

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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



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IEC 60601-2-52

Edition 1.0 2009-12

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX

XC

ICS 11.140

ISBN 2-8318-1068-1

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-52: Particular requirements for the basic safety
and essential performance of medical beds**

FOREWORD

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

It is published as double logo standard.

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

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

FDIS	Report on voting
62D/795/FDIS	62D/815/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 20 P-members out of 20 having cast a vote.

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

In this standard, the following print types are used:

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

In referring to the structure of this standard, the term

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

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

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

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

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

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

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

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

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

INTRODUCTION

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

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

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

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

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

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard¹⁾ applies, except as follows:

201.1.1 * Scope

Replacement:

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

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

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

NOTE See also 4.2 of the General Standard.

201.1.2 Object

Replacement:

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

201.1.3 Collateral standards

Addition:

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

IEC 60601-1-3, IEC 60601-1-8 and IEC 60601-1-10²⁾ do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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

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

201.1.4 Particular standards

Replacement:

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

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

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

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

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

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

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

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

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

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

201.2 Normative references

NOTE Informative references are listed in the bibliography on page 81.

Clause 2 of the general standard applies except as follows:

Addition:

IEC 60068-2-31:2008, *Environmental testing – Part 2-31: Tests – Test Ec: Rough handling shocks, primarily for equipment-type specimens*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 apply, except as follows:

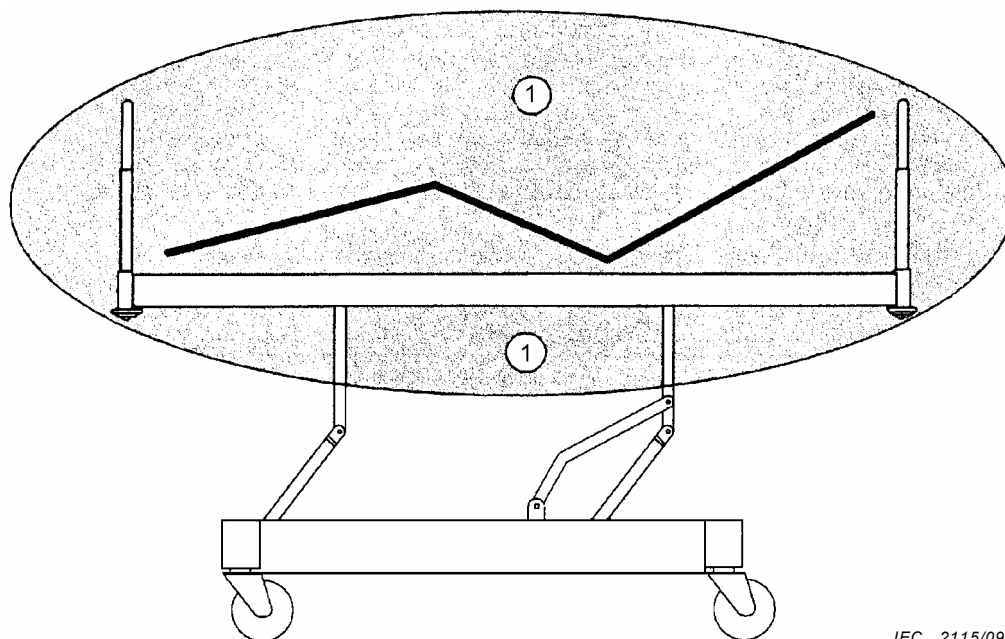
NOTE An index of defined terms is found beginning on page 82.

201.3.8

APPLIED PART

Addition:

The APPLIED PART includes all parts of the MEDICAL BED that are within reach of the PATIENT, even if they are underneath the MATTRESS SUPPORT SURFACE (see Figure 201.101)



IEC 2115/09

Key

1 Region of APPLIED PART including ACCESSORIES

Figure 201.101 – APPLIED PART

201.3.76

PATIENT

Replacement:

person undergoing a medical procedure or DISABLED PERSON

201.3.131*** TRAPPING ZONE**

Addition:

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

Addition:

201.3.201*** APPLICATION ENVIRONMENT 1**

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

201.3.202*** APPLICATION ENVIRONMENT 2**

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

201.3.203*** APPLICATION ENVIRONMENT 3**

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

NOTE This includes use in nursing homes and in rehabilitation and geriatric facilities.

201.3.204*** APPLICATION ENVIRONMENT 4**

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

NOTE This excludes use in all other APPLICATION ENVIRONMENTS (e.g. nursing homes, rehabilitation and geriatric facilities) when a MEDICAL BED is purely designed for APPLICATION ENVIRONMENT 4.

201.3.205*** APPLICATION ENVIRONMENT 5**

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

201.3.206**BED-LIFT**

height adjustable mechanism on which a MATTRESS SUPPORT PLATFORM can be mounted

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

201.3.207**DISABLED PERSON**

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

[ISO 9999:2007]

201.3.208

HEAD/FOOT BOARD

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

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

201.3.209

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

201.3.210

MATTRESS OVERLAY

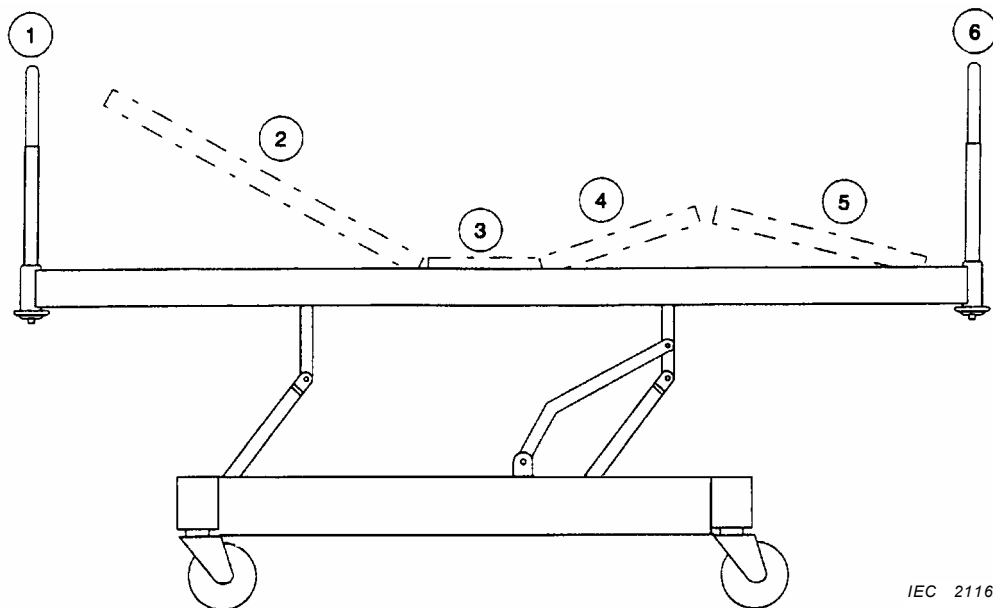
supplementary mattress (support surface), which is intended to be placed on an existing mattress, and generally used for prophylactic or therapeutic effect

201.3.211

MATTRESS SUPPORT PLATFORM

structure which supports a PATIENT surface (for example mattress)

NOTE It can articulate or change positions to facilitate various therapeutic, diagnostic and convenience positions (See Figures 201.102 and 201.119 a) to 201.119 d)).



IEC 2116/09

Key

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

**Figure 201.102 – MEDICAL BED, general arrangement
(example, schematic presentation only)**

201.3.212*** MEDICAL BED**

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

NOTE 1 A BED-LIFT and/or a detachable MATTRESS SUPPORT PLATFORM in combination with a compatible non-MEDICAL BED as specified by the MANUFACTURER is also considered a MEDICAL BED.

NOTE 2 Excluded are devices for which the INTENDED USE is mainly for examination or transportation under medical supervision (e.g. stretcher, examination table).

201.3.213**MOTION LOCKOUT CONTROL**

auxiliary subsystem that deactivates motion controls

201.3.214**PENDANT CONTROL**

handheld device, which has a FUNCTIONAL CONNECTION to the MEDICAL BED, controlling at least MEDICAL BED articulations and/or movements

NOTE PENDANT CONTROLS may be wired, or wireless, and may integrate other functions, (e.g. communications, radio/tv, etc.).

201.3.215**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 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.

