# IEC 80601-2-52

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# INTERNATIONAL STANDARD

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

ICS 11.140

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

## FOREWORD

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IEC 80601-2-52 has been prepared by a Joint Working Group of IEC subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems, and ISO technical committee 173: Assistive products. It is an International Standard.

This first edition cancels and replaces the first edition of IEC 60601-2-52 published in 2009 and its Amendment 1:2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) scope updated to state standard applies to both electrical and non-electrical MEDICAL BEDS;
b) updates to scope to explain the potential overlap with the IEC 80601-2-89;
c) introduction of APPLICATION ENVIRONMENT 6 (psychiatric care or mental health care environment) and multiple requirements for APPLICATION ENVIRONMENT;

d) alignment of requirements with IEC 60601-1:2005/AMD2:2020;

e) new test to address snagging (201.9.3.101);

f) moved required tests applicable to most application environments from Annex BB to 201.9.8.3.3, so the durability testing is in one subclause;

g) new rating of jet stream washing and updated requirements in 201.11.6.5;

h) updated the machine washing test (201.11.6.6.101) to define cycles by application environment and clarified evaluation after cycles;

i) updated test tools to ensure tolerances and drawings.

It is published as double logo standard.

The text of this International Standard is based on the following documents of IEC:

| Draft | Report on voting |
|---|---|
| 62D/2271/FDIS | 62D/2291/RVD |

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, in this document or as noted: SMALL CAPITALS.

In referring to the structure of this document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

– "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 80601 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 document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

– reconfirmed,

– withdrawn, or

– revised.

# 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 PERSONS WITH DISABILITY 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 published in 2005. 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 IEC 60601-1:2005. 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 PERSONS WITH DISABILITY. This is the effort of a joint working group of the IEC and the ISO.

IEC 80601-2-52 is a continuation of the IEC 60601-2-52 standard. It will align with the CHILDREN version of the standard, IEC 80601-2-89. The standard number was changed from IEC 60601-2-52 to IEC 80601-2-52 to indicate joint work between the ISO and the IEC.

## 201.1 Scope, object and related standards

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 1 applies, except as follows:

### 201.1.1 * Scope

*Replacement:*

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL BEDS as defined in 201.3.214, intended for ADULTS as defined in 201.3.222. Included in the scope are both electrical and non-electrical (manual) MEDICAL BEDS with or without adjustable functions.

This document is applicable to either a BED-LIFT or a detachable MATTRESS SUPPORT PLATFORM or both. The combination of BED-LIFT or a detachable MATTRESS SUPPORT PLATFORM with a compatible non-MEDICAL BED as specified by the MANUFACTURER is also considered a MEDICAL BED.

This document does not apply to:

- MEDICAL BEDS for CHILDREN and ADULTS with atypical anatomies (ADULTS ranging outside the definition for ADULTS in 201.3.222) covered by IEC 80601-2-89[1][1];
- SPECIALITY MATTRESS covered by ISO 20342 series[2];
- devices for which the INTENDED USE is mainly for examination or transportation under medical supervision (e.g. stretcher, examination table);
- all requirements for MEDICAL BEDS with special functionality.

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 document are not covered by specific requirements in this document except in 7.2.13 and 8.4.1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

NOTE 1 See also 4.2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

NOTE 2 Whenever the term MEDICAL ELECTRICAL EQUIPMENT (MEE, ME EQUIPMENT) is used within the series of IEC 60601 standards, it refers to MEDICAL BEDS (both electrical and non-electrical).

### 201.1.2 Object

*Replacement:*

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MEDICAL BEDS as defined in 201.3.214, intended for ADULTS as defined in 201.3.222.

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1 Numbers in square brackets refer to the Bibliography.

### 201.1.3 Collateral standards

*Addition:*

This document refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and Clause 2 of this document.

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.

NOTE Some IEC 60601-1-8 requirements can be excluded if they do not affect PATIENT safety, could lead to user confusion, or are inappropriate to MEDICAL BED usage.

### 201.1.4 Particular standards

*Addition:*

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, including the 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020

The numbering of clauses and subclauses of this particular standard corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) 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 document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is replaced completely by the text of this document.

"*Addition*" means that the text of this document is additional to the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"*Amendment*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.154, additional definitions in this document 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.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

## 201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 Informative references are listed in the Bibliography.

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 2, applies except as follows:

*Replacement:*

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*
IEC 60529:1989/AMD1:1999
IEC 60529:1989/AMD2:2013

*Addition:*

IEC 60601-1:2005, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

ISO 3746, *Acoustics - Determination of sound power levels and sound energy levels of noise sources using sound pressure - Survey method using an enveloping measurement surface over a reflecting plane*

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 the ignitability of mattresses and upholstered bed bases - Part 2: Ignition source match-flame equivalent*

## 201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

– IEC Electropedia: available at https://www.electropedia.org/
– ISO Online browsing platform: available at https://www.iso.org/obp

**201.3.8**
**APPLIED PART**

*Addition:*

Note 4 to entry: The APPLIED PART includes all parts of the MEDICAL BED that are within the reach of the PATIENT even if they are underneath the MATTRESS SUPPORT PLATFORM.

**201.3.76**
**PATIENT**

*Replacement:*

living person undergoing a medical PROCEDURE or PERSON WITH DISABILITY

**201.3.109**
**SAFE WORKING LOAD**
**SWL**

*Replacement:*

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**

*Replacement:*

location 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 BOARD, FOOT BOARD, MATTRESS SUPPORT PLATFORM or mattress

*Additional terms and definitions:*

**201.3.201**
*** APPLICATION ENVIRONMENT 1**
intensive care or critical care provided in a hospital where 24 h medical supervision and constant monitoring is required and provision of life support equipment used in medical PROCEDURES is essential to maintain or improve the vital functions of the PATIENT

**201.3.202**
*** APPLICATION ENVIRONMENT 2**
acute care provided in a hospital or other medical facility where medical supervision and monitoring is required and MEDICAL BED used in medical PROCEDURES is often provided to help maintain or improve the condition of the PATIENT

**201.3.203**
*** APPLICATION ENVIRONMENT 3**
long-term care in a medical area where medical supervision is required and monitoring is provided if necessary and MEDICAL BED 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 nursing homes and in rehabilitation and geriatric facilities.

**201.3.204**
*** APPLICATION ENVIRONMENT 4**
care provided in a domestic area where MEDICAL BED 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. nursing homes, rehabilitation and geriatric facilities) when a MEDICAL BED is purely designed for APPLICATION ENVIRONMENT 4.

**201.3.205**
*** APPLICATION ENVIRONMENT 5**
outpatient care or ambulatory care, which is provided in a hospital or other medical facility, under medical supervision where MEDICAL BED, is provided for the need of persons with illness, injury or disability for treatment, diagnosis or monitoring

**201.3.206**
*** APPLICATION ENVIRONMENT 6**
psychiatric care or mental health care environment where medical supervision is required, and monitoring is provided. MEDICAL BED used in medical PROCEDURES may be provided to help maintain, improve condition and protect the PATIENT

Note 1 to entry: Environment where a patient may be a harm to themselves or others.

Note 2 to entry: Includes prisons, jails, correctional facilities.

**201.3.207**
**BED-LIFT**
height adjustable mechanism on which a MATTRESS SUPPORT PLATFORM can be mounted

Note 1 to entry: The combination of a BED LIFT and a compatible non-MEDICAL BED as specified by the MANUFACTURER is considered to be a MEDICAL BED.

**201.3.208**
**CHILD**
PATIENT having a physical size equal to or less than 155 cm and a mass equal to or less than 70 kg and may display cognitive immaturity, exploratory behaviours, RISK-taking tendencies or any combination

Note 1 to entry: Physical size is measured from crown to sole.

[SOURCE: IEC 80601-2-89:2025[1], 201.3.207, modified – “Body length” replaced with “physical size” in the definition and in Note 1 to entry.]

**201.3.209**
**PERSON WITH DISABILITY**
person with one or more impairments, one or more activity limitations, one or more participation restrictions or a combination thereof

[SOURCE: ISO 9999:2022[3], 3.10]

**201.3.210**
**HEAD OR FOOT BOARD**
assembly mounted to a MEDICAL BED, which identifies for the PATIENT the edge of the head or foot end of either the MEDICAL BED or MATTRESS SUPPORT PLATFORM or both

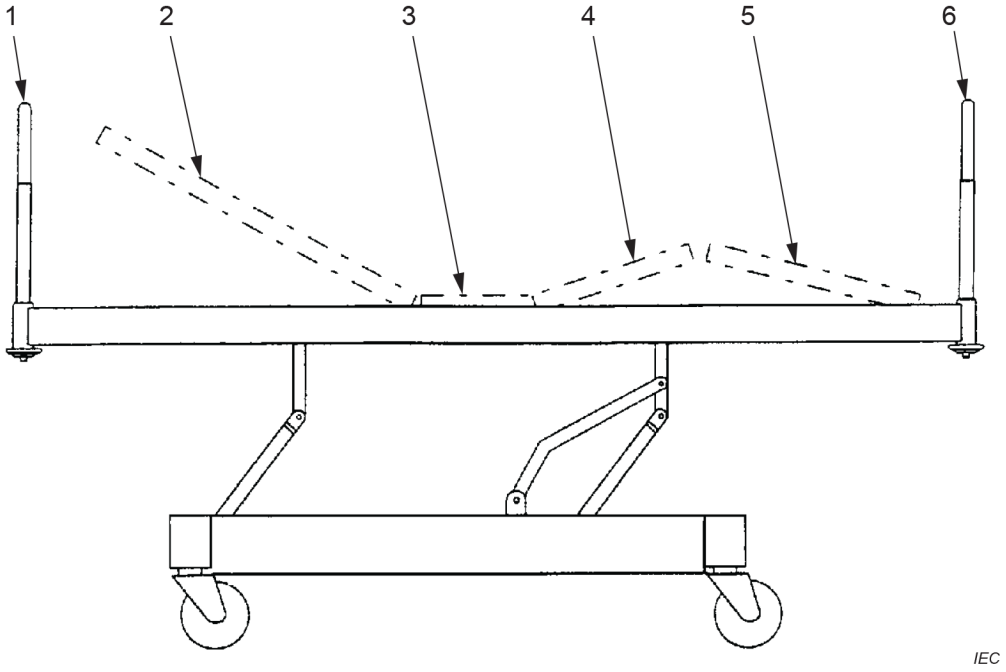
Note 1 to entry: It can be used as handles to push a MEDICAL BED intended to transport PATIENTS.

**201.3.211**
**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

**201.3.212**
**MATTRESS OVERLAY**
supplementary mattress, which is intended to be placed on an existing mattress, and generally used for prophylactic or therapeutic effect

**201.3.213**
**MATTRESS SUPPORT PLATFORM**
structure which supports a PATIENT surface

Note 1 to entry: The platform can articulate or change positions to facilitate various therapeutic, diagnostic and convenience positions (See Figure 201.101).




**Key**

1 HEAD BOARD

2 Back section (part of MATTRESS SUPPORT PLATFORM)

3 Seat section (part of MATTRESS SUPPORT PLATFORM)

4 Upper leg section (part of MATTRESS SUPPORT PLATFORM)

5 Lower leg section (part of MATTRESS SUPPORT PLATFORM)

6 FOOT BOARD

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

**201.3.214**
*** MEDICAL BED**
device for which the INTENDED USE is sleeping, resting or both that contains a MATTRESS SUPPORT PLATFORM and intended to assist in diagnosis, monitoring, prevention, treatment, alleviation of disease or compensation for an injury or disability

**201.3.215**
**MOTION LOCKOUT CONTROL**
auxiliary subsystem that deactivates motion controls

**201.3.216**
**PENDANT CONTROL**
hand-held device, which has a FUNCTIONAL CONNECTION to the MEDICAL BED, controlling at least MEDICAL BED articulations or movements or both

Note 1 to entry: PENDANT CONTROLS can be wired, or wireless, and can integrate other functions such as communications, radio, tv, etc.

**201.3.217**
**SIDE RAIL**
physical barrier, which may be a detachable ACCESSORY or integral to the overall construction of a MEDICAL BED and is mounted to the side(s) of the MEDICAL BED

Note 1 to entry: When a SIDE RAIL is located in the "up" position it provides a physical barrier, which is intended to reduce the RISK of the PATIENT accidentally slipping or rolling off the mattress.

**201.3.218**
**SPECIALTY MATTRESS**
mattress intended for prophylactic or therapeutic effect

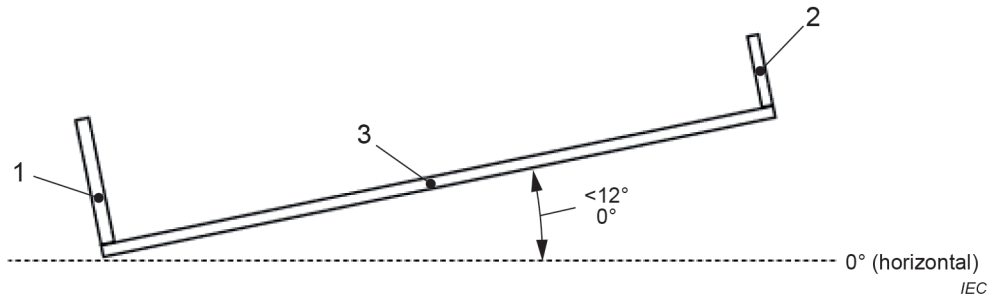
**201.3.219**
**TEST BED BOARD**
flat, rigid loading board of dimensions as specified by the MANUFACTURER representing the dimensions of the MEDICAL BED

**201.3.220**
**TRENDELENBURG**
specific therapeutic position used in some medical PROCEDURES requiring a minimum 12° head down angle of the entire MATTRESS SUPPORT PLATFORM with respect to horizontal

**201.3.221**
**UNDERCARRIAGE**
all components of the MEDICAL BED or BED-LIFT below the MATTRESS SUPPORT PLATFORM

**201.3.222**
*** 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

**201.3.223**
**HEAD DOWN TILT**
entire MATTRESS SUPPORT PLATFORM positioned in a head down angle less than 12° with respect to horizontal




**Key**

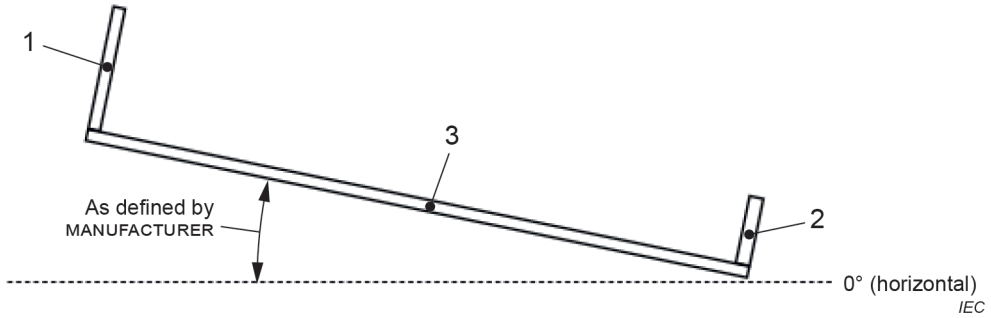
1 HEAD BOARD

2 FOOT BOARD

3 MATTRESS SUPPORT PLATFORM

**Figure 201.102 – HEAD DOWN TILT, Example**

**201.3.224**
**FOOT DOWN TILT**
entire MATTRESS SUPPORT PLATFORM positioned in any foot down angle with respect to horizontal




**Key**

1 HEAD BOARD

2 FOOT BOARD

3 MATTRESS SUPPORT PLATFORM

**Figure 201.103 – FOOT DOWN TILT, Example**

## 201.4 General requirements

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 4 applies, except as follows:

### 201.4.2.2 * General requirement for RISK MANAGEMENT

*Addition:*

The MANUFACTURER shall include, in the RISK MANAGEMENT PROCESS, HAZARDS (e.g. entrapment, PATIENT falls) related to PATIENTS taller than 185 cm, or having a physical size, mass and body mass index (BMI) outside the definition of ADULT.

Bariatric PATIENT population shall also be considered in the RISK MANAGEMENT PROCESS. Alternative means not described in this document to ensure an equivalent level of BASIC SAFETY and ESSENTIAL PERFORMANCE shall be justified by the MANUFACTURER in the RISK MANAGEMENT FILE.

The ACCOMPANYING DOCUMENT shall document any HAZARDS associated with this use case

For MEDICAL BEDS intended for APPLICATION ENVIRONMENT 6, the RISK MANAGEMENT shall include:

– strangulation HAZARDS;
– snagging HAZARDS;
– disassembly resulting in choking, ingestion or both;
– material flammability.

*Compliance is checked by inspection of the RISK MANAGEMENT FILE.*

#### 201.4.6 ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

*Addition:*

All parts within the reach of the PATIENT, even if they are underneath the MATTRESS SUPPORT PLATFORM (see Figure 201.118) shall be included in the RISK MANAGEMENT PROCESS for determination if they should be treated as APPLIED PARTS.

For APPLICATION ENVIRONMENT 4 and APPLICATION ENVIRONMENT 6, all ACCESSIBLE PARTS shall be treated as APPLIED PARTS (the entire MEDICAL BED).

### 201.5 General requirements for testing of ME EQUIPMENT

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 5 applies, except as follows:

#### 201.5.9.2 ACCESSIBLE PARTS

*Addition:*

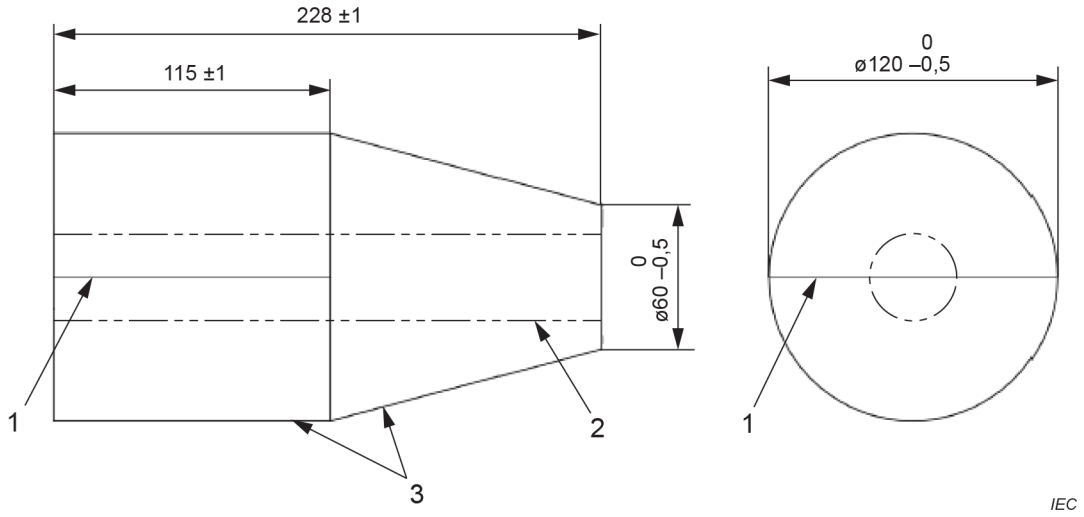
NOTE For APPLICATION ENVIRONMENT 6, accessibility of parts considers the use of specialty or safety fasteners and robustness of ENCLOSURE material to prevent access or removal of parts (see 201.15.4.104).

*Additional subclauses:*

#### 201.5.101 * Entrapment test tools

Figure 201.104 a) and b) illustrate entrapment test TOOLS (a cone TOOL and a cylinder TOOL respectively).

Dimensions in millimeters




**Key**

1 Marked centre line

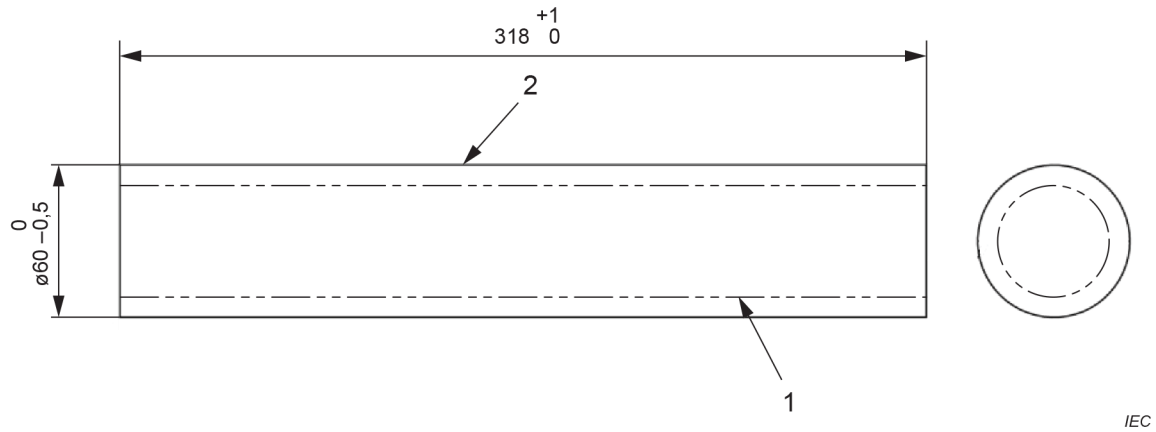
2 Drilling hole for weight adjustment, if necessary

Total weight 5,13 kg ±0,05 kg

3 The surface roughness of the TOOL is less than or equal to 1,6 µm

**a) Cone tool schematic**

Dimensions in millimeters




**Key**

1 Drilling hole for weight adjustment, if necessary

Total weight 3,34 kg ±0,05 kg

2 The surface roughness of the TOOL is less than or equal to 1,6 µm

**b) Cylinder tool schematic**

**Figure 201.104 – Entrapment test tools**

### 201.5.102 Loading pad

The loading pad (see Figure 201.105) is a rigid circular object, 355 ± 5 mm in diameter, the face of which has a convex spherical curvature of 800 mm radius ± 5 mm (R800) with a 20 ± 5 mm (R20) front edge radius.

Dimensions in millimeters

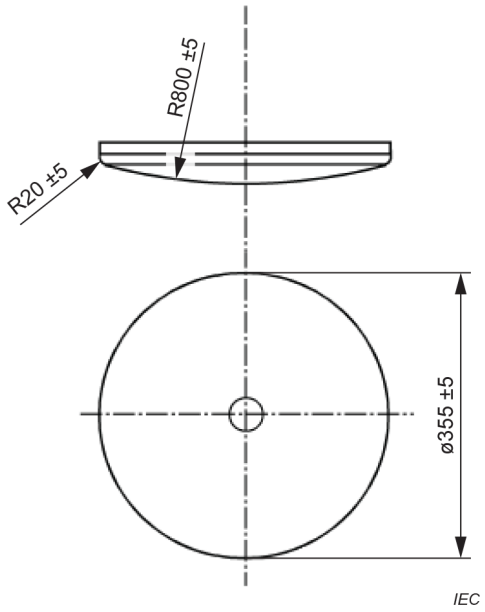
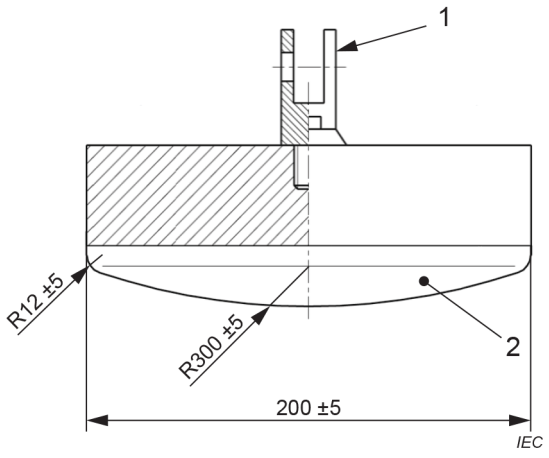



**Figure 201.105 – Loading pad**

### 201.5.103 *Impactor

The impactor body is 200 ± 5 mm in diameter and is mounted to the striking surface. The total mass of the assembly shall be 25 kg ± 0,1 kg.

The striking surface shall be a rigid circular object, 200 ± 5 mm in diameter, the face of which has a convex spherical curvature of 300 ± 5 mm radius (R300) with a 12 ± 5 mm (R12) front edge radius.



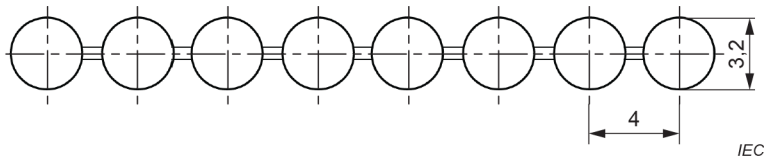

**Key**

1 Connecting part of the lifting device which shall not restrain the free fall

2 Striking surface

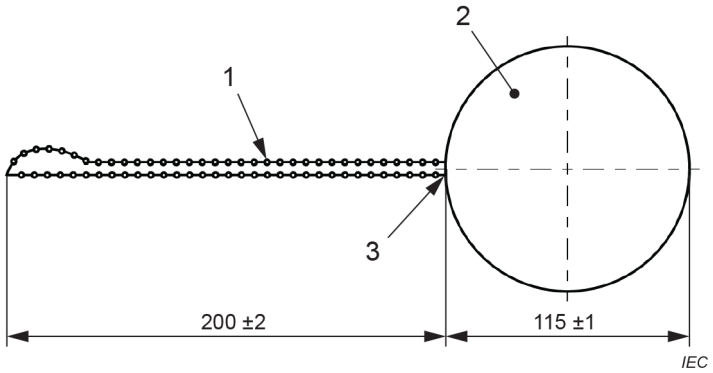
**Figure 201.106 – Impactor**

Dimensions in millimetres




**a) Ball chain**

Dimensions in millimetres




**Key**

1 Ball chain loop with a length of 200 ± 2 mm

2 Spherical mass, weight 2,5 ± 0,05 kg and diameter 115 ± 1 mm

3 Fixing point

NOTE The ball chain loop is formed by the ball chain entering the spherical mass at a common fixing point.

**b) Ball chain loop and spherical mass**

**Figure 201.107 – Ball chain loop and spherical mass**

## 201.6 Classification of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 6 applies, except as follows:

### 201.6.2 * Protection against electric shock

*Addition:*

For APPLICATION ENVIRONMENT 4, the MEDICAL BED shall be CLASS II.

## 201.7 ME EQUIPMENT identification, marking and documents

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 7 applies, except as follows:

### 201.7.2.2 Identification

*Replacement of the first paragraph:*

The MEDICAL BED shall be marked with the name or trademark and address of the MANUFACTURER, MODEL or TYPE REFERENCE and means to allow traceability.

The detachable components shall be marked with the name or trademark and address of the MANUFACTURER, MODEL or TYPE REFERENCE and means to allow traceability unless mis-identification does not present an unacceptable RISK.

*Additional subclauses:*

**201.7.2.2.101 * Marking of maximum PATIENT weight and SAFE WORKING LOAD**

j) The MEDICAL BED shall be marked with the corresponding maximum PATIENT weight (see 201.9.8.3.1) and SAFE WORKING LOAD (for symbol see Figure 201.108).

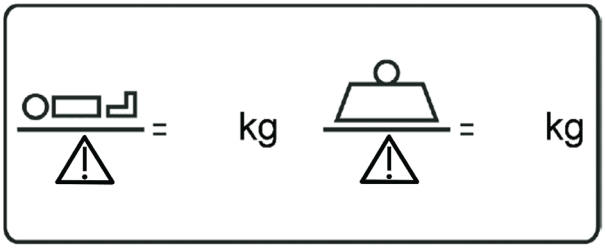



**Figure 201.108 – Graphic symbol for maximum PATIENT weight and SAFE WORKING LOAD**

k) Detachable parts of a MEDICAL BED of a mass of more than 20 kg shall be marked with the symbol, including the actual mass, at least in kg, as in Figure 201.109.




