



SLOVENSKI STANDARD

SIST EN 50637:2018

01-januar-2018

Medicinska električna oprema - Posebne zahteve za osnovno varnost in bistvene lastnosti medicinskih postelj za otroke

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

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

[SIST EN 50637:2018](https://standards.iteh.ai/catalog/standards/sist/446d008f-d748-471c-aaa4-0095c514b3f1/sist-en-50637-2018)

Ta slovenski standard je istoveten z: **EN 50637:2017**

ICS:

11.140 Oprema bolnišnic Hospital equipment

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EUROPEAN STANDARD

EN 50637

NORME EUROPÉENNE

EUROPÄISCHE NORM

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.

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Contents

Page

European foreword	5
Introduction	6
201.1 Scope, object and related standards	7
201.1.1 * Scope	7
201.1.2 Object	7
201.1.3 Collateral standards	7
201.1.4 Particular standards	8
201.2 Normative references	8
201.3 Terms and definitions	9
201.4 General requirements	14
201.4.2 *Risk management process for ME EQUIPMENT and ME SYSTEM	14
201.5 General requirements for testing of ME EQUIPMENT	14
201.5.101 * Entrapment test TOOLS	14
201.5.102 Loading pad	17
201.5.103 Impactor	18
201.5.104 Side impactor	19
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	19
201.6.2 *Protection against electrical shock	19
201.7 ME EQUIPMENT identification, marking and documents	19
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	28
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	28
201.9.1 *Mechanical HAZARDS of ME EQUIPMENT	29
201.9.2 HAZARDS associated with moving parts	36
201.9.3 HAZARDS associated with surfaces, corners and edges	40
201.9.8 HAZARDS associated with support systems	45
201.9.101 *Protection against inadvertent PATIENT falls	54
201.10 Protection against unwanted and excessive radiation HAZARDS	56
201.11 Protection against excessive temperatures and other HAZARDS	56
201.11.7 Biocompatibility of MEDICAL BED	59
201.11.8 *Interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT	59
201.12 Accuracy of controls and instruments and protection against hazardous outputs	59
201.12.2 USABILITY	59
201.13 HAZARDOUS SITUATIONS and fault conditions	59
201.14 Programmable electrical medical systems (PEMS)	60
201.15 Construction of ME EQUIPMENT	60
201.15.3 Mechanical strength	60
201.15.4 ME EQUIPMENT components and general assembly	61
201.16 ME SYSTEMS	63
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	63
Annex AA (normative) Particular guidance and rationale	64
AA.1 General guidance	64
AA.1.1 Rationale for particular clauses and subclauses	64
Annex BB (normative) Design requirements and recommendations for MEDICAL BED	77
BB.1 General	77
BB.2 Human factors (ergonomic)	77
BB.2.1 General	77
BB.2.2 Range of adjustment of the height of the mattress support platform	77
BB.2.3 Dimensions for handles and pedals	78
BB.2.4 Operating forces for handles and pedals	78
BB.3 Functionality	78
BB.3.1 General	78
BB.3.2 Combination of MEDICAL BED and MOBILE hoists	78