201.3.216**SPECIALTY MATTRESS**

mattress intended for prophylactic or therapeutic effect

201.3.217**TEST BED BOARD**

flat, rigid loading board of dimensions as specified by the MANUFACTURER representing the dimensions of the MEDICAL BED

201.3.218**UNDERCARRIAGE**

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

201.4 General requirements

Clause 4 of the general standard applies.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

Additional subclauses:

201.5.101 * Entrapment test tools

Figures 201.103a and 201.103b illustrate entrapment test tools (a cone tool and a cylinder tool respectively).

Dimensions in millimetres

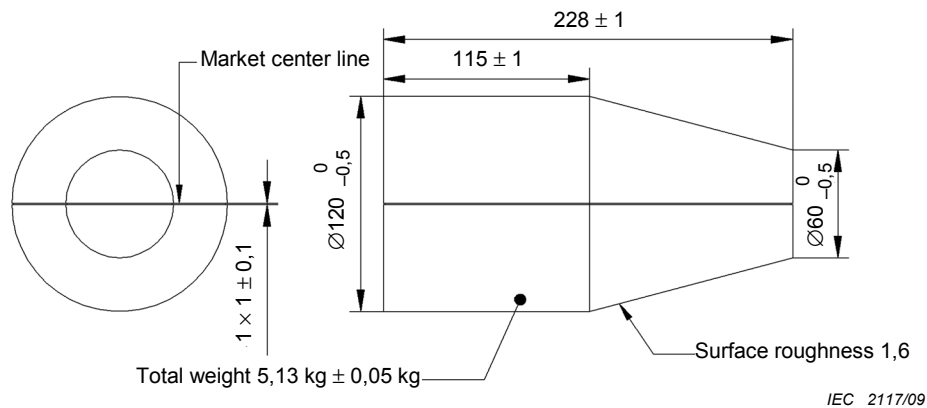


Figure 201.103a – Cone tool

Dimensions in millimetres

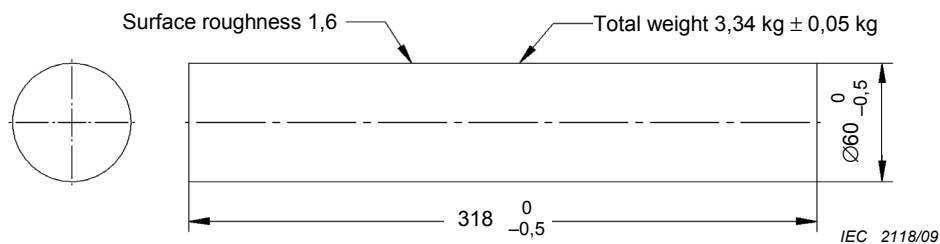


Figure 201.103b – Cylinder tool

Figure 201.103 – Entrapment test tools

201.5.102 Loading pad

The loading pad (see Figure 201.104) is a rigid circular object, (355+/-5) mm in diameter, the face of which has a convex spherical curvature of 800 mm radius with a 20 mm front edge radius.

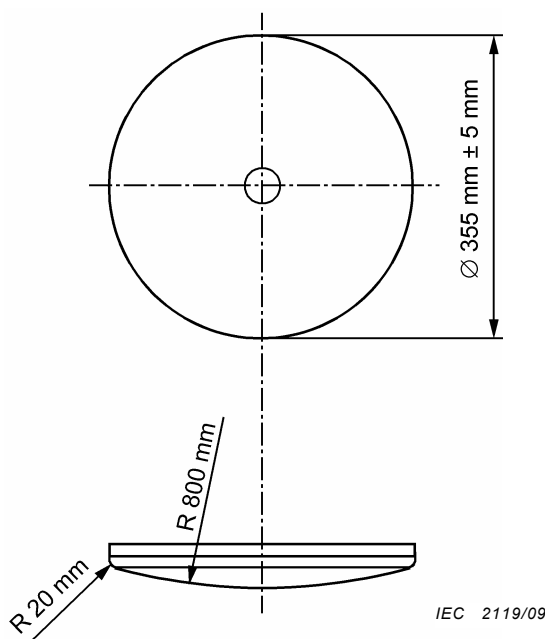


Figure 201.104 – Loading pad

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.2 * Protection against electrical shock

Addition:

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

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard 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

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 201.105).

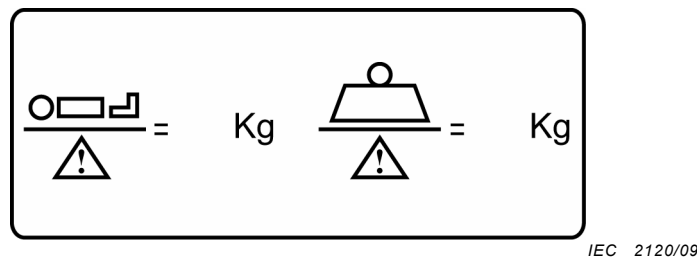


Figure 201.105 – Graphic symbol for maximum PATIENT weight and SAFE WORKING LOAD

Detachable parts of a MEDICAL BED of a mass of more than 20 kg shall be marked with symbol ISO 7000-1321 (2004-01): .

201.7.2.2.102 Marking for machine washable MEDICAL BEDS by an automatic washing system

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: “Caution, for cleaning purposes this bed can be used with automatic washing systems.”

201.7.2.2.103 Marking for MEDICAL BEDS intended for jet stream washing

MEDICAL BEDS intended for use with jet stream washing shall be marked with the following text: “Caution, for cleaning purposes this bed can be used with jet stream washing.”

201.7.2.2.104 Width of carriage of BED-LIFT

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

201.7.2.2.105 * Marking of replacement mattresses

MEDICAL BEDS designed to have replacement mattresses shall be marked with the following sentence as a warning: “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 AA.1).

201.7.2.2.106 * Marking of detachable SIDE RAILS

MEDICAL BEDS designed to have detachable SIDE RAILS shall be marked with the following sentence as a warning: “Incompatible SIDE RAILS can create HAZARDS. Read instructions for use” or use a symbol as appropriate on a prominent place near the attachment point of the SIDE RAIL, indicating the compatible SIDE RAILS (see example in AA.2).

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 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 Figure 201.106).

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

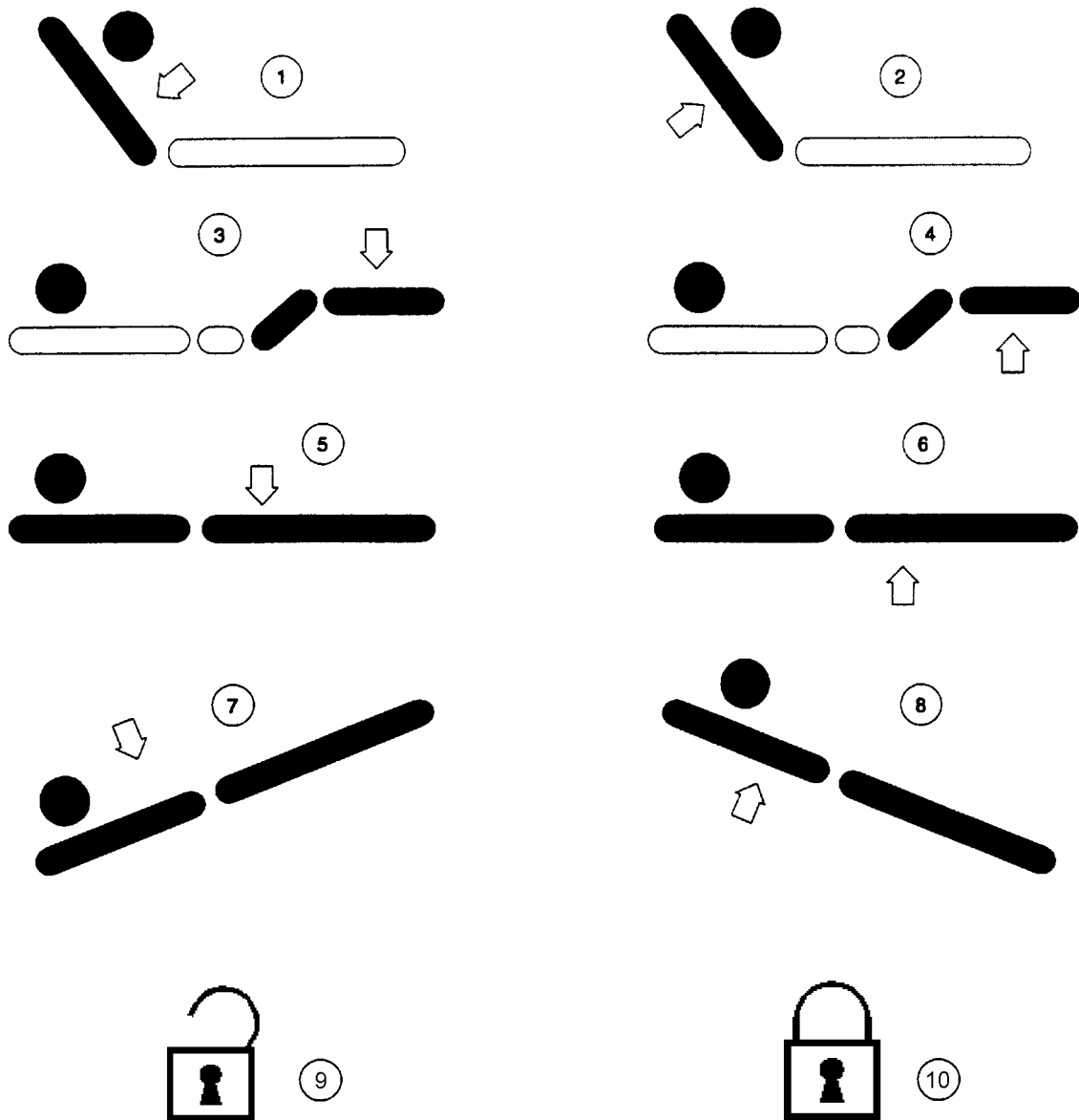
Compliance is checked by inspection of the MEDICAL BED.