SOURCE: Symbol ISO 7000-1321B (2014-08).

**Figure 201.109 – Graphic symbol for mass; weight**

**201.7.2.2.102 Marking for MEDICAL BED washing systems**

a) MEDICAL BEDS intended for use with an automatic washing system shall be marked with the following text to distinguish them from MEDICAL BEDS which cannot tolerate such cleaning methods: "For cleaning purposes, this bed can be used with automatic washing systems." or be marked with the corresponding symbol (see Figure 201.110).



SOURCE: Symbol ISO 7000-3897 (2022-06).

**Figure 201.110 – Graphic symbol for machine washable MEDICAL BED**

b) MEDICAL BEDS intended for use with jet stream washing shall be marked with the following text: "For cleaning purposes this bed can be used with jet stream washing." or be marked with the corresponding symbol (see Figure 201.111)



SOURCE: Symbol ISO 7000-3890 (2022-03).

**Figure 201.111 – Graphic symbol for jet stream washable MEDICAL BED**

c) MEDICAL BEDS which are limited to only manual wipe down methods, shall be marked with suitable cautionary text or symbol ISO 7000-0423 (2004-01), see Figure 201.112.



SOURCE: Symbol ISO 7000-0423 (2004-01).

**Figure 201.112 – Graphic symbol for manual cleaning only**

d) For all other wash systems, the MANUFACTURER shall mark the MEDICAL BED with suitable cautionary text or the appropriate symbol.

#### 201.7.2.2.103 Width of carriage of BED-LIFT

If a BED-LIFT has an adjustable-width carriage, the range shall be marked, e.g. a by a linear measurement indicator fixed to the adjustable parts.

#### 201.7.2.2.104 * Marking of replacement mattresses

MEDICAL BEDS designed to have replacement mattresses shall be marked with:

– the general warning sign ISO 7010:W001 (2011-05) (See Table D.2, safety sign 2 in the IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) placed together with the text: "Incompatible mattresses can create HAZARDS. Read instructions for use" or

– a symbol as appropriate on a prominent place on the MATTRESS SUPPORT PLATFORM indicating the compatible mattresses (see example in Figure AA.1).

#### 201.7.2.2.105 * Marking of detachable SIDE RAILS

MEDICAL BEDS designed to have detachable SIDE RAILS shall be marked with:

– the general warning sign ISO 7010-W001 (2011-05) (See Table D.2, safety sign 2 in the IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) placed together with the text: "Incompatible SIDE RAILS can create HAZARDS. Read instructions for use" or

– a symbol as appropriate on a prominent place near the attachment point of the SIDE RAIL, indicating the compatible SIDE RAILS (see example in Figure AA.2).

#### 201.7.2.2.106 Marking on the MEDICAL BED for PATIENTS

The MEDICAL BEDS shall be marked on a prominent place with the symbol including displaying the minimum values for intended PATIENT indicated in Figure 201.113.

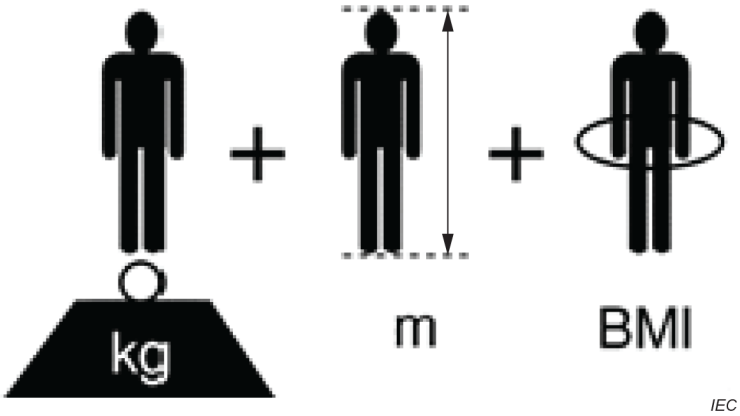



**Figure 201.113 – Physical description of PATIENT**

#### 201.7.2.2.107 * Marking on the MEDICAL BED for PENDANT CONTROL STORAGE

MEDICAL BEDS intended for APPLICATION ENVIRONMENT 6 shall be marked at the designated location of storage of the PENDANT CONTROL.

NOTE See Annex AA for examples of this marking.

#### 201.7.2.4 ACCESSORIES

*Addition:*

Where an overload on an ACCESSORY that is intended to support loads can create an unacceptable RISK, the corresponding part of the SAFE WORKING LOAD shall be marked on the ACCESSORY.

*Compliance is checked by inspection.*

#### 201.7.4.2 Control devices

*Addition:*

Where reliance to prevent unintended movement of the MATTRESS SUPPORT PLATFORM is based on a MOTION LOCKOUT CONTROL which requires activation by the OPERATOR, this shall be disclosed by markings or symbols as appropriate on the outside of the MEDICAL BED and which are visible from a position of NORMAL USE (see examples in Figure 201.114).

NOTE Example: "Engage the MOTION LOCKOUT CONTROL if a PATIENT could be injured due to inadvertent motion of the MATTRESS SUPPORT PLATFORM."

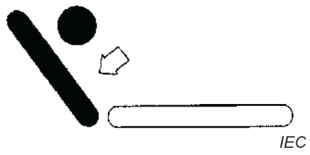
*Compliance is checked by inspection of the MEDICAL BED.*

### 201.7.6.3 Symbols for controls and performance

*Addition:*

Controls or indicators or both, when possible, shall be marked using symbols that convey the intended function of those controls or indicators without the need for additional text.

NOTE Figure 201.114 is intended as a guideline when designing these symbols. In all cases where standard international symbols exist, they can be used.




**Back section down function**



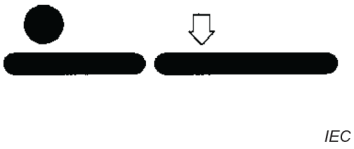

**Back section up function**




**Leg down function**




**Leg up function**



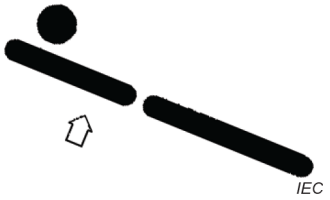

**MATTRESS SUPPORT PLATFORM down**




**MATTRESS SUPPORT PLATFORM up**




**TRENDELENBURG or HEAD DOWN TILT or both**




**FOOT DOWN TILT**




SOURCE: 60417-5570 (2002-10)

**Unlocked padlock-symbol for MOTION LOCKOUT CONTROL**




SOURCE: 60417-5569 (2005-08)

**Locked padlock-symbol for MOTION LOCKOUT CONTROL**

**Figure 201.114 – MEDICAL BED function controls or actuators or both: guidelines for creating graphic symbols**

### 201.7.9.2 Instructions for use

#### 201.7.9.2.1 General

*Addition:*

The instructions for use shall include:

a) a description according to 201.3 of the intended APPLICATION ENVIRONMENT(S);

b) the maximum PATIENT weight and SAFE WORKING LOAD;

c) an explanation of how to deactivate any MEDICAL BED function if movement caused by that function could cause injury to the PATIENT;

d) the result of the measurement of audible acoustic energy measured in accordance with 201.9.6.2.1;

e) the description of the intended PATIENT group(s).

#### 201.7.9.2.2 Warning and safety notices

*Addition:*

The instructions for use shall provide

a) a warning that the MEDICAL BED should be left in its lowest position when the PATIENT is unattended in order to reduce RISK of injury due to falls.

b) a warning on HAZARDS caused by inappropriate handling of the POWER SUPPLY CORD, e.g. by kinking, shearing or other mechanical damages.

c) a warning, stating that when routing cables from other equipment in the MEDICAL BED, precautions shall be taken to avoid squeezing those between parts of the MEDICAL BED.

d) a warning if a MEDICAL BED shall only be used with certain hoists, because of the limited space underneath the MEDICAL BED (see BB.3.2).

e) a warning if a MEDICAL BED is limited to a specific group of PATIENTS.

f) a warning that incompatible SIDE RAILS and mattresses can cause an entrapment HAZARD.

g) a warning that equipment in close proximity or attached to the MEDICAL BED can cause a HAZARD, e.g. entrapment or tipping over.

h) for MEDICAL BEDS intended for use in APPLICATION ENVIRONMENT 6, a warning that the PENDANT control, and its cable if applicable, shall be stored in a secured location out of reach of the PATIENT when not in use.

i) a warning if the MEDICAL BED is not intended to be used for transportation of a PATIENT outside of the facility.

NOTE 1 Would not apply for products compliant with IEC 60601-1-12.

NOTE 2 Professional healthcare facilities include hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, first aid rooms or rescue rooms and multiple treatment facilities.

j) a warning that the use of MATTRESS OVERLAY can cause RISKS for suffocation, entrapment, stability, and effective SIDE RAIL height.

#### 201.7.9.2.5 ME EQUIPMENT description

*Additional subclauses:*

#### 201.7.9.2.5.101 Selection of mattress

The instructions for use shall contain information on the selection of mattress(es), including mattress dimensions and mattress characteristics (e.g. to reduce the RISK of entrapment and falls (see also 201.7.2.2.104)).

#### 201.7.9.2.5.102 Selection of SIDE RAILS

The instructions for use shall contain information on the selection of SIDE RAILS, including SIDE RAIL dimensions and SIDE RAIL characteristics (e.g. to reduce the RISK of entrapment and falls (see also 201.7.2.2.105)).

#### 201.7.9.2.5.103 * Angles and height of MEDICAL BED

The instructions for use shall identify the maximum angles for A, B and D (Figure BB.2), HEAD DOWN TILT (Figure 201.102) and FOOT DOWN TILT (Figure 201.103) which can be achieved in NORMAL USE by each part of the MATTRESS SUPPORT PLATFORM with reference to horizontal. They shall also identify the maximum and minimum heights from the floor which can be achieved by the MATTRESS SUPPORT PLATFORM in NORMAL USE. They shall also identify any emergency position(s) and the controls by which such position(s) are obtained.

#### 201.7.9.2.5.104 * Maximum mass of MEDICAL BED

The instructions for use shall identify the maximum mass (in kg) of the MEDICAL BED. If the MEDICAL BED is intended to be disassembled into parts, the maximum mass (in kg) of any parts shall be stated in the instructions for use.

### 201.7.9.2.13 Maintenance

*Replacement:*

The instruction for use shall instruct the OPERATOR or RESPONSIBLE ORGANIZATION in sufficient detail concerning preventive inspection, maintenance and calibration to be performed by them, including the frequency of such maintenance.

The instruction for use shall provide information for the safe performance of such routine maintenance necessary to ensure the continued safe use of the MEDICAL BED.

Additionally, the instructions for use shall identify the parts on which preventive inspection and maintenance shall be performed by SERVICE PERSONNEL, including the periods to be applied and details about the actual performance of such maintenance.

For MEDICAL BEDS containing rechargeable batteries that are intended to be maintained by anyone other than SERVICE PERSONNEL, the instruction for use shall contain instructions to ensure adequate maintenance.

NOTE Additional information regarding periodic inspections can be found in Annex DD.

## 201.8 Protection against electrical HAZARDS from ME EQUIPMENT

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 8 applies, except as follows:

### 201.8.11.2 MULTIPLE SOCKET-OUTLETS

*Addition:*

For APPLICATION ENVIRONMENT 6, if MULTIPLE SOCKET-OUTLETS are supplied, they shall be out of reach of the PATIENT, e.g. in a lockable box.

#### 201.8.11.3.2 * Types

*Replacement:*

For APPLICATION ENVIRONMENTS 1 through 5 POWER SUPPLY CORDS shall be a minimum of 2,5 m measured from the plug to the outside perimeter of the MEDICAL BED.

For APPLICATION ENVIRONMENT 6 any POWER SUPPLY CORDS shall be as short as possible, or other means shall be used (e.g. lockable box, detachable cord) in order to minimize the RISK of strangulation. This shall be part of the RISK ANALYSIS of the MANUFACTURER. If the MEDICAL BED is intended for additional APPLICATION ENVIRONMENT(S), except 4, the requirements of APPLICATION ENVIRONMENT 6 shall apply.

POWER SUPPLY CORDS and other external flexible mains cables and cords on MEDICAL BEDS shall be medium or heavy-duty use rating. Light-duty cords are not adequate.

NOTE See subclause within Annex AA with examples of cord types. This list is not an all-inclusive list and other types can exist with appropriate robustness.

A polyvinyl chloride insulated POWER SUPPLY CORD shall not be used for MEDICAL BED having external metal parts with a temperature exceeding 75 °C and which can be in contact with the POWER SUPPLY CORD in NORMAL USE conditions, unless it is RATED for that temperature.

POWER SUPPLY CORDS shall be equipped with appropriate strain relief and bend protection. POWER SUPPLY CORD sets shall have a moulded-on plug or other means to withstand the ingress of water during the cleaning PROCESS for which the MEDICAL BED is intended.

The MEDICAL BED shall be equipped with a means to keep the POWER SUPPLY CORD clear of any moving MEDICAL BED part or mechanism, when the MEDICAL BED is in use, transport or not in use to avoid a damage of the POWER SUPPLY CORD.

POWER SUPPLY CORDS shall be adequately protected against damages from contact with moving part(s) or from friction at sharp corners and edges within the MEDICAL BED.

*Compliance is checked by inspection.*

## 201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, Clause 9 except as follows:

NOTE SIDE RAILS are not required on MEDICAL BEDS. Clauses including SIDE RAIL requirements are only applicable if SIDE RAILS are provided.

### 201.9.1 * MECHANICAL HAZARDS of ME EQUIPMENT

*Additional subclauses:*

#### 201.9.1.101 * Protection against PATIENT entrapment in non-moving parts

Any openings or areas ($A_1$, $A_2$, $A_3$, $A_4$, $A_5$, $A_6$, B, C and D) within the MEDICAL BED system and which are above the MATTRESS SUPPORT PLATFORM shall meet the dimensional and constructional requirements of Figure 201.115, Figure 201.116 and Table 201.101. Where a RISK of PATIENT entrapment exists and is addressed in another way, this shall be justified by the MANUFACTURER in the RISK MANAGEMENT FILE.

For APPLICATION ENVIRONMENT 6 any opening or area under the MATTRESS SUPPORT PLATFORM with regards to PATIENT ENTRAPMENT shall meet the applicable dimensional and constructional requirements of Figure 201.115, Figure 201.116 and Table 201.101.

*Compliance is checked before and after application of the SIDE RAIL strength and latch reliability tests (see 201.9.8.3.3.103).*

*Compliance is checked with the MATTRESS SUPPORT PLATFORM in the flat position unless otherwise noted as indicated in Table 201.101. The test shall be performed with the SIDE RAIL in all raised and locked positions.*

All the tests are performed without the mattress except the test for dimension *D*. For requirements involving dimension *D*, all mattresses as specified (type and MANUFACTURER or mattress dimensions and characteristics) by the MANUFACTURER are evaluated including SPECIALTY MATTRESS. If a SPECIALTY MATTRESS does not comply with dimension *D*, a RISK ASSESSMENT shall be performed.

A RISK ASSESSMENT shall be performed to evaluate:

– SPECIALTY MATTRESSES;

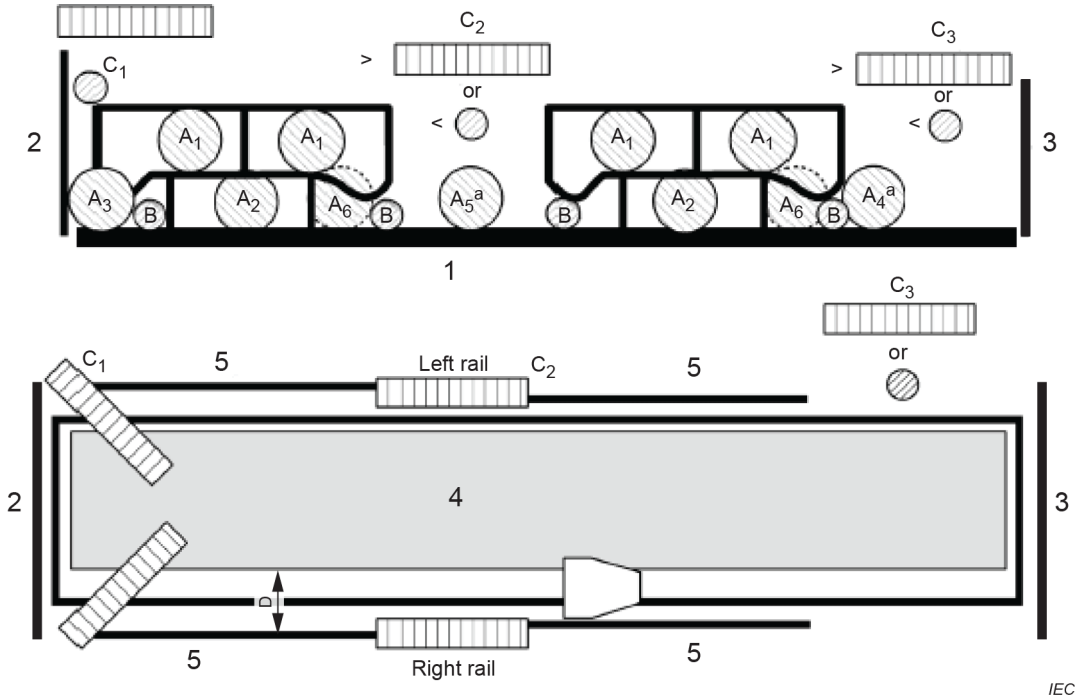
– MATTRESS OVERLAYS, e.g. PATIENT being trapped between mattresses and MATTRESS OVERLAY;

– asphyxiation, e.g. face pressed against a non-air permeable flexible surface;

– ACCESSORIES;

– articulated MATTRESS SUPPORT PLATFORM positions.

*Compliance is checked by the following tests in Table 201.101 and inspection of the RISK MANAGEMENT FILE.*




**Key**

1 MATTRESS SUPPORT PLATFORM

2 HEAD BOARD

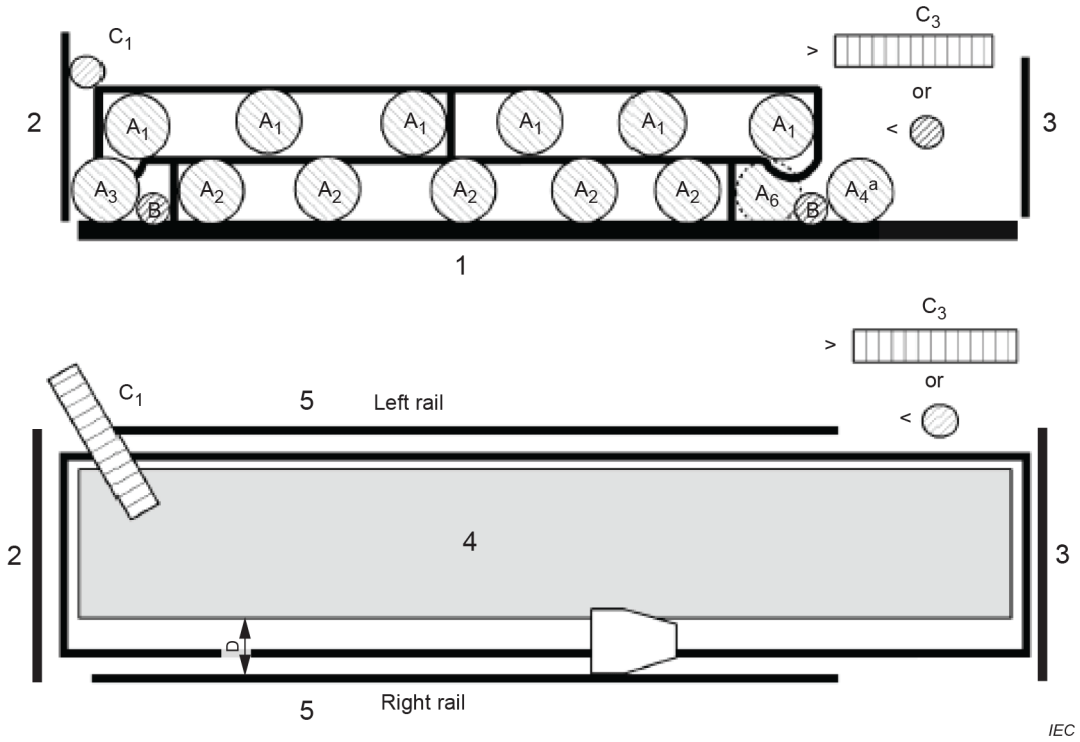
3 FOOT BOARD

4 Mattress

5 SIDE RAIL

[a] Only applies when the area C above is < 60 mm.

**Figure 201.115 – Example of MEDICAL BED with segmented or split SIDE RAIL**




**Key**

1 MATTRESS SUPPORT PLATFORM

2 HEAD BOARD

3 FOOT BOARD

4 Mattress

5 SIDE RAIL

[a] Only applies when the area C above is < 60 mm.

**Figure 201.116 – Example of MEDICAL BED with single piece SIDE RAIL**

**Table 201.101 – Protection against PATIENT entrapment**

| Area | Description | Requirement and compliance method |
|---|---|---|
| $A_1$ | Fully enclosed openings within a SIDE RAIL, HEAD BOARD or FOOT BOARD | The gap is specified to be less than 120 mm as defined by the following test.<br>*Compliance is checked by the following test:*<br>*Except for $A_3$ articulate the MEDICAL BED and find the largest opening. Insert 60 mm diameter part of cone TOOL (see Subfigure a) of Figure 201.104, See Figure 201.115 and Figure 201.116) through opening from inside of the MEDICAL BED system. Bring cone TOOL to bear on opening of interest. Exert 250 N force applied to 60 mm cylindrical end of cone TOOL in the most disadvantageous direction.*<br>*Acceptance criterion: The opening shall not allow 120 mm diameter part of the cone TOOL to enter and pass through.* |
| $A_2$ | Fully enclosed opening defined by the SIDE RAIL, its supports, and the MATTRESS SUPPORT PLATFORM | |
| $A_3$ | Partially enclosed opening defined by the HEADBOARD, MATTRESS SUPPORT PLATFORM, and SIDE RAIL | |
| $A_4$ | Partially enclosed opening defined by the FOOT BOARD, MATTRESS SUPPORT PLATFORM, and SIDE RAIL (except where the gap between the SIDE RAIL and the FOOT BOARD > 318 mm) | |
| $A_5$ | Partially enclosed opening between segmented or split SIDE RAILS and the MATTRESS SUPPORT PLATFORM (except where the gap between the SIDE RAILS is > 318 mm) | |
| $A_6$ | Partially enclosed opening defined by the lowest point of a SIDE RAIL, the adjacent SIDE RAIL support, and MATTRESS SUPPORT PLATFORM, to the outside of the SIDE RAIL supports. | |
| A | Other opening(s) defined by ACCESSORIES (e.g. IV poles, fracture frames) and SIDE RAILS, HEAD BOARD, FOOT BOARD, and MATTRESS SUPPORT PLATFORM. This is not in Figure 201.115 and Figure 201.116 as it depends on the position of ACCESSORIES and construction of the MEDICAL BED. | |
| B | The distance between the MATTRESS SUPPORT PLATFORM and the lowest point of the SIDE RAIL outside of the SIDE RAIL support.<br>**AND**<br>The angle between SIDE RAIL and the MATTRESS SUPPORT PLATFORM at the range of the mattress height defined by the MANUFACTURER ± 20 mm.<br>NOTE 1 ± 20 mm takes into account the mattress compression and the height of the neck above the mattress. | *The gap is specified to be less than 40 mm.*<br>*Compliance is checked by using the cylinder TOOL (see* Figure 201.104*b) to confirm the Gap < 60 mm.*<br>***AND***<br>*Angle between MATTRESS SUPPORT PLATFORM and the SIDE RAIL interface > 60° over the entire range of mattress heights from the minimum recommended mattress height, minus 20 mm to the maximum recommended mattress height, plus 20 mm.*<br>NOTE 2 The RISK MANAGEMENT addresses the possibility of the use of a mattress not specified by the MANUFACTURER.<br>The RISK MANAGEMENT to address the entrapment condition of area B (as illustrated in Figure AA.14) should be performed, taking the following into consideration:<br>– The SIDE RAIL shape and geometry.<br>– The distance between the lowest point of the SIDE RAIL and the MATTRESS SUPPORT PLATFORM.<br>– The mattress material properties.<br>– The mattress dimensions.<br>– The fit relationship between the SIDE RAIL, mattress and MATTRESS SUPPORT PLATFORM.<br>*Compliance is checked by inspection of the RISK MANAGEMENT FILE.*<br>*See also Annex AA and Annex CC for further information.* |

| Area | Description | Requirement and compliance method |
|---|---|---|
| $C_1$ | Gap between the HEAD BOARD and adjacent SIDE RAIL. | For APPLICATION ENVIRONMENTS 2 through 6, the gap between the HEAD BOARD and adjacent SIDE RAIL is required to be < 60 mm.<br>For APPLICATION ENVIRONMENT 1, the gap between the HEAD BOARD and adjacent SIDE RAIL is required to be < 60 mm or > 318 mm. See 201.9.101 for falls HAZARD.<br>NOTE Evaluation of the gap considers any ACCESSORIES placed in gap being evaluated.<br>*Compliance for a gap < 60 mm is checked by the following test:*<br>*The cylinder TOOL (see Subfigure b) Figure 201.104) shall be oriented parallel to floor, in the most disadvantageous angle in the horizontal plane above the gap. The 60 mm cylinder TOOL shall rest with the full weight on the gap where the cylinder TOOL intersects. Extra vertical force shall not be used. The cylinder TOOL shall not be used to pry apart parts of the MEDICAL BED.*<br>*Acceptance criteria:*<br>*The 60 mm cylinder TOOL shall not slide into the opening. See Annex AA and Annex CC for further clarification.*<br>***OR***<br>*Compliance for a gap > 318 mm is checked by the following test:*<br>*The cylinder TOOL (see Figure 201.104b) shall be oriented in the line between the two closest points in the gap.*<br>*Acceptance criterion:*<br>*The entire gap shall be > 318 mm.*<br>*See also Annex AA and Annex CC for further information.* |
| $C_2$ | Gap between segmented or split SIDE RAILS with both SIDE RAILS raised. | The gap between segmented or split SIDE RAILS with both SIDE RAILS raised is required to be < 60 mm **or** > 318 mm.<br>NOTE Evaluation of the gap considers any ACCESSORIES placed in gap being evaluated.<br>*Compliance for a gap < 60 mm is checked by the following test:*<br>*The cylinder TOOL (see Figure 201.104b) shall be oriented parallel to floor, in the most disadvantageous angle in the horizontal plane above the gap. The 60 mm cylinder TOOL shall rest with the full weight on the gap where the cylinder intersects. Extra vertical force shall not be used. The cylinder TOOL shall not be used to pry apart parts of the MEDICAL BED.*<br>*For MEDICAL BED with split SIDE RAILS, articulate the MATTRESS SUPPORT PLATFORM to identify the worst case opening between the SIDE RAILS and perform the test.*<br>*Acceptance criteria:*<br>*The 60 mm cylinder TOOL shall not slide into the opening. See Annex AA and Annex CC for further clarification.*<br>***OR***<br>*For a gap > 318 mm:*<br>*The cylinder TOOL (see Figure 201.104b) shall be oriented in the line between the two closest points in the gap.*<br>*Acceptance criterion:*<br>*The entire gap shall be > 318 mm.*<br>*See Annex AA and Annex CC for further information.* |

| Area | Description | Requirement and compliance method |
|---|---|---|
| $C_3$ | Gap between SIDE RAIL and FOOT BOARD. | The gap between SIDE RAIL and FOOT BOARD is required to be < 60 mm **OR** > 318 mm.<br>NOTE Evaluation of the gap considers any ACCESSORIES placed in gap being evaluated.<br>*Compliance for a gap < 60 mm is checked by the following test:*<br>*The cylinder TOOL (see Figure 201.104b) shall be oriented parallel to floor, in the most disadvantageous angle in the horizontal plane above the gap. The 60 mm cylinder TOOL shall rest with the full weight on gap where the cylinder intersects. Extra vertical force shall not be used. The cylinder TOOL shall not be used to pry apart parts of the MEDICAL BED.*<br>*Acceptance criteria:*<br>*The 60 mm cylinder TOOL shall not slide into the opening. See Annex AA and Annex CC for further clarification.*<br>***OR***<br>*For a gap > 318 mm:*<br>*The cylinder TOOL (see Figure 201.104b) shall be oriented in the line between the two closest points in the gap.*<br>*Acceptance criterion:*<br>*The entire gap shall be > 318 mm.*<br>*See Annex AA and Annex CC for further information.* |
| D | Region defined between the SIDE RAIL and the mattress. | *Compliance is checked by the following test:*<br>*Push the mattress away from the SIDE RAIL being measured until the mattress retention system, or the opposing SIDE RAIL stops the mattress. Pull outward on the SIDE RAIL to remove any lateral play and during application of the force the cone TOOL (see Subfigure a) Figure 201.104) is placed with its longitudinal axis parallel to the SIDE RAIL, resting on the mattress in the horizontal gap between the SIDE RAIL and mattress. Turn the cone TOOL until the line on the face of the 120 mm diameter end is horizontal. Let the cone TOOL sink into the space by its own weight.*<br>*If a mattress retention system, SIDE RAIL support or other structure keeps the cone TOOL from sinking in the gap, the cone TOOL shall be placed at a different location along the SIDE RAIL where there is no interference.*<br>*Acceptance criteria:*<br>*The large end of the cone TOOL shall not sink below the mattress surface by 50 % or more of its 120 mm diameter.*<br>NOTE The gap between HEAD BOARD and MATTRESS SUPPORT PLATFORM is covered by the measurement of A (See designator A: other opening(s) defined by ACCESSORIES (e.g. IV poles, fracture frames) and SIDE RAILS, HEAD BOARDS, FOOT BOARDS, and MATTRESS SUPPORT PLATFORM. This is not in Figure 201.115 or Figure 201.116 as it depends on the construction of the MEDICAL BED) Gap between HEAD BOARD and top of mattress: The mattresses specified by the MANUFACTURER normally have no reasonable gaps between HEAD BOARD and top end of mattresses for a possible head entrapment. |

#### 201.9.1.102 Protection against strangulation

For APPLICATION ENVIRONMENT 6, strangulation HAZARD shall be considered in the RISK MANAGEMENT FILE.