BB.3.3	Combination of MEDICAL BED and mattress	79
BB.3.4	Range of adjustment of moveable sections of the MATTRESS SUPPORT PLATFORM	79
Annex CC (informative)	Particular guidance for assessing risk of entrapment in v-shaped openings	81
Bibliography		87
FIGURE 201.101	MEDICAL BED, GENERAL ARRANGEMENT (EXAMPLE, SCHEMATIC PRESENTATION ONLY)	13
FIGURE 201.102A	CONE TOOL	15
FIGURE 201.102B	FINGER PROBE FOR MESH	15
FIGURE 201.102C	CYLINDER TOOL	15
FIGURE 201.102D	BALL CHAIN	16
FIGURE 201.102E	BALL CHAIN LOOP AND SPHERICAL MASS	16
FIGURE 201.102	ENTRAPMENT TEST TOOLS	16
FIGURE 201.103	LOADING PAD	17
FIGURE 201.104	IMPACTOR	18
FIGURE 201.105	SIDE IMPACTOR	19
FIGURE 201.106	GRAPHICAL SYMBOL FOR MAXIMUM PATIENT WEIGHT AND SAFE WORKING LOAD	20
FIGURE 201.107	MARKING FOR COMPATIBLE MATTRESSES SPECIFIED BY THE MANUFACTURER	21
FIGURE 201.108	MARKING FOR DETACHABLE SIDE RAILS SPECIFIED BY THE MANUFACTURER	21
FIGURE 201.109	DESCRIPTION OF ALLOWED LENGTH OF PATIENT	22
FIGURE 201.110	EXAMPLE OF MARKING ON THE MEDICAL BED FOR POSITIONING PATIENT IN MEDICAL BED	23
FIGURE 201.111	MEDICAL BED FUNCTION CONTROLS AND/OR ACTUATORS: GUIDELINES FOR CREATING GRAPHICAL SYMBOLS	25
FIGURE 201.112	MARKING ON THE MEDICAL BED OF STORAGE LOCATION FOR PENDANT CONTROL	26
FIGURE 201.113	EXAMPLE OF MEDICAL BED WITH SEGMENTED OR SPLIT SIDE RAIL	30
FIGURE 201.114	EXAMPLE OF MEDICAL BED WITH SINGLE PIECE SIDE RAIL AND PROTECTION SIDE RAIL	31
FIGURE 201.115	DIMENSION OF HANDLE FOR LIFTING POLE	35
FIGURE 201.116	ALLOWABLE SPACING FOR FINGERS IN AREAS OF NORMAL REACH AROUND THE PERIMETER OF THE MATTRESS SUPPORT PLATFORM	37
FIGURE 201.117	EXAMPLE USING BARRIERS FOR CLEARANCE MEASUREMENT AROUND THE PERIMETER OF THE MATTRESS SUPPORT PLATFORM TO MITIGATE PATIENT-FINGER ENTRAPMENT	38
FIGURE 201.118A	FOOT AND TOE CLEARANCE AREA BETWEEN MOVING PARTS AND THE FLOOR	38
FIGURE 201.118B	TOE CLEARANCE AREA BETWEEN MOVING PARTS AND THE FLOOR	39
FIGURE 201.118	CLEARANCE AREAS	39
FIGURE 201.119	REQUIRED MINIMUM RADII OF EDGES AND CORNERS	40
FIGURE 201.120	RETENTION OF LOOP AND MASS	41
FIGURE 201.121	LATERAL STABILITY TEST ALONG THE SIDE OF THE MEDICAL BED	42
FIGURE 201.122	LONGITUDINAL STABILITY TEST WITH REMOVABLE FOOT BOARD	43
FIGURE 201.123	LONGITUDINAL STABILITY TEST WITH FIXED HEAD/FOOT BOARDS	43
FIGURE 201.124	DISTRIBUTION OF SAFE WORKING LOAD FOR TESTS	47
FIGURE 201.125	POSITION OF LOADING PAD AND IMPACTOR	49
FIGURE 201.126	IMPACT TO SLATS AND SOLID ELEMENTS OF MEDICAL BEDS	51
FIGURE 201.127	APPLICATION OF FORCES FOR TEST OF SIDE RAIL	53
FIGURE 201.128	HEIGHT OF SIDE RAIL / PROTECTION SIDE RAIL	55
FIGURE 201.129A	ANGLE γ BETWEEN THE BACK SECTION AND THE LEG SECTION OF THE MATTRESS SUPPORT PLATFORM	61
FIGURE 201.129B	ANGLE γ BETWEEN THE BACK SECTION AND THE UPPER LEG SECTION OF THE MATTRESS SUPPORT PLATFORM	61
FIGURE 201.129C	ANGLE γ BETWEEN THE ANGLED BACK SECTION AND UPPER LEG SECTION OF THE MATTRESS SUPPORT PLATFORM	62
FIGURE 201.129D	ANGLE γ BETWEEN THE ANGLED BACK SECTION AND THE LEG/UPPER LEG SECTION OF THE MATTRESS SUPPORT PLATFORM	62
FIGURE 201.129	CONFIGURATIONS OF THE MATTRESS SUPPORT PLATFORM	62
FIGURE AA.1	RESULTANT FORCES WITHOUT MATTRESS	68
FIGURE AA.2	RESULTANT FORCES WITH MATTRESS	68

EN 50637:2017 (E)

