

BS EN 60601-2-52:2010+A1:2015

Incorporating corrigenda September 2010 and April 2011



BSI Standards Publication

Medical electrical equipment

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

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National foreword

This British Standard is the UK implementation of EN 60601-2-52:2010+A1:2015, incorporating corrigendum April 2011. It is identical to IEC 60601-2-52:2009, incorporating amendment 1:2015 and corrigendum September 2010. It supersedes BS EN 60601-2-52:2010 which will be withdrawn on 22 April 2018.

The start and finish of text introduced or altered by corrigendum is indicated in the text by tags. Text altered by IEC corrigendum September 2010 is indicated in the text by AC1 AC1.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/4, Electromedical equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Date	Text affected
31 September 2011	Implementation of IEC corrigendum September 2010 and CENELEC corrigendum April 2011: modification of EN foreword
30 June 2015	Implementation of IEC amendment 1:2015 with CENELEC endorsement A1:2015

English version

**Medical electrical equipment -
Part 2-52: Particular requirements for basic safety and essential
performance of medical beds
(IEC 60601-2-52:2009)**

Appareils électromédicaux -
Partie 2-52: Exigences particulières
pour la sécurité de base
et les performances essentielles
des lits médicaux
(CEI 60601-2-52:2009)

Medizinische elektrische Geräte -
Teil 2-52: Besondere Festlegungen
für die Sicherheit einschließlich
der wesentlichen Leistungsmerkmale
von medizinischen Betten
(IEC 60601-2-52:2009)

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

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CEN-CENELEC

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

Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

Foreword

This European Standard is the result of a CENELEC lead joint collaboration between CLC/TC 62 and CEN/TC 293.

The text of document 62D/795/FDIS, future edition 1 of IEC 60601-2-52, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-52 on 2010-04-01.

This European Standard supersedes EN 60601-2-38:1996 + A1:2000 and EN 1970:2000.

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

The following dates were fixed:

- | | | |
|--|-------|------------|
| – latest date by which the EN has to be implemented
at national level by publication of an identical
national standard or by endorsement | (dop) | 2011-01-01 |
| – latest date by which the national standards conflicting
with the EN have to be withdrawn | (dow) | 2013-04-01 |

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-52:2009 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standards indicated:

IEC 60601-2-38	NOTE Harmonized as EN 60601-2-38
----------------	----------------------------------

Foreword to amendment A1

The text of document 62D/1186/FDIS, future IEC 60601-2-52:2009/A1, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-52:2010/A1:2015.

The following dates are fixed:

- latest date by which the document has to be (dop) 2016-01-22
implemented at national level by
publication of an identical national
standard or by endorsement
- latest date by which the national (dow) 2018-04-22
standards conflicting with the
document have to be withdrawn

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

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For the relationship with EU Directive see informative Annex ZZ, included in EN 60601-2-52:2010.

Endorsement notice

The text of the International Standard IEC 60601-2-52:2009/A1:2015 was approved by CENELEC as a European Standard without any modification.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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 When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Addition to Annex ZA of EN 60601-2:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60068-2-31	2008	Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens	EN 60068-2-31	2008

Annex ZZ (informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC except the following:

- Essential Requirement 7.1

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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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:

A1 This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL BEDS as defined in 201.3.212, intended for ADULTS as defined in 201.3.219. **A1**

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:

A1 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 intended for ADULTS as defined in 201.3.219. **A1**