*Compliance is checked by inspection of the RISK MANAGEMENT FILE.*

#### 201.9.2.2 Trapping zone

#### 201.9.2.2.1 General

*Addition:*

The entire region in the UNDERCARRIAGE shall be considered in the RISK ANALYSIS with regard to trapping HAZARDS due to height adjustment (high motion and low motion) e.g. scissor actions and V-shaped openings.

Special attention shall be made for APPLICATION ENVIRONMENT 6.

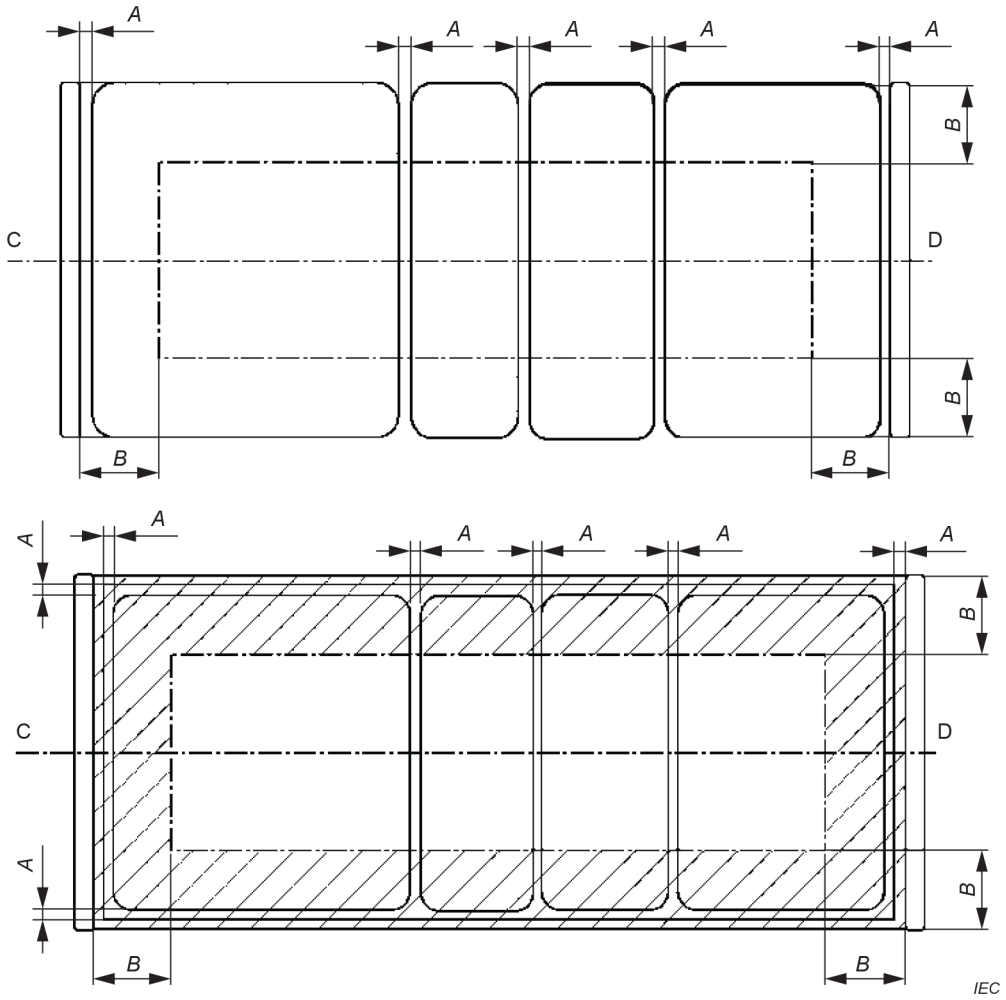
*Compliance is checked by inspection of the RISK MANAGEMENT FILE.*

#### 201.9.2.2.2 Gaps

*Amendment:*

The locations identified in Figure 201.117 and Figure 201.118 shall be considered as TRAPPING ZONES for fingers.

Distances between moving parts shall always be either less than 8 mm or more than 25 mm (as dimensioned in Figure 201.117). The 200 mm cross-hatched area represents the areas of normal reach around the perimeter of the MATTRESS SUPPORT PLATFORM. The 200 mm distance can be measured taking into account any barrier preventing access to fingers (see Figure 201.118). The SIDE RAILS, if provided, shall also be considered. The region within the APPLIED PART and above the MATTRESS SUPPORT PLATFORM shall be considered in the RISK ANALYSIS with regard to finger spacing between moving parts.




**Key**

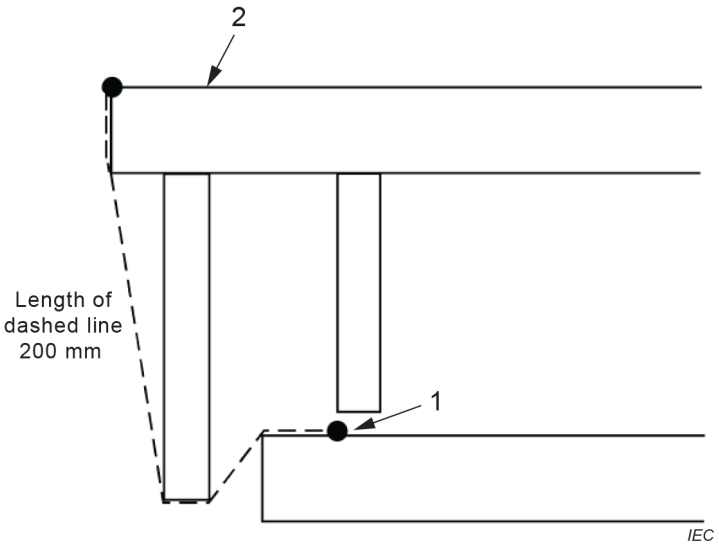
*A* Spacing between moving parts shall be less than 8 mm (non opening) or more than 25 mm

*B* Cross-hatched area representing entrapment reach zone for fingers 200 mm in from the outer edge

C HEAD BOARD

D FOOT BOARD

**Figure 201.117 – Allowable spacing for fingers in areas of normal reach around the perimeter of the MATTRESS SUPPORT PLATFORM**




**Key**

1 Pinch point (TRAPPING ZONE)

2 MATTRESS SUPPORT PLATFORM

**Figure 201.118 – Example using barriers for clearance measurement around the perimeter of the MATTRESS SUPPORT PLATFORM to mitigate PATIENT finger entrapment**

The locations identified in Figure 201.119 a) and b) shall be considered as TRAPPING ZONES for feet and toes. They only apply to gaps created between the floor and parts of the MEDICAL BED that are not free to move in the upward direction when the MEDICAL BED or its parts move in the downward direction.

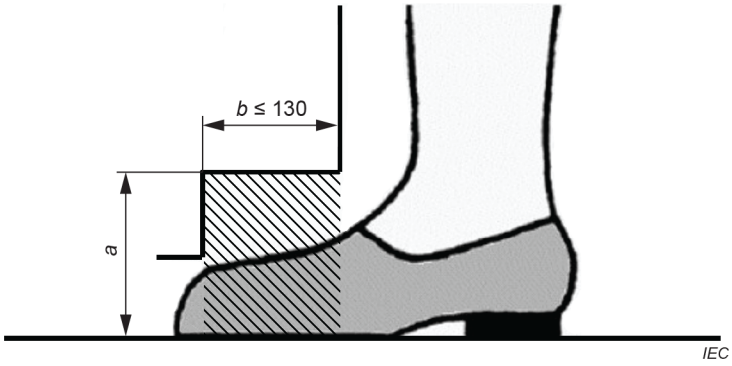
Additional mitigations shall be applied for MEDICAL BEDS reducing the gap below the number specified and documented in the RISK MANAGEMENT FILE. The instruction for use shall document the actions necessary to achieve the reduced gap and warn the user about the HAZARDS caused by this function.

NOTE A SIDE RAIL, while in an unlocked position, is an example of a MEDICAL BED part that can be designed in such a way that allows it to move in the upward direction when the MEDICAL BED or its parts move in the downward direction.

*Compliance is checked by the following test:*

*The part of the MEDICAL BED shall be driven downward at maximum speed, such as dropping the SIDE RAIL from its raised position or driving the MEDICAL BED to which the part is attached downward at maximum speed. The total load imposed on the foot or toe shall not be greater than the total mass of the descending part(s) plus 50 N.*

Dimensions in millimeters

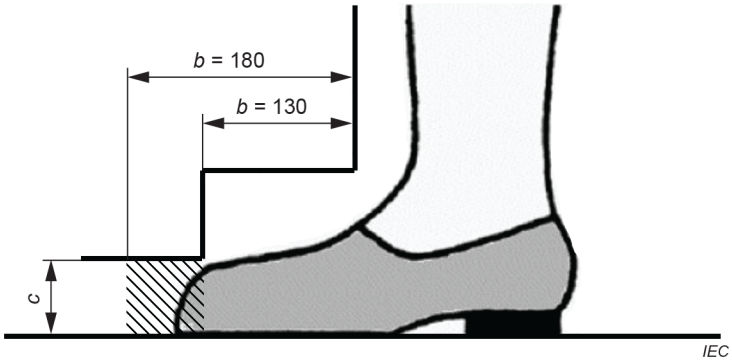



For area where $b \leq 130$ mm, $a$ shall always be $\geq 120$ mm.

NOTE The dimension "*a*" is only measured from the floor. The dimension "*b*" is measured from the outer edge of the MEDICAL BED. Including any permanently fixed ACCESSORIES (e.g. SIDE RAIL), if applicable.

**a) Foot clearance area between moving parts and the floor**

Dimensions in millimeters




For area where $b$ is between 130 mm to 180 mm, $c$ shall always be $\geq 50$ mm.

NOTE The dimension "*c*" is only measured from the floor. The dimension "*b*" is measured from the outer edge of the MEDICAL BED. Including any permanently fixed ACCESSORIES (e.g. SIDE RAIL), if applicable.

**b) Toe clearance area between moving parts and the floor**

**Figure 201.119 – Clearance areas**

Measurements shall be done in the most disadvantageous condition for Figure 201.117, Figure 201.118 and Subfigures a) and b) of Figure 201.119.

### 201.9.2.2.3 Safe distances

*Addition:*

For the reach of a hand the safe distance is 200 mm for the PATIENT lying in the MEDICAL BED (see Figure 201.117 and Figure 201.118).

#### 201.9.2.2.5 Continuous activation

*Replacement of item b):*

b) all movement of the MEDICAL BED or its parts is possible only by the activation of control device(s) which initiate and maintain operation of the MEDICAL BED elements only as long as the manual control is actuated and where the manual control automatically returns to the 'Stop' or 'Off' position when released.

NOTE Manually and foot-operated movements are considered to comply with this clause, as long as mass and velocity allow adequate control of positioning without causing an unacceptable RISK.

*Compliance is checked by inspection and functional tests.*

#### 201.9.2.3.1 * Unintended movement

*Addition:*

Except for emergency MEDICAL BED movements specified by the MANUFACTURER, the means to deactivate the MEDICAL BED movement (such as those in PENDANT CONTROL and SIDE RAIL function controls intended to be activated to the PATIENT, OPERATOR, or visitor) shall be designed such that it cannot be accidentally re-activated by the PATIENT when the PATIENT is in the MEDICAL BED.

*Compliance is checked by inspection.*

Foot operated controls shall be designed to prevent accidental activation.

If the MEDICAL BED design cannot exclude trapping or crushing there shall be a means to deactivate any foot-operated controls used for any MEDICAL BED movement which is not manually operated. The control shall deactivate without OPERATOR action after use. Consideration shall be given to unintended activation by the PATIENT or other persons crawling under the MEDICAL BED or by objects used in close proximity.

If means for the foot-operated MEDICAL BED movement are provided, the means to deactivate foot-operated MEDICAL BED movement shall be located or designed such that a PATIENT cannot accidentally re-activate the functions, taking into account PATIENT mobility and medical supervision.

*Compliance is checked by inspection.*

*Addition:*

#### 201.9.3.101 Snagging HAZARDS

For MEDICAL BEDS intended for APPLICATION ENVIRONMENT 6, protruding parts accessible from inside or outside the MEDICAL BED shall be designed to avoid snagging of clothing or cords around or close to the PATIENT'S neck. This is particularly important where a PATIENT will spend time in the MEDICAL BED unattended by the carer.

Holes, gaps and similar openings shall be designed to avoid snagging of clothing, buttons, decorations and similar parts around or close to the PATIENT'S neck.

Where a RISK of snagging HAZARDS from ACCESSORIES (e.g. IV poles, LIFTING POLES) as specified by the MANUFACTURER is addressed in another way this shall be justified by the MANUFACTURER in the RISK MANAGEMENT FILE

*Compliance is checked by inspection of the RISK MANAGEMENT FILE and using the ball chain loop and spherical mass in Figure 201.107.*

*Hold the spherical mass in one hand only allowing the loop to hang freely over the product, move the spherical mass along and around the product so that the loop is draped or dragged over and across any protruding parts and if the ball chain loop is retained by a protruding part slowly lower the spherical mass, see Figure 201.120 (below). Place MATTRESS SUPPORT PLATFORM in its flat and horizontal position (RISK ASSESSMENT is used to evaluate articulated MATTRESS SUPPORT PLATFORM positions). For locations inside the MEDICAL BED, the test is performed without the mattress in place if removable without a TOOL.*

*Repeat the test for a total of 3 times. If during any of the 3 tests, the ball chain loop and spherical mass is retained by a protruding part, this is considered to be a failure.*

NOTE If the ball is supported by the MATTRESS SUPPORT PLATFORM, it is considered passing.

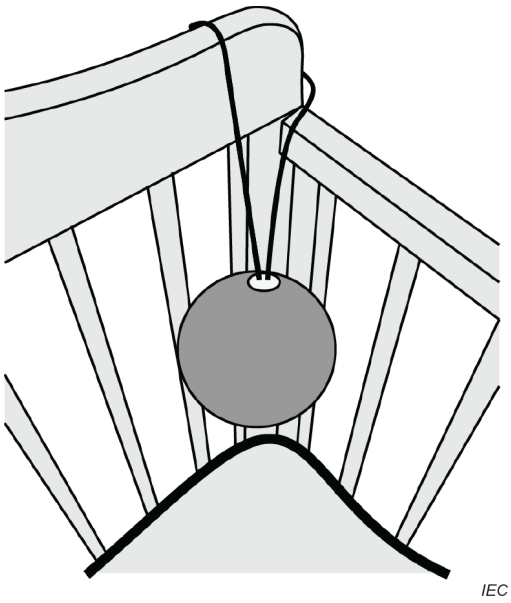



**Figure 201.120 – Retention of loop and mass**

### 201.9.4.2 Instability – overbalance

#### 201.9.4.2.1 * Instability in transport position

*Replacement:*

The MEDICAL BED shall not overbalance when placed in any transport position of NORMAL USE on a plane inclined at an angle of 6° from the horizontal plane.

NOTE The meaning of transport in this subclause is moving the MEDICAL BED from room to room during NORMAL USE.

*Compliance is checked by the following test:*

*Prior to the test the MEDICAL BED is prepared as indicated in the ACCOMPANYING DOCUMENTS (or, if not specified, as in 201.9.4.2.2). The MEDICAL BED or its parts is placed on a plane inclined at an angle of 6° from the horizontal plane. If the MEDICAL BED or its parts overbalances, it constitutes a failure.*

**201.9.4.2.2 * Instability excluding transport position**

*Replacement:*

The MEDICAL BED or its parts shall not overbalance when placed in any position of NORMAL USE, excluding any transport positions, on a plane inclined at an angle of 5° from the horizontal plane.

If the MEDICAL BED or its parts overbalances when placed in any position of NORMAL USE, excluding any transport positions, on a plane inclined at an angle of 6° from the horizontal plane, it shall carry a warning notice stating that transport should only be undertaken in a certain condition that shall be clearly described in the instructions for use or marked on the MEDICAL BED with an indication of the RESIDUAL RISK if the MEDICAL BED or its parts overbalances.

NOTE 1 For warning notice requirements, see 7.9.2.2.

*Compliance is checked by the following tests:*

*Prior to conducting the test, the MEDICAL BED is prepared as follows:*

*a) The MEDICAL BED is provided with all specified connection leads, the POWER SUPPLY CORD and any interconnecting cords. It is provided with the worst case combination of possible detachable parts, ACCESSORIES and loads (PATIENT and ACCESSORY) as specified in NORMAL USE.*

NOTE 2 The test considers both loaded and unloaded condition and variations in between for determining the worst case condition.

*b) A MEDICAL BED having an APPLIANCE INLET is provided with the specified detachable POWER SUPPLY CORD.*

*c) The connection leads are laid down on the inclined plane in the position most unfavourable for stability.*

*d) If castors or wheels are present, they are temporarily immobilized, if necessary by blocking, in their most disadvantageous position.*

*e) Doors, drawers, shelves and the like are placed in the most disadvantageous position and fully loaded or unloaded whichever represents "worst case" as specified in NORMAL USE according to the ACCOMPANYING DOCUMENTS.*

*f) MEDICAL BEDS having containers for liquids is tested with these containers completely or partly filled or empty, whichever is least favourable.*

*g) The MEDICAL BED is not connected to the SUPPLY MAINS.*

*h) If the MEDICAL BED has a bed extension, the tests shall be performed with the extension in place and fully extended.*

*The test floor surface shall be hard and flat (e.g. concrete floor covered with 2 mm to 4 mm thick vinyl flooring material).*

*The MEDICAL BED or the MEDICAL BED parts shall be placed on a plane inclined at an angle of 5° from the horizontal plane, or, if a warning notice is present, compliance is checked by inspection of the warning notice and the MEDICAL BED or its parts shall be placed on a plane inclined at an angle of 6° from the horizontal plane. If the MEDICAL BED or its parts overbalances, it constitutes a failure.*

When the following tests are performed, the MEDICAL BED shall not overbalance (tip over) with the height and length of the MATTRESS SUPPORT PLATFORM, castors, SIDE RAILS and other ACCESSORIES with their part of SAFE WORKING LOAD in their most adverse position of NORMAL USE, and the MEDICAL BED equipped with the lightest mattress as specified by the MANUFACTURER or a load representing the weight of the specified mattress that is uniformly distributed and centered on the MATTRESS SUPPORT PLATFORM.

*Compliance is checked by the following tests conducted with the MATTRESS SUPPORT PLATFORM in the flat and horizontal position. The MEDICAL BED is placed on a horizontal plane.*

– *Lateral stability test:*

*A load of 2 200 N is placed at the side edge of the MATTRESS SUPPORT PLATFORM and evenly distributed over an area 250 mm × 950 mm (see Figure 201.121).*

*If the maximum PATIENT load according to the MANUFACTURER exceeds 2 200 N, the maximum PATIENT load shall be used and is evenly distributed over an area 950 mm long and 250 mm wide (see Figure 201.121).*

*Perform the test at each corner of the MEDICAL BED.*

– *Longitudinal stability test:*

- *If the FOOT BOARDS are removable without the use of TOOLS:*

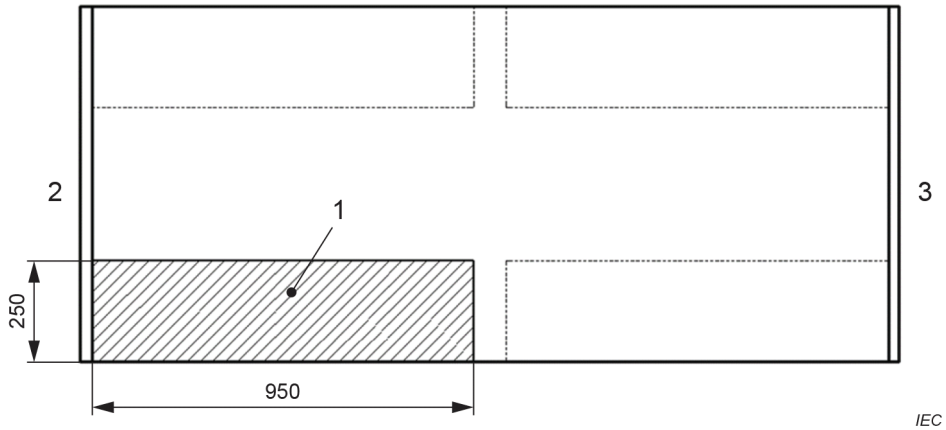
  *Remove the FOOT BOARD; a load of 2 200 N for APPLICATION ENVIRONMENTS 1, 2, 3, 5 and 6 and 1 850 N for APPLICATION ENVIRONMENT 4 is evenly distributed over an area of 250 mm across the full width of the MEDICAL BED (see Figure 201.122).*

  *If the maximum PATIENT load according to the MANUFACTURER exceeds 2 200 N (or 1 850 N for APPLICATION ENVIRONMENT 4), the maximum PATIENT load is to be used.*

- *If the HEAD BOARDS and FOOT BOARDS are permanently fixed or require the use of TOOLS to remove them:*

  *Two loads each of 1 100 N for APPLICATION ENVIRONMENTS 1, 2, 3, 5 and 6 and two loads each of 925 N for APPLICATION ENVIRONMENT 4 are at the same time evenly distributed over an area of 250 mm × 475 mm (Figure 201.123). Perform the test at both ends of the MEDICAL BED.*

Dimensions in millimeters




**Key**

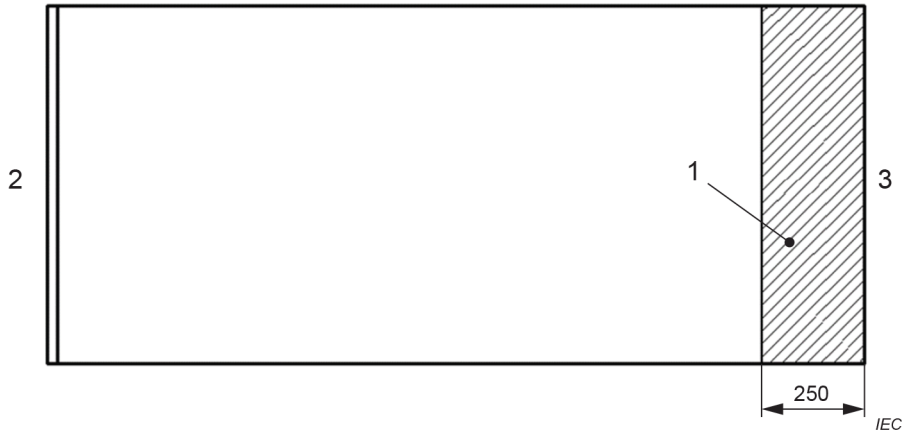
1 Load of 2 200 N evenly distributed or greater if maximum PATIENT load exceeds this.

2 HEAD BOARD

3 FOOT BOARD

**Figure 201.121 – Lateral stability test along the side of the MEDICAL BED**

Dimensions in millimeters




**Key**

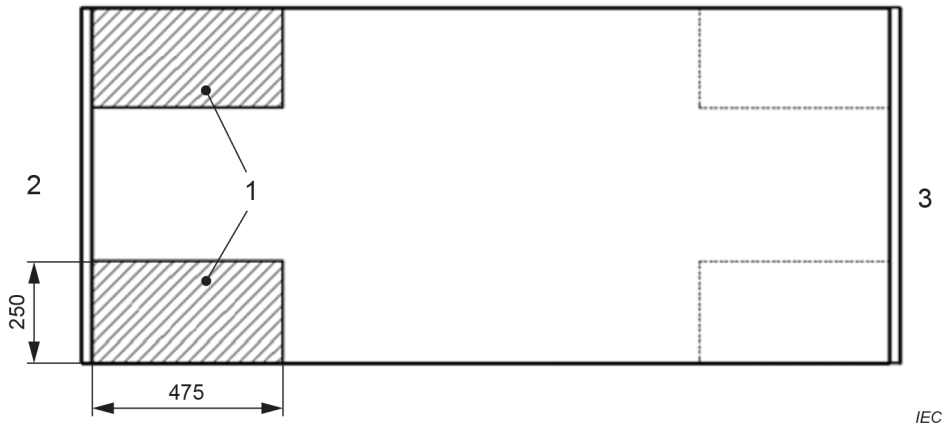
1 Load of 2 200 N, 1 850 N for APPLICATION ENVIRONMENT 4, evenly distributed, or greater if maximum PATIENT load exceeds this.

2 HEAD BOARD

3 FOOT BOARD removed

**Figure 201.122 – Longitudinal stability test with removable FOOT BOARD**

Dimensions in millimetres




**Key**

1 Two loads of 1 100 N, two loads of 925 N for APPLICATION ENVIRONMENT 4, evenly distributed

2 HEAD BOARD

3 FOOT BOARD

**Figure 201.123 – Longitudinal stability test with fixed HEAD BOARD and FOOT BOARD**

### 201.9.4.2.3 Instability from horizontal and vertical forces

*Replacement of item b):*

b) The MEDICAL BED shall not overbalance (tip over) due to sitting or stepping.

