SVENSK STANDARD SS-EN 50637

Fastställd	Utgåva	Sida	Ansvarig kommitté
2018-04-11	1	1 (1+89)	SEK TK 62

Elektrisk utrustning för medicinskt bruk – Säkerhet och väsentliga prestanda – Särskilda fordringar på sjukvårdssängar för barn

Medical electrical equipment –
Particular requirements for the basic safety and essential performance of medical beds for children

Som svensk standard gäller europastandarden EN 50637:2017. Den svenska standarden innehåller den officiella engelska språkversionen av EN 50637:2017.

Nationellt förord

Standarden ska användas tillsammans med svensk standard som överför EN 60601-1:2006, vid denna standards fastställande SS-EN 60601-1, utgåva 2, 2006 eller SS-EN 60601-1, utgåva 2.1, 2013.

ICS 11.140.00

Denna standard är fastställd av SEK Svensk Elstandard,
som också kan lämna upplysningar om **sakinnehållet** i standarden.
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Standarder underlättar utvecklingen och höjer elsäkerheten

Det finns många fördelar med att ha gemensamma tekniska regler för bl a mätning, säkerhet och provning och för utförande, skötsel och dokumentation av elprodukter och elanläggningar.

Genom att utforma sådana standarder blir säkerhetsfordringar tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

Många standarder inom elområdet beskriver tekniska lösningar och metoder som åstadkommer den elsäkerhet som föreskrivs av svenska myndigheter och av EU.

SEK är Sveriges röst i standardiseringsarbetet inom elområdet

SEK Svensk Elstandard svarar för standardiseringen inom elområdet i Sverige och samordnar svensk medverkan i internationell och europeisk standardisering. SEK är en ideell organisation med frivilligt deltagande från svenska myndigheter, företag och organisationer som vill medverka till och påverka utformningen av tekniska regler inom elektrotekniken.

SEK samordnar svenska intressenters medverkan i SEKs tekniska kommittéer och stödjer svenska experters medverkan i internationella och europeiska projekt.

Stora delar av arbetet sker internationellt

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

Standardiseringsarbetet inom SEK är organiserat i referensgrupper bestående av ett antal tekniska kommittéer som speglar hur arbetet inom IEC och CENELEC är organiserat.

Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

Var med och påverka!

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 50637

November 2017

ICS 11.140

English Version

Medical electrical equipment - Particular requirements for the basic safety and essential performance of medical beds for children

Appareils électromédicaux - Exigences particulières de sécurité de base et de performances essentielles des lits médicaux pour enfants

Medizinische elektrische Geräte - Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von medizinischen Betten für Kinder

This European Standard was approved by CENELEC on 2017-08-30. 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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre 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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 50637:2017 E

SEK Svensk Elstandard

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European foreword

This document (*EN 50637:2017*) has been prepared by CLC/TC 62 "*Electrical equipment in medical practice*".

The following dates are fixed:

• latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2018-08-30
• latest date by which the national standards conflicting with this document have to be withdrawn	(dow)	2020-08-30

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

This document has been prepared under a mandate given to CEN and CENELEC by the European Commission.

Introduction

EN 60601-2-52 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL BEDS for ADULTS, hence not covering requirement for beds for CHILDREN and ADULTS with atypical anatomy. This particular standard is based on the Mandate M/467 Medical beds issued by the European Commision with the following background information:

It appears, from a first analysis undertaken by Competent Authorities, that the current set of standards is not adapted to the needs of CHILDREN or ADULTS with an atypical anatomy. EN 60601-2-52 does not foresee a maximum distance for the bars that is small enough to prevent accidents.

According to the Competent Authorities' representatives, a part of the safety problem is due to the fact that medical beds for ADULTS are not appropriately labelled as being designed only for ADULTS with a normal anatomy. Users are therefore not always aware of the risk of medical beds for young PATIENTS or for ADULTS with an atypical anatomy. Hospital administrations do not always see a need to buy medical beds which are appropriate for CHILDREN or for ADULTS with an atypical anatomy. Therefore, clear labelling of the targeted PATIENT groups for medical beds complying with EN 60601-2-52 could reduce the risk of inappropriate use of this kind of medical beds for CHILDREN or for ADULTS with an atypical anatomy. Labeling is taken care of by Amendment 1 of EN 60601-2-52.

Competent Authorities' representatives also stated that there is a need for the development of requirements for MEDICAL BEDS and COTS for CHILDREN and ADULTS with an atypical anatomy.

In order to prevent EN 60601-2-52 from being extraordinary complex to use, CLC/TC 62 decided to develop this particular standard rather than further amending EN 60601-2-52 in relation to use for CHILDREN and ADULTS with an atypical anatomy.

This standard is based on input from the following standards and reports:

- EN 60601-2-52, *Medical electrical equipment — Part 2-52: Particular requirements for basic safety and essential performance of medical beds (IEC 60601-2-52)*[1)];
- EN 716-1, *Furniture — Children's cots and folding cots for domestic use — Part 1: Safety requirements*;
- EN 716-2, *Furniture — Children's cots and folding cots for domestic use — Part 2: Test methods*;
- EN 1130-2, *Furniture — Cribs and cradles for domestic use — Part 2: Test methods*;
- EN 747-1, *Furniture — Bunk beds and high beds — Part 1: Safety, strength and durability requirements*;
- EN 747-2, *Furniture — Bunk beds and high beds — Part 2: Test methods*;
- CEN/TR 13387 (all parts), *Child use and care articles — General safety guidelines*;
- DIN 32623, *Hospital children's cots made from metal and plastic — Safety requirements and testing*;
- Nordic Requirements specification for Adjustable beds for disabled children.