FIGURE AA.3 – EXAMPLE OF 40 MM GAP MEASUREMENT OF B	68
FIGURE AA.4 – ANGLE MEASUREMENT EXAMPLE OF B	68
FIGURE AA.5 – PLACEMENT OF MEASUREMENT TOOL FOR MEASUREMENT OF D_x	69
FIGURE AA.6 – EXAMPLE OF AREA D_x MEASUREMENT THAT PASSES.....	70
FIGURE AA.7 – EXAMPLE OF AREA D_x MEASUREMENT THAT FAILS	70
FIGURE AA.8 – EXAMPLE OF AREA D_x MEASUREMENT THAT FAILS (ON LIMIT).....	70
FIGURE AA.9 – EXAMPLE OF POTENTIAL PATIENT ENTRAPMENT IN AREA A WITHIN THE SIDE RAIL.....	71
FIGURE AA.10 – EXAMPLE OF POTENTIAL PATIENT ENTRAPMENT IN AREA A BELOW THE SIDE RAIL	71
FIGURE AA.11 – EXAMPLE OF POTENTIAL PATIENT ENTRAPMENT IN AREA B.....	71
FIGURE AA.12 – EXAMPLE OF POTENTIAL PATIENT ENTRAPMENT IN AREA C BETWEEN SPLIT SIDE RAIL	71
FIGURE AA.13 – EXAMPLE OF POTENTIAL PATIENT ENTRAPMENT IN AREA C BETWEEN SIDE RAIL AND HEAD BOARD ...	71
FIGURE AA.14 – EXAMPLE OF POTENTIAL PATIENT ENTRAPMENT IN AREA D_x	71
FIGURE AA.15 – EXAMPLE OF POTENTIAL PATIENT ENTRAPMENT IN AREA A BELOW A SINGLE PIECE SIDE RAIL	72
FIGURE BB.1 – SCHEMATIC PRESENTATION OF UNDER MEDICAL BED CLEARANCE	79
FIGURE BB.2 – RECOMMENDATIONS AND REQUIREMENTS REGARDING ANGLES FOR DIFFERENT SECTIONS OF THE MATTRESS SUPPORT PLATFORM.....	80
FIGURE CC.1 – WEDGE TOOL	82
FIGURE CC.2 – V-SHAPED OPENING IN RELATION TO B	83
FIGURE CC.3 – PASS/FAIL IN RELATION TO AREA B	83
FIGURE CC.4 – POSITIONING OF WEDGE TOOL	84
FIGURE CC.5 – PASS/FAIL IN RELATION TO AREA C BETWEEN HEAD BOARD AND FOOT BOARD	85
FIGURE CC.6 – PASS/FAIL IN RELATION TO AREA C BETWEEN SPLIT SIDE RAILS	86

iTeh STANDARD PREVIEW

*TABLE 201.101 – PROTECTION AGAINST PATIENT ENTRAPMENT.....	32
TABLE 201.102 – PROTECTION AGAINST INADVERTENT PATIENT FALLS AND CLIMBING OUT OF MEDICAL BED	56
TABLE 24 – ALLOWABLE MAXIMUM TEMPERATURES FOR SKIN CONTACT WITH MEDICAL BED APPLIED PARTS.....	57
TABLE AA.1 – PROTECTION AGAINST PATIENT ENTRAPMENT IN NON-MOVING PARTS	67
TABLE AA.2 – HEIGHT OF PROTECTIVE BARRIER ACCORDING TO AGE.....	75

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.

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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 Commission 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 associated 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.

EN 50637:2017 (E)**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)*

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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 EN 60601-1:2006 apply, except as follows.

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

201.3.8

APPLIED PART

Addition:

all parts of the MEDICAL BED

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 A MULTIPLE SOCKET-OUTLET can be a separate item or an integral part of equipment.

EN 50637:2017 (E)**201.3.76****PATIENT***Replacement:*

person undergoing a medical procedure or DISABLED PERSON

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

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

[SOURCE: EN 60601-2-52:2010/A1:2015, 201.3.219]

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 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 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**