201.7.6.3 Symbols for controls and performance

Addition:

Controls and/or indicators, 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 201.106 is intended as a guideline when designing these symbols. In all cases where standard international symbols exist, they should be used.



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Key

- 1 Back section down function
- 2 Back section up function
- 3 Leg down function
- 4 Leg up function
- 5 MATTRESS SUPPORT PLATFORM down
- 6 MATTRESS SUPPORT PLATFORM up
- 7 Trendelenburg
- 8 Anti-Trendelenburg/reverse Trendelenburg
- 9 Padlock-symbol (unlocked) for MOTION LOCKOUT CONTROL
- 10 Padlock-symbol (locked) for MOTION LOCKOUT CONTROL

**Figure 201.106 – MEDICAL BED function controls and/or actuators:
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. The SAFE WORKING LOAD is the sum of:
 - the PATIENT;
 - the mattress;
 - the ACCESSORIES of the MEDICAL BED (only if they are supported by the support system of the MEDICAL BED); and
 - the load supported by those ACCESSORIES (excluding PATIENT weight);
- c) an explanation of how to deactivate any MEDICAL BED function if movement caused by that function could cause injury to the PATIENT;
- d) for APPLICATION ENVIRONMENT 4 intended MEDICAL BEDS, the result of the measurement of auditable acoustic energy in accordance with ISO 3746.

201.7.9.2.2 Warning and safety notices

Addition:

- a) The instructions for use shall provide 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) The instructions for use shall provide a warning on HAZARDS caused by inappropriate handling of the POWER SUPPLY CORD, e. g. by kinking, shearing or other mechanical damages.
- c) The instructions for use shall provide 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) The instructions for use shall provide a warning if a MEDICAL BED shall only be used with certain hoists, because of the limited space underneath the MEDICAL BED.

201.7.9.2.5 ME EQUIPMENT description

Addition:

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 201.7.2.2.105)).

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 201.7.2.2.106)).

201.7.9.2.5.103 * Angles and height of MEDICAL BED

The instructions for use shall identify the maximum angles, 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.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.11.3.2 Types

Replacement:

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

POWER SUPPLY CORDS and other external flexible mains cables and cords on MEDICAL BEDS shall be type HD22.10 H05-BQ-F [1]³⁾ or equivalent quality for mechanical robustness.

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.

³⁾ Figures in square brackets refer to the bibliography.

Compliance is checked by inspection.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies, except as follows:

201.9.1 * MECHANICAL HAZARDS of ME EQUIPMENT

Addition:

201.9.1.101 * Protection against PATIENT entrapment in non-moving parts

Any openings or areas (A₁, A₂, A₃, A₄, A₅, A₆, 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 Figures 201.107, 201.108 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.

Compliance is checked before and after application of the SIDE RAIL strength and latch reliability tests (see 201.9.8.3.3.3).

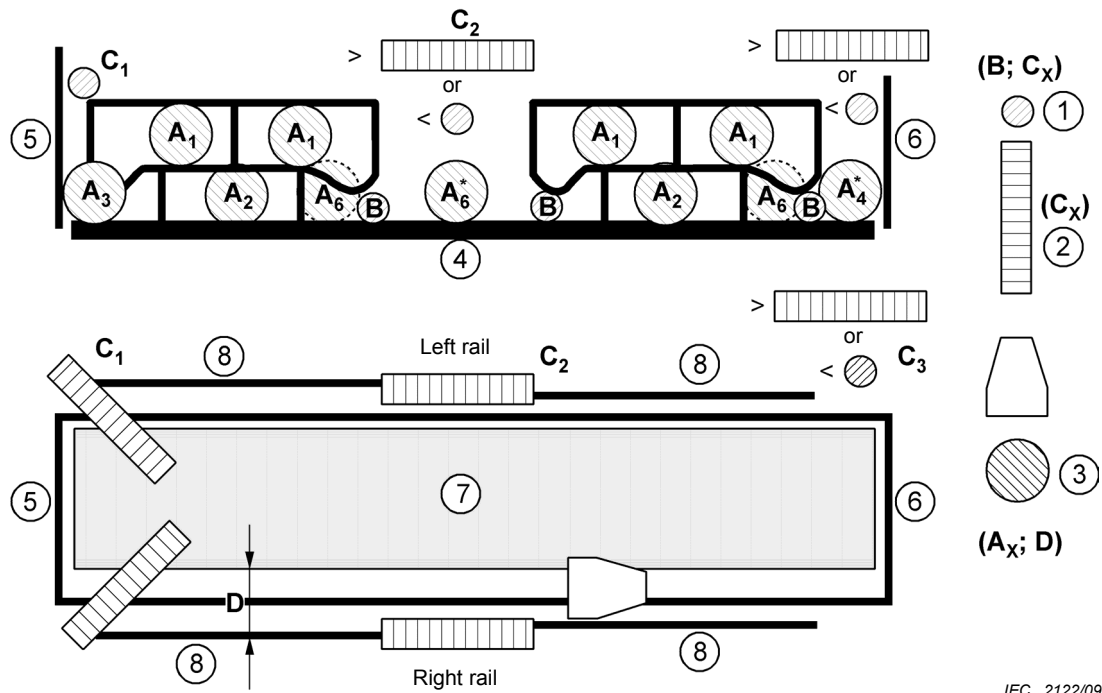
Compliance is checked with the MATTRESS SUPPORT PLATFORM in the flat position unless otherwise noted as indicated in Table 201.101. The test shall be performed with the SIDE RAIL in all raised and locked positions.

All the tests are performed without the mattress except the test for Dimension D. Requirements involving the mattress are checked with the mattress(es) as specified by the MANUFACTURER. Requirements of Figures 201.107, 201.108 and Table 201.101 involving the mattress are excluded for SPECIALTY MATTRESSES.

A RISK ASSESSMENT shall be performed to evaluate:

- SPECIALTY MATTRESSES;
- MATTRESS OVERLAYS;
- ACCESSORIES;
- articulated MATTRESS SUPPORT PLATFORM positions.

Compliance is checked by the following tests and inspection of the RISK MANAGEMENT FILE.