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

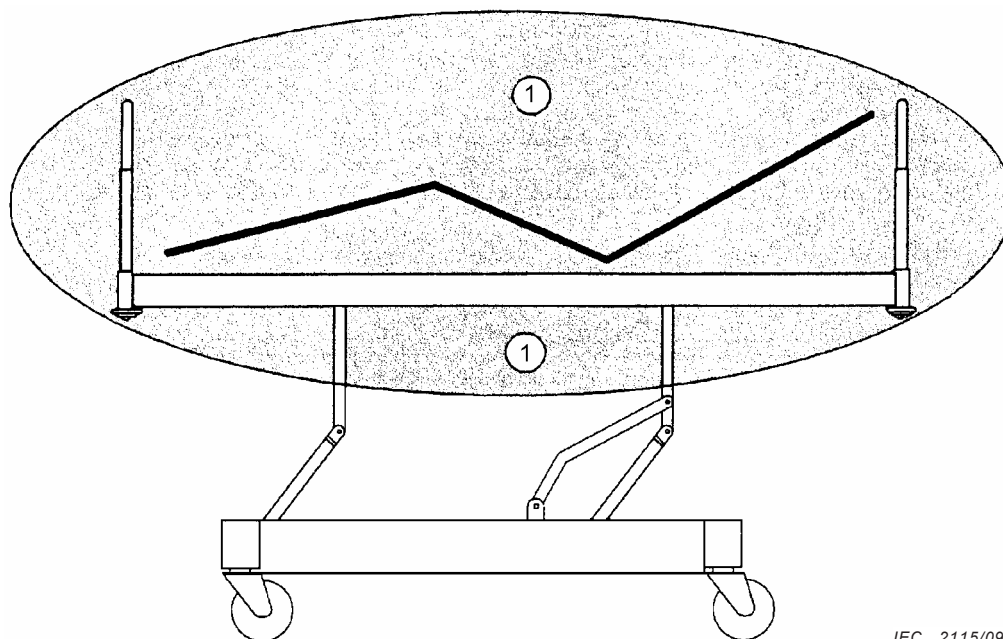
For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 apply, except as follows:

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

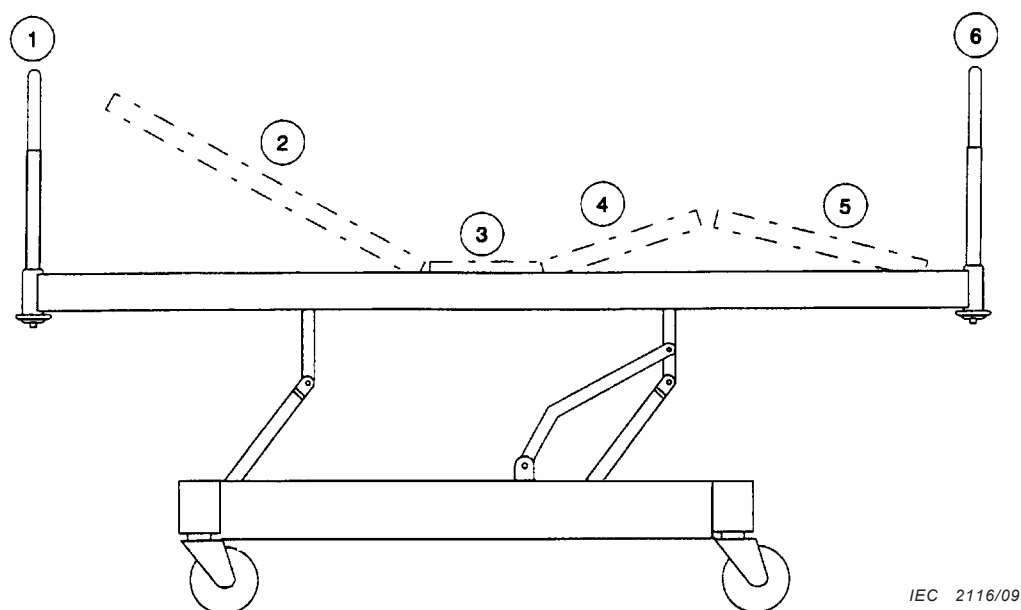
supplementary mattress (support surface), which is intended to be placed on an existing mattress, and generally used for prophylactic or therapeutic effect

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)).



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

A1 201.3.219

*** 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 A1

201.4 General requirements

A1 Clause 4 of the general standard applies, except as follows:

201.4.2.2 * General requirement for RISK MANAGEMENT

Addition:

The MANUFACTURER shall include, in the RISK MANAGEMENT PROCESS, HAZARDS related to PATIENTS taller than 185 cm.