NOTE Requirements for PATIENT support surfaces are found in 201.9.8.3.

*Compliance is checked by inspection and by the following test:*

*The MEDICAL BED is placed on a horizontal plane and a constant downward force of 1 100 N is applied at the point of maximum moment to any working surface, excluding the MATTRESS SUPPORT PLATFORM, offering an obvious foothold or sitting surface of a minimum 200 mm by 200 mm area, and at a height not exceeding 1 m from the floor. Prior to the test the MEDICAL BED is prepared as described in 201.9.4.2.2.*

#### 201.9.4.2.4.2 Force for propulsion

*Addition:*

For MOBILE MEDICAL BEDS intended for PATIENT transport:

– perform the test with the MEDICAL BED with SAFE WORKING LOAD in place.

For MOBILE MEDICAL BEDS not intended for PATIENT transport:

– perform the test with the MEDICAL BED without SAFE WORKING LOAD in place.

For APPLICATION ENVIRONMENT 4, see BB.2.4.4 for additional test requirements.

#### 201.9.4.2.4.3 * Movement over a threshold

*Replacement:*

MOBILE MEDICAL BED intended to transport PATIENTS shall withstand the stresses caused by rough handling. The following threshold test shall be used.

This requirement does not apply to a MEDICAL BED specified by the MANUFACTURER only to be moved within the PATIENT room for cleaning or PATIENT access.

*Compliance is checked by the following test:*

*The SIDE RAILS are raised and latched, with all other ACCESSORIES intended for NORMAL USE during transport attached to the MEDICAL BED and with the SAFE WORKING LOAD in place and the height in the worst case position.*

*The MEDICAL BED shall be moved at a speed of 0,8 m/s ± 0,1 m/s, or for motor-driven MEDICAL BEDS for transportation, the maximum speed shall be used, while all castors shall impact and pass over an obstruction which is fixed flat on the floor, with a rectangular cross-section, 10 mm ± 0,5 mm high and 80 mm wide with a radius of 2 mm ± 0,1 mm at the top edges. The MEDICAL BED, with all castors, shall then be pulled back over the obstruction and back to the starting position of the test.*

*This is repeated 10 times.*

*Acceptance criteria for MOBILE and motor-driven MEDICAL BED:*

*The MEDICAL BED shall go over the obstruction. The MEDICAL BED shall not overbalance (tip over). The MEDICAL BED or MEDICAL BED parts shall not present an unacceptable RISK. Unacceptable RISK is determined by inspection of the MEDICAL BED, its parts, and relevant information from the RISK MANAGEMENT FILE.*

*At the end of the test, the MEDICAL BED, MEDICAL BEDS parts, ACCESSORIES shall present no loss of function, and without unlocking or unlatching of the SIDE RAILS, or physical deterioration, (e.g. deterioration of fixings, unlocking of ACCESSORIES if fixed on the MEDICAL BED (like SIDE RAILS), which can reduce the NORMAL USE or create a RISK like collapsing, or permanent deformation, modifying gap for entrapment or pinching etc).*

#### 201.9.4.3.1 * Instability in transport position

*Amendment:*

*Delete all of a)*

*Replacement of item c):*

c) MOBILE MEDICAL BED shall not result in an unacceptable RISK due to unwanted horizontal movement.

*Compliance is checked by the following test:*

*Prior to the test, the MEDICAL BED is prepared with the following in the most disadvantageous position of NORMAL USE or in transport position as defined in the instructions for use:*

- *the height, articulation, and length of the MATTRESS SUPPORT PLATFORM;*
- *castors;*
- *SIDE RAILS;*
- *ACCESSORIES with their part of the SAFE WORKING LOAD in place, including in combination with other ACCESSORIES (e.g. a platform with its SAFE WORKING LOAD; a LIFTING POLE without its SAFE WORKING LOAD);*
- *mattress (e.g. height and weight) as specified by the MANUFACTURER or a load representing the weight of the specified mattress that is uniformly distributed and centred on the MATTRESS SUPPORT PLATFORM.*

*The MOBILE MEDICAL BED is placed with the SAFE WORKING LOAD in place as shown in Figure 201.124, and the locking device (e.g. brakes) activated, on a plane covered with 2 mm to 4 mm thick vinyl flooring material and inclined at 6° from the horizontal plane on a concrete floor. Following initial elastic movement, initial creepage, and initial pivoting of castors, there shall be no movement of the MOBILE MEDICAL BED greater than 50 mm (in relation to the inclined plane). Any initial movement shall not result in an unacceptable RISK, taking into account the NORMAL USE of the MEDICAL BED.*

#### 201.9.4.3.2 Instability excluding transport position

*Delete all of a)*

#### 201.9.4.4 Grips and other handling devices

This subclause does not apply to APPLICATION ENVIRONMENTS 1, 2, 3, 5 and 6.

#### 201.9.6.2.1 Audible acoustic energy

*Replace 1st paragraph of the compliance criteria:*

*Compliance is checked by measuring the maximum A-weighted sound pressure level at the minimum distances of PATIENT, OPERATOR and other persons from the source of acoustic energy (noise) in NORMAL USE, and if necessary, calculating the A-weighted sound pressure level produced by the MEDICAL BED in accordance with ISO 3746. The following conditions apply.*

### 201.9.8 HAZARDS associated with support systems

#### 201.9.8.1 General

*Amendment:*

Delete the first dashed item.

#### 201.9.8.2 * TENSILE SAFETY FACTOR

This subclause does not apply (see 201.9.8.3.2).

#### 201.9.8.3 Strength of PATIENT or OPERATOR support or suspension systems

#### 201.9.8.3.1 General

*Replacement:*

MEDICAL BED parts serving for support or immobilization of the PATIENT shall be designed to minimize the RISK of physical injuries and of accidental loosening of fixings.

The minimum SAFE WORKING LOADS for MEDICAL BEDS and BED-LIFTS shall be as shown in Table 201.102 below:

**Table 201.102 – Minimum SAFE WORKING LOADS**

| Bed type | Required minimum SWL[a] kg | Considered to be the sum of: | | | |
|---|---|---|---|---|---|
| | | PATIENT kg | Mattress kg | ACCESSORIES[b] kg | Other kg |
| APPLICATION ENVIRONMENTS 1 and 2 | 200 | 135 | 20 | 45 | - |
| APPLICATION ENVIRONMENTS 3, 4 and 5 | 170 | 135 | 20 | 15 | - |
| APPLICATION ENVIRONMENT 6 | 250 | 135 | 20 | 15 | 80[c] |
| MEDICAL BED-LIFT | 220 | 135 | 20 | 15 | 50[d] |

[a] If the SAFE WORKING LOAD specified by the MANUFACTURER is greater than the required minimum values, it shall be used as a basis for testing.

[b] Includes both the ACCESSORIES and the mass of the SAFE WORKING LOAD supported by those ACCESSORIES but excluding PATIENT weight.

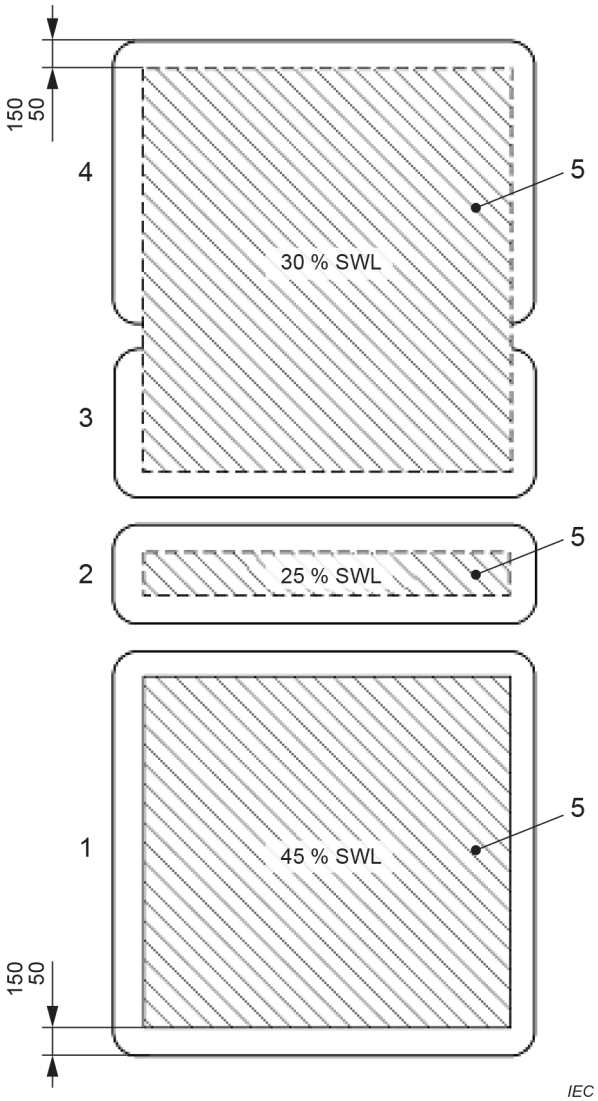
[c] For staff leaning or sitting on the MEDICAL BED during therapy or restraining the PATIENT.

[d] For those parts of the MEDICAL BED intended to be lifted by the BED-LIFT.

The SAFE WORKING LOAD shall be placed at the worst-case position permitted by the configuration or ACCESSORIES attachment on the support or suspension parts. The SAFE WORKING LOAD is distributed as shown in Figure 201.124.

NOTE The position of the human body varies depending on the configuration of the support or suspension system and therefore the load acting on different sections will vary. In analyzing loading forces and torques on support assemblies, the part of the SAFE WORKING LOAD represents the mass as defined.

Dimensions in millimetres




**Key**

1 Back section

2 Seat section

3 Upper leg section

4 Lower leg section

5 SWL = Safe Working Load

**Figure 201.124 – Distribution of SAFE WORKING LOAD / maximum PATIENT weight for tests**

For a foot rest, the SAFE WORKING LOAD representing the mass of the maximum PATIENT weight is distributed over an area of 0,1 $m^2$ or over the complete foot rest if the foot rest is smaller than 0,1 $m^2$.

The part of the SAFE WORKING LOAD specified for the LIFTING POLE (included PATIENT handle) shall be at least 750 N.

**201.9.8.3.2 *Static forces due to loading from persons**

*Replace the 1st two paragraphs:*

The MEDICAL BED and BED-LIFT shall be capable of withstanding a static load equal to two times the SAFE WORKING LOAD or 4 000 N, whichever is greater, in the most disadvantageous position on the MATTRESS SUPPORT PLATFORM in a horizontal position without articulation (see Figure 201.124).

When impairment by wear, corrosion, material fatigue or aging is expected, relevant supporting parts shall have a safety factor not less than 4 times the SAFE WORKING LOAD.

NOTE It can be applicable to support assemblies that are connected to the assembly under test but do not require such a high safety factor, e.g. an assembly under test requires a TENSILE SAFETY FACTOR of 4 and the assembly supporting it is designed with a lower TENSILE SAFETY FACTOR. Use of additional support is explained in the test report.

Item a) – Applies

Item b) – Deleted

*Add the following new items:*

c) For MEDICAL BEDS:

*Compliance is checked by the following test:*

*Permanent deformation is acceptable only if the MEDICAL BED is in compliance with its intended function. The static load shall be applied for at least 1 min, unless material creep can be an issue, in which case the time shall be increased to at least 1 h.*

d) For BED-LIFTS:

*Compliance is checked by the following test:*

*Mount a TEST BED BOARD to a BED-LIFT not supplied with a bed board.*

*Apply a vertical load of two times the SAFE WORKING LOAD or 4 000 N, whichever is greater, equally distributed over the TEST BED BOARD.*

*Permanent deformation is acceptable only if the BED-LIFT is in compliance with its intended function. The static load shall be applied for at least 1 min, unless material creep can be an issue in which case the time shall be increased to at least 1 h.*

e) For ACCESSORIES:

All ACCESSORIES (including those not supporting PATIENT weight) shall be designed to support a load that is at least two times the part of the SAFE WORKING LOAD specified for the ACCESSORY. This load is applied in the most disadvantageous direction and position on the ACCESSORY.

*Compliance is checked by the following test:*

*With the ACCESSORY (other than LIFTING POLES) in its worst case NORMAL USE position, attach a static load equal to two times the part of the SAFE WORKING LOAD specified for the ACCESSORY for at least 1 min, unless material creep can be an issue in which case the time shall be increased to at least 1 h.*

*There shall be no HAZARD or loss of function.*

f) For LIFTING POLES:

The fastenings of LIFTING POLES shall still function normally and present no HAZARDS after the following tests. For the LIFTING POLE, permanent deformation is acceptable in the first test but a sudden movement of the LIFTING POLE shall be considered a HAZARD:

1) *Compliance is checked by the following test:*

   *Position the LIFTING POLE to the MEDICAL BED in its most adverse position intended for use.*

   *Apply a downward load of two times the part of the SAFE WORKING LOAD specified for the LIFTING POLE (at least 1 500 N) to the outermost suspension point for the handle for at least 1 min, unless material creep can be an issue in which case the time shall be increased to at least 1 h.*

   *Examine the LIFTING POLE and its fastenings during and after application of the load.*

2) *Compliance is checked by the following test:*

   *Position the LIFTING POLE to the MEDICAL BED in its most adverse position intended for use. Fixate the MEDICAL BED during the test if necessary due to instability.*

   *Apply perpendicular to the MEDICAL BED side a horizontal force of 350 N to the outermost suspension point for the handle. Examine the LIFTING POLE and its fastenings during and after application of the load.*

**201.9.8.3.3 * Dynamic forces due to loading from persons**

*Replacement:*

MEDICAL BEDS shall provide adequate levels of protection from HAZARDS throughout their EXPECTED SERVICE LIFE. The following tests in this subclause shall be used to determine if appropriate levels of protection are maintained during that period. The tests shall be performed in the sequence in which they are listed on one sample.

*Additional subclauses:*

**201.9.8.3.3.101 General**

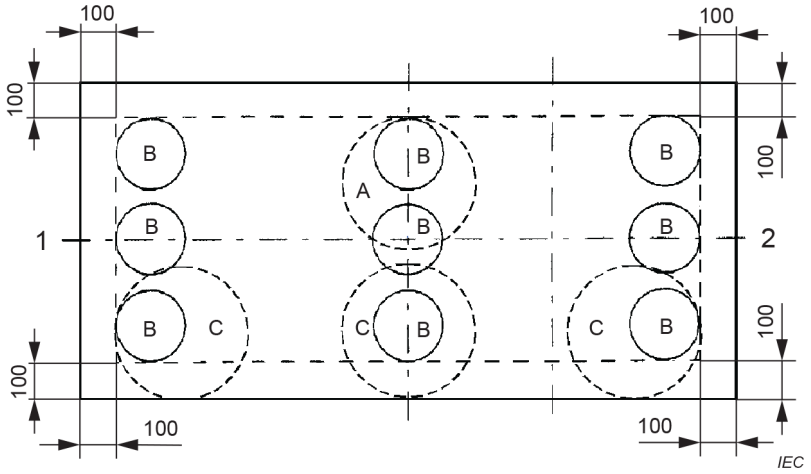
Where dynamic forces (due to sitting down, standing up, PATIENT handling PROCESS or the like) can be exerted on equipment parts intended to support or suspend a PATIENT in NORMAL USE, they shall not result in an unacceptable RISK.

Durability shall be considered with regards to the most disadvantageous position of the MEDICAL BED parts intended to support or suspend a PATIENT in NORMAL USE.

*Compliance is checked by the following tests:*

*Place the worst-case mattress specified by the MANUFACTURER onto the MEDICAL BED in its flat position. If height-adjustable, adjust the height to the worst-case position. Utilize loading pad (Figure 201.105) at position A in Figure 201.125, at whichever side is regarded to be the weaker.*

Dimensions in millimeters




**Key**

1 Head end of MEDICAL BED

2 Foot end of MEDICAL BED

Circle "A" is used for durability testing of loading from persons according to 201.9.8.3.3.101.

Circle "B" is used for testing the effects of impacts to the MATTRESS SUPPORT PLATFORM according to 201.9.8.3.3.105.

Circle "C" is used for testing the effects of loading on the edge of the MATTRESS SUPPORT PLATFORM according to 201.9.8.3.3.106.

**Figure 201.125 – Positions of dynamic loading**
**(see Figure 201.103 for loading pad and Figure 201.104 for impactor)**

*Apply the loading pad (Figure 201.105) 10 000 times at the position A shown in Figure 201.125, with a load of 1 350 N or the maximum PATIENT load, whichever is greater.*

*When tested in accordance with the above, the MEDICAL BED shall still function normally and present no HAZARDS after removal of the loading pad.*

*Remove the mattress and perform the following:*

– *evaluate entrapment HAZARDS according to 201.9.1.101;*
– *evaluate TRAPPING ZONES according to 201.9.2.2;*
– *conduct test according to 201.9.8.3.2.*

### 201.9.8.3.3.102 * Dynamic testing of the height adjustment mechanism

The height adjustment of MEDICAL BED or BED-LIFT shall function normally and present no unacceptable RISK after 3 000 cycles in NORMAL USE.

*Compliance is checked by the following test:*

*Place the MEDICAL BED in its flat position. If the BED-LIFT is separate from a MATTRESS SUPPORT PLATFORM, mount a TEST BED BOARD to the BED-LIFT. Apply the SAFE WORKING LOAD distributed as indicated in 201.9.8.3.1 (Figure 201.124) on the MATTRESS SUPPORT PLATFORM. For BED-LIFTS apply the SAFE WORKING LOAD minus the weight of the TEST BED BOARD distributed as indicated in 201.9.8.3.1 (Figure 201.124) on the MATTRESS SUPPORT PLATFORM.*

*The MEDICAL BED, or BED-LIFT is raised and lowered completely 3 000 times in accordance with the PROCEDURE stated in the instructions for use. After the test, remove the SAFE WORKING LOAD.*

**201.9.8.3.3.103 * SIDE RAIL strength and latch reliability**

SIDE RAIL latches or locks shall remain secure when subjected to the forces of NORMAL USE.

*Compliance is checked by the following test. Forces are applied at the worst-case accessible location for latching or locking:*

*Cycle the SIDE RAIL mechanism (from the latched, upper position, to the unlatched, lowered position, and back to the latched, upper position) for 30 000 cycles. A force A or B or C or D or E or F (as specified in Figure 201.126) shall then be applied to the worst-case position for locking or latching of the SIDE RAIL in the direction of unlatching or unlocking. The SIDE RAIL shall not become unlatched or unlocked or create any other unacceptable RISK.*

SIDE RAILS shall be designed to withstand the forces applied during reasonably foreseeable misuse over the product life cycle without creating an unacceptable RISK.

*Compliance is checked by the following test with the SIDE RAIL in upper position:*

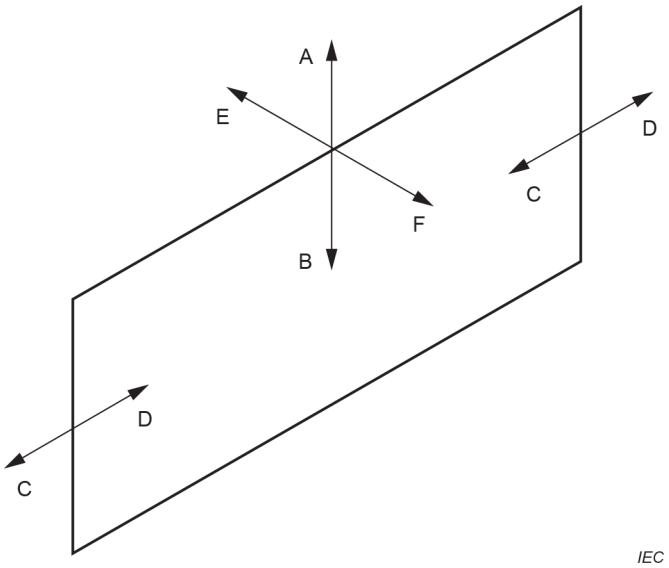
*a) Lateral force cycling test. Exert a force of 100 N that is perpendicular to the SIDE RAIL at the top middle section of the SIDE RAIL in the direction indicated by E or F in Figure 201.126. Reverse direction. Repeat for 3 000 cycles.*

*b) Longitudinal force cycling test. Exert a force of 100 N on the SIDE RAIL in the lengthwise direction of the SIDE RAIL as indicated by C or D in Figure 201.126. Reverse direction. Repeat for 3 000 cycles.*

*c) Vertical force cycling test. Exert a force of 100 N on the uppermost part of the SIDE RAIL in the vertical direction of the SIDE RAIL as indicated by B in Figure 201.126. Repeat for 3 000 cycles. No test is required in direction A.*

*d) Upon completion of a), b) and c) above, apply a static load in the directions of Figure 201.126 in worst case positions. The SIDE RAIL shall not become unlatched or unlocked or create any other unacceptable RISK.*

The MANUFACTURER shall take into account when these forces can be applied in the lowered position.




| Direction of force | Force |
|---|---|
| A | 500 N |
| B | 750 N |
| C | 500 N |
| D | 500 N |
| E | 500 N |
| F | 500 N |

**Figure 201.126 – Application of forces for test of SIDE RAIL**

#### 201.9.8.3.3.104 Dynamic testing of the LIFTING POLE

The LIFTING POLE and its fastenings shall still function normally and present no HAZARDS after the following test. A sudden movement of the LIFTING POLE or its handle shall be considered a HAZARD.

*Compliance is checked by the following test:*

*Position the LIFTING POLE to the MEDICAL BED in its most adverse position intended for use.*

*Apply a vertical downward load of the part of the SAFE WORKING LOAD specified for the LIFTING POLE (at least 750 N) 1 000 times onto the handle of the LIFTING POLE. Examine the LIFTING POLE and its fastenings during and after application of the force and record deflection and deformation.*

*Deflection while under load and permanent deformation is acceptable only if the LIFTING POLE maintains its intended function. The LIFTING POLE shall not create a sudden movement while the load is applied (upward or downward).*

#### 201.9.8.3.3.105 The effect of impacts to the MATTRESS SUPPORT PLATFORM

The MEDICAL BED shall be able to withstand the effect of impacts to the MATTRESS SUPPORT PLATFORM being applied during NORMAL USE.

*Compliance is checked by the following test:*

*Place the mattress, as specified by the MANUFACTURER, onto the MATTRESS SUPPORT PLATFORM, in a position in which moving element are free of supporting elements and their inclination is less than 7° in relation to horizontal, and if height-adjustable, the MATTRESS SUPPORT PLATFORM shall be placed in the middle of the possible range of the adjustment.*

*From a height of 180 mm above the mattress, drop the impactor (see Figure 201.106) onto the MEDICAL BED 20 times onto each of the locations marked "B" in Figure 201.125. The impactor shall be allowed to fall freely, but guides can be used to help ensure that the impacts occur as close as is possible to the indicated locations.*

*After application of the load, no elements of the MEDICAL BED shall become loose, fractured or present any HAZARD.*

#### 201.9.8.3.3.106 The effect of loading on the edge of the MATTRESS SUPPORT PLATFORM

The MEDICAL BED shall be able to withstand the effect of loading on the edge of the MATTRESS SUPPORT PLATFORM as applied during NORMAL USE.

*Compliance is checked by the following test:*

*Place the MEDICAL BED in its flat position. If the BED-LIFT is separate from a MATTRESS SUPPORT PLATFORM, mount a TEST BED BOARD to the BED-LIFT.*

*Adjust the height to the most adverse position.*

*Load three loading pads (Figure 201.105) each having a load of 750 N to the MATTRESS SUPPORT PLATFORM to the locations marked "C" in Figure 201.125 at whichever side is regarded to be the weaker at the same time.*

NOTE Stability HAZARD is not evaluated in this clause, see 201.9.4.2.2.

*Examine the specimen during and after application of the loads to determine if the deflections present any HAZARD.*

*After application of the loads, no elements of the MEDICAL BED shall become loose, fractured or present any HAZARD.*

*Permanent deformation is acceptable only if the MEDICAL BED maintains its intended function. Loss of articulation, deterioration of fixings, unlocking of ACCESSORIES if fixed on the MEDICAL BED (like SIDE RAILS), which can reduce the NORMAL USE or create a RISK like collapsing, or permanent deformation, modifying gap for entrapment or pinching, etc. are not acceptable.*

#### 201.9.8.3.3.107 Durability of the moveable sections (if provided) of the MATTRESS SUPPORT PLATFORM

The moveable sections of the MATTRESS SUPPORT PLATFORM shall comply with the following test:

*Apply the maximum PATIENT weight, maximum weight of mattress as specified by the MANUFACTURER and applicable ACCESSORIES (with their SAFE WORKING LOAD) distributed as indicated in Figure 201.124 on the MATTRESS SUPPORT PLATFORM. Applicable ACCESSORIES are ACCESSORIES attached to the movable parts of the MATTRESS SUPPORT PLATFORM.*

*Each of the moveable sections of the MATTRESS SUPPORT PLATFORM are operated through their full range of travel as in NORMAL USE.*

*The test is performed for 1 000 cycles.*

*Inspect the MEDICAL BED 5 min after cycling is completed.*

*After application of the load, no elements of the MEDICAL BED shall become loose, fractured or present any HAZARD. Deformation of less than 10 mm (after removal of the load) from the corresponding measurements taken before the application of the load is acceptable.*

#### 201.9.8.4 Systems with MECHANICAL PROTECTIVE DEVICES

##### 201.9.8.4.1 General

*This subclause does not apply.*

#### 201.9.8.5 Systems without MECHANICAL PROTECTIVE DEVICES

This subclause does not apply.

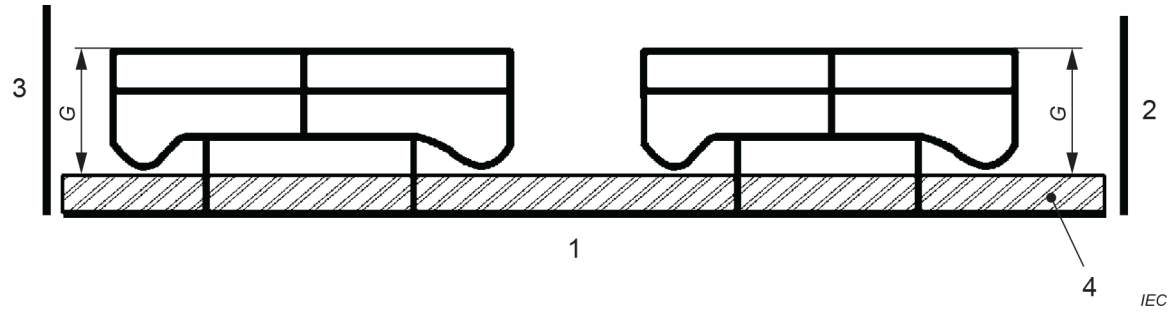
*Additional subclause:*

#### 201.9.101 *Protection against inadvertent PATIENT falls

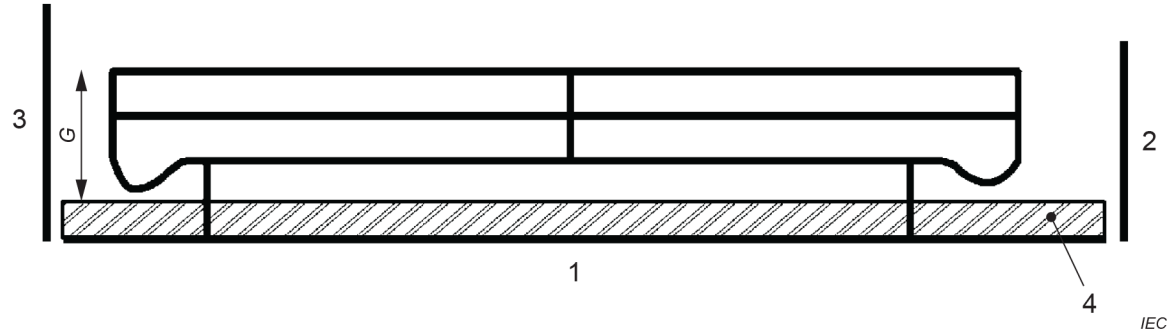
SIDE RAILS, if provided, shall be designed with minimum height requirements as indicated by *G* in Figure 201.127 and Table 201.103.