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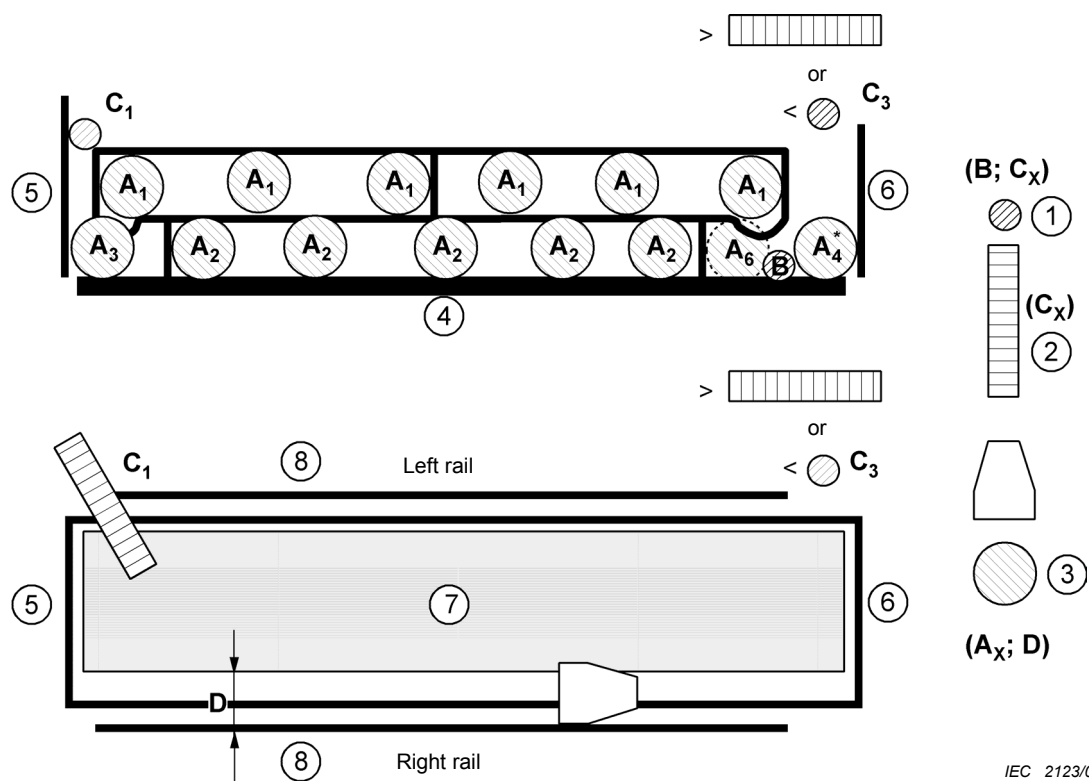
Only applies when the area C above is < 60 mm.

A_x represents the different areas A₁, A₂, A₃, A₄, A₅ and A₆

Key

- 1 Area of TOOL representing neck diameter (60 mm).
- 2 Area of TOOL representing chest breadth (318 mm).
- 3 Area of TOOL representing head breadth (120 mm).
- 4 MATTRESS SUPPORT PLATFORM
- 5 HEAD BOARD
- 6 FOOT BOARD
- 7 Mattress
- 8 SIDE RAIL

Figure 201.107 – Example of MEDICAL BED with segmented or split SIDE RAIL



IEC 2123/09

Only applies when the area C is < 60 mm.

Key

- 1 Area of TOOL representing neck diameter (60 mm).
- 2 Area of TOOL representing chest breadth (318 mm).
- 3 Area of TOOL representing head breadth (120 mm).
- 4 MATTRESS SUPPORT PLATFORM
- 5 HEAD BOARD
- 6 FOOT BOARD
- 7 Mattress
- 8 SIDE RAIL

Figure 201.108 – Example of MEDICAL BED with single piece SIDE RAIL

Table 201.101 – Protection against PATIENT entrapment

Area	Description	Requirement/Compliance method
A ₁	Fully enclosed openings within a SIDE RAIL, HEAD or FOOT BOARD	Gap is specified to be less than 120 mm as defined by the following test. <i>Compliance is checked by the following test:</i> <i>Except for A₃ articulate the MEDICAL BED and find the largest opening. Insert 60 mm diameter part of cone tool (see Figure 201.103a, See Figures 201.107 and 201.108) 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 most disadvantageous direction.</i> <i>Pass/fail criterion: Opening shall not allow 120 mm diameter part of cone tool to enter and pass through.</i>
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 HEAD BOARD, 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/FOOT BOARDS, and/or MATTRESS SUPPORT PLATFORM. This is not in Figure 201.107 and Figure 201.108 as it depends on the position of ACCESSORIES and construction of the MEDICAL BED.	
B	Distance between the MATTRESS SUPPORT PLATFORM and the lowest point of the SIDE RAIL outside of the SIDE RAIL support. AND The angle between SIDE RAIL and the MATTRESS SUPPORT PLATFORM at the range of the mattress height defined by the MANUFACTURER ± 2 cm. NOTE ± 2 cm takes into account mattress compression and height of the neck above the mattress.	Gap < 60 mm. AND 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 2 cm. to the maximum recommended mattress height, plus 2 cm. NOTE The RISK MANAGEMENT has to address the possibility of the use of a mattress not specified by the MANUFACTURER. RISK MANAGEMENT to address the entrapment condition of area B (as illustrated in Figure AA.13) should be performed, taking the following into consideration: i) The SIDE RAIL shape and geometry. ii) The distance between the lowest point of the SIDE RAIL and the MATTRESS SUPPORT PLATFORM. iii) The mattress material properties. iv) The mattress dimensions. v) The fit relationship between the SIDE RAIL, mattress and MATTRESS SUPPORT PLATFORM. <i>Compliance is checked by inspection of the RISK MANAGEMENT FILE. See also Annex CC for further information.</i>
C ₁	Gap between the HEAD BOARD and adjacent SIDE RAIL.	Gap between the HEAD BOARD and adjacent SIDE RAIL is required to be < 60 mm. <i>Compliance for a gap < 60 mm is checked by the following test:</i>

Area	Description	Requirement/Compliance method
		<i>The cylinder tool (see Figure 201.103b) 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.</i> <i>Pass/fail criterion:</i> <i>The 60 mm cylinder tool shall not slide into the opening. See Annex CC for further clarification.</i> <i>SEE ALSO ANNEX CC FOR FURTHER INFORMATION.</i>
C ₂	Gap between segmented or split SIDE RAILS with both SIDE RAILS raised.	Gap between segmented or split SIDE RAILS with both SIDE RAILS raised is required to be < 60 mm or > 318 mm. <i>Compliance for a gap < 60 mm is checked by the following test:</i> <i>The cylinder tool (see Figure 201.103b) 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.</i> <i>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.</i> <i>Pass/fail criterion:</i> <i>The 60 mm cylinder tool shall not slide into the opening. See Annex CC for further clarification.</i> OR For a gap > 318 mm: The gap shall be > 318 mm for the entire vertical distance. <i>See Annex CC for further information.</i>

Area	Description	Requirement/Compliance method
C ₃	Gap between SIDE RAIL and FOOTBOARD. Other openings(s) defined by ACCESSORIES (e.g. IV poles, fractures frames,.....) and SIDE RAILS, HEAD BOARD, FOOT BOARD, and / or MATTRESS SUPPPORT PLATFORM.	Gap between SIDE RAIL and FOOTBOARD is required to be < 60 mm OR > 318 mm. <i>Compliance for a gap < 60 mm is checked by the following test:</i> <i>The cylinder tool (see Figure 201.103b) 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.</i> <i>Pass/fail criterion:</i> <i>The 60 mm cylinder tool shall not slide into the opening. See Annex CC for further clarification.</i> OR For a gap > 318 mm: The gap shall be > 318 mm for the entire vertical distance. SEE ANNEX CC FOR FURTHER INFORMATION.
D	Region defined between the SIDE RAIL and the mattress.	<i>Compliance is checked by the following test:</i> <i>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 Figure 201.103a) 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.</i> <i>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.</i> <i>Pass/fail criterion:</i> <i>The large end of the cone tool shall not sink below the mattress surface by 50 % or more of its 120 mm diameter.</i> NOTE The gap between HEADBOARD 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/FOOT BOARDS, and/or MATTRESS SUPPORT PLATFORM. This is not in Figure 201.107 or Figure 201.108 as it depends on the construction of the MEDICAL BED) Gap between HEADBOARD and top of mattress: The mattresses specified by the MANUFACTURER normally have no reasonable gaps between HEADBOARD and top end of mattresses for a possible head entrapment.