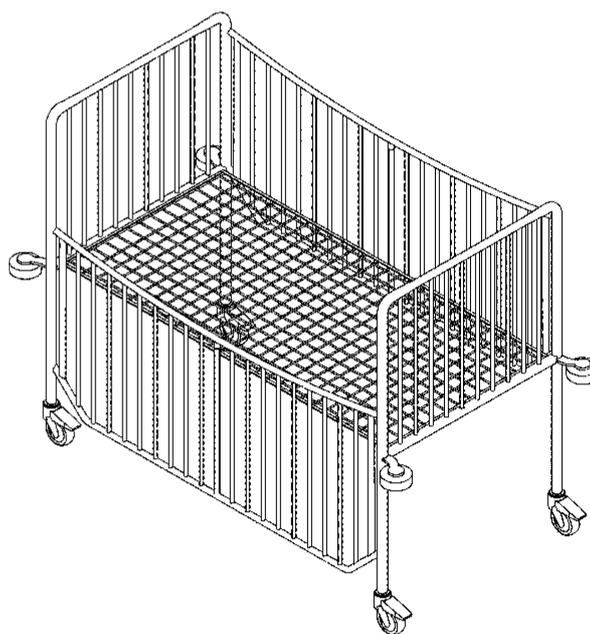
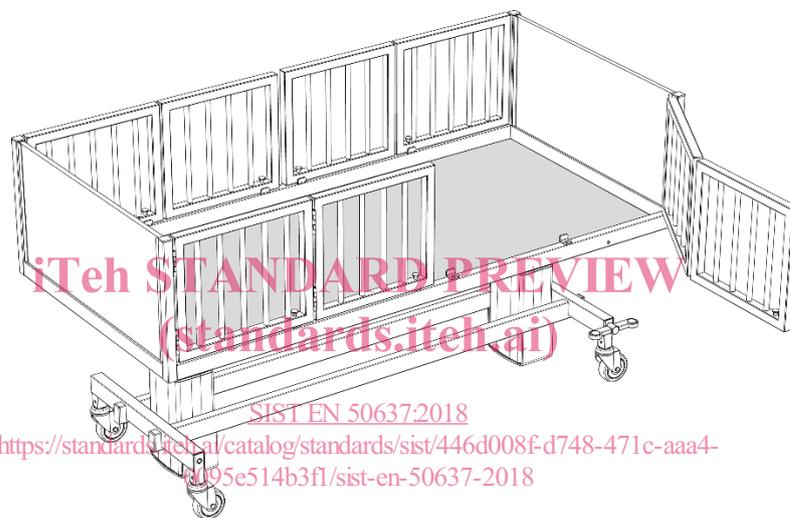
PATIENT having a physical size equal to or less than 155 cm and a mass equal to or less than 70 kg

NOTE Mean length of approx. 145 cm is in several countries like Japan, China and Hungary equivalent to the age of 12 years. In the Netherlands 156 cm is equivalent to the mean length of a 12 year old boy and girl (Childata The Handbook of Child Measurements and Capabilities [7].)

A 12 year old boy with a length of 155 cm and a mass of 70 kg has a BMI of 29,1 which for CHILDREN is considered obese. The 97th percentile weight of a 12 year old girl from Netherlands is 62 kg.

201.3.208**COT**

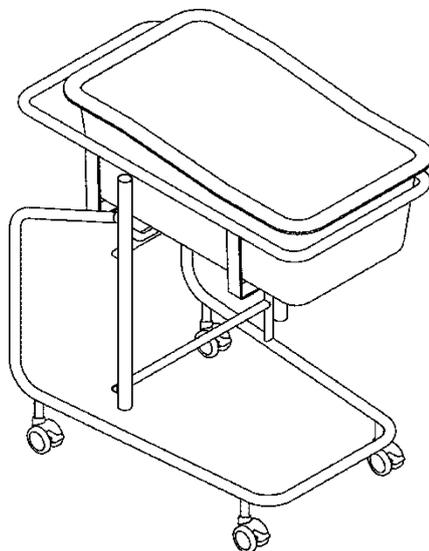
MEDICAL BED with an internal length from and including 90 cm up to 140 cm provided with PROTECTION SIDE RAILS also intended for CHILDREN able to stand up in bed



EN 50637:2017 (E)**201.3.209****CRIB**

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

NOTE Excluded are medical beds with a swinging or rocking function.



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201.3.210**DISABLED PERSON**

person with one or more impairments, one or more activity limitations, one or more participation restrictions or a combination thereof

[SOURCE: EN ISO 9999:2011]

[SIST EN 50637:2018](https://standards.iteh.ai/catalog/standards/sist/446d008f-d748-471c-aaa4-0095e514b3f1/sist-en-50637-2018)

<https://standards.iteh.ai/catalog/standards/sist/446d008f-d748-471c-aaa4-0095e514b3f1/sist-en-50637-2018>

201.3.211**HEAD/FOOT BOARD**

assembly/assemblies mounted to MEDICAL BED, which identifies for the PATIENT the edge of the head or foot end of the MEDICAL BED and/or MATTRESS SUPPORT PLATFORM

NOTE It may be used as handles to push a MEDICAL BED intended to transport PATIENTS.

