SLOVENSKI STANDARD
oSIST prEN IEC 80601-2-89:2024

01-maj-2024

Medicinska električna oprema - 2-89. del: Posebne zahteve za osnovno varnost in bistvene lastnosti medicinskih postelj za otroke

Medical electrical equipment - Part 2-89: Particular requirements for the basic safety and essential performance of medical beds for children

Ta slovenski standard je istoveten z: **prEN IEC 80601-2-89:2024**

ICS:

11.140	Oprema bolnišnic	Hospital equipment

oSIST prEN IEC 80601-2-89:2024 **en**

62D/2113/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 80601-2-89 ED1**	
DATE OF CIRCULATION: **2024-03-01**	CLOSING DATE FOR VOTING: **2024-05-24**
SUPERSEDES DOCUMENTS: **62D/1758A/CD, 62D/1783A/CC**	

IEC SC 62D : PARTICULAR MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS

SECRETARIAT: United States of America	SECRETARY: Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.

FUNCTIONS CONCERNED:

☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY

☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

Attention IEC-CENELEC parallel voting

The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting.

The CENELEC members are invited to vote through the CENELEC online voting system.

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Recipients of this document are invited to submit, with their comments, notification of any relevant “In Some Countries” clauses to be included should this proposal proceed. Recipients are reminded that the CDV stage is the final stage for submitting ISC clauses. (SEE AC/22/2007 OR NEW GUIDANCE DOC).

TITLE:

Medical electrical equipment - Part 2-89: Particular requirements for the basic safety and essential performance of medical beds for children

PROPOSED STABILITY DATE: 2030

NOTE FROM TC/SC OFFICERS:

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-89: Particular requirements for the basic safety and essential performance of medical beds for children

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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International standard IEC 80601-2-89 has been prepared by IEC subcommittee 62D: 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 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 the base publication and its amendment will remain unchanged until the stability 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

IEC 80601-2-52 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 EN 50637, which was created pursuant to Mandate M/467 Medical beds issued by the European Commission with the following background information:

It appears, from a first analysis undertaken by EU Competent Authorities, that the current set of standards is not adapted to the needs of CHILDREN or ADULTS with an atypical anatomy. IEC 80601-2-52 does not foresee a maximum distance for the bars that is small enough to prevent accidents.

According to the EU 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 IEC 80601-2-52 could reduce the risk of inappropriate use of this kind of medical beds for CHILDREN or for ADULTS with an atypical anatomy.

EU 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 IEC 80601-2-52 from being extraordinarily complex to use, CLC/TC 62 decided to develop this particular standard rather than further amending IEC 80601-2-52 in relation to use for CHILDREN and ADULTS with an atypical anatomy.

This standard is based on EN50637 and IEC 80601-2-52 with input from the following standards and reports:

- 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

201.1. Scope, object and related standards

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

[1] The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

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 201.3.219, 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 electrical or non-electrical 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. INTERNAL LENGTH of 180 cm or more, then it shall fulfil both IEC 80601-2-52 and this particular standard.

This Standard does not apply to:

- ADULT *only* beds covered by IEC 80601-2-52
- incubators covered by IEC 60601-2-19;
- devices for which the INTENDED USE is mainly for examination or transportation under medical supervision (e.g. stretcher, examination table).

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 BEDS 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 and test methods for MEDICAL BEDS as defined in 201.3.219 intended for CHILDREN as defined in 201.3.207 and ADULTS with atypical anatomy.

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 corrigenda and Clause 2 of this particular standard.

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

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 this particular standard takes priority over the general standard.

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 60601-1-2:2015 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3:2008 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 EN 60601-1:2006 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 3.147, 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 IEC 60601-1-2, 203 for IEC 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 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.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

Clause 2 of the general standard 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 597-1 *Furniture – Assessment of the ignitability of mattresses and upholstered bed bases – Part 1: Ignition Source: Smouldering Cigarette*

EN 597-2 *Furniture — Assessment of ignitability of mattresses and upholstered bed bases — Part 2: Ignition source: match-flame equivalent*

ISO 7619-2, *Rubber, vulcanized or thermoplastic - Determination of indentation hardness - Part 2: IRHD pocket meter method*

IEC 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*

IEC 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 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*

Deletion:

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

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in Clause 3 of the general standard apply, except as follows.

NOTE An index of defined terms is found at the end of this document.

201.3.67
MULTIPLE SOCKET-OUTLET
MSO

Replacement:

one or more socket-outlets intended to be connected to, or integral with, flexible cables or cords or ME EQUIPMENT for SUPPLY MAINS or equivalent voltage

NOTE 1 to entry: A MULTIPLE SOCKET-OUTLET can be a separate item or an integral part of equipment.

201.3.76
PATIENT

Replacement:

person undergoing a medical procedure or PERSON WITH DISABILITY

NOTE 1 to entry: Whenever the term PATIENT is used, it comprises both ADULTS with an atypical anatomy and CHILDREN.

201.3.109
SAFE WORKING LOAD
SWL

Replacement:

The SAFE WORKING LOAD is the sum of:

1) the PATIENT;
2) the mattress;

3) the ACCESSORIES of the MEDICAL BED, only if they are supported by the support system of the MEDICAL BED; and

4) the SAFE WORKING LOADS supported by those ACCESSORIES, excluding PATIENT weight.