201.9.2.2 TRAPPING ZONE**201.9.2.2.1 General***Addition:*

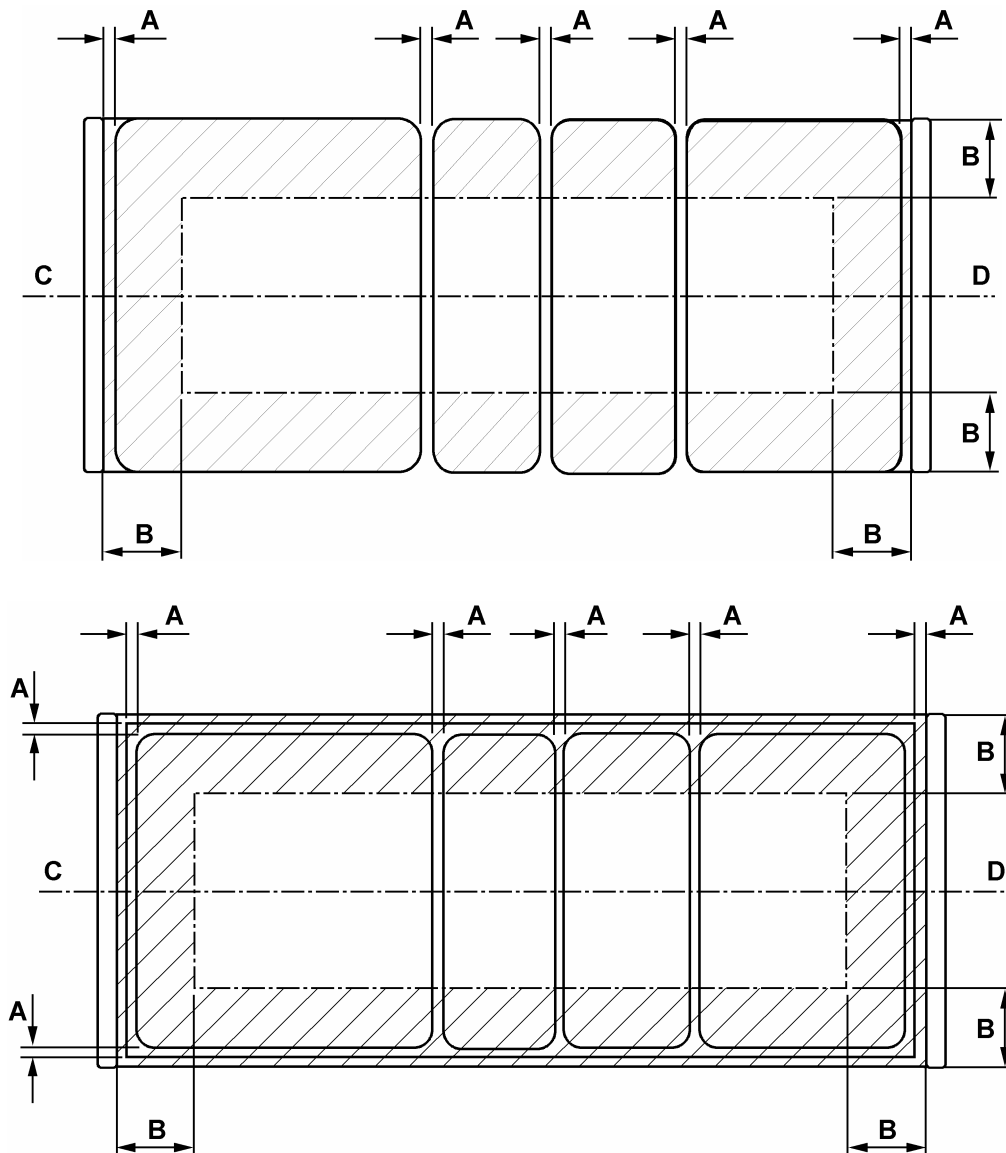
The entire region in the UNDERCARRIAGE shall be considered in the RISK ANALYSIS with regard to trapping HAZARDS due to high/low motion.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.9.2.2.2 Gaps*Amendment:*

The locations identified in Figure 201.109 and 201.110 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 201.109). 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 201.110). 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.

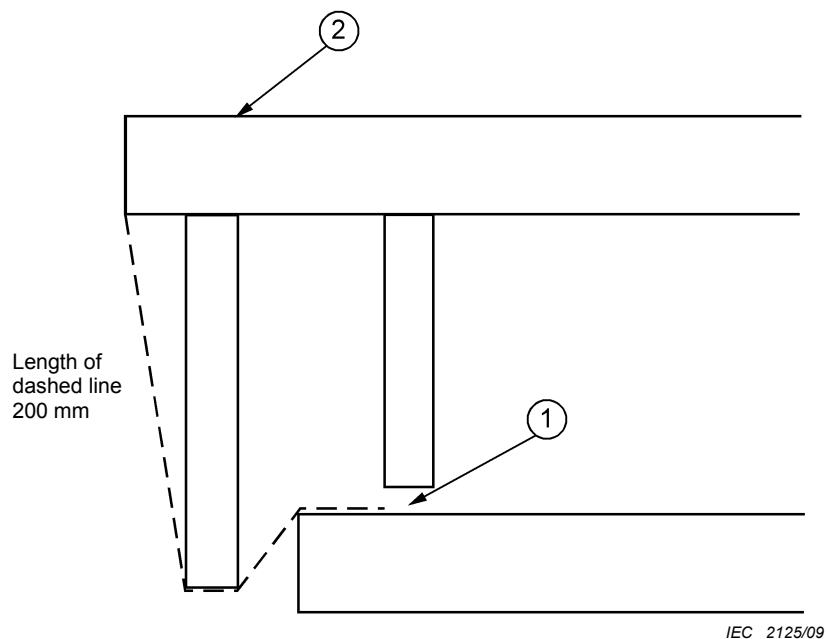


IEC 2124/09

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

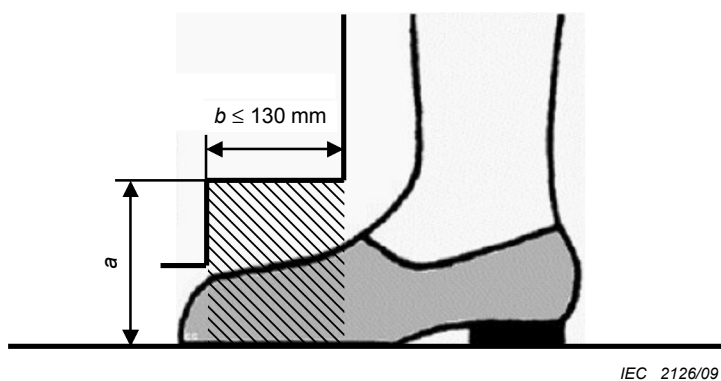
Figure 201.109 – Allowable spacing for fingers in areas of normal reach around the perimeter of the MATTRESS SUPPORT PLATFORM

**Key**

- 1 Pinch point (TRAPPING ZONE)
- 2 MATTRESS SUPPORT PLATFORM

Figure 201.110 – Example using barriers for clearance measurement around the perimeter of the MATTRESS SUPPORT PLATFORM to mitigate PATIENT-finger entrapment

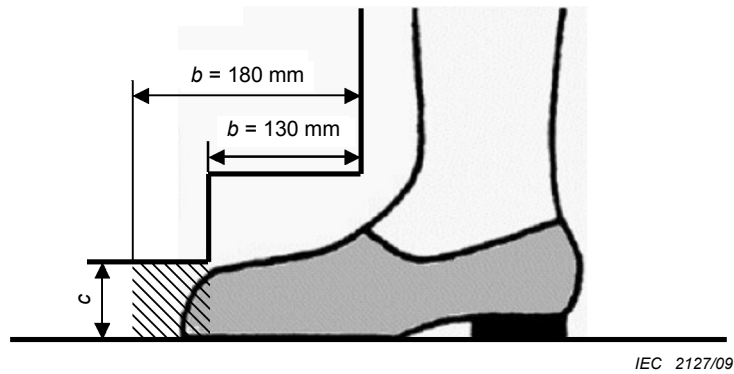
The locations identified in Figures 201.111 a) and 201.111 b) shall be considered as TRAPPING ZONES for feet.

**Key**

For area where $b \leq 130 \text{ mm}$;
shall always be $a \geq 120 \text{ mm}$

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.

Figure 201.111 a) – Foot and toe clearance area between moving parts and the floor



Key

For area where b is between 130 mm to 180 mm;

shall always be $c \geq 50$ 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.

Figure 201.111 b) – Toe clearance area between moving parts and the floor

Figure 201.111 – Clearance areas

Measurements shall be done in the most disadvantageous condition for Figures 201.109, 201.110, 201.111a) and Figure 201.111b).

201.9.2.2.3 Safe distances

Addition:

For the reach of a hand the safe distance is 200 mm (see Figure 201.109 and Figure 201.110).

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 MEDICAL BED movement (such as those in PENDANT CONTROL and/or 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.

201.9.4.2 Instability – overbalance

201.9.4.2.2 * Instability excluding transport

Addition:

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 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 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.

- *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 201.112).

