SLOVENSKI STANDARD
SIST EN 60601-2-52:2010

01-junij-2010

Medicinska električna oprema - 2-52. del: Posebne zahteve za osnovno varnost in bistvene lastnosti medicinskih postelj (IEC 60601-2-52:2009)

Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds (IEC 60601-2-52:2009)

Medizinische elektrische Geräte - Teil 2-52: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von medizinischen Betten (IEC 60601-2-52:2009)

Appareils électromédicaux - Partie 2-52: Exigences particulières de sécurité de base et de performances essentielles des lits médicaux (CEI 60601-2-52:2009)

Ta slovenski standard je istoveten z: **EN 60601-2-52:2010**

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11.140	Oprema bolnišnic	Hospital equipment

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-52

April 2010

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Supersedes EN 60601-2-38:1996 + A1:2000, EN 1970:2000

English version

Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds

(IEC 60601-2-52:2009)

Appareils électromédicaux - Partie 2-52: Exigences particulières pour la sécurité de base et les performances essentielles des lits médicaux (CEI 60601-2-52:2009)

Medizinische elektrische Geräte - Teil 2-52: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von medizinischen Betten (IEC 60601-2-52:2009)

This European Standard was approved by CENELEC on 2010-04-01. 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, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CEN-CENELEC

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

Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 60601-2-52:2010 E

Foreword

The text of document 62D/795/FDIS, future edition 1 of IEC 60601-2-52, 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 60601-2-52 on 2010-04-01.

This European Standard supersedes EN 60601-2-38:1996 + A1:2000 and EN 1970:2000.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN and CENELEC shall not be held responsible for identifying any or all such patent rights.

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)	2011-01-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2013-04-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-52:2009 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standards indicated:

IEC 60601-2-38 NOTE Harmonized as EN 60601-2-38

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

Addition *to Annex ZA of EN 60601-2:*

Publication	Year	Title	EN/HD	Year
IEC 60068-2-31	2008	Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens	EN 60068-2-31	2008

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC except the following:

– Essential Requirement 7.1

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

IEC 60601-2-52

Edition 1.0 2009-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-52: Particular requirements for the basic safety and essential performance of medical beds

Appareils électromédicaux –
Partie 2-52: Exigences particulières de sécurité de base et de performances essentielles des lits médicaux

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-52: Particular requirements for the basic safety and essential performance of medical beds

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). 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. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 60601-2-52 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and by ISO technical committee 173: Assistive products for persons with disability.

It is published as double logo standard.

This first edition cancels and replaces the first edition of IEC 60601-2-38, published in 1996, and its Amendment 1 (1999). This edition constitutes a technical revision.

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

FDIS	Report on voting
62D/795/FDIS	62D/815/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. In ISO, the standard has been approved by 20 P-members out of 20 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– Requirements and definitions: roman type.
– *Test specifications: italic type.*
– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this collateral standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

In 1996, the IEC published the first edition of the particular standard for electrically operated hospital beds, IEC 60601-2-38. The publication was in response to demand in the field for a universal standard addressing HAZARDS specific to the safety of the hospital bed. Used in conjunction with a MANUFACTURER'S RISK ASSESSMENT, the standard was felt to be the current thinking on establishing a basic safety benchmark for industry.

An amendment of IEC 60601-2-38 issued in 1999 recognized the need to mitigate against a RISK of PATIENT entrapment in the SIDE RAILS, again combined with the use of the MANUFACTURER'S RISK ASSESSMENT. Although this improved the particular standard, it still was centered upon electrically operated hospital beds, and failed to take into account manually operated hospital beds and products in other medical environments.

In 2000, the EN 1970 standard (*Adjustable beds for DISABLED PERSONS – Requirements and test methods*) was published, which addressed beds used by DISABLED PERSONS to alleviate or compensate for a disability or handicap. This standard offered a broadened scope in conjunction with IEC 60601-2-38, but after the edition of Amendment 1 to IEC 60601-2-38, the opportunity presented itself to combine the two standards to a common, international standard.

As work began on the integration, the IEC adjusted its stance on BASIC SAFETY and ESSENTIAL PERFORMANCE, integrating them into the third edition of IEC 60601-1. It therefore became necessary to align the new standard with the third edition. The particular standard was given a new number, IEC 60601-2-52, and work began on alignment to third edition.

This particular standard, therefore, is the realization of much work in alignment, and scope adjustment between IEC 60601-2-38, EN 1970, and the third edition of IEC 60601-1. It represents the current thinking in BASIC SAFETY and ESSENTIAL PERFORMANCE of the MEDICAL BED as used to alleviate illness of PATIENTS and disability of DISABLED PERSONS. This is the effort of a joint working group of the IEC and the ISO.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-52: Particular requirements for the basic safety and essential performance of medical beds

201.1 Scope, object and related standards

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL BEDS intended for adults, hereafter referred to as MEDICAL BED as defined in 201.3.212.

If a clause or subclause is specifically intended to be applicable to a MEDICAL BED only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to MEDICAL BED and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of MEDICAL BED or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the General Standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MEDICAL BEDS as defined in 201.3.212.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 2 of this particular standard.

IEC 60601-1-3, IEC 60601-1-8 and IEC 60601-1-10[2)] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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1) The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

2) IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). 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 or applicable collateral 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 or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.