Compliance is checked by inspection of the RISK MANAGEMENT FILE. **A1**

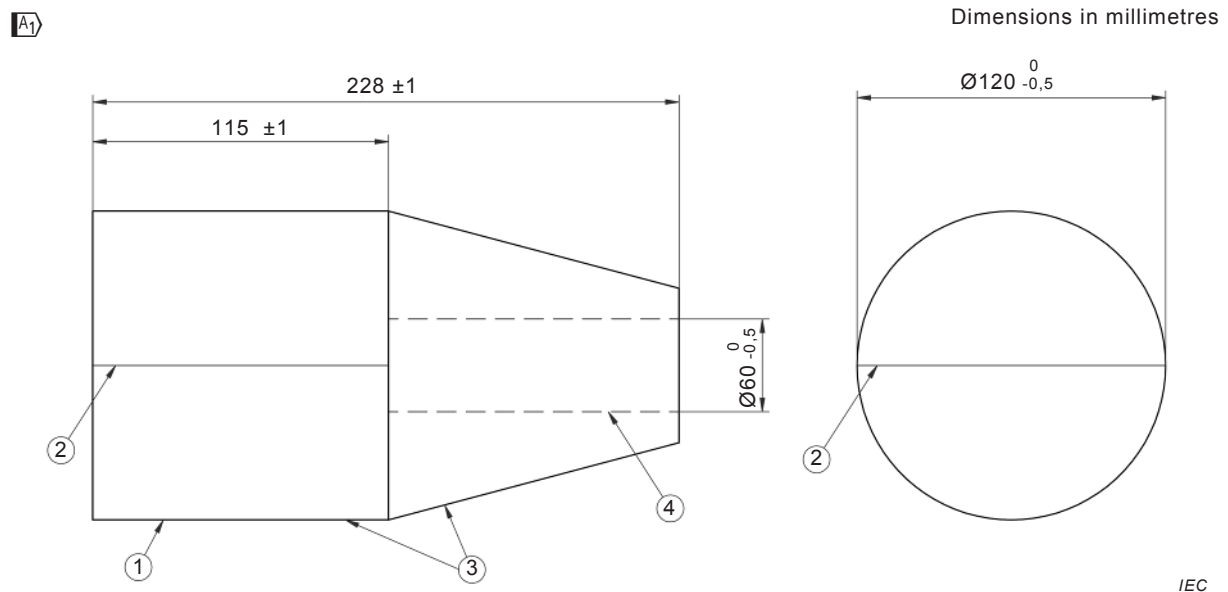
201.5 General requirements for testing of ME EQUIPMENT

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).



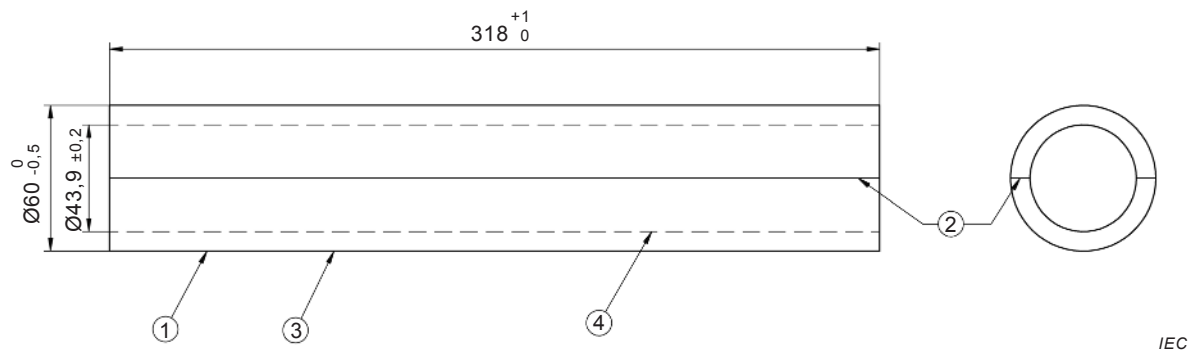
Key

- 1 Total weight 5,1 kg $\pm 0,05$ kg
- 2 Marked centre line
- 3 Surface roughness 1,6
- 4 Drilling hole for weight adjustment