If the maximum PATIENT load according to the MANUFACTURER exceeds 2 200 N, the maximum PATIENT load is to be used and is evenly distributed over an area 950 mm long and 250 mm wide (see Figure 201.112).

Perform the test at each corner of the MEDICAL BED.

- *Longitudinal stability test:*

aa) If the FOOT BOARDS are removable without the use of TOOLS:

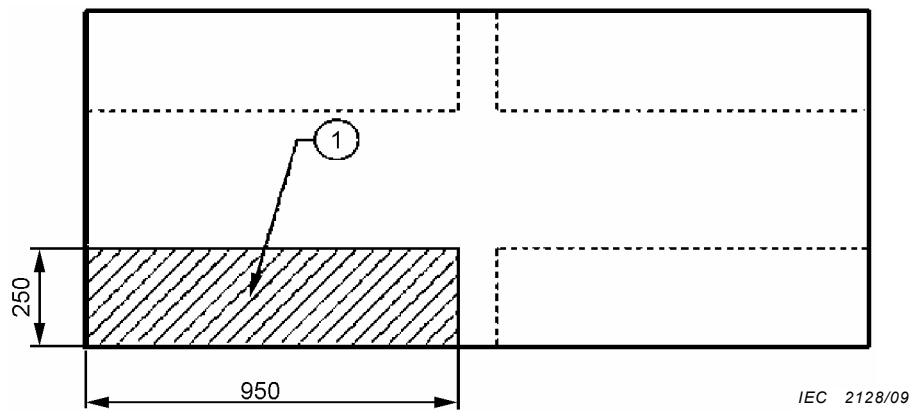
Remove the FOOT BOARD; a load of 2 200 N for APPLICATION ENVIRONMENTS 1, 2, 3 and 5 and 1 850 N for APPLICATION ENVIRONMENT 4 is evenly distributed over an area of 250 mm across the full width of the MEDICAL BED (see Figure 201.113).

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.

bb) If the HEAD/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 and 5 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 201.114). Perform the test at both ends of the MEDICAL BED.

Dimensions in millimetres

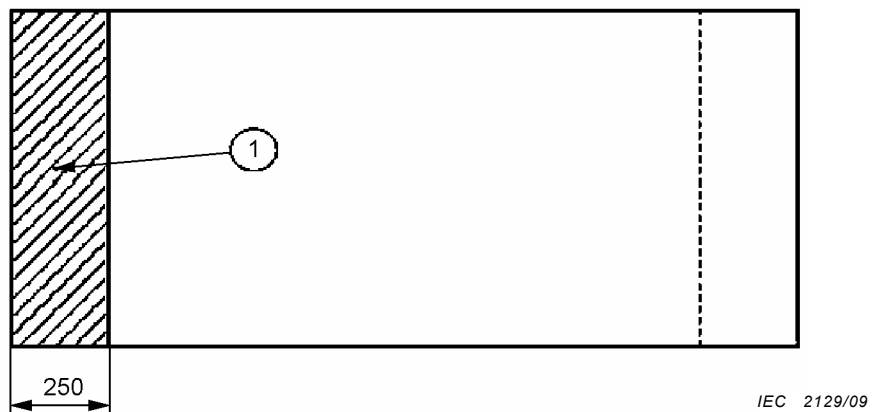


Key

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

Figure 201.112 – Lateral stability test along the side of the MEDICAL BED

Dimensions in millimetres

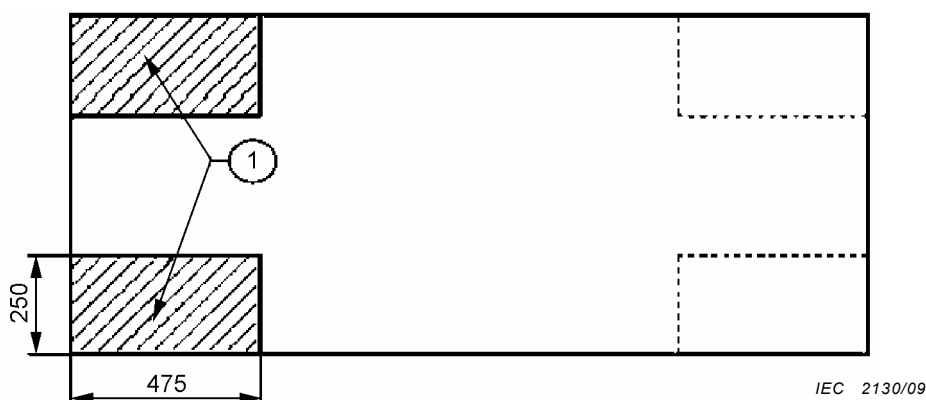


Key

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

Figure 201.113 – 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.

Figure 201.114 – Longitudinal stability test with fixed HEAD/FOOT BOARDS

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 20 cm by 20 cm 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 MEDICAL BEDS intended for PATIENT transport:

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

For MEDICAL BEDS not intended for PATIENT transport:

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

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 $0,8 \text{ m/s} \pm 0,1 \text{ m/s}$, 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, 20 mm high and 80 mm deep. 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:

At the end of the test, the MEDICAL BED, MEDICAL BEDS parts, ACCESSORIES shall present no loss of function, and without unlocking/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.).

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.

201.9.4.3.1 * Instability in transport

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:

- the height, articulation, and length of the MATTRESS SUPPORT PLATFORM;*
- castors;*
- SIDE RAILS;*
- ACCESSORIES with their 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 centered on the MATTRESS SUPPORT PLATFORM.*

The MOBILE MEDICAL BED is placed with the SAFE WORKING LOAD in place, 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

Replacement of item a):

See 201.9.4.3.1.

201.9.4.4 Grips and other handling devices

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

201.9.6.2.1 Audible acoustic energy

Addition:

The results of the measurement shall be given in the instruction for use

Amendment of 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 ME EQUIPMENT 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.

For APPLICATION ENVIRONMENTS 1 and 2, the SAFE WORKING LOAD of the MEDICAL BED shall be at least 2 000 N. It is considered to be the sum of the following minimum loads:

- 1 350 N, corresponding approximately to a mass of 135 kg for the PATIENT;
- 200 N, corresponding approximately to a mass of 20 kg for the mattress;
- 450 N, corresponding approximately to a mass of 45 kg for both the ACCESSORIES and the mass of the SAFE WORKING LOAD supported by those ACCESSORIES but excluding PATIENT weight.

For APPLICATION ENVIRONMENTS 3, 4 and 5, the SAFE WORKING LOAD of the MEDICAL BED shall be at least 1 700 N. It is considered to be the sum of the following minimum loads:

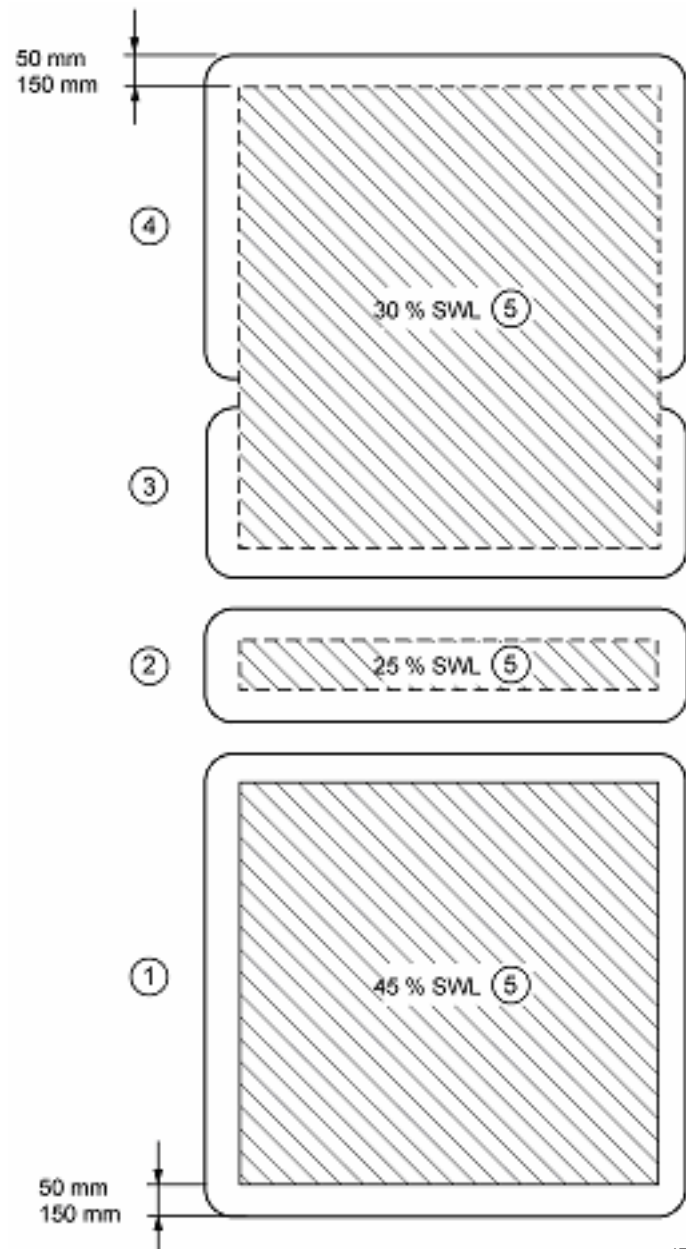
- 1 350 N, corresponding approximately to a mass of 135 kg for the PATIENT;
- 200 N, corresponding approximately to a mass of 20 kg for the mattress;
- 150 N, corresponding approximately to a mass of 15 kg for both the ACCESSORIES and the mass of the SAFE WORKING LOAD supported by those ACCESSORIES but excluding PATIENT weight.