1) This document is currently impacted by the amendment EN 60601-2-52:2010/A1:2015 and the corrigendum EN 60601-2-52:2010/AC:2011.

201.1 Scope, object and related standards

Clause 1 of EN 60601-1:2006, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*, applies, except as follows:

201.1.1 * Scope

Replacement:

This Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL BEDS, hereafter referred to as MEDICAL BEDS as defined in 201.3.218, intended for CHILDREN as defined in 201.3.207, and ADULTS with atypical anatomy (ADULTS ranging outside the definition for ADULTS in 201.3.201).

This standard applies to medical beds with nonadjustable and electrical / mechanical adjustable functions.

This Standard applies to MEDICAL BEDS with an internal length of up to 180 cm suitable to a body length of 155 cm.

NOTE 1 The limitation of 180 cm is in order to minimize the foreseeable misuse, of a parent sharing the bed with the child or that the bed will be used by an ADULT.

If a manufacturer wishes to make a bed that can be used by both a child and an ADULT, e.g. length of 180 cm or more, then it will fulfil both EN 60601-2-52 and this particular standard.

This Standard does not apply to MEDICAL BEDS intended for ADULTS as defined in 201.3.201 (covered by EN 60601-2-52).

This Standard does not apply to :

- incubators covered by EN 60601-2-19 ;
- beds for children, covered by EN 716-1 and EN 716-2 ;
- cribs and cradles covered by EN 1130 (all parts) ;
- bunk beds and high beds, covered by EN 747-1 and 747-2.

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 BEDS 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 EN 60601-1:2006.

NOTE 2 See also 4.2 of EN 60601-1:2006.

NOTE 3 Body length is measured from crown to sole.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements and test methods for MEDICAL BEDS as defined in 201.3.218 intended for CHILDREN as defined in 201.3.207.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of EN 60601-1:2006 standard and its accociated amendments and corrigenda and Clause 2 of this particular standard.

EN 60601-1-3 and EN 60601-1-10 do not apply. All other published collateral standards in the EN 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the EN 60601 series, particular standards may modify, replace or delete requirements contained in EN 60601-1:2006 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 this particular standard takes priority over EN 60601-1:2006.

The numbering of clauses and subclauses of this particular standard corresponds to that of EN 60601-1:2006 with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of EN 60601-1:2006) 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 EN 60601-1-2:2015 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the EN 60601-1-3:2008 collateral standard, etc.). The changes to the text of EN 60601-1:2006 are specified by the use of the following words:

"Replacement" means that the clause or subclause of EN 60601-1:2006 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 EN 60601-1:2006 or applicable collateral standard.

"Amendment" means that the clause or subclause of EN 60601-1:2006 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 EN 60601-1:2006 are numbered starting from 201.101. However, due to the fact that definitions in EN 60601-1:2006 are numbered 3.1 through 3.147, 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 EN 60601-1-2, 203 for EN 60601-1-3, etc.

The term "this standard" is used to make reference to EN 60601-1:2006, 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 EN 60601-1:2006 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of EN 60601-1:2006 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

Clause 2 of EN 60601-1:2006, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*, applies except as follows:

Addition:

EN 71-3, *Safety of toys — Part 3: Migration of certain elements*

EN 716-2, *Furniture — Children's cots and folding cots for domestic use — Part 2: Test methods*

EN 1021-1, *Furniture — Assessment of the ignitability of upholstered furniture — Part 1: Ignition source smouldering cigarette*

EN 1021-2, *Furniture — Assessment of the ignitability of upholstered furniture — Part 2: Ignition source match flame equivalent*

EN 13501-1, *Fire classification of construction products and building elements — Part 1: Classification using data from reaction to fire tests*

EN 50525-2-21, *Electric cables — Low voltage energy cables of rated voltages up to and including 450/750 V (Uo/U) — Part 2-21: Cables for general applications — Flexible cables with crosslinked elastomeric insulation*

EN 60068-2-31, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily for equipment-type specimens (IEC 60068-2-31)*

Replacement of the reference to ISO 10993 (all parts) (reference to the corresponding EN ISO series):

EN ISO 10993 (all parts), *Biological evaluation of medical devices (ISO 10993, all parts)*

Replacement of the references to IEC 60227-1:1993 and IEC 60245-1:2003 (not to be dated anymore):

IEC 60227-1, *Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V — Part 1: General requirements*

IEC 60245-1, *Rubber insulated cables — Rated voltages up to and including 450/750 V — Part 1: General requirements*

Replacement of the references to EN 60601-1-2 and EN 60601-1-3 (now to be dated):

EN 60601-1-2:2015, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests (IEC 60601-1-2:2014)*

EN 60601-1-3:2008, *Medical electrical equipment — Part 1-3: General requirements for basic safety and essential performance — Collateral Standard: Radiation protection in diagnostic X-ray equipment (IEC 60601-1-3:2008)*

Deletion:

ISO 9614-1, *Acoustics — Determination of sound power levels of noise sources using sound intensity — Part 1: Measurement at discrete points*