Where a SPECIALTY MATTRESS or MATTRESS OVERLAY is used and the SIDE RAIL does not meet *G* as indicated in Table 201.103, a RISK ASSESSMENT shall be performed to assure equivalent safety.

*Compliance is checked by measurement of G and inspection of the RISK MANAGEMENT FILE.*




**a) ADULT MEDICAL BED split SIDE RAIL**




**b) ADULT MEDICAL BED single piece SIDE RAIL**

**Key**

1 MATTRESS SUPPORT PLATFORM

2 FOOT BOARD

3 HEAD BOARD

4 Mattress

*G* Height of the top edge of the SIDE RAIL above the mattress

**Figure 201.127 – Height of SIDE RAIL**

**Table 201.103 – Protection against inadvertent PATIENT falls**

| Designator | Description | Requirement and compliance method |
|---|---|---|
| *G* | Height of the top edge of the SIDE RAIL above the mattress without compression in at least 50 % of the length of the MATTRESS SUPPORT PLATFORM. Other raised and locked positions not meeting the height of ≥ 220 mm or length at least 50 % for SIDE RAILS and specified for purposes other than SIDE RAIL application (e.g. mobilization bar or grab handles) shall be covered in the MANUFACTURER'S RISK MANAGEMENT FILE. When SIDE RAILS cover less than the full length of the MATTRESS SUPPORT PLATFORM, those parts that are above 220 mm shall be placed strategically to help prevent accidental falls from the MEDICAL BED. All dimensions *C* of Table 201.101 shall be respected. | ≥ 220 mm<br>*Compliance is checked by measurement* |

## 201.10 Protection against unwanted and excessive radiation HAZARDS

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 10 applies.

## 201.11 Protection against excessive temperatures and other HAZARDS

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 11 applies, except as follows:

### 201.11.1.1 Maximum temperature during NORMAL USE

*Amendment:*

*Replacement of Table 24:*

**Table 24 – Allowable maximum temperatures for skin contact with MEDICAL BED APPLIED PARTS**

| APPLIED PARTS of MEDICAL BEDS | | Maximum temperature [a] [b] °C | | |
|---|---|---|---|---|
| | | Metal and liquids | Glass, porcelain, vitreous material | Moulded material, plastic, rubber, wood |
| APPLIED PART having contact with the PATIENT for a time "*t* " | *t* < 1 min | 51 | 56 | 60 |
| | 1 min ≤ *t* < 10 min | 48 | 48 | 48 |
| | 10 min ≤ *t* | 41 | 41 | 41 |

[a] These temperature limit values are applicable for the healthy skin. A limitation temperature duration of more than 10 min for persons with sensitive skin or no sensation have been considered. They are not applicable when large areas of the skin (greater than 10 % of total body surface or head surface) can be in contact with a hot surface. Where this is the case, appropriate limits shall be determined and documented in the RISK MANAGEMENT FILE.

[b] Where it is necessary for APPLIED PARTS to exceed the temperature limits of Table 24 in order to provide clinical benefit, the RISK MANAGEMENT FILE shall contain documentation showing that the resulting benefit exceeds any associated increase in RISK.

*Additional subclause:*

### 201.11.2.101 Flammability of textiles, coated textiles and plastics coverings

MANUFACTURERS shall consider in the RISK MANAGEMENT FILE the environments, materials and methods of use to which a MEDICAL BED, or any materials that are usually used in combination with this MEDICAL BED, will be exposed and take appropriate steps to minimize any fire HAZARD.

The MANUFACTURER shall include a warning in the instructions for use about safe combinations of flame resistant and non-flame resistant materials.

When considering the flame resistance, MANUFACTURERS should note that PERSONS WITH DISABILITY can be at greater RISK than able-bodied persons as they can be unable to escape from fire. HAZARDS which should be considered include but are not limited to smokers' materials, fires and other space heaters, electrostatic discharges.

Particular care is necessary if the MEDICAL BED can be used near or in conjunction with flammable substances (e.g. candles).

If the MANUFACTURER claims that upholstered parts are resistant to ignition by cigarette, progressive smouldering ignition and flaming ignition shall not occur when the materials used for the upholstered parts of a MEDICAL BED are tested in accordance with EN 597-1 and EN 597-2 or other standard with an equivalent or higher safety level.

*Compliance is checked by review of the relevant EN 597-1, EN 597-2 or other standards.*

### 201.11.6.5 Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

*Amendment:*

ENCLOSURES of MEDICAL BED shall provide a minimum protection degree of IPX4 in accordance with the classification of IEC 60529. MEDICAL BEDS marked for jet stream washing (per Clause 201.7.2.2.103), shall additionally provide protection degree of IPX9 in accordance with the classification of IEC 60529.

*Compliance is checked by the tests of IEC 60529 with the MEDICAL BED placed in the least favourable position of NORMAL USE (as defined in the instructions for use) and by inspection.*

*All parts that can be removed without a TOOL shall be removed (detached or opened) before the test. The test shall be executed without a mattress. After these PROCEDURES, the MEDICAL BED shall show no signs of bridging of insulation (or electrical components) that could result in a HAZARD in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION (based on a visual inspection) followed by the appropriate dielectric strength and LEAKAGE CURRENT tests.*

*The MEDICAL BED shall comply with its BASIC SAFETY and ESSENTIAL PERFORMANCE after the test.*

### 201.11.6.6 Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS

*Addition:*

If the MEDICAL BED is intended for use with equipment for cleaning and disinfection, the MANUFACTURER shall specify the cleaning or disinfection PROCESS or both.

*Additional subclause:*

**201.11.6.6.101 Machine washable MEDICAL BED**

A MEDICAL BED or BED-LIFT specified by the MANUFACTURER to be machine washable by an automatic washing system shall function as specified by the INTENDED USE and shall not create any unacceptable HAZARD after the test.

Any variations documented in instruction for use that modify the test PROCEDURE regarding test-cycle, temperature, time and cleaning fluids shall be covered in the RISK MANAGEMENT FILE of the MANUFACTURER.

The test method below represents a basic PROCEDURE for disinfection of a MEDICAL BED in a washing machine. Any documented variations shall additionally be subjected to the test below with the revised conditions.

*Compliance is checked by the following test:*

*a) Parts and access covers which can be detached or opened without the use of a TOOL shall be detached or opened.*

*b) The MEDICAL BED shall be kept at room temperature for not less than 16 h.*

*c) For APPLICATION ENVIRONMENTS 1, 2 3, 5, and 6, perform 250 test cycles; for APPLICATION ENVIRONMENT 4 perform 50 cycles, according to the PROCEDURE below:*

*1) 2 min wash with 70 ° C water at a ph value 5-8, 0,5 % cleaning and disinfectant solution as specified by the MANUFACTURER;*

*2) 20 s rinse with 85 ° C water at a ph value 5-8, and 0,2 % clear rinsing solution according to the data of the MANUFACTURER.*

*3) 10 min cooling at 20 ° C ambient temperature.*

*d) Compliance is checked by the PROCEDURE specified in Table 201.104.*

**Table 201.104 – Machine washable compliance PROCEDURE**

| When | Test number | Test description and criteria |
|---|---|---|
| *After 125 and after 250 cycles for APPLICATION ENVIRONMENTS 1, 2 3, 5, and 6; or after 50 cycles for APPLICATION ENVIRONMENT 4:* | | |
| *Immediately* | *1* | *Disconnect all internal electrical connectors of replaceable electrical components as specified by the MANUFACTURER and visually check for ingress of water and function of sealing. There shall be no water inside the connector creating any unacceptable HAZARD.*<br>*Reconnect after testing and continue washing.* |
| *After 250 cycles for APPLICATION ENVIRONMENTS 1, 2 3, 5, and 6; or after 50 cycles for APPLICATION ENVIRONMENT 4:* | | |
| *Immediately* | *2* | *The MEDICAL BED is connected to mains. No unintentional movements shall arise.* |
| *5 min ± 1 min* | *3* | *Perform dielectric strength and LEAKAGE CURRENT tests according to 8.8.3 and 8.7 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.* |
| | *4* | *Operate each articulation control within its entire range, from end stop to end stop.*<br>– *Each control, activated from each control device within the MEDICAL BED, shall work while the corresponding control is operated and shall stop when the corresponding control is released.*<br>– *When reaching either end stop the electrical adjustment function shall stop even when the corresponding control is kept pressed.* |

| When | Test number | Test description and criteria |
|---|---|---|
| *60 min ± 5 min* | *5* | *SIDE RAIL latches and locks shall remain secure when subjected to the forces of NORMAL USE.*<br>*Perform a functional inspection of the SIDE RAIL mechanism:*<br>– *Cycle the SIDE RAIL mechanism once from the latched, upper position, to the unlatched, lowered position, and back to the latched, upper position.*<br>– *The SIDE RAIL shall not become unlatched and unlocked or create any other unacceptable RISK.*<br>*Perform a visual inspection of the SIDE RAIL mechanism:*<br>– *Any corrosion, aging or embrittlement of load-bearing parts shall not result in loss of SIDE RAIL strength and latch reliability nor create any other HAZARD.*<br>– *In any case of doubt, check again the compliance of SIDE RAIL strength and latch reliability according to 201.9.8.3.3.103 item d).*<br>*This test can be performed later, within 10 days.* |
| | *6* | *Repeat test 4. (Operate each articulation)* |
| | *7* | *Articulate each manually powered adjustment function within its entire range, from end stop to end stop.*<br>– *Any latch and locking function shall work as specified.* |
| | *8* | *Check castor locking (brakes) function:*<br>*The unloaded MOBILE MEDICAL BED shall be placed on a flat horizontal floor (e.g. concrete floor covered with 2 mm to 4 mm thick vinyl flooring material).*<br>– *Operate the locks to ensure they engage and unlock the brakes and confirm they unlock and allow movement.*<br>– *In any case of doubt, the test of 9.4.3.2, Item b) of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 shall be conducted.*<br>*This test can be performed later, within 10 days.* |
| *24 h ± 30 min* | *9* | *Repeat test 3 (Dielectric strength).* |
| | *10* | *Repeat test 4 (Operate each articulation).* |
| | *11* | *Repeat test 7 (Manually powered adjustment).* |
| | *12* | *Perform a visual inspection for ingress of water that can result in an unacceptable RISK (i.e. shorting of isolation barriers and violation of creepage distances).* |
| NOTE For some MEDICAL BEDS, not all tests and acceptance criteria apply; i.e. for manual MEDICAL BEDS, electrical tests and acceptance criteria would not apply. | | |

### 201.11.7 Biocompatibility of ME EQUIPMENT and ME SYSTEMS

*Addition:*

NOTE 1 A potential HAZARD can arise from ingesting a hazardous substance as a result of licking or sucking, another HAZARD can arise from skin contact. Material properties can become hazardous during use because of degradation of the material.

NOTE 2 EN 71-3[4] addresses additional HAZARDS not covered by the ISO 10993 series.

### 201.11.8 * Interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT

*Addition:*

In an emergency situation when MAINS VOLTAGE has been interrupted, ESSENTIAL PERFORMANCE functions defined by the MANUFACTURER shall be able to be operated by other means and back section lowering or any other emergency position (specified by the MANUFACTURER) shall be achievable within 30 s.

*Compliance is checked by functional test in the most adverse conditions.*

## 201.12 Accuracy of controls and instruments and protection against hazardous outputs

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 12 applies, except as follows:

### 201.12.2 USABILITY of ME EQUIPMENT

*Addition:*

USABILITY ENGINEERING PROCESS shall take into account MEDICAL BED design aspects such as the MATTRESS SUPPORT PLATFORM height, with regard to both OPERATOR and PATIENT, as relevant to the APPLICATION ENVIRONMENT.

USABILITY ENGINEERING PROCESS shall consider that:

- all handles and pedals are reachable from normal working positions and placed so that they allow operations to be carried out in a safe and ergonomic manner, and
- the locations and configurations of all buttons, switches, and actuators minimize the RISK of unintentional activation.
- access to PATIENT for the purposes of medical treatment shall not be delayed significantly by the SIDE RAILS and their respective control systems.

For APPLICATION ENVIRONMENT 4, See Clause BB.2.

## 201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 13 applies, except as follows:

### 201.13.1.4 * Specific MECHANICAL HAZARDS

*Addition:*

Protection shall be provided in the motion controls of electrical MEDICAL BEDS such that a SINGLE FAULT CONDITION does not cause a movement without human intervention.

NOTE A MOTION LOCKOUT CONTROL can be used as a means of compliance. A MOTION LOCKOUT CONTROL can be activated automatically or as an OPERATOR option (see also 201.7.4.2).

For APPLICATION ENVIRONMENT 6, if the MEDICAL BED controls are accessible by the PATIENT, the MEDICAL BED shall have a MOTION LOCKOUT CONTROL.

If an auxiliary subsystem that deactivates motion controls (MOTION LOCKOUT CONTROL) is provided, it shall remain functional under SINGLE FAULT CONDITION.

For switches and other components that control motion in electrical MEDICAL BEDS, COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS are required if their failure can cause a HAZARD.

Hydraulic, pneumatic, and mechanical subsystems of MEDICAL BEDS shall not cause unintended movement of the MATTRESS SUPPORT PLATFORM in SINGLE FAULT CONDITION, where such movement could cause a HAZARD.

Protection of SINGLE FAULT CONDITION for pneumatic, hydraulic, or mechanical MEDICAL BEDS, or for pneumatic, hydraulic, or mechanical subsystems of electrical MEDICAL BEDS, shall be met by

compliance with 9.7.2 of the IEC 60601-1:2005, and other applicable clauses of the IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and this document pertaining to safety factors.

*Compliance is checked by inspection of the MEDICAL BED and inspection of the RISK MANAGEMENT FILE.*

#### 201.13.2.2 Electrical SINGLE FAULT CONDITION

*Additional subclause:*

#### 201.13.2.2.101 Power-driven MEDICAL BED for transportation

Power-driven MEDICAL BEDS for transportation shall have a means to allow transport by the OPERATOR under SINGLE FAULT CONDITION of the transport system.

NOTE A power-driven MEDICAL BED incorporates a propulsion system.

### 201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 14 applies.

### 201.15 Construction of ME EQUIPMENT

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 15 applies, except as follows:

#### 201.15.3 Mechanical strength

##### 201.15.3.4.1 HAND-HELD ME EQUIPMENT

*Replacement:*

PENDANT CONTROLS shall not result in an unacceptable RISK as a result of a free fall.

NOTE An example of unacceptable RISK would be unintended motion of the MEDICAL BED, such as the backrest lowering or alteration of the TRENDELENBURG angle.

*Compliance is checked by the following test:*

*The PENDANT CONTROL shall fall 1 000 times minimum from a height of 1 m onto a 50 mm ± 5 mm thick hardwood board (hardwood > 600 kg/m$^3$) lying flat on a concrete or similar rigid base. Alternate test methods are acceptable as defined in IEC 60068-2-31[5].*

*After the test the PENDANT CONTROL is checked by inspection for unacceptable RISKS and relevant electrical safety requirements.*

*If the PENDANT CONTROL is the only means of control of the MEDICAL BED ACCESSIBLE for the PATIENT lying in the MEDICAL BED, it shall also function normally after the test.*

**201.15.3.5 * Rough handling test**

*Replacement of item c):*

*c) Door frame shock*

*The MEDICAL BED is moved three times in its normal direction of travel at a speed of 0,4 m/s ± 0,1 m/s with the MATTRESS SUPPORT PLATFORM in the worst-case position, unless transport position is specified by the MANUFACTURER, against a hardwood vertical obstacle having a width and thickness of 40 mm affixed to a vertical rigid support (e.g. concrete). The height of the vertical obstacle shall be at the same level as the MEDICAL BED contact point(s). The direction of movement is parallel to the vertical rigid support (wall). See Figure 201.128 below.*

Dimensions in millimeters

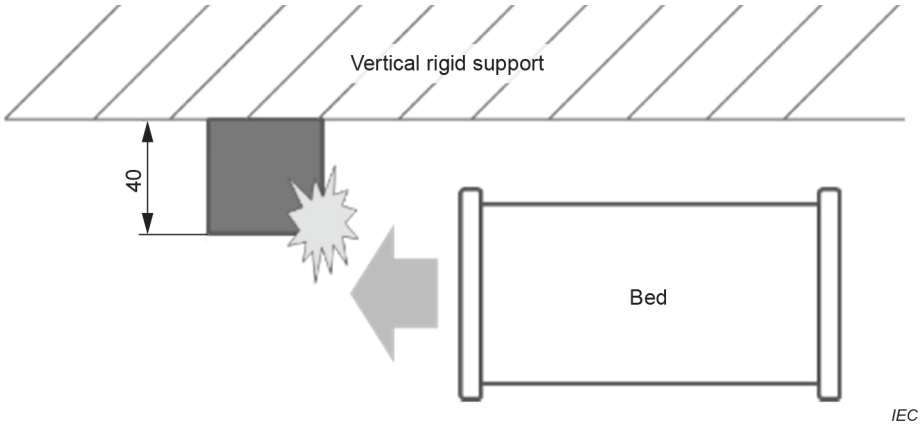



**Figure 201.128 – Direction of movement for rough handling test**

*Addition at the end of the paragraph:*

This requirement does not apply to MEDICAL BEDS specified by the MANUFACTURER only to be moved within the PATIENT room for cleaning or PATIENT access.

**201.15.4 ME EQUIPMENT components and general assembly**

**201.15.4.3.1 Housing**

*Addition:*

For APPLICATION ENVIRONMENT 6, if rechargeable battery pack is used it shall be placed in a locked box (e.g. requiring a key or specialized TOOL to open) or secured in any other way that requires a TOOL for removal.

**201.15.4.4 * Indicators**

*Amendment:*

Delete the first two paragraphs.

**201.15.4.6.2 * Limitation of movement**

*Addition:*

The angle (designated *"γ"* in Figure 201.129) between the back section and leg section or upper leg section for various configurations of the MATTRESS SUPPORT PLATFORM shall always be greater than 90° under NORMAL CONDITIONS.

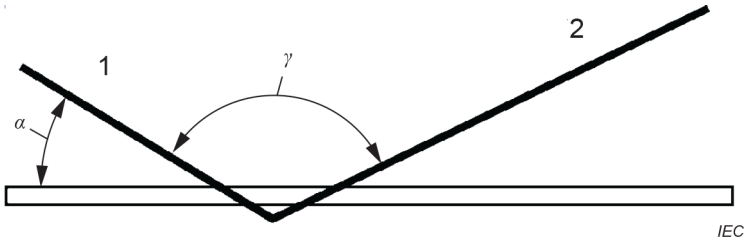
In APPLICATION ENVIRONMENT 4, the angle α of the back section in relation to the horizontal shall always be greater than or equal to 0°.

If a MEDICAL BED in APPLICATION ENVIRONMENTS 1, 2, 3, 5 or 6 is provided with TRENDELENBURG position, the entire MATTRESS SUPPORT PLATFORM shall be able to achieve a minimum of 12° so that the PATIENT'S head is lower than the circulatory centre point of the body.

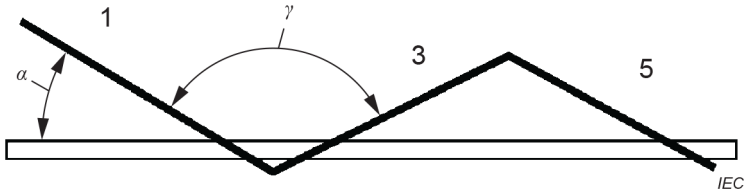
It is permissible to have HEAD DOWN TILT angles less than 12°; however, TRENDELENBURG cannot be claimed.

See Annex BB for additional requirements.

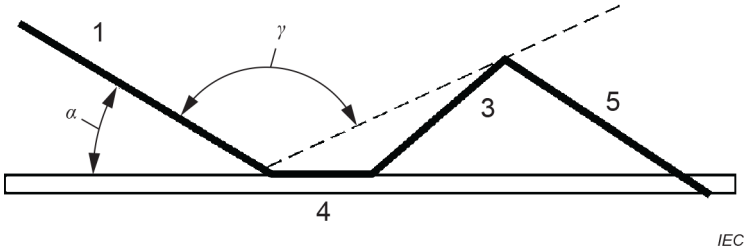
*Compliance is checked by operating the controls to achieve the maximum angle $\gamma$ and then measuring this angle.*



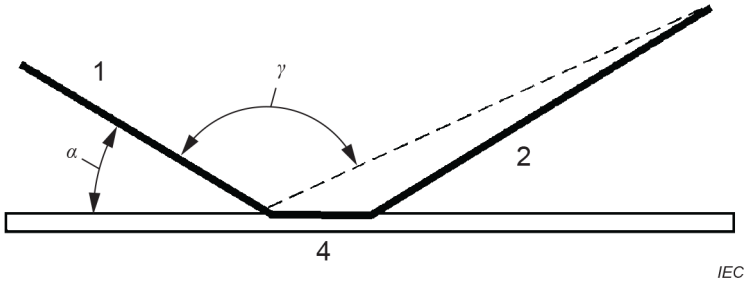

**a) Angle γ between the back section and the leg section of the MATTRESS SUPPORT PLATFORM**




**b) Angle γ between the back section and the upper leg section of the MATTRESS SUPPORT PLATFORM**




**c) Angle γ between the back section and upper leg section of the MATTRESS SUPPORT PLATFORM**




**d) Angle γ between the back section and the leg section of the MATTRESS SUPPORT PLATFORM**

**Key**

1 Back section

2 Leg section

3 Upper leg section

4 Seat section

5 Lower leg section

Subfigures a) to d) specify how to measure the two angles γ and α for different configurations of a MATTRESS SUPPORT PLATFORM. They are not intended to be prescriptive in terms of articulation joints or pivot points. Other MATTRESS SUPPORT PLATFORM configurations are permitted.

**Figure 201.129 – Configurations of the MATTRESS SUPPORT PLATFORM**

#### 201.15.4.7.1 Mechanical strength

*Amendment to item b):*

*This requirement does not apply if the foot-operated control device is in a location that does not allow the OPERATOR to put their entire weight on it.*

*Compliance is checked by application to the foot-operated control device, in its position of NORMAL USE, of an actuating force of 1 350 N for 1 min. The force is applied over an area of 30 mm diameter. There shall be no damage to the device resulting in an unacceptable RISK.*

*Addition to item b):*

*Where the entire weight cannot be placed on the foot-operated control device, the RISK MANAGEMENT FILE shall specify the compliance criteria.*

*Compliance is checked by inspection of the RISK MANAGEMENT FILE.*

#### 201.15.4.7.3 Entry of liquids

*Amendment:*

Foot-operated controls shall be at least IPX4.

*Additional subclauses:*

#### 201.15.4.101 HEAD BOARD assembly

The design of the MEDICAL BED shall allow immediate and unimpeded access to the PATIENT from the head end of the MEDICAL BED in emergency situations. This applies for APPLICATION ENVIRONMENTS 1 and 2 only.

NOTE One means of accomplishing this is by a HEAD BOARD, which is removable without the use of a TOOL by one person.

*Compliance is checked by the following test:*

*A trained OPERATOR shall be able to remove the HEAD BOARD within 15 s.*

#### 201.15.4.102 Mattress retention

The MEDICAL BED shall be designed to retain the mattress in position during NORMAL USE and prevent sliding off MATTRESS SUPPORT PLATFORM.

*Compliance is checked by inspection of the RISK MANAGEMENT FILE.*

#### 201.15.4.103 Combination of MEDICAL BED and mattress

For all MEDICAL BEDS, at the area of the MATTRESS SUPPORT PLATFORM intended for the ingress or egress of the BED, the minimum height of the compatible, uncompressed mattress(es) shall be at least 20 mm higher than any construction part e.g. MEDICAL BED frame, side structure or the lowered SIDE RAILS of the MATTRESS SUPPORT PLATFORM.

When SPECIALITY MATTRESSES are used, a RISK ASSESSMENT shall be performed if the requirement cannot be fulfilled.

*Compliance is checked by the following test:*

*The worst-case mattress as specified by MANUFACTURER shall be placed on the MEDICAL BED. The distance from top of the mattress to the MEDICAL BED frame, side structure or lowered SIDE RAILS shall be measured to confirm at least 20 mm.*

*Compliance is checked by inspection of the RISK MANAGEMENT FILE for SPECIALITY MATTRESSES.*

#### 201.15.4.104 Parts removable by the PATIENT

For MEDICAL BEDS intended for use in APPLICATION ENVIRONMENT 6, parts accessible to the PATIENT shall only be removable by the use of a TOOL.

*Compliance is checked by inspection.*

NOTE This is to prevent disassembly or accidental ingestion by the PATIENT.

#### 201.15.4.105 Storage for PENDANT CONTROL

For APPLICATION ENVIRONMENT 6, the PENDANT CONTROL, and its cable if applicable, shall be protected from access by the PATIENT, e.g. in a lockable box, tamper proof construction, or other suitable means when the MEDICAL BED is not attended by the caregiver.

NOTE This prevents RISK from unintended activation and strangulation for PATIENTS and others.

See Figure AA.3 for labelling of PENDANT CONTROL storage.

It shall be possible to identify a wireless PENDANT CONTROL with the corresponding MEDICAL BED.

The solution shall be based on the MANUFACTURER'S RISK ASSESSMENT.

*Compliance is checked by inspection of MEDICAL BED and inspection of the RISK MANAGEMENT FILE.*

### 201.16 ME SYSTEMS

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 16 applies.

### 201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 17 applies.

## Annexes

The annexes of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 apply.

# Annex AA
(informative)

# Particular guidance and rationale

## AA.1 General guidance

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 the 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 PERSONS WITH DISABILITY 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 PERSONS WITH DISABILITY. This is the effort of a joint working group of the IEC and the ISO.

## AA.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this document, with clause and subclause numbers parallel to those in the body of the document.

Unless otherwise stated, the ADULT data is from item [6] in the Bibliography.

**Subclause 201.1.1 – Scope**

The working group recognizes that the definitions of the terms "ADULT" and "CHILD" are based on physical characteristics, which vary from one country to another. If the highest level of safety is to be achieved for PATIENTS and OPERATORS, it is necessary to rely on caregivers to use their professional judgement to differentiate the needs of CHILDREN from those of ADULTS in relation to the MEDICAL BED, taking into consideration not only the physical, psychological and medical needs of the individual, but also the PATIENT's preference. The dimensional requirements of this particular standard are based on anthropometric data based on PATIENTS ranging in physical size from a 146 cm tall female ($5^{th}$ percentile female[6]) to a 185 cm tall male ($95^{th}$ percentile male[6]) a weight of equal to or more than 40 kg and a body mass index (BMI) equal to or more than 17. For MEDICAL BEDS intended for use with PATIENTS outside this range, all dimensional characteristics in this document should be adjusted accordingly.