201.3.212**JUNIOR BED**

MEDICAL BED with an internal length from and including 140 cm up to 180 cm

201.3.213**LIFTING POLE**

ACCESSORY attached to a MEDICAL BED and intended to assist support of a PATIENT when changing position by providing a gripping support above the PATIENT

201.3.214**LOCKING DEVICE**

mechanism intended to maintain the MEDICAL BED or parts of it in its locked position

201.3.215**LOCKING SYSTEM**

mechanism consisting of a LOCKING DEVICE and one or more operating devices, which can deactivate the LOCKING DEVICE, e.g. by pushing a button, pressing a lever or turning a knob

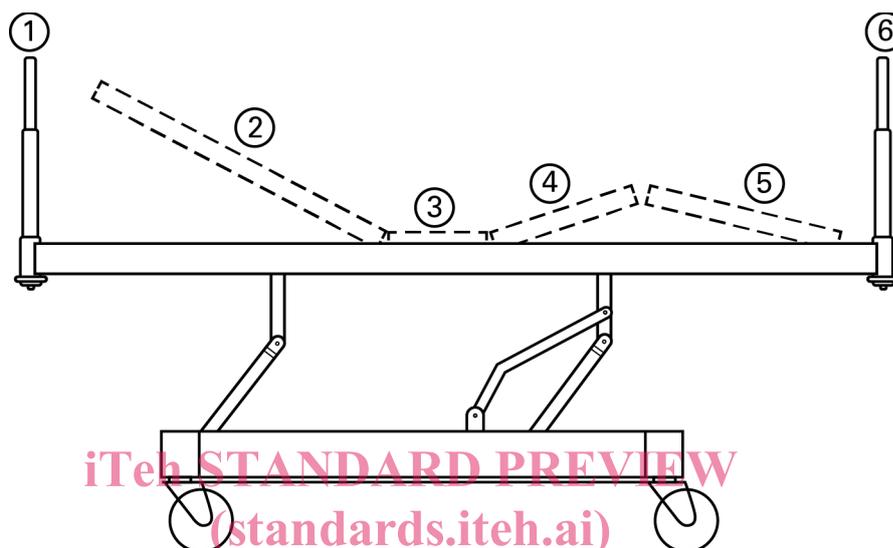
201.3.216**MATTRESS OVERLAY**

supplementary support surface, which is intended to be placed on an existing mattress, and generally used for prophylactic or therapeutic effect

201.3.217**MATTRESS SUPPORT PLATFORM**

structure which supports a PATIENT surface (for example mattress). It may articulate or change positions to facilitate various therapeutic, diagnostic and convenience positions

NOTE See Figure 201.101 and 201.129 a) to 201.129 d).

**Key**

- 1 HEAD BOARD
- 2 Back section
- 3 Seat section
- 4 Upper leg section
- 5 Lower leg section
- 6 FOOT BOARD

SIST EN 50637:2018

<https://standards.iteh.ai/catalog/standards/sist/446d008f-d748-471c-aaa4-0095e514b3f1/sist-en-50637-2018>

**Figure 201.101 – MEDICAL BED, general arrangement
(example, schematic presentation only)**

201.3.218*** MEDICAL BED**

device for which the INTENDED USE is sleeping/resting that contains a MATTRESS SUPPORT PLATFORM and intended to assist in diagnosis, monitoring, prevention, treatment, alleviation of disease or compensation for an injury or handicap

NOTE 1 Excluded are devices for which the INTENDED USE is mainly for examination or transportation under medical supervision (e.g. stretcher, examination table)

NOTE 2 Whenever the term MEDICAL BED is used it comprises CRIBS, COTS AND JUNIOR BEDS.

201.3.219**MOTION LOCKOUT CONTROL**

auxiliary subsystem that deactivates motion controls

201.3.220**OVERSIZE COT**

COT with an internal length from and including 140 cm up to 180 cm provided with PROTECTION SIDE RAILS also intended for CHILDREN able to stand up in bed