated hospital beds
(IEC 601-2-38:1996)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité des lits d'hôpital électriques
(CEI 601-2-38:1996)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit von elektrisch betriebenen Krankenhausbetten
(IEC 601-2-38:1996)

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

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Foreword

The text of document 62D/192/FDIS, future edition 1 of IEC 601-2-38, 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 60601-2-38 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 ZA is normative and annexes AA and BB are informative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 601-2-38:1996 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 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 529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529 + corr. May	1991 1993
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
IEC 601-1-2	1993	2. Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	1993
ISO 2204	1979	Acoustics - Guide to International Standards on the measurement of airborne acoustical noise and evaluation of its effects on human beings	-	-

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Partie 2: Règles particulières de sécurité des lits d'hôpital électriques

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2: Particular requirements for the safety of electrically operated hospital beds

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 601-2-38 has been prepared by subcommittee 62D: Electro-medical 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/192/FDIS	62D/214/RVD

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

Annexes AA and BB are for information only.

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 DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD IEC 601-1 OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2: Particular requirements for the safety of electrically operated hospital beds

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 safety of ELECTRICALLY OPERATED HOSPITAL BEDS, hereinafter referred to as BED, as defined in 2.2.101.

1.2 *Object*

Replacement:

The object of this Particular Standard for BEDS is to keep the SAFETY HAZARDS to PATIENTS, OPERATORS, and the environment as low as possible, and to describe tests to verify that these requirements are attained.

1.3 *Particular Standards*

Addition:

This Particular Standard amends and supplements a set of IEC publications, hereinafter referred to as "General Standard", consisting of IEC 601-1: 1988, *Medical electrical equipment – Part 1: General requirements for safety*, amendment 1, amendment 2 and IEC 601-1-1: 1992, *Medical electrical equipment – Part 1 : General requirements for safety – 1. Collateral Standard: Safety requirements for medical electrical systems.*

For brevity, IEC 601-1 is referred to in this Particular Standard either as the "General Standard" or as the "General Requirement(s)", and IEC 601-1-1 as the "Collateral Standard".

The term "this Standard" covers the Particular Standard, used together with the General Standard and any Collateral Standards.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with 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.

Clauses and subclauses to which there is a rationale are marked with an asterisk *. These rationales can be found in an informative annex AA. Annex AA should be used in determining the relevance of the requirements addressed, but should never be used to establish additional test requirements.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard or the Collateral Standard applies without modification.

Where it is intended that any part of the General Standard or the Collateral Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard or the Collateral Standard takes precedence over the corresponding General Requirement(s).

2 Terminology and definitions

This clause of the General Standard applies except as follows:

2.1.5 *APPLIED PART*

Replacement:

All parts of the BED which can intentionally or unintentionally come into contact with the PATIENT, are considered an APPLIED PART. (See figure 111.)

Additional definitions:

2.1.101 *PENDANT CONTROL*

Means, used by either PATIENT or OPERATOR to control the drives that activate various BED functions.

2.1.102 *SIDE RAIL*

Rail mounted to both sides of the BED which, when located in the "up" position, identifies the edge of the MATTRESS SUPPORT PLATFORM and by doing so, reduces the risk of the PATIENT accidentally slipping or rolling off the mattress.

2.1.103 *CONTROL SIDE RAIL*

SIDE RAIL which incorporates BED function controls for PATIENT activation.

2.1.104 *INTEGRATED PATIENT MONITORING/COMMUNICATIONS SYSTEMS CONTROL SIDE RAIL*

See 2.1.103. CONTROL SIDE RAIL with the addition of PATIENT/OPERATOR station communication control, and/or PATIENT television/radio entertainment control, and/or PATIENT room lighting control, and/or PATIENT egress detection system, etc.

2.1.105 *HEAD/FOOT PANEL ASSEMBLY*

Assemblies mounted to BED end which may be used as handles to push the BED.

2.1.106 *MOMENTARY CONTACT SWITCH*

Control device which initiates and maintains operation of operating elements only as long as the control (actuator) is actuated. The manual control (actuator) returns automatically to the stop position when released. MOMENTARY CONTACT SWITCHES are also known as “hold-to-run control devices”.

2.1.107 *MATTRESS SUPPORT PLATFORM*

Structural surface on which the PATIENT sleeping surface (for example mattress) rests in NORMAL USE. The MATTRESS SUPPORT PLATFORM articulates or changes positions to facilitate various therapeutic, diagnostic and convenience positions. (See figures 101 and 112.)

*2.1.108 *TRENDELENBURG*

With the MATTRESS SUPPORT PLATFORM in the flat position, tilting of the entire MATTRESS SUPPORT PLATFORM a minimum of 12° so that the PATIENT's head is lower than the circulatory centre point of the body.

2.1.109 *SQUEEZING and SHEARING POINTS*

Points where the spacing between moveable parts of the BED which in positions of NORMAL USE fail to maintain a clearance of less than or equal to 8 mm, or greater than or equal to 25 mm.

2.2.101 *ELECTRICALLY OPERATED HOSPITAL BED (hereinafter referred to as BED)*

BED intended for use in the diagnosis, treatment or monitoring of a PATIENT while under medical supervision with electrical operation of operating elements.

3 General requirements

This clause of the General Standard applies except as follows:

Addition:

*3.101 If, in order to accomplish other specialized functions which provide benefit to the PATIENT, it is not technically feasible to meet specific requirements in this Particular Standard, the BED shall be accepted only if clear and specific instructions (in the INSTRUCTIONS FOR USE) restrict the NORMAL USE of the BED so that no SAFETY HAZARD exists.