Examples of MEDICAL BEDS with special functionality are rotary beds and stand-up beds.

**Definition 201.3.131 – TRAPPING ZONE**

The term "entrapment" describes an event in which a PATIENT is caught, trapped, or entangled in spaces in or about the SIDE RAIL, mattress, or MEDICAL BED frame.

**Definitions 201.3.201 – 201.3.206 – APPLICATION ENVIRONMENTS 1, 2, 3, 4, 5 and 6**

The working group discussed many different APPLICATION ENVIRONMENTS in evaluating this document. For example, a maternity bed designed to aid in the birthing PROCESS is primarily used with PATIENTS below the age of 50. These PATIENTS generally do not fit into a high entrapment RISK category, thus entrapment guidelines cannot be considered, unless the product is designed to be used in various APPLICATION ENVIRONMENTS in NORMAL USE, or there is reasonable foreseeable misuse.

**Definition 201.3.214 – MEDICAL BED**

This document merges two pre-existing standards: IEC 60601-2-38 (*Medical electrical equipment – Particular requirements for the safety of electrically-operated hospital beds*), and EN 1970 (*Adjustable beds for disabled persons – Requirements and test methods*). Since different products exist within different healthcare markets, requirements are divided into different APPLICATION ENVIRONMENTS. Certain products can exist across APPLICATION ENVIRONMENTS, or different APPLICATION ENVIRONMENTS developed in the future that are not specified in this document. The environment of use shall be addressed through the MANUFACTURER'S RISK MANAGEMENT PROCESS.

Excluded are special requirements to MEDICAL BEDS with special functionality. Any alternative means not described in this document to ensure an equivalent BASIC SAFETY level and ESSENTIAL PERFORMANCE shall be justified by the MANUFACTURER in the RISK MANAGEMENT FILE.

**Definition 201.3.222 – ADULT**

The body mass index is calculated by the following formula:

$$BMI = \frac{m}{l^2}$$

where

$m$ is the mass in kg;

$l$ is the length in m.

The body mass index (BMI) as an additional measure for the shape of the human body was included in IEC 80601-2-52, since the physical size of some PATIENTS is indeed inside the limits of the first version of IEC 60601-2-52 (exceeding 146 cm and 40 kg) but nevertheless due to their particular atypical anatomy, there might be a RISK of being entrapped in the SIDE RAILS.

The body mass index (BMI) is a measure for the human body shape based on an individual's mass and height. BMI provides a simple numeric measure of a person's thickness or thinness, allowing health professionals to discuss overweight and underweight problems more objectively with their PATIENTS.

For an explanation, see also 201.1.1.

**Subclause 201.4.2.2 – General requirement for RISK MANAGEMENT**

Possible HAZARDS can be rolling over the SIDE RAIL, entrapment in MEDICAL BED extension and HAZARDS related to the TRAPPING ZONES described in 201.9.2.2.

**Subclause 201.5.101 – Entrapment test tools**

The dimensions and weight of the cone TOOL and cylinder TOOL derived from the following observation:

a) Cone TOOL:

   For a 95$^{th}$ percentile male head this weight is 5,13 Kg [7].

b) Cylinder TOOL:

   60 mm is a conservative measure of 83 mm neck 5$^{th}$ percentile female [6].

**Subclause 201.5.103 – Impactor**

The test apparatus used in previous version of the standard came from a furniture standard EN 1728[8]. The mattress included in testing provides adequate spring rate removing the need to include this feature in the test TOOL. The committee decided a simplified TOOL avoiding difficulty in the impactor TOOL validation and construction.

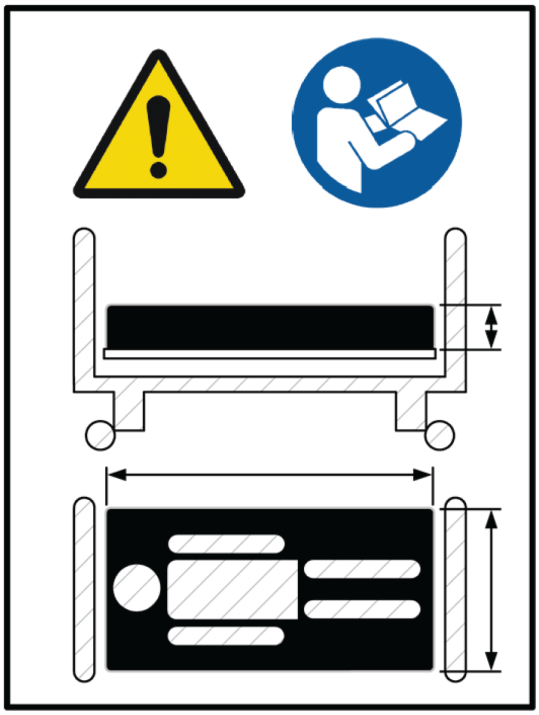
**Subclause 201.6.2 – Protection against electrical shock**

In some countries a protective earthing system are not available or reliable in the home environment (APPLICATION ENVIRONMENT 4).

**Subclause 201.7.2.2.101 – Marking of maximum PATIENT weight and SAFE WORKING LOAD**

It is important that the RESPONSIBLE ORGANIZATION and OPERATOR clearly understand the maximum PATIENT weight and SAFE WORKING LOAD of the MEDICAL BED, and of any ACCESSORY that is intended to support potentially hazardous masses, so that the MEDICAL BED and its ACCESSORIES are not used in ways, which could create a HAZARD.

**Subclause 201.7.2.2.104 – Marking of replacement mattresses**

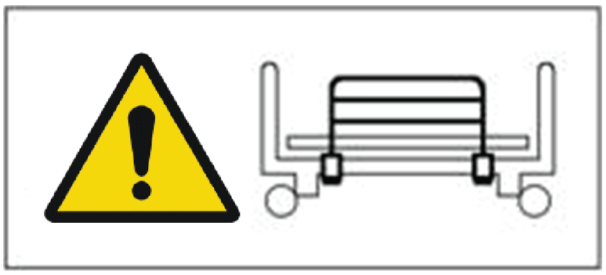


IEC

SOURCE: ISO 7010-W001 (2011-05) and ISO 7010-M002 (2011-05).

**Figure AA.1 – Example of marking to select recommended mattresses specified by the MANUFACTURER**

**Subclause 201.7.2.2.105 – Marking of detachable SIDE RAILS**

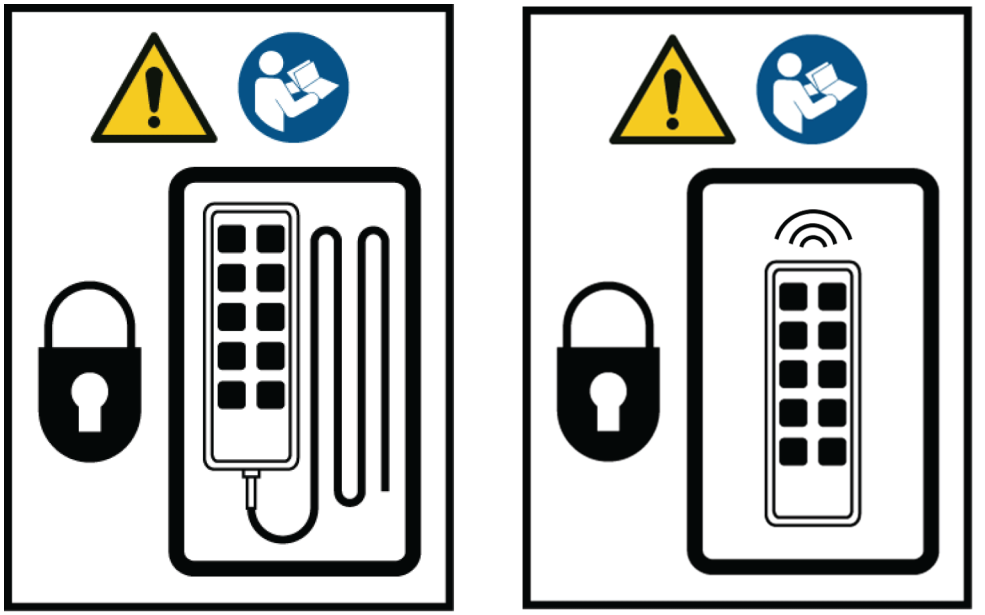


IEC

SOURCE: ISO 7010-W001 (2011-05).

**Figure AA.2 – Example of marking for detachable SIDE RAILS specified by the MANUFACTURER**

**Subclause 201.7.2.2.107 – Marking on the MEDICAL BED for PENDANT CONTROL storage**



SOURCE: ISO 7010-W001 (2011-05) and ISO 7010-M002 (2011-05).

**Figure AA.3 – Examples of marking on the MEDICAL BED of storage location for wired and wireless PENDANT CONTROLS**

**Subclause 201.7.9.2.5.103 – Angles and height of MEDICAL BED**

When determining the adjustable height range of the MEDICAL BED, consideration should be given to regional anthropometrics for caregiver, OPERATOR and PATIENT.

Attention should be paid to:

– PATIENT falling from the MEDICAL BED, where a low height minimizes injuries;
– ease of PATIENT entry and egress;
– transfers to and from a wheelchair;
– caregivers' and OPERATORS' safe working height in order to minimize back problems.

**Subclause 201.7.9.2.5.104 – Maximum mass of MEDICAL BED**

Where a MEDICAL BED can be disassembled for transport by hand, knowledge of the mass of the main parts can be useful in avoiding strain.

**Subclause 201.8.11.3.2 Types**

Common national types of POWER SUPPLY CORDS:

| | |
|---|---|
| **Europe**: | H05BQH8-F, 05BQH8-F, H05BQ-F, H05BQH8-F, H05RR-F, H05VV-F, H05VVH2-F, H05VVH8-F, H07BQ-F |
| **North America**: | SJ, SJE, SJT, SVE |
| **China**: | RVV |
| **Japan**: | VCTF, VCTFK, VFF |
| **India**: | YY |

Not an exhaustive list: other types can be acceptable with appropriate robustness.

Equivalent national quality standards for mechanical robustness can be used to demonstrate duty rating (i.e: H05BQ-F, H05VV-F, SJT, VCTF, RVV). Light-duty cords (i.e: H03) are not adequate.

**Subclause 201.9.1 – MECHANICAL HAZARDS of ME EQUIPMENT**

General rationale for 201.9.1.101, and 201.9.101: There are various recognized RISKS that have been accepted on the basis of RISK benefit or RISK tradeoffs. SPECIALTY MATTRESSES are excluded from some tests because the clinical benefits derived from such mattresses can outweigh the RISKS involved with their use, and it might not be possible to satisfy the test requirements without compromising the clinical benefit of the SPECIALTY MATTRESS. However this document requires a RISK ASSESSMENT to be performed.

The requirements are only applied with the MATTRESS SUPPORT PLATFORM in the flat position unless otherwise indicated. The reason is that there are various clinical benefits associated with the ability of MEDICAL BEDS to perform various articulations. It is not apparent how the functionality of MEDICAL BEDS, particularly the most advanced, most clinically beneficial MEDICAL BEDS, could be preserved if the requirements were extended to articulated positions. MANUFACTURERS are encouraged to understand the RISK involved and to strive to minimize this RISK by analysis and novel approaches to mitigation, while maintaining clinical utility of the bed.

The dimensional requirements form a baseline, but they are not relevant to every bed application, and they can occasionally interfere with intended usage without mitigating RISK. The MANUFACTURER is responsible for justifying deviations for specialty MEDICAL BEDS or surfaces in the RISK ANALYSIS.

**Subclause 201.9.1.101 – Protection against PATIENT entrapment in non-moving parts**

The dimensional requirements listed in Figure 201.109 and Figure 201.110 and in Table 201.101 are intended to restrict openings in and around the MEDICAL BED system so that parts of the anatomy cannot enter or can pass through easily. Each requirement is based on commonly available anthropometric data. PATIENTS most vulnerable to entrapment are those who have cognitive disability or have uncontrolled body movement. These PATIENTS most often are frail, elderly or confused. Few adverse event reports indicate the angular position of the MATTRESS SUPPORT PLATFORM in which entrapment occurs, or what position the SIDE RAILS are in. Therefore this document requires that entrapment be evaluated by the MANUFACTURER's RISK ASSESSMENT in flat and articulated bed positions, with the SIDE RAILS fully raised and in intermediate positions.

Three key body parts at RISK for life-threatening entrapment in MEDICAL BED systems are the head, neck, and chest.

– Head

The 120 mm dimension is based on the 5$^{th}$ percentile Sri Lanka female head breadth, the distance across the face from ear to ear. Gaps <120 mm were chosen as this dimension represents a conservative measurement to reduce entrapment. A dimension of 120 mm includes all 5$^{th}$ percentile smallest female head breadth references and most 1$^{st}$ percentile international references.

In case of a permanently FIXED mattress specifically dedicated to the MEDICAL BED and SIDE RAIL and if sliding of the mattress on the MATTRESS SUPPORT PLATFORM is not possible, the test is performed by inserting the 60 mm cylindrical end of the cone TOOL with 120 mm cone between the permanently FIXED mattress and the SIDE RAIL ($A_2$ and $A_3$ areas).

– Neck

The 60 mm dimension is based on the 5th percentile width of a small ADULT female neck.

It is noted that people of small stature have a 1st percentile female neck diameter of 79 mm (5th percentile = 83 mm). Several factors, such as neck compressibility, loss of muscle mass in the neck as PATIENTS age, and the asymmetrical shape of the neck, all support a conservative measure of less than 60 mm.

To reduce the RISK of neck entrapment, gaps in the MEDICAL BED system should be small enough to prevent passage of a small neck. Additionally to reduce neck entrapment with regards to wedging of the neck, angles for V-shaped openings (Reference [9]) should be greater than 60°. The 60° angle reflects an understanding that at some point, a narrow angle creates a V-shape space or geometry that could be conducive to entrapment. The 60° angle was chosen by reviewing the TOOLS to assess entrapment RISK for swimming pool equipment [9]), and a corresponding mathematical analysis which shows that when a cylinder-shaped weight is supported by two offsetting force vectors, each of the perpendicular forces becomes equal to the weight of the cylinder when the angles relative to the vertical are 60°. An assumption is made that 60° can be considered to be an inflection point for angles where wedging can become a prominent consideration (see Figure AA.6 and Figure AA.7).

See also Annex CC Particular guidance for assessing V-shaped opening

– Chest

The 318 mm is based on the 95th percentile male chest depth. There have been reports of chest entrapment in MEDICAL BEDS in the space between split SIDE RAILS. To avoid chest entrapments, the spaces should be wide enough (greater than 318 mm) to allow a large chest to slip through without being entrapped.

Specification of cone TOOL and cylinder TOOL used to evaluate entrapment see Figure 201.104 a) and Figure 201.104 b).

– Rationale for measurement of B

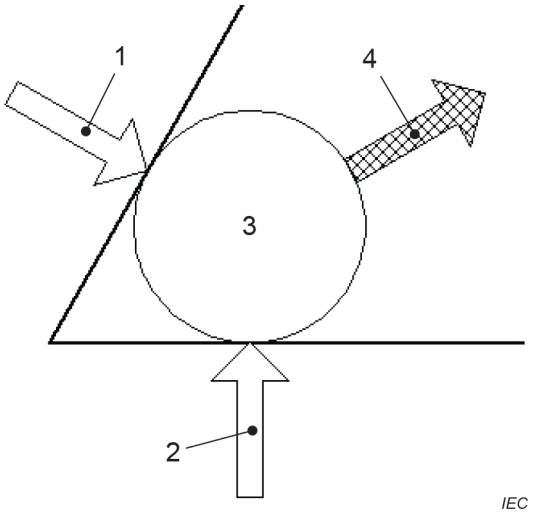
The measurement of area B includes two separate measurements: a measurement of the gap beneath the SIDE RAIL (see Figure AA.6), and a measurement of the interface angle at the mattress height, plus and minus 20 mm (Figure AA.7). The decision to include the mattress height in the measurement of the interface angle comes from an analysis of the forces on a neck with and without the mattress (Figure AA.4 and Figure AA.5). It is demonstrated that the mattress plays a significant part in entrapment where there is a wedging effect. It is understood that the measurement is done at the mattress height as specified by the MANUFACTURER. The measurement should represent a most adverse condition of the MEDICAL BED (i.e. smallest thickness mattress minus 20 mm, and thickest mattress plus 20 mm).

The angle measurements are taken for the range defined by (4) in Figure AA.7. For complex geometries in this range, measure to the tangential(s) of the SIDE RAIL.

See also Annex CC Particular guidance for assessing V-shaped opening.

– Rationale for measurement of C

The measurement of C1 allows for greater than 318 mm for APPLICATION ENVIRONMENT 1 since 24 h medical supervision and constant monitoring is provided.




**Key**

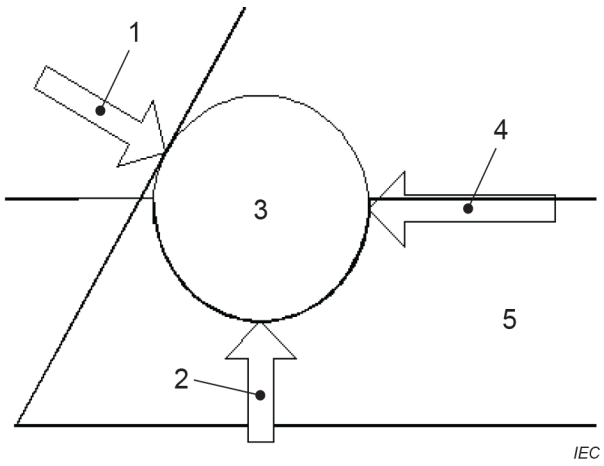
1 Normal force from SIDE RAIL

2 Normal force from MATTRESS SUPPORT PLATFORM

3 Neck

4 Resultant (ejecting) force

**Figure AA.4 – Resultant forces without mattress**




**Key**

1 Normal force from SIDE RAIL

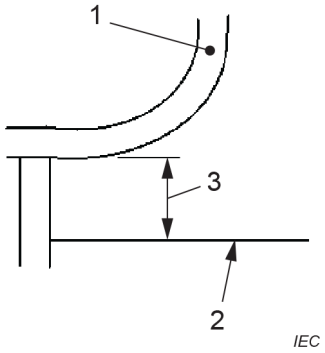
2 Normal force to neck from MATTRESS

3 Neck

4 Resultant force from MATTRESS

5 Mattress

**Figure AA.5 – Resultant forces with mattress**



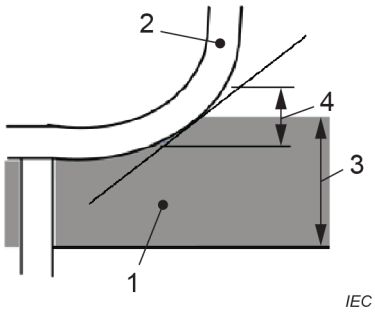

**Key**

1 SIDE RAIL

2 MATTRESS SUPPORT PLATFORM

3 Gap measurement (< 60 mm)

**Figure AA.6 – Example of 60 mm gap measurement of B**




**Key**

1 Mattress

2 SIDE RAIL

3 Mattress height(s) (specified by the MANUFACTURER)

4 Angle measurement zone

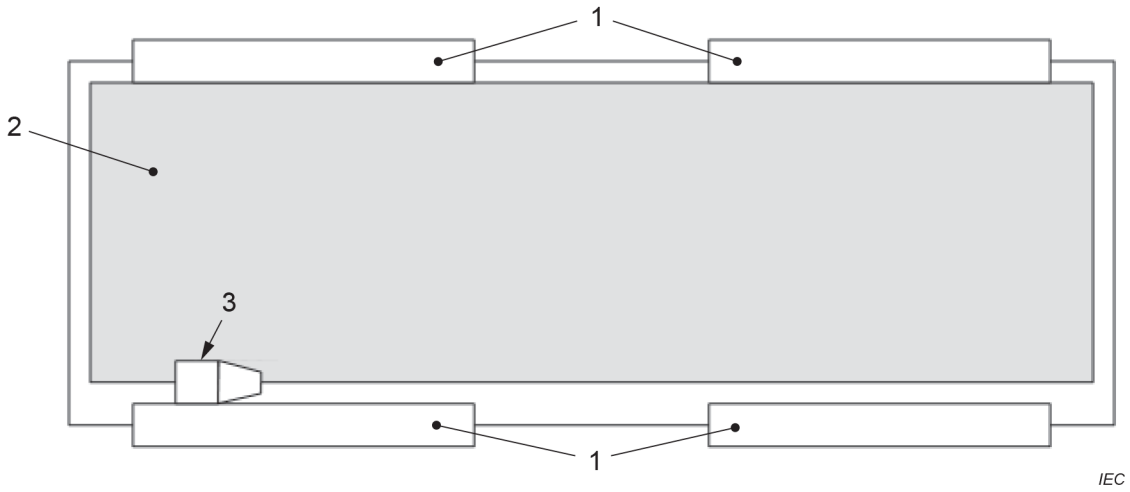
**Figure AA.7 – Angle measurement example of B**

– Rationale for measurement of D

Area D is the space between the inside surface of the SIDE RAIL and the mattress compressed by the weight of a PATIENT'S head. The space should be small enough to prevent head entrapment when taking into account the mattress compressibility, any lateral shift of the mattress or SIDE RAIL, and the degree of play from loosened SIDE RAILS. A dimension of less than 120 mm is required by document because the head is presumed to enter the space before the neck.

The goal of testing Area D is to assess if a PATIENT could trap his head in the horizontal space between the mattress and inside of the SIDE RAIL.

Additional examples of measurement of D are given in Figure AA.8 to Figure AA.11.



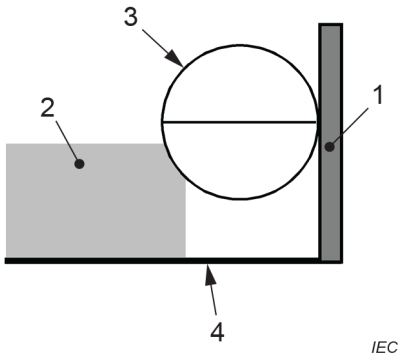

**Key**

1 SIDE RAILS

2 Mattress

3 Cone TOOL

**Figure AA.8 – Placement of measurement TOOL for measurement of D**




**Key**

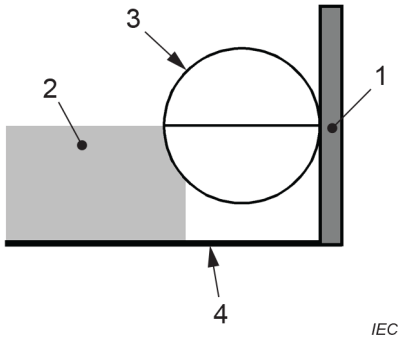
1 SIDE RAIL

2 Mattress

3 Cone TOOL

4 MATTRESS SUPPORT PLATFORM

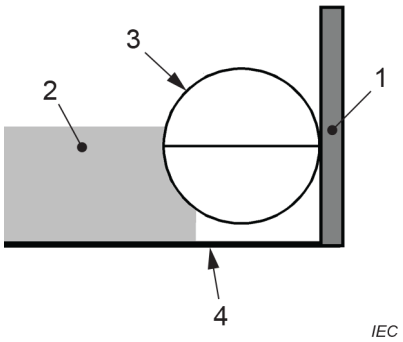
**Figure AA.9 – Example of area D measurement that passes**




**Key**

1 SIDE RAIL
2 Mattress
3 Cone TOOL
4 MATTRESS SUPPORT PLATFORM

**Figure AA.10 – Example of area D measurement that fails (on limit)**




**Key**

1 SIDE RAIL
2 Mattress
3 Cone TOOL
4 MATTRESS SUPPORT PLATFORM

**Figure AA.11 – Example of area D measurement that fails**

Some artist sketches are provided in Figure AA.12 to Figure AA.18 in order to demonstrate how entrapment can occur in each of the areas.

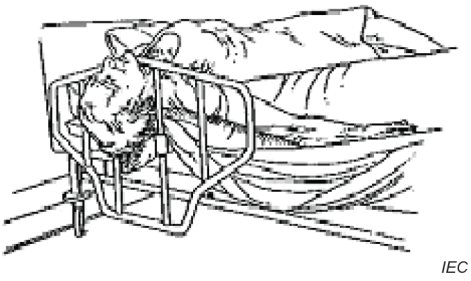



**Figure AA.12 – Example of potential PATIENT entrapment in area A within the SIDE RAIL**

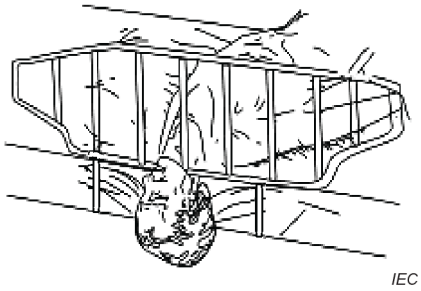



**Figure AA.13 – Example of potential PATIENT entrapment in area A below the SIDE RAIL**




**Figure AA.14 – Example of potential PATIENT entrapment in area B**




**Figure AA.15 – Example of potential PATIENT entrapment in area C between split SIDE RAIL**




**Figure AA.16 – Example of potential PATIENT entrapment in area C between SIDE RAIL and HEAD BOARD**

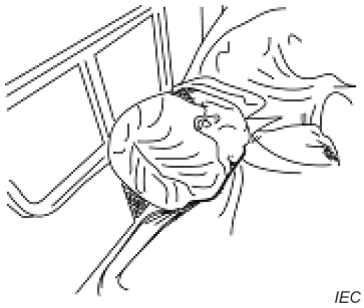



**Figure AA.17 – Example of potential PATIENT entrapment in area D**

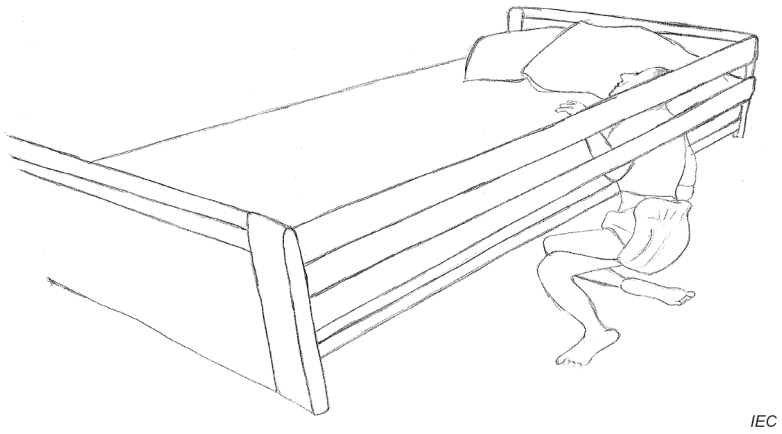



**Figure AA.18 – Example of potential PATIENT entrapment in area A below a single piece SIDE RAIL**

– Rationale for test force of 250 N instead of 50 N for SIDE RAIL

The investigations of incidents with entrapment in full-length SIDE RAILS that fulfil the standard EN 1970 or IEC 60601-2-38 regarding the measurement *A*, show that seven incidents were registered. Four of these incidents occurred between the lower bar and the MATTRESS SUPPORT PLATFORM, the other three occurred between the upper (or middle) bar and the lower bar of the SIDE RAIL.

In five of the seven incidents the PATIENTS died, one of seven led to a fracture and one had no serious consequences. The five PATIENTS died due to entrapment of the chest or the neck (body completely slipped under the bar (see Figure AA.18)).