The SAFE WORKING LOAD of a BED-LIFT shall be at least 2 200 N. It is considered to be the sum of the following minimum loads:

- 1 350 N, corresponding approximately to a mass of 135 kg for the PATIENT;
- 200 N, corresponding approximately to a mass of 20 kg for the mattress;
- 150 N, corresponding approximately to a mass of 15 kg for both the ACCESSORIES and the mass of the SAFE WORKING LOAD supported by those ACCESSORIES but excluding PATIENT weight;
- 500 N, corresponding approximately to a mass of 50 kg for those parts of the MEDICAL BED intended to be lifted by the BED-LIFT.

If the SAFE WORKING LOAD as specified by the MANUFACTURER is greater than 2 000 N for MEDICAL BEDS for APPLICATION ENVIRONMENTS 1 and 2, 1 700 N for MEDICAL BEDS FOR APPLICATION ENVIRONMENTS 3,4 and 5 or 2 200 N for BED-LIFTS, it shall be used as a basis for testing.

The SAFE WORKING LOAD shall be placed at the worst-case position permitted by the configuration or ACCESSORIES attachment on the support/suspension parts. The SAFE WORKING LOAD is distributed as shown in Figure 201.115.



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Key

- 1 Back section
- 2 Seat section
- 3 Upper leg section
- 4 Lower leg section
- 5 SWL = SAFE WORKING LOAD

Figure 201.115 – Distribution of SAFE WORKING LOAD for tests

For a foot rest, the part of the SAFE WORKING LOAD representing the mass of PATIENTS is distributed over an area of $0,1 \text{ m}^2$ or whatever is available.

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

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

201.9.8.3.2 *Static forces due to loading from persons

Replacement:

The MEDICAL BED and BED-LIFT shall be capable of withstanding a uniformly distributed 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 (see Figure 201.115).

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.

a) 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 may be an issue, in which case the time shall be increased to at least 1 h.

b) 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.

Place the mattress, as specified by the MANUFACTURER, onto the bed board/TEST BED BOARD, in its flat position.

Apply a vertical load of two times the SAFE WORKING LOAD or 4 000 N, whichever is greater (excluding the mass of the mattress placed onto the MEDICAL BED or the mass of the TEST BED BOARD), equally distributed over the mattress.

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 may be an issue in which case the time shall be increased to at least 1 h.

All ACCESSORIES (including those not supporting PATIENT weight) shall be designed to support a load that is at least two times 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 (others than LIFTING POLES) in its worst case NORMAL USE position, attach a static load equal to two times its SAFE WORKING LOAD for at least 1 min, unless material creep may 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.

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 SAFE WORKING LOAD of LIFTING POLES (at least 1 500 N) to the outermost suspension point for the handle for at least 1 min, unless material creep may 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:

201.9.8.3.3.1 General

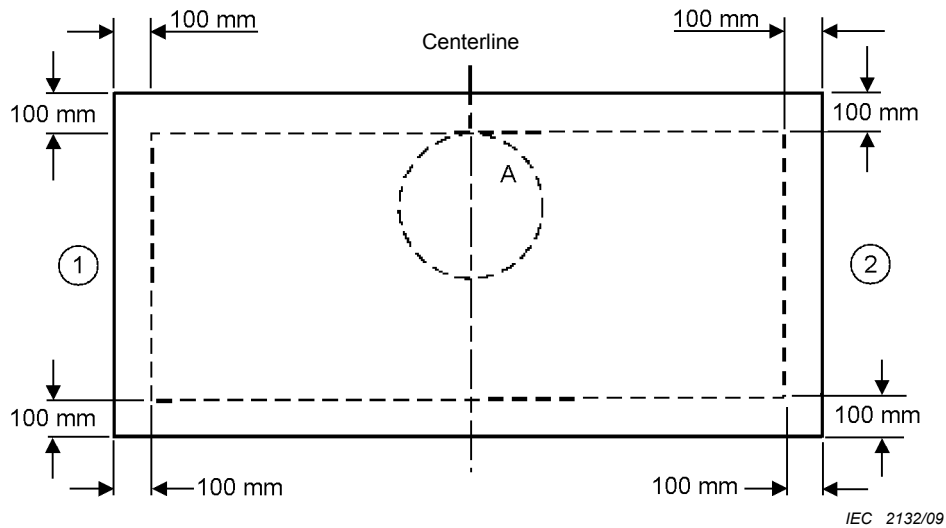
Where dynamic forces (due to sitting down, standing up, PATIENT handling PROCESS or the like) can be exerted on equipment parts intended to support or suspend a PATIENT in NORMAL USE, they shall not result in an unacceptable RISK.

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:

Condition of test:

Place the worst-case mattress specified by MANUFACTURER onto the MEDICAL BED in its flat position. If height-adjustable, adjust the height to the worse case position. Utilize loading pad (Figure 201.104) at position A in Figure 201.116, at whichever side is regarded to be the weaker.



Key

- 1 Head-end of MEDICAL BED
- 2 Foot-end of MEDICAL BED

Figure 201.116 – Position of loading pad
(see Figure 201.104)

Test method:

Apply the loading pad (Figure 201.104) 10 000 times at the position A shown in Figure 201.116, with a load of 1 350 N or the maximum PATIENT load, whichever is greater.

Acceptance criteria/Compliance method:

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.

201.9.8.3.3.2 * 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 201.115) 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 201.115) 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.

201.9.8.3.3.3 * SIDE RAIL strength and latch reliability

SIDE RAIL latches/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/locking:

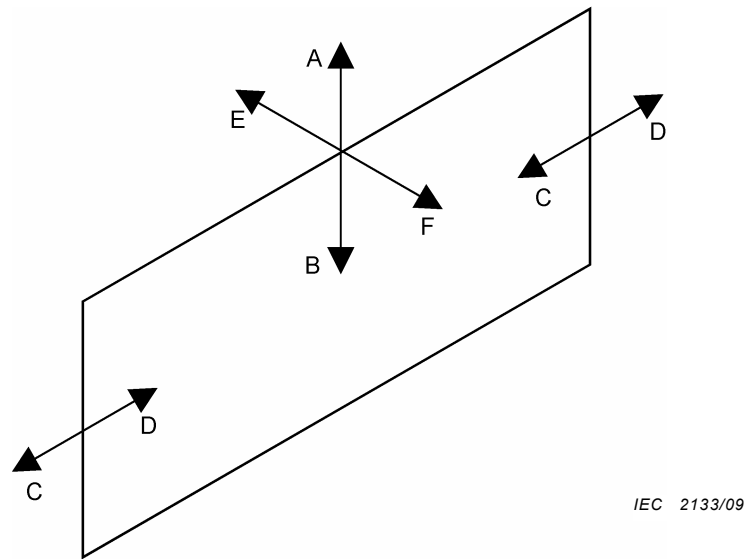
Cycle the SIDE RAIL mechanism (from the latched, upper position, to the unlatched, lowered position, and back to the latched, upper position) for 30 000 cycles. A force A or B or C or D or E or F (as specified in Figure 201.117) shall then be applied to the worst-case position for locking/latching of the SIDE RAIL in the direction of unlatching/unlocking. The SIDE RAIL shall not become unlatched/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 201.117. 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 201.117. 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 201.117. 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 201.117 in worst case positions. The SIDE RAIL shall not become unlatched/unlocked or create any other unacceptable RISK.*

NOTE 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 201.117 – Application of forces for test of SIDE RAIL

201.9.8.3.3.4 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 SAFE WORKING LOAD to 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.