201.3.131
*** TRAPPING ZONE**

Addition:

locations where the PATIENT or other persons can become entrapped, entangled, wedged, or stuck in or between parts of the MEDICAL BED, such as the SIDE RAILS, HEAD/FOOT BOARD, MATTRESS SUPPORT PLATFORM or mattress

Addition:

201.3.201
ADULT
PATIENT having a physical size equal to or more than 146 cm, a mass equal to or more than 40 kg and a body mass index (BMI) equal to or more than 17, or having a physical size, mass, and body index as defined by the MANUFACTURER'S RISK MANAGEMENT FILE

[Source: IEC 80601-2-52, 201.3.222]

201.3.202
*** APPLICATION ENVIRONMENT 1**

intensive/critical care provided in a hospital where 24 h medical supervision and constant monitoring is required and provision of life support system/equipment used in medical procedures is essential to maintain or improve the vital functions of the PATIENT

201.3.203
*** APPLICATION ENVIRONMENT 2**

acute care provided in a hospital or other medical facility where medical supervision and monitoring is required and ME EQUIPMENT used in medical procedures is often provided to help maintain or improve the condition of the PATIENT

201.3.204
*** APPLICATION ENVIRONMENT 3**

long-term care in a medical area where medical supervision is required and monitoring is provided if necessary and ME EQUIPMENT used in medical procedures may be provided to help maintain or improve the condition of the PATIENT

NOTE 1 to entry: This includes use in CHILDREN'S nursing homes and in rehabilitation facilities.

201.3.205
*** APPLICATION ENVIRONMENT 4**

care provided in a domestic area where ME EQUIPMENT is used to alleviate or compensate for an injury, disability or disease

NOTE 1 to entry: This excludes use in all other application environments (e.g. CHILDREN'S nursing homes and rehabilitation facilities) when a MEDICAL BED is purely designed for APPLICATION ENVIRONMENT 4.

201.3.206
*** APPLICATION ENVIRONMENT 5**

outpatient (ambulatory) care, which is provided in a hospital or other medical facility, under medical supervision where ME EQUIPMENT, is provided for the need of persons with illness, injury or disability for treatment, diagnosis or monitoring

201.3.207
CHILD

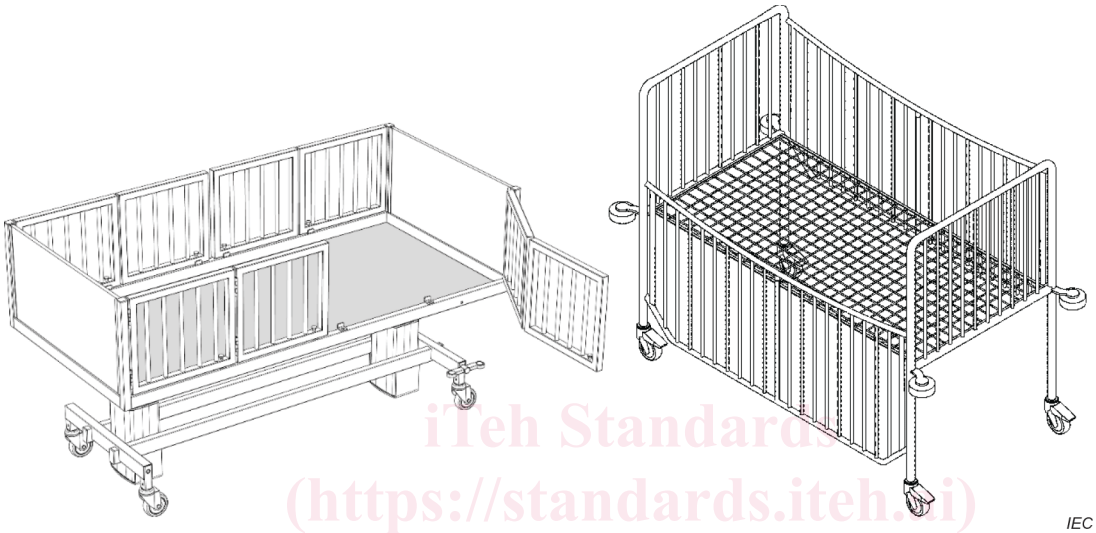
PATIENT having a body length equal to or less than 155 cm and a mass equal to or less than 70 kg and may display cognitive immaturity, exploratory behaviours and/or risk taking tendencies

NOTE 1 to entry: Body length is measured from crown to sole.

201.3.208
COT

MEDICAL BED with an INTERNAL LENGTH ≥ 90 cm and < 140 cm provided with PROTECTION PANELS also intended for CHILDREN able to stand up in bed

NOTE 1 to entry: In other countries this may be referred to as other terms (e.g. crib).



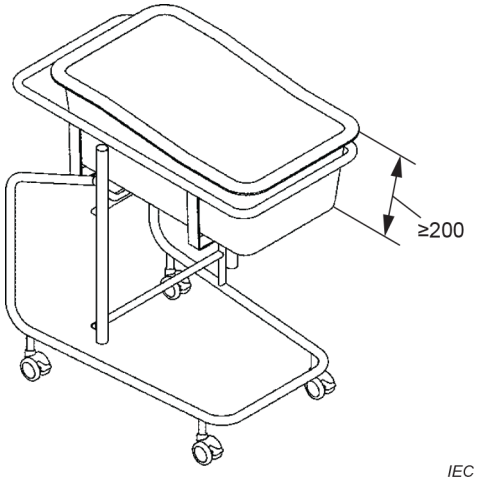
IEC

201.3.209
CRIB

MEDICAL BED with an INTERNAL LENGTH < 90 cm provided with PROTECTION PERIMETER, intended for CHILDREN until they are able to sit, kneel or to pull themselves up

NOTE 1 to entry: Excluded are MEDICAL BEDS with a swinging or rocking function.

NOTE 2 to entry In other countries this may be referred to as other terms (e.g. bassinet).



IEC

201.3.210
PERSON WITH DISABILITY