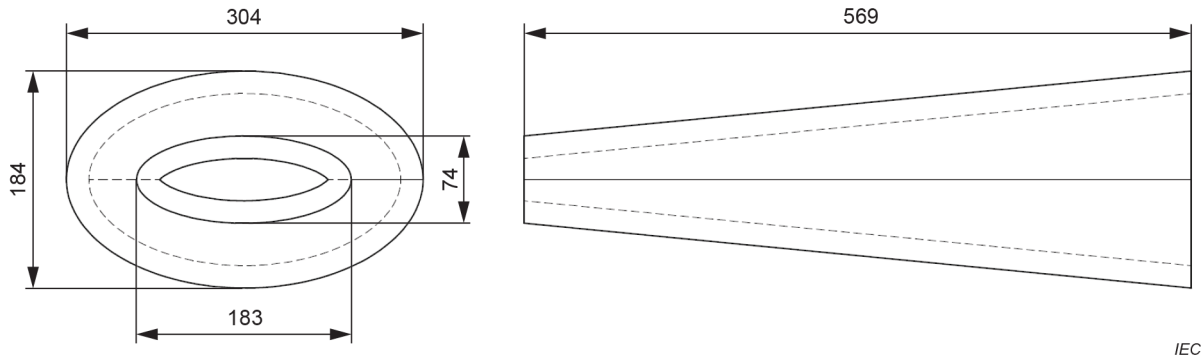
These results lead to the conclusion that the current test force of 50 N in IEC 60601-2-38 and the 30 N in EN 1970 is not sufficient.

The detailed review shows that in some cases the whole body of the PATIENT was lying on the bar and even when the PATIENT was very thin, 40 kg to 45 kg (estimated weight, weight was not registered) the body would have been pressing onto the bar. The bar bent and the (thin) person slipped with the legs under the bar and got stuck with the chest or the neck.

Even when it is considered that not the whole weight might be applied on the bar, it is estimated that at least 25 kg are pressed against it. Based on this estimate, the test force has been raised to 250 N for the testing of dimension *A* of SIDE RAILS.

The test TOOL of Figure AA.19 is not validated at the moment and it is placed in this informative annex to receive comments from the IEC/ISO community for future adoptions. The intent of TOOL was to be evaluated with a force of 250 N for dimension *A* of SIDE RAILS for foot 1$^{st}$ entrapment.

Dimensions in millimeters




Small end, ellipse representing knee

– 5th % female height

– 5th % male width

Large end, ellipse representing hip

– 5th % female height

– 5th % male width

Length, representing thigh

– 95th % male

**Figure AA.19 – Concept of potential PATIENT foot-first entrapment tool for area A below a SIDE RAIL**

**Subclause 201.9.2.3.1 – Unintended movement**

The probability of inadvertent motion due to component failure is significantly reduced when the lockout is engaged.

Several accidents have occurred involving foot-operated control pedals where PATIENTS, OPERATOR or visitors were injured or killed in the UNDERCARRIAGE of MEDICAL BEDS. The majority of the reported accidents occurred in long-term care environments. The factors of primary significance are:

– the existence of exposed MECHANICAL HAZARDS in the moving UNDERCARRIAGE,

– foot-operated control design which allows inadvertent activation, especially by unintended users,

– intermittent caregiver supervision, PATIENTS or OPERATORS accidentally falling or crawling over the control, and

– PATIENT, resident, or visitor characteristics such that the OPERATOR of the control lacks normal ADULT judgement.

Some of these factors can exist simultaneously to create a HAZARD of mechanical injury in the MEDICAL BED UNDERCARRIAGE, so elimination of some eliminates the RISK. The RISK for this HAZARD varies with the care environment. In APPLICATION ENVIRONMENT 1 and APPLICATION ENVIRONMENT 5 (intensive care and ambulatory), PATIENTS are generally under nearly continuous supervision, which minimizes RISK without regard to PATIENT characteristics or the MEDICAL BED design. RISK is comparatively high in long-term care unless protections are implemented in the MEDICAL BED design, because of intermittent caregiver supervision and resident mobility, mental characteristics or both of the MEDICAL BED occupants.

Experience in some countries with foot control (some incidents over recent years, including several deaths) shows that:

– incidents are more frequent in long-term services and with weak, disoriented or agitated PATIENTS but some other incidents occurred in acute care services or intensive care services and with normal ADULT judgement PATIENT;
– foot controls can generate an unacceptable RISK regarding its utility;
– a manual disconnection of foot controls or MOTION LOCKOUT CONTROL, without another safety system to prevent unacceptable RISK can require an additional RISK control because this function is not used consistently by OPERATOR.

**Subclause 201.9.4.2.1 – Instability in transport position**

See 201.9.4.3.1 for rationale on the change to 6 degrees from the base standard 10 degrees.

**Subclause 201.9.4.2.2 – Instability excluding transport position**

– Use of 1 100 N for PATIENT weight

1 100 N is used to simulate a PATIENT, resident or visitor weight. 110 kg is the 99$^{th}$ percentile male weight [6]. 110 kg corresponds to 1 078 N, or approximately 1 100 N.

– Explanation of the area on which load is applied

For the lateral test, having 2 persons sitting on the side edge of the MEDICAL BED, as close as possible to the end of the MEDICAL BED is reasonable. Since a 95$^{th}$ percentile male has a hip breadth, while sitting, of 466 mm [6], the weight of 2 × 1 100 N = 2 200 N is distributed over a length of 950 mm (466 mm rounded to 475 mm, × 2) and a width of 250 mm as in IEC 60601-2-38 and EN 1970. For the single person load in the longitudinal test (with fixed HEAD BOARD or FOOT BOARDS), the weight would be distributed over an area of 475 mm × 250 mm and these loads are placed on each side of the MEDICAL BED since the HEAD BOARD and FOOT BOARD prevents sitting on the end of the MEDICAL BED. For the longitudinal test where the FOOT BOARD is removable, the 2 200 N load is placed at the foot-end of the MEDICAL BED and distributed across the entire width of the MEDICAL BED, which is about 950 mm.

Testing is done without the SAFE WORKING LOAD, as it is common for visitors to sit on the side or end of a MEDICAL BED when the PATIENT is NOT in the MEDICAL BED; this is the worst case. The SAFE WORKING LOAD in place on the MEDICAL BED during the test would only help stabilise the MEDICAL BED and is therefore not used. The loads specified in the lateral and longitudinal stability tests should be placed on the side or end of the MEDICAL BED that is heaviest in order to maximise the potential for tipping, but since it is difficult to determine which side is heaviest, the test is done on both sides and both ends.

– Explanation for use of 1 850 N load in APPLICATION ENVIRONMENT 4

There have not been reported any accidents with the loading of 1 350 N at the foot end of the bed as required in EN 1970. The MEDICAL BED in APPLICATION ENVIRONMENT 4 is still safe for the MEDICAL BED PATIENT to sit anywhere on the MEDICAL BED, as the maximum PATIENT load always shall be used both for this test and the lateral stability test, if it exceeds 1 850 N. Higher loads for the test will be in conflict with ergonomic requirement in APPLICATION ENVIRONMENT 4.

– Longitudinal stability test rationale

In the longitudinal stability test, the primary concern is testing the foot end with removable FOOT BOARDS. The head end is not a concern as it is unlikely for a guest to sit there.

**Subclause 201.9.4.2.4.3 – Movement over a threshold**

The use of 0,8 m/s instead of 0,4 m/s in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 is necessary to achieve that the MEDICAL BED will pass over the threshold with all castors. The speed of 0,8 m/s represents the real situation, because the OPERATOR will use this speed to pass the threshold. Therefore the construction of MOBILE MEDICAL BEDS in APPLICATION ENVIRONMENTS 1, 2, 3, 5 and 6 shall withstand this situation.

**Subclause 201.9.4.3.1 – Instability in transport position**

The 6° angle was determined from building code regulations in different countries. Such regulations set the maximum angle allowed for floors at 5,7° in Canada, 4,76° in the UK, 4,76° in the USA and 2,86° in Denmark.

**Subclause 201.9.8.2 – TENSILE SAFETY FACTOR**

The safety factor requirements from pre-existing standard IEC 60601-2-38 and EN 1970 were demonstrated to be sufficient by several years of field application. Consequently these requirements are carried over into this document. Also, durability tests are given with regard to the real situation over the lifetime of a MEDICAL BED (see 201.9.8.3.3.101, 201.9.8.3.3.104, 201.9.8.3.3.105, 201.9.8.3.3.106 and 201.9.8.3.3.107).

**Subclause 201.9.8.3.2 – Static forces due to loading from persons**

– Static strength

EN 1970 was substantially similar to IEC 60601-2-38 in this regard with the exception of the MEDICAL BED being in the worst-case position. IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 refers to the worst-case as the "most disadvantageous" position. IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 text was therefore chosen, where "most disadvantageous height" refers to the adjustment up or down of the height of the MEDICAL BED. The test method requires also most disadvantageous length, as this could be worse case for MEDICAL BEDS, with built-in or added length adjustment. Additionally, a 1-hour time duration should be applied only when assemblies contain elements subject to material creep (plastics or other non-metals). Where all metal assemblies are being tested, timeframes above 1 min are not needed (see IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 9.8.2, Note 2).

– ACCESSORIES strength

Terminology of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 was adopted. Where ACCESSORIES can be cycled to induce similar wear of components, use of the part of the SAFE WORKING LOAD specified for the ACCESSORY is acceptable to prove compliance with the requirement, provided expected wear is simulated on the ACCESSORY or attachment point prior to testing. The expected distribution of weight upon the ACCESSORY during reasonably foreseeable misuse should be considered when testing the ability of the ACCESSORY load support.

The 1 h requirement is only required in designs where material creep is a concern (plastic parts are used). For assemblies that are all metal, 1 min is enough to determine if the design is capable of withstanding the SAFE WORKING LOAD times the TENSILE SAFETY FACTOR (see IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 9.8.2 Note 2).

**Subclause 201.9.8.3.3 – Dynamic forces due to loading from persons**

– Loading from persons

The above requirements were added due to issues seen in the field that were perceived to have been caused by improper specification of dynamic strength. The issues included the failure of the MEDICAL BED or UNDERCARRIAGE assemblies, resulting in the MEDICAL BED surface dropping to the lowest level. It was therefore felt that a minimum standard test should be specified. The dynamic strength tests are designed to be a minimum standard to assess the dynamic strength of the MEDICAL BED. Testing should be modified as per the MANUFACTURER'S RISK ASSESSMENT program based on such things as elimination of RISK by design, normal and abuse conditions by the OPERATOR or PATIENT, environmental issues and others. Components, which loosen, or malfunction during tests that do not contribute to additional RISK, or sudden collapse of product, can be replaced.

**Subclause 201.9.8.3.3.102 – Dynamic testing of the height adjustment mechanism**

The experience of the experts from test houses and MANUFACTURER with the market observation leads to the result that a dynamic test as described is necessary to provide a minimum of safety between reasonable service intervals.

The number of 3 000 cycles is calculated on the base of 1 to 2 cycles a day, which represents a product life time of approximately 4-8 years.

**Subclause 201.9.8.3.3.103 – SIDE RAIL strength and latch reliability**

This requirement combines the proposed cycle test with the load test in IEC 60601-2-38 to ensure proper latching of the SIDE RAIL after a simulated life cycle. "HAZARD" was changed to "RISK" to use terminology of IEC 60601-1:2005. 30 000 cycles is used considering an average product life cycle of 10 years, with 4 usages per day (14 600 cycles) multiplied by a safety factor of 2. The number of cycles should be representative of the actual product life cycle, and product estimated usage of the SIDE RAILS. Components, which loosen, or malfunction during tests that do not contribute to additional RISK or sudden collapse of SIDE RAILS, can be replaced.

– SIDE RAIL latch

Lateral and longitudinal cycling: The number of cycles chosen is arbitrary in an effort to reproduce the action of an agitated PATIENT exerting reasonably foreseeable misuse on the SIDE RAIL. Once again, testing should be tailored to the MANUFACTURER'S indicated life cycle, estimated SIDE RAIL usage and RISK ANALYSIS with regards to number of cycles, forces applied and direction of force.

The specified maximum PATIENT weight is used to simulate a PATIENT climbing over the SIDE RAIL, as an additional reasonably foreseeable misuse. No data has been presented on PATIENTS over 1 112 N climbing over SIDE RAILS, resulting in a fall.

100 N is selected for this test as an approximation of an agitated PATIENT shaking the SIDE RAIL from the MEDICAL BED.

For Figure 201.126 Force A represents someone pulling up on the SIDE RAIL, the application of force should be on top of the SIDE RAIL.

For Figure 201.126 Force B represents a PATIENT climbing over the top of the SIDE RAIL, the force should be applied to top the SIDE RAIL also.

For Figure 201.126 Forces C, D, E and F represent a PATIENT and OPERATOR using the SIDE RAIL as a grab handle.

**Subclause 201.9.101 – Protection against inadvertent PATIENT falls**

The requirement for SIDE RAILS height is intended to ensure that SIDE RAILS reduce the RISK of the PATIENT accidentally slipping or rolling off the mattress. Due to the nature of the SIDE RAIL entrapment HAZARD, compliance with the listed dimensional requirements is not in itself considered adequate to address all possible dangers (including entrapment of legs and arms, or the RISK of a PATIENT falling from an attempt to climb over the SIDE RAILS). For this reason, an additional requirement to perform a RISK ASSESSMENT (evaluating all issues pertaining to SIDE RAILS) has been included.

The 220 mm dimension is the minimum height requirement for the top edge of a SIDE RAIL above the upper surface of the mattress and is based on the midpoint (center of gravity) of an ADULT male torso at the 95$^{th}$ percentile lying on the shoulder on a compressed mattress.

The minimum height requirement for SIDE RAILS can increase the RISK of injury when a PATIENT climbs over and falls. The minimum length requirement on SIDE RAILS can increase entrapment RISK by reducing egress points for the PATIENT, and while it can decrease inadvertent fall RISK from rolling out of MEDICAL BED, it can increase RISK where PATIENTS can opt to climb over the SIDE RAILS. The dimensional requirements in this document reflect an attempt to make the best RISK tradeoffs on the basis of available information. Future data can demonstrate that some of these requirements should be revised at a future date.

**Subclause 201.11.8 – Interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT**

Examples of emergency PROCEDURES (as specified by the MANUFACTURER) that are needed during an interruption of the SUPPLY MAINS to MEDICAL BEDS are:

– positions for cardiopulmonary resuscitation (CPR), for example, emergency back flattening;
– others as specified by the MANUFACTURER.

**Subclause 201.13.1.4 – Specific MECHANICAL HAZARDS**

The U.S. Food and Drug Administration incident database was reviewed in the preparation of this document to relate field incidents of unintended movement to the concept of SINGLE FAULT CONDITION and abnormal operation in IEC 60601-1:2005. This review indicates such incidents mainly manifest when an electrically driven actuation starts unexpectedly and drives to its limit in one direction. The apparent cause is a fault occurring in MEDICAL BED function controls.

Abnormal operation and fault condition requirements emphasize protection against faults in the motion control systems of electrically powered MEDICAL BEDS. An interpretation is also developed to extend the SINGLE FAULT SAFE concept for unintended motion to non-electrically powered MEDICAL BEDS and pneumatic and hydraulic subsystems of electrical MEDICAL BEDS.

The requirement to provide a means (not accessible by the PATIENT) for deactivating controls that are accessible by the PATIENT is retained from the previous standard, but regarded as a human factors aspect that is not inherently integral to SINGLE FAULT CONDITION and abnormal operation requirements.

Tradeoffs are required among human factors, clinical benefits available from positioning the MATTRESS SUPPORT PLATFORM, and technology. For instance, it is possible to reduce the probability of a SINGLE FAULT CONDITION causing a movement without human intervention by the use of redundant circuits and parallel switches, which shall be closed simultaneously. Such a requirement is out of proportion to the RISK for the vast majority of PATIENTS and clinical situations. It would degrade the USABILITY of the product for clinical users and be equivalent to removing PATIENT controls for those PATIENTS whose lack of dexterity or medical condition prevents them from operating two controls simultaneously.

This document introduces the concept of the MOTION LOCKOUT CONTROL. The MOTION LOCKOUT CONTROL provides a means to reconcile varying PATIENT needs. Some PATIENTS need controls with a high degree of USABILITY and have little RISK exposure in the event of rare unintended motion. Other PATIENTS require exceptional protection against possible unintended motion, even if control ergonomics are entirely sacrificed. A MOTION LOCKOUT CONTROL deployable at OPERATOR option can meet both needs.

**Subclause 201.15.3.5 – Rough handling test**

The reason for the difference to the speed of 0,8 m/s used in 201.9.4.2.4.3 is because the OPERATOR normally did not intend to hit the door frame and will stay with the speed (0,4 m/s) according to the requirements of the IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

**Subclause 201.15.4.4 – Indicators**

MEDICAL BEDS connected to MAINS VOLTAGE are generally operational at all times. This is generally understood by the OPERATORS; therefore no indicator light is required.

**Subclause 201.15.4.6.2 – Limitation of movement**

Loss of blood flow to legs (from over-flexing of the torso) or build-up of blood or other fluids in the abdomen can cause severe damage to PATIENT.

# Annex BB
(normative)

# Additional design requirements and recommendations for MEDICAL BEDS

## BB.1 General

Although it is recognized that the responsibility for defining the INTENDED USE (and therefore the configuration of features) of the MEDICAL BED rests with the MANUFACTURER, certain factors shall be taken into consideration. The following is intended both as requirements for MEDICAL BEDS intended for certain APPLICATION ENVIRONMENTS and also as guidelines for MANUFACTURERS when designing MEDICAL BEDS for other APPLICATION ENVIRONMENTS.

The following parts of Annex BB are normative based on APPLICATION ENVIRONMENTS:

For APPLICATION ENVIRONMENT 4: all of Annex BB.

For APPLICATION ENVIRONMENT 1, 2, 3, 5 and 6: BB.3.2 and BB.3.3 (angles C and E).

## BB.2 Human factors

### BB.2.1 General

It is recognized that for a MEDICAL BED to accommodate the medical practices and PROCEDURES for which it will be used, the interaction of the human body (OPERATOR and PATIENT) with the MEDICAL BED shall be considered as a method of assuring efficient and safe operation. The issues and any dimensions shall be based on statistical analyses of regional populations. When used, appropriate dimensions shall always be determined based on anthropometric data for the population in the area in which the MEDICAL BED is intended to be used.

### BB.2.2 Range of adjustment of the height of the MATTRESS SUPPORT PLATFORM

Range of adjustment (if applicable) of the height of the MATTRESS SUPPORT PLATFORM above the floor:

For height adjustable MEDICAL BEDS the MATTRESS SUPPORT PLATFORM, in its flat position, shall have a range of adjustment which at least allows positioning between 400 mm and 800 mm above the floor, measured at the uppermost part of the MATTRESS SUPPORT PLATFORM.

MEDICAL BEDS without the possibility of adjustment of height are only suitable for persons not needing caregivers.

### BB.2.3 Dimensions for handles and pedals

**BB.2.3.1** The surface of buttons shall at least cover a circle of 15 mm in diameter. Any distance between buttons shall be more than 10 mm.

The buttons can have any shape.

**BB.2.3.2** The free distance between any handle (those parts intended to be grabbed) requiring an operating force of more than 10 N and any construction part shall be more than 35 mm.

**BB.2.3.3** The free distance between the upper side of any pedal (those parts intended to be stepped on) and any construction part shall be more than 75 mm.

**BB.2.3.4** The diameter of operating handles requiring an operating force of more than 10 N shall be between 19 mm and 43 mm.

**BB.2.3.5** Pedals shall not be more than 300 mm above the floor.

### BB.2.4 Operating forces for handles and pedals

**BB.2.4.1** In the case of electrically operated functions, the force to operate the control unit buttons shall be less than 5 N.

**BB.2.4.2** In the case of non-electrically operated functions, the force to release operating handles shall be no more than 10 N and the force required to lift any part of the MATTRESS SUPPORT PLATFORM shall be no more than 200 N, when loads are fixed to the MATTRESS SUPPORT PLATFORM as shown in Figure 201.124, with their centre of gravity in the middle of the sections, unless the instructions for use state that more than one person is required.

**BB.2.4.3** The static force to operate pedals shall be no more than 300 N when loads are fixed to the MATTRESS SUPPORT PLATFORM, as shown in Figure 201.124, with their centre of gravity in the middle of the sections.

**BB.2.4.4** For MOBILE MEDICAL BEDS intended to transport PATIENTS, the force required to initiate movement of the MEDICAL BED with the SAFE WORKING LOAD shall not exceed 160 N. The force required to maintain movement (after it has been initiated) shall not exceed 85 N.

## BB.3 Functionality

### BB.3.1 General

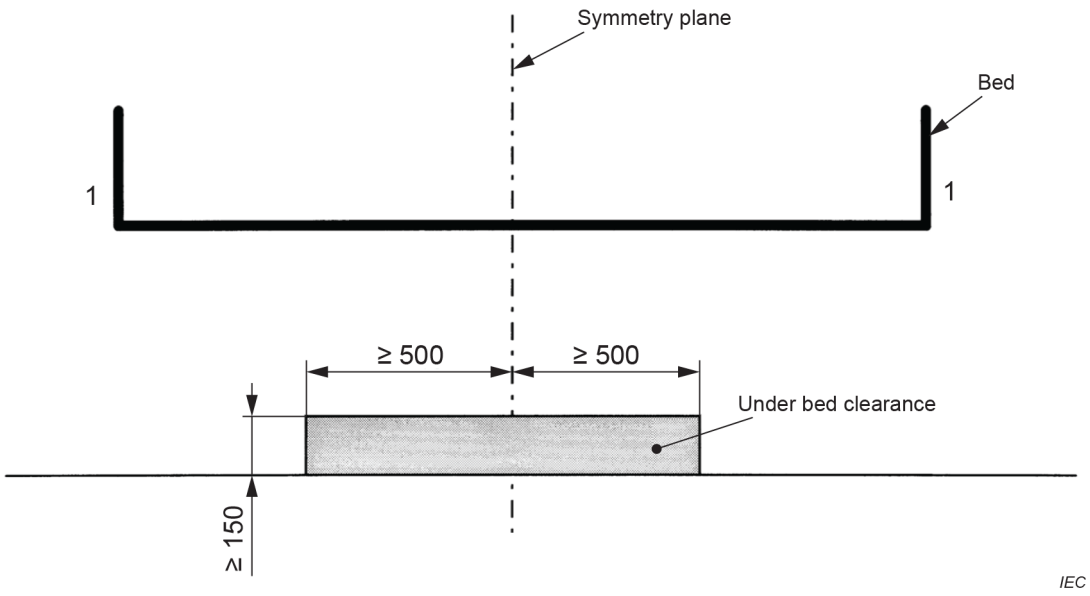
Frequently, MEDICAL BEDS are designed for use in combination with other ME EQUIPMENT. MANUFACTURERS are encouraged to evaluate not only those characteristics of the MEDICAL BED that could affect the safe operation of the system (the MEDICAL BED in combination with the ME EQUIPMENT) but also the characteristics of the MEDICAL BED which facilitate the use of the system.

### BB.3.2 Combination of MEDICAL BED and MOBILE hoists

With the MATTRESS SUPPORT PLATFORM lowered to any position higher than 400 mm, the height of the under MEDICAL BED clearance shall be at least 150 mm at a length of at least 500 mm positioned on each side of the symmetry plane of the MATTRESS SUPPORT PLATFORM (see Figure BB.1).

If the requirement cannot be fulfilled because of a particular product feature specified by the MANUFACTURER (e.g. 5$^{th}$ wheel), the instructions for use shall provide a warning about compatibility of hoists (see 201.7.9.2.2 d)). In this case compliance is checked by the inspection of the RISK MANAGEMENT FILE.

Dimension in millimeters




**Key**

1 Bed ends

**Figure BB.1 – Schematic presentation of under MEDICAL BED clearance**

### BB.3.3 Range of adjustment of moveable sections of the MATTRESS SUPPORT PLATFORM

The ranges of adjustment (if applicable) for back, upper leg, and lower leg sections of the MATTRESS SUPPORT PLATFORM are as follows:

– The angle *A* between the back rest section and the MEDICAL BED board frame (see Figure BB.2) shall have a minimum adjustable range of 0° (horizontal) and 70°. A maximum of 85° shall only be reachable when the MEDICAL BED is intended to raise a person to an upright sitting position for transfer.

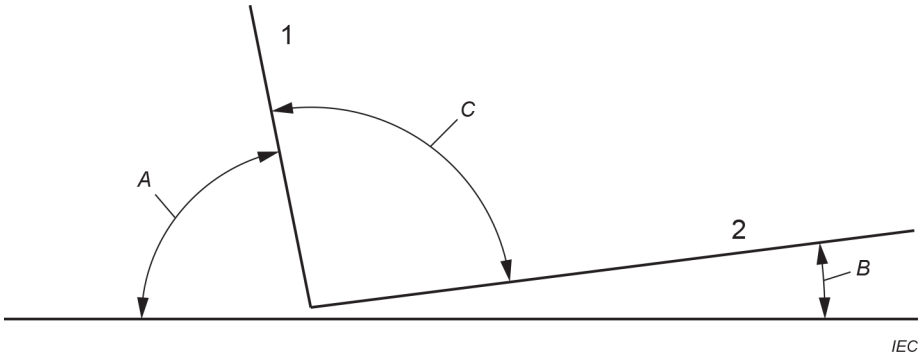
– The angle *A* (see Figure BB.2) of the back section in relation to the horizontal shall always be greater than or equal to 0°.

– The angle *B* between a line drawn between the turning point of the back rest section and seat section and the turning point of the upper leg section and lower leg section and horizontal (see Figure BB.2) shall at least be adjustable between 0° and 12°.

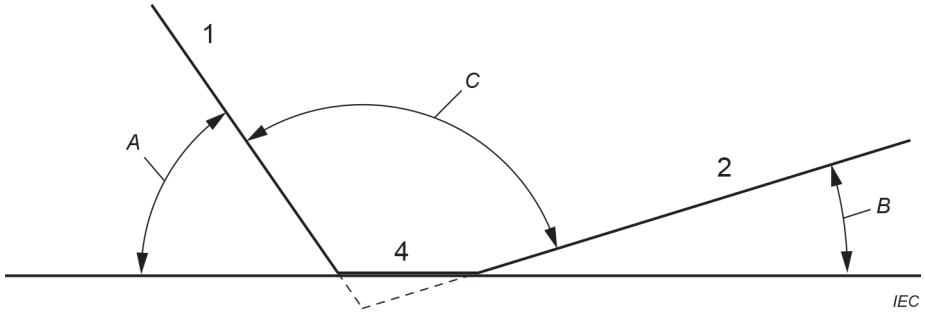
– The angle *C* – See 201.15.4.6.2 (angle “ɣ” )

– The angle *D* between the lower leg section and horizontal (see Figure BB.2) shall at least be adjustable between 0° and 20° under horizontal.

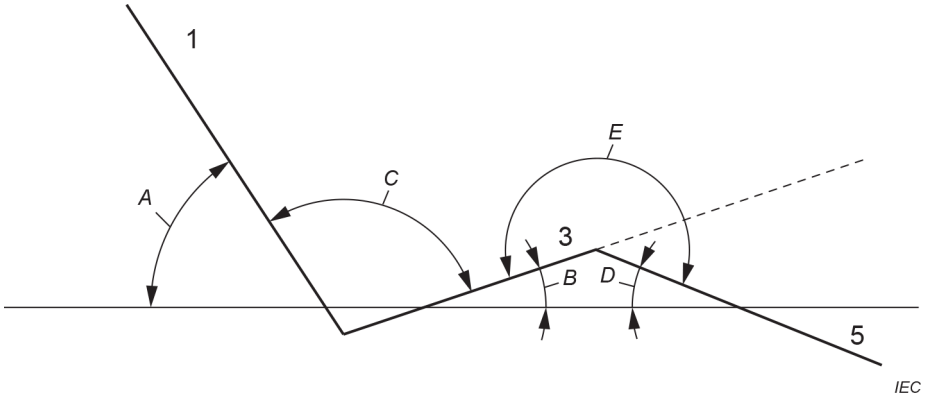
– The angle *E* between the upper side of the upper leg section and the upper side of the lower leg section (see Figure BB.2) shall be at least 180° for all MEDICAL BEDS.