The deflection of the LIFTING POLE shall not be greater than 100 mm during application of the SAFE WORKING LOAD and the permanent deformation not more than 20 mm after the durability test measured in relation to the MATTRESS SUPPORT PLATFORM.

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.

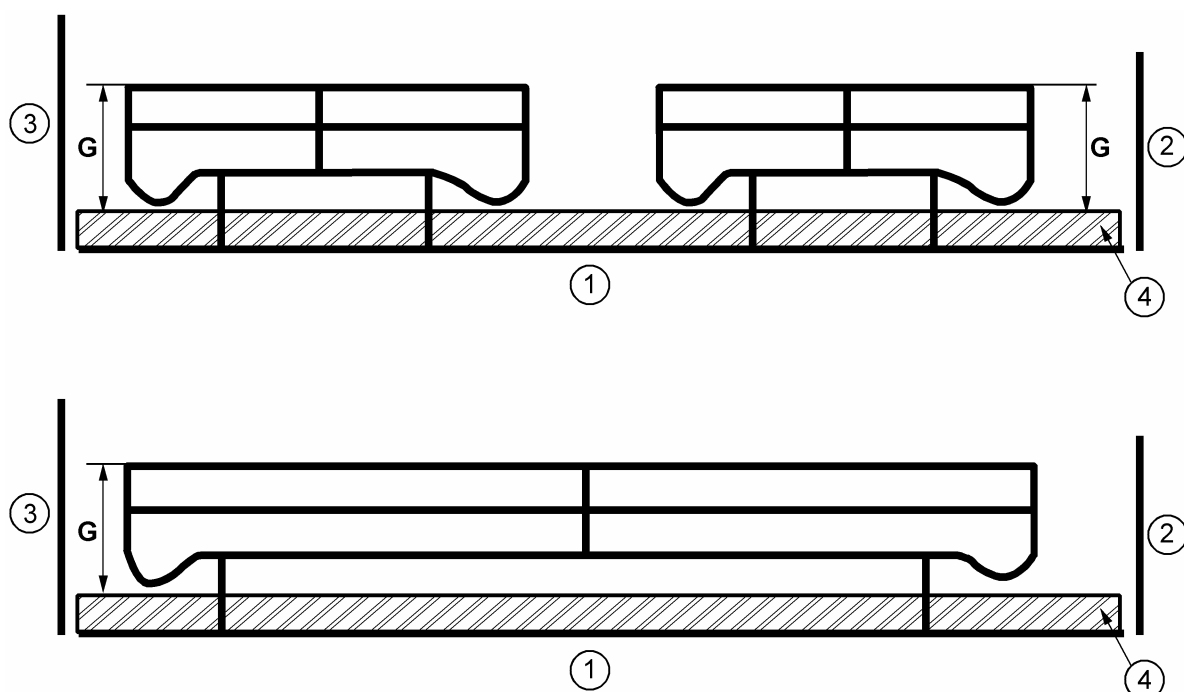
Additional subclause:

201.9.101 *Protection against inadvertent PATIENT falls

SIDE RAILS shall be designed with minimum height requirements as indicated by G in Figure 201.118 and Table 201.102.

Where a SPECIALTY MATTRESS or MATTRESS OVERLAY is used and the SIDE RAIL does not meet G as indicated in Table 201.102, a RISK ASSESSMENT shall be performed to assure equivalent safety.

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



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

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Figure 201.118 – Height of SIDE RAIL

Table 201.102 – Protection against inadvertent PATIENT falls

Designator	Description	Requirement/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. NOTE Placement of the 220 mm portions of the rail may need to be placed next to those parts of the body that are highest (e.g. shoulder for a PATIENT lying on their side) and the parts which could lead to slipping out of the MEDICAL BED (legs) in order to prevent accidental rollout or sliding out. See Figure 201.116, for guidance on distribution of body mass.	≥ 220 mm <i>Compliance is checked by measurement</i>

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard 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”	$t < 1 \text{ min}$	51	56	60
	$1 \text{ min} \leq t < 10 \text{ min}$	48	48	48
	$10 \text{ min} \leq t$	41	41	41
^a These temperature limit values are applicable for the healthy skin of adults, but in the limitation for temperature for duration more than 10 min also DISABLED PERSONS with sensible skin or no sensation have been considered. They are not applicable when large areas of the skin (10 % of total body surface or more) can be in contact with a hot surface. They are not applicable in the case of skin contact with over 10 % of the head 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 201.103 in order to provide clinical benefit, the RISK MANAGEMENT FILE shall contain documentation showing that the resulting benefit exceeds any associated increase in RISK.				

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

Addition:

201.11.6.5.101 Ingress of water

ENCLOSURES of MEDICAL BED shall provide a minimum protection degree of IPX4 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/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 INTENDED USE.

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 and/or disinfection PROCESS.

201.11.6.6.101 Machine washable MEDICAL BED

MEDICAL BED or BED-LIFT specified by the MANUFACTURER to be machine washable by an automatic washing system shall function normally after the test.

Variations to the test procedure regarding test-cycle, temperature, time and cleaning fluids shall be covered in the RISK MANAGEMENT FILE of the MANUFACTURER.

The present test method represents a basic procedure for disinfection of a MEDICAL BED in a washing machine.

Compliance is checked by the following test:

- a) *Parts and access covers which can be detached/opened without the use of a TOOL shall be detached/opened;*
 - *temperature preconditioning treatment of 10 days at 65 °C ± 2 °C or at maximum value of the rated storage temperature, if higher, is carried out;*
 - *the MEDICAL BED shall then be kept at room temperature for not less than 16 h;*
- b) *50 test cycles according to the procedure the MANUFACTURER described in the instructions for use or consisting of:*
 - *2 min wash with 70 °C water at a ph-value 5-8, 0,5 % cleaning and disinfectant solution as specified by the MANUFACTURER;*
 - *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.*
 - *10 min cooling at 20° C ambient temperature.*
 - *Acceptance criteria:*
 - 1) *Immediately after the test cycles, the MEDICAL BED is connected to mains. No unintentional movements shall arise.*
 - 2) *The MEDICAL BED shall function as specified by the INTENDED USE at the following intervals:*
 - *immediately after the test cycles;*
 - *5 min (± 1 min) after the test cycles;*
 - *60 min (± 5 min) after the test cycles;*
 - *24 h (± 30 min) after the test cycles;*
 - 3) *Perform dielectric strength and LEAKAGE CURRENT tests according to 8.8.3 and 8.7 at the following intervals:*
 - *immediately after the test cycles*
 - *24 h (± 30 min) after the test cycles*
 - 4) *Perform a visual inspection for ingress of water that may result in an unacceptable RISK (i.e., shorting of isolation barriers and violation of creepage distances).*

NOTE For some MEDICAL BED not all acceptance criteria apply (i.e. for manual MEDICAL BEDS, electrical acceptance criteria would not apply).

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

Clause 12 of the general standard applies, except as follows:

201.12.2 USABILITY

Addition:

USABILITY analysis 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.

NOTE Access to PATIENT for the purposes of medical treatment should not be delayed significantly by the SIDE RAILS and their respective control systems.

201.13 HAZARDOUS SITUATIONS and fault conditions

Clause 13 of the general standard 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 may be used as a means of compliance. A MOTION LOCKOUT CONTROL may be activated automatically or as an OPERATOR option. (See also 201.7.4.2.).

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 general standard, and other applicable clauses of the general standard and this standard pertaining to safety factors.

201.13.2.2 Electrical SINGLE FAULT CONDITION

Addition:

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)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

201.15.3 Mechanical strength

201.15.3.4.1 HAND-HELD ME EQUIPMENT

Replacement:

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

Compliance is checked by the following test:

The PENDANT CONTROL has to fall 1 000 times as specified in IEC 60068-2-31:2008.

After the test the PENDANT CONTROL is checked by inspection, functional test and relevant electrical safety tests.

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 $\pm$ 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 perpendicular to the face of the obstacle.

Addition at the end of the paragraph:

This requirement does not apply to MEDICAL BED 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

201.15.4.4 * Indicators

Amendment:

Delete the first two paragraphs.

201.15.4.6.2 * Limitation of movement

Addition:

The angle (designated " γ " in Figure 201.119) between the back section and leg/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°.