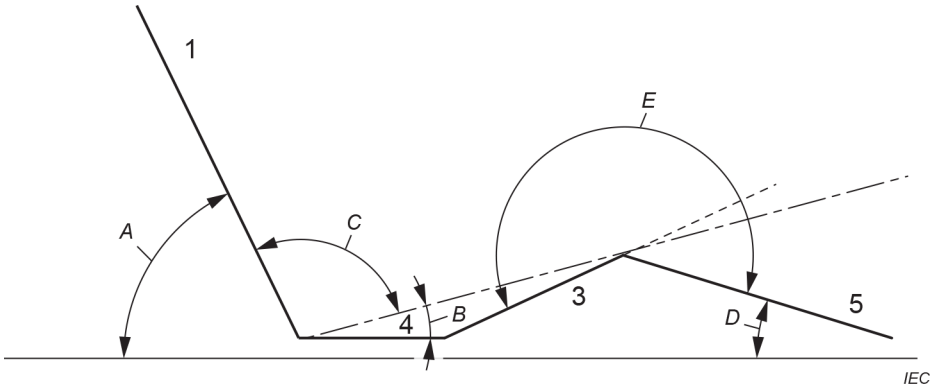

**a) Back to leg articulations**




**b) Back to seat and seat to leg articulations**




**c) Back to upper leg and upper to lower leg articulations**




**d) Back to seat, seat to upper leg and upper leg to lower leg articulations**

**Key**

1 Back section

2 Leg section

3 Upper leg section

4 Seat section

5 Lower leg section

Subfigures a) to d) specify how to measure the two angles C and A for different configurations of a MATTRESS SUPPORT PLATFORM. They are not intended to be prescriptive to serve as a reference to common articulation configurations only and are not intended to be prescriptive in terms of articulation joints or pivot points. Other MATTRESS SUPPORT PLATFORM configurations are permitted.

**Figure BB.2 – Recommendations and requirements regarding angles for different sections of the MATTRESS SUPPORT PLATFORM**

# Annex CC
(informative)

# Particular guidance for assessing RISK of entrapment in V-shaped openings

An additional proposed test method of assessing RISK of entrapment in V-shaped openings in relation to areas B and C (see Table 201.101) between the elements of SIDE RAIL, HEAD BOARD, FOOT BOARD and MATTRESS SUPPORT PLATFORM is offered. This test method is not validated at the moment and it is placed as an informative annex to receive comments from the IEC community for future adoptions.

The reasons for offering this additional method are as follows:

For area B it offers an additional method of assessing the contribution to entrapment into the gap between the elements due to the geometry of the V-shaped openings. The test method at the same time reduces the influence of MATTRESS depth and compressibility.

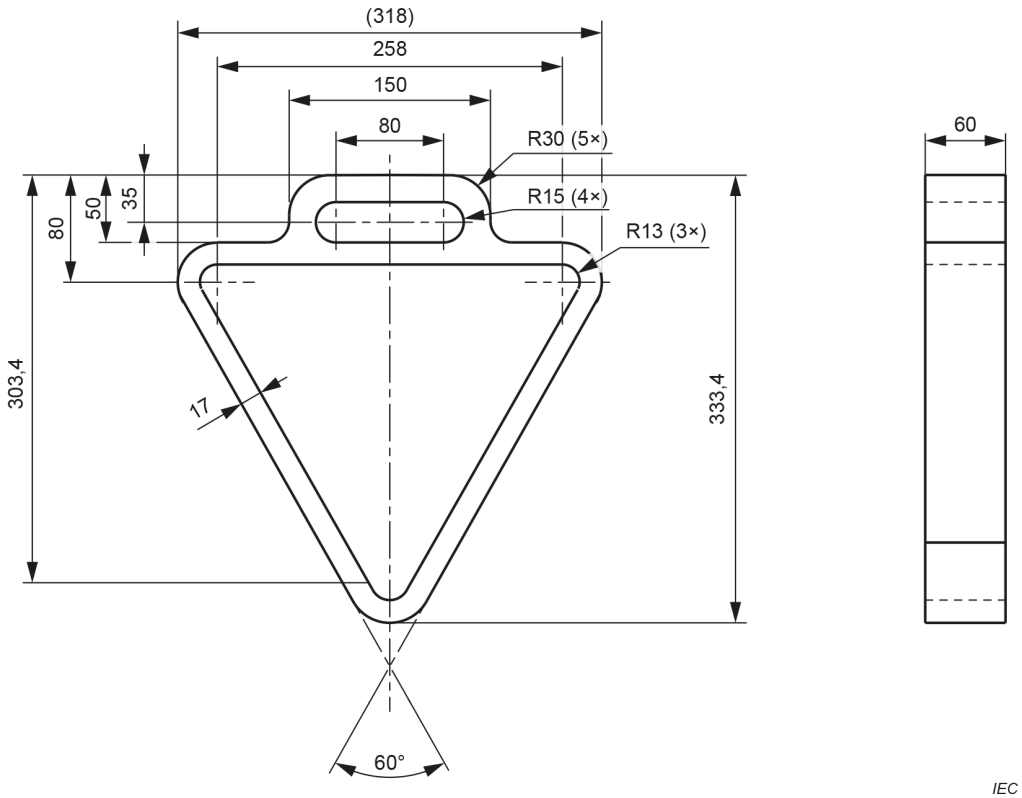
For any C areas it offers a means of assessing the contribution to entrapment into the gap between the elements due to the geometry of the V-shaped openings, this is not covered in the normative part of the document (see Table 201.101, area C).

### Subclause 201.9.1.101 – Protection against PATIENT entrapment in non-moving parts

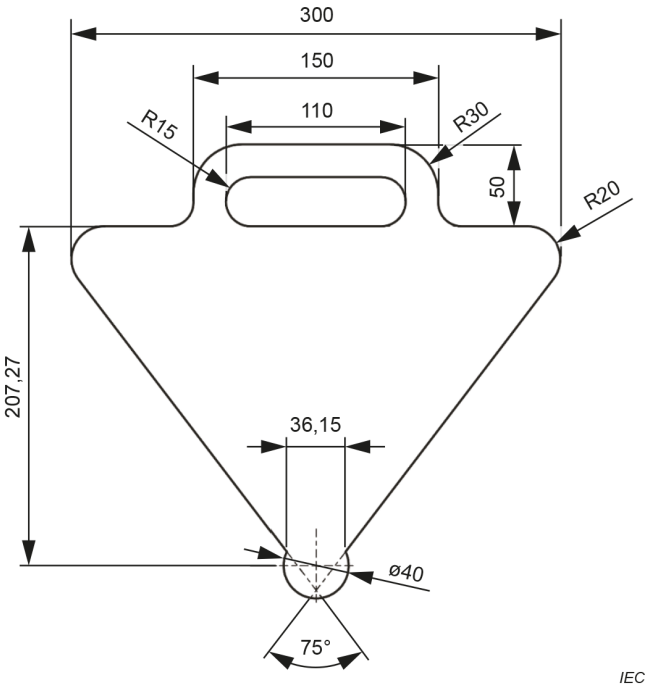
To reduce the RISK of neck entrapment, openings between elements in the MEDICAL BED system above the MATTRESS SUPPORT PLATFORM should be small enough to prevent passage of a small neck. Additionally to reduce neck entrapment with regards to wedging of the neck, angles for V-shaped entry into the openings should be greater than 75°. The 75° angle reflects an understanding that at some point, a narrow angle creates a V-shaped space or geometry that could be conducive to entrapment. The 75° angle was chosen by reviewing the TOOLS to assess entrapment RISK for swimming pool equipment (see EN 13451-1[9]) and making changes suitable to application on MEDICAL BEDS by increasing the wedging minimum angle of 60° to 75°. The 75° angle reduces the RISK of PATIENT entrapment through hooking of the neck and head in the V-shaped opening (See Figure AA.14 and Figure AA.16). The wider angle allows the PATIENT to pull his head free from a vertical opening with less effort. This is essential when considering a weak or confused PATIENT.

To measure V-shaped openings in relation to areas B and C, a test method and wedge TOOL (see Figure CC.1) has been developed. The TOOL is made from aluminium and weighs 3,34 kg representing the mass of a small ADULTS head and neck [6], the wedge angle is 75° and has a 60 mm diameter cylindrical end representing the small ADULT neck.

Dimension in millimeters




**a) Version 60°**




**b) Version 75°**

Material: Aluminium

Weight: 3,34 kg

NOTE Inner profile only can be adjusted accordingly to suit weight requirements.

**Figure CC.1 – Wedge tool**

– Proposed rationale for measurement of area B

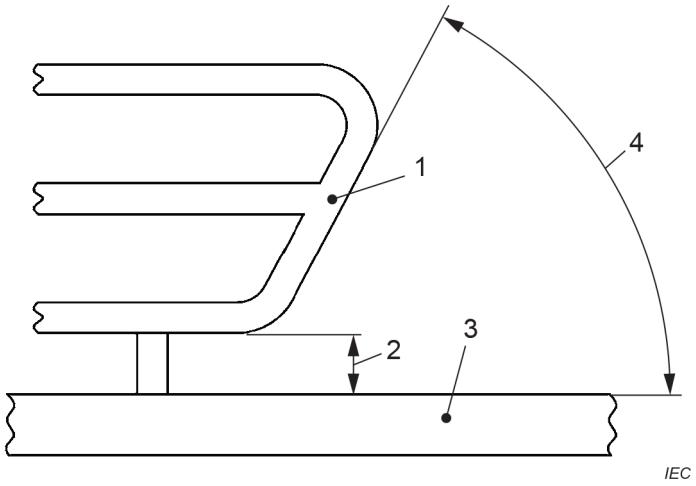
The measurement of area B includes the gap beneath the SIDE RAIL, the V-shaped opening between the underneath of the SIDE RAIL and the leading edge of the SIDE RAIL to the MATTRESS SUPPORT PLATFORM (see Figure CC.2). The 75° angle reduces the RISK of PATIENT entrapment through hooking of the neck and head in the V-shaped opening (see Figure AA.14).

– Proposed and unvalidated test method for V-shaped openings

The MATTRESS SUPPORT PLATFORM is set in the flat horizontal position (and at the most disadvantageous height depending on the design) with the SIDE RAILS raised and locked (with segmented SIDE RAILS test independently and together).

Rest the wedge TOOL against the edge of the MATTRESS SUPPORT PLATFORM and push it into the V-shaped opening between the lowest point of the SIDE RAIL outside of the SIDE RAIL support and the MATTRESS SUPPORT PLATFORM orientating the wedge TOOL into the narrowest opening. The wedge TOOL shall contact against both sides of the 60 mm cylinder diameter part of the wedge TOOL (it should not pass through). The opening should not allow the wedge TOOL to come into contact with both sides of the 75° angle at the same time, see compliance criteria examples Figure CC.3.

The influence of any specified mattress fitted on the areas of potential entrapment should be assessed for acceptability and justified in the MANUFACTURERS RISK MANAGEMENT FILE.




**Key**

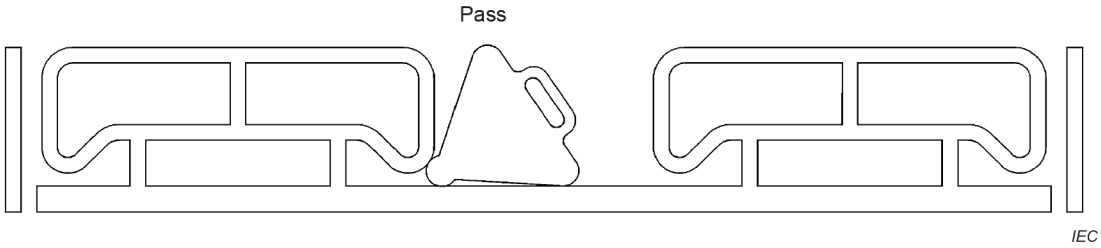
1 Leading edge of safety side

2 Gap (< 60 mm)

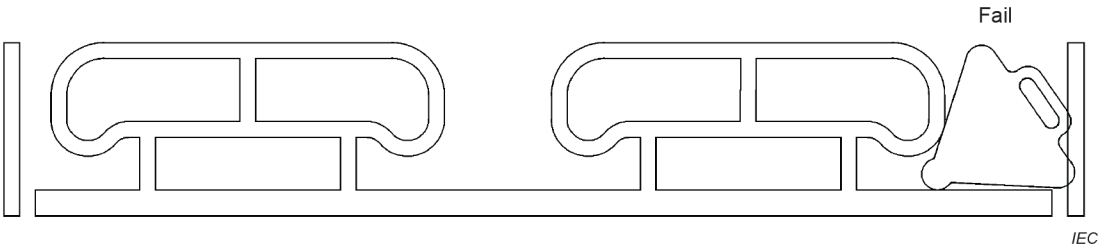
3 MATTRESS SUPPORT PLATFORM

4 V-shaped opening (> 75°)

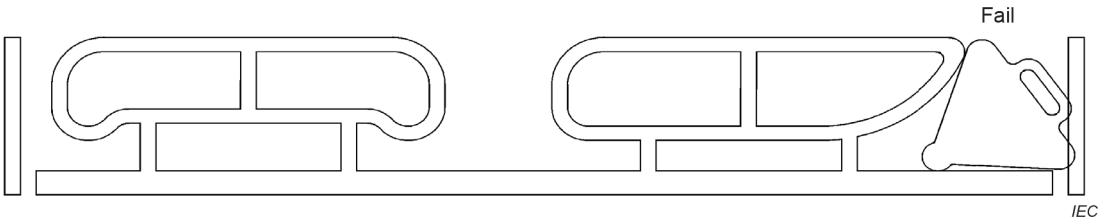
**Figure CC.2 – V-shaped opening in relation to B**




**a) SIDE RAIL to MATTRESS SUPPORT PLATFORM (one side contact), Area B - Pass**




**b) SIDE RAIL to MATTRESS SUPPORT PLATFORM (two side contact) - 1, Area B - Fail**




**c) SIDE RAIL to MATTRESS SUPPORT PLATFORM (two side contact)- 2, Area B – Fail**

**Figure CC.3 – Acceptance criteria in relation to area B**

– Proposed rationale for measurement of area C with the wedge TOOL

The measurement of area C includes the V-shaped openings between the SIDE RAIL and the head end and foot end and the V-shaped opening between split SIDE RAILS. The 75° angle reduces the RISK of PATIENT entrapment through hooking of the neck and head in the V-shaped opening (see Figure AA.15 and Figure AA.16).

– Proposed and unvalidated test method area C for V-shaped openings

The MATTRESS SUPPORT PLATFORM is set in the flat horizontal position (and at the most disadvantageous height depending on the design) with the SIDE RAILS in any raised and locked positions. For MEDICAL BEDS with split SIDE RAILS the test shall also be performed in the worst case opening between SIDE RAILS in articulated positions.

Hold the wedge TOOL by the handle and place it between the narrowest distance between the gap in the V-shaped opening. Allow the TOOL to rest under its own weight in the opening, the 60 mm diameter cylindrical end should always contact both sides of the V-shaped opening and should not pass through into the gap. Rotate the TOOL until one of the 75° angled sides touches the edge of one side of the opening (it can be necessary angle the TOOL to locate it against the narrowest part of the opening, see Figure CC.4).

The opening should not allow the wedge TOOL to come into contact with both sides of the 75° angle at the same time, see acceptance criteria examples Figure CC.5 and Figure CC.6.

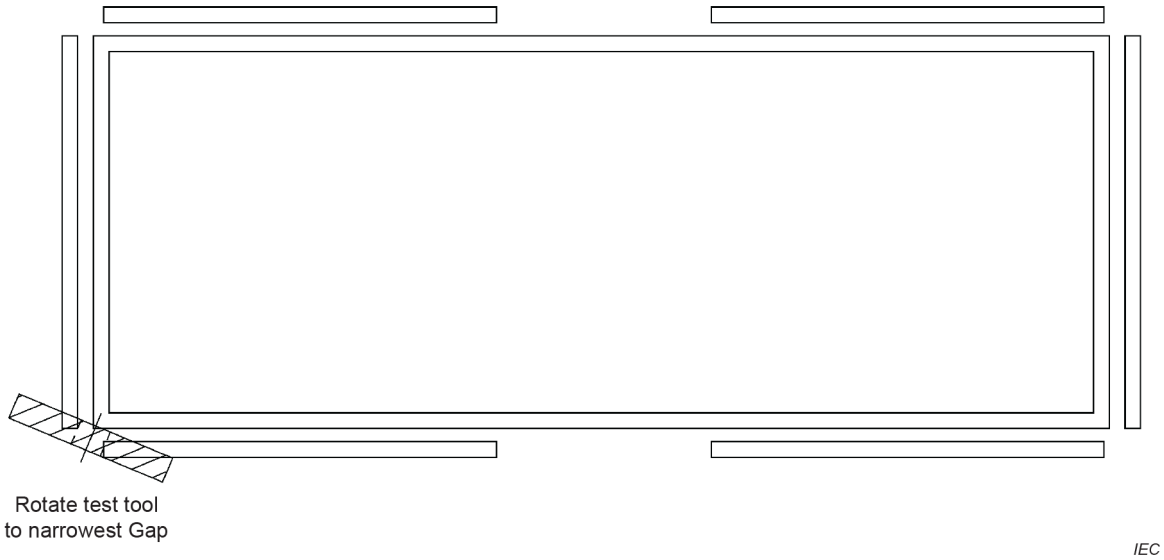
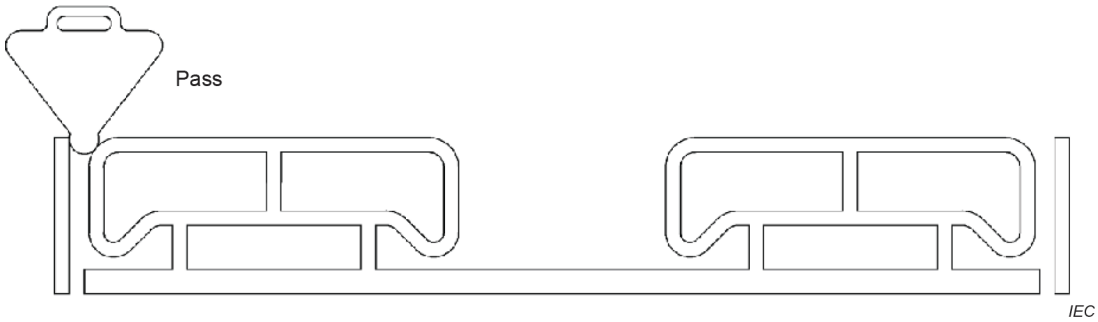
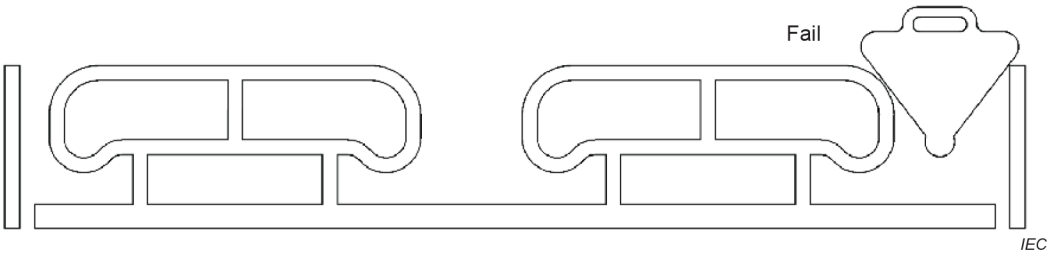


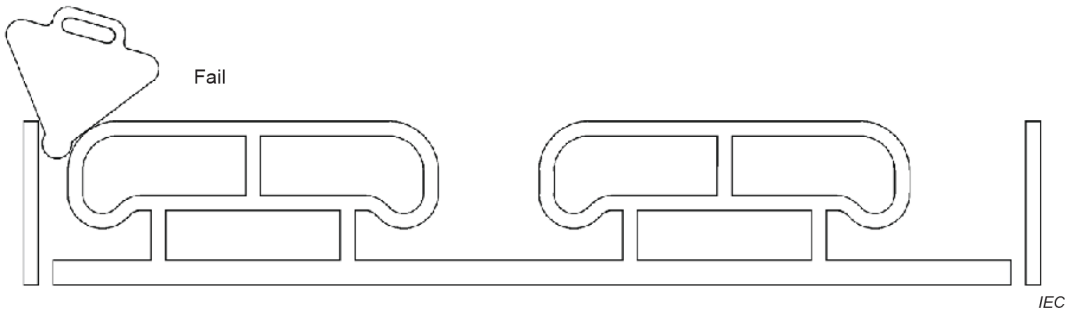

**Figure CC.4 – Positioning of wedge TOOL**




**a) HEAD BOARD to SIDE RAIL - pass**

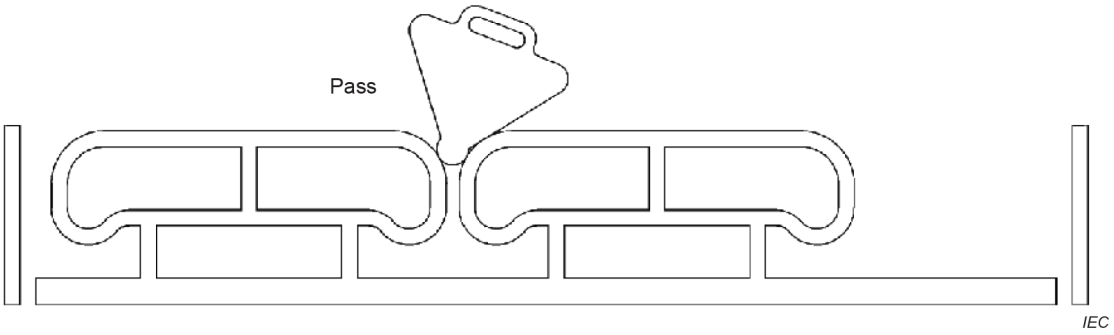



**b) SIDE RAIL to FOOT BOARD - fail**

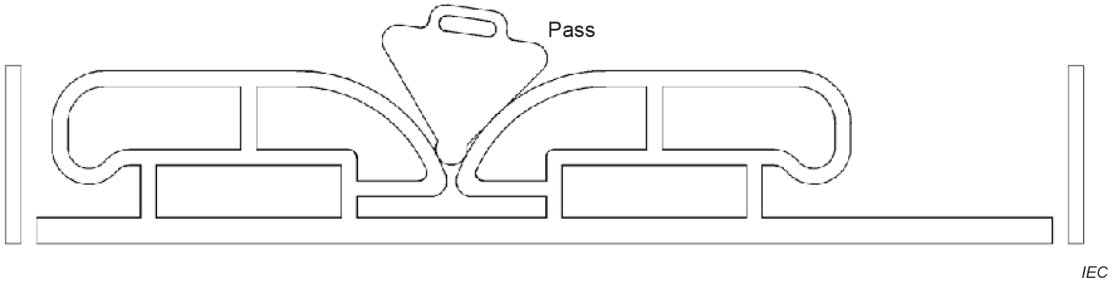



**c) HEAD BOARD to SIDE RAIL - fail**

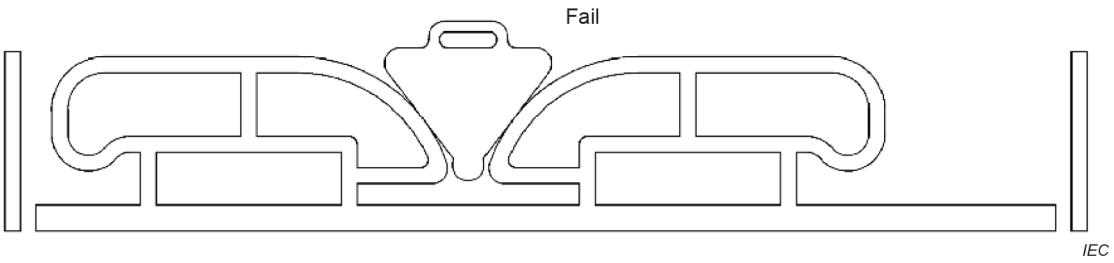
**Figure CC.5 – Acceptance criteria in relation to area C between HEAD BOARD and FOOT BOARD**




**a) Between split SIDE RAILS – pass**




**b) Between curved split SIDE RAILS – pass**




**c) Head board to split SIDE RAILS – fail**

**Figure CC.6 – Acceptance criteria in relation to area C between split SIDE RAILS**

# Annex DD
(informative)

# Guidance and recommendations for periodic inspection

## DD.1 Inspection intervals

Periodic inspection of the MEDICAL BED should be undertaken at the time intervals stated by the MANUFACTURER, but at least once a year.

## DD.2 Inspection content

A periodic inspection means a visual examination (particularly of the MEDICAL BED'S load bearing structure and lifting mechanism with attachments, brakes, controls, safety devices and person-support devices) and whatever function tests and maintenance measures required, e.g. adjustment of brakes, tightening of fasteners.

The content of the periodic inspection should be included in the instructions for use supplied by the MANUFACTURER.

## DD.3 Qualification of personnel

Periodic inspection should be performed by a person who is suitably and properly qualified, and well acquainted with the design, use and care of the MEDICAL BED.

## DD.4 Inspection results

Inspection results should be entered into a logbook which includes the following:

a) the date of inspection of the MEDICAL BED,
b) identification and signature of the inspector,
c) identification of the item(s) inspected, including
    1) serial numbers, where applicable
    2) any detachable ACCESSORIES included in the inspection should be plainly marked for identification and noted,
    3) the situation of use (home or type of institution, etc.).
d) any observations of importance for the condition and safety of the MEDICAL BED
e) the date when corrective actions are taken, in response to noted observations
f) if periodic inspection reveals any defect, wear or other damage that jeopardizes the safety of the MEDICAL BED:
    1) the owner should immediately be notified. In the event of immediate danger to safety, the MEDICAL BED should immediately be taken out of service until the deficiency has been eliminated.
    2) defects and damage of importance to the safety of the MEDICAL BED which have occurred between inspections and have already led to corrective actions should be entered in the logbook.
    3) defects and damages should be reported back to the MANUFACTURER for action. This feedback should be reported in the logbook.
g) The date that the next inspection is due.

## DD.5 Inspection record

The inspection record should be retained safely for examination in the event of an incident, by the person(s) responsible for the servicing and maintenance.

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[4] EN 71-3, *Safety of toys - Part 3: Migration of certain elements*

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[7] *Air Force Research Laboratory Design and Development of Anthropometrically Correct Head Forms for Joint Strike Fighter Ejection Seat Testing - February 2005*

[8] EN 1728, *Furniture - Seating - Test methods for the determination of strength and durability*

[9] EN 13451-1, *Swimming pool equipment - General safety requirements and test methods for equipment installed in pools for public use2*

[10] EN 50525-2-21:2012, *Electric cables - Low voltage energy cables of rated voltages up to and including 450/750 V (U0/U) - Part 2-21: Cables for general applications - Flexible cables with crosslinked elastomeric insulation*

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[12] ISO/IEC Guide 71:2014, *Guide for addressing accessibility in standards*

2 This publication was withdrawn.

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