Figure 201.103a) – Cone tool schematic **A1**

A1

Dimensions in millimetres



Key

- 1 Total weight 3,34 kg $\pm 0,05$ kg
- 2 Marked centre line
- 3 Surface roughness 1,6
- 4 Drilling hole for weight adjustment

Figure 201.103b) – Cylinder tool schematic A1

Figure 201.103 – Entrapment test tools

201.5.102 Loading pad

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

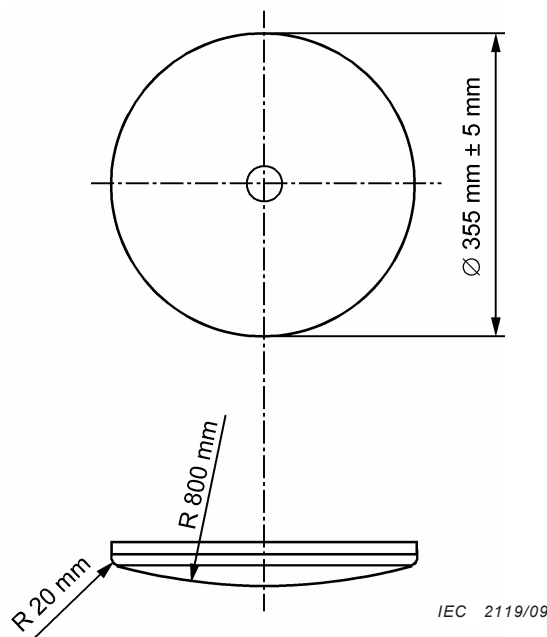


Figure 201.104 – Loading pad

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).

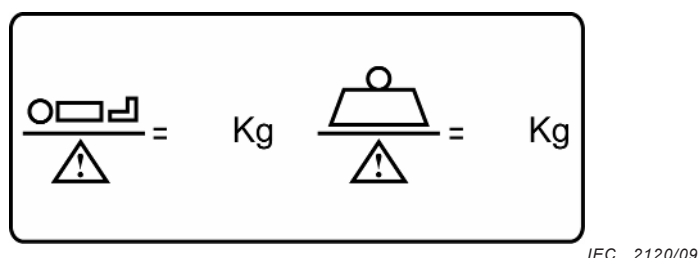


Figure 201.105 – Graphic symbol for maximum PATIENT weight and SAFE WORKING LOAD

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).

A1 201.7.2.2.107 Marking on the MEDICAL BED for ADULTS

The MEDICAL BEDS shall be marked on a prominent place with the symbol indicated in Figure 201.106.

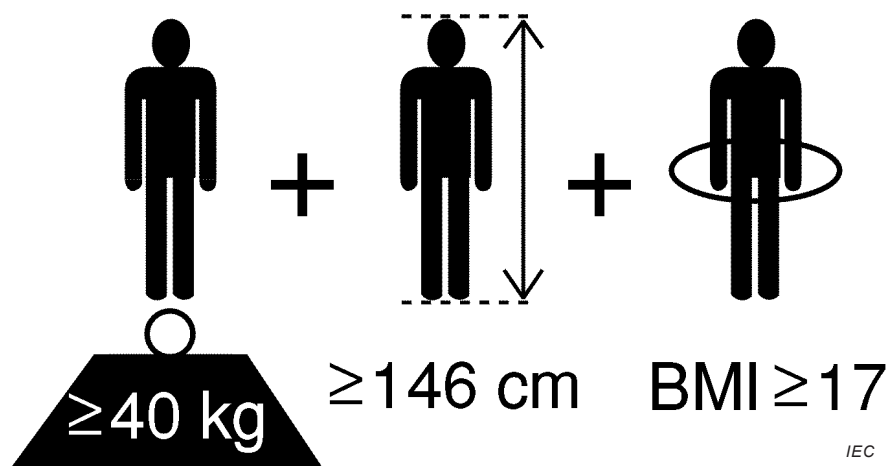


Figure 201.120 – Physical description of an ADULT **A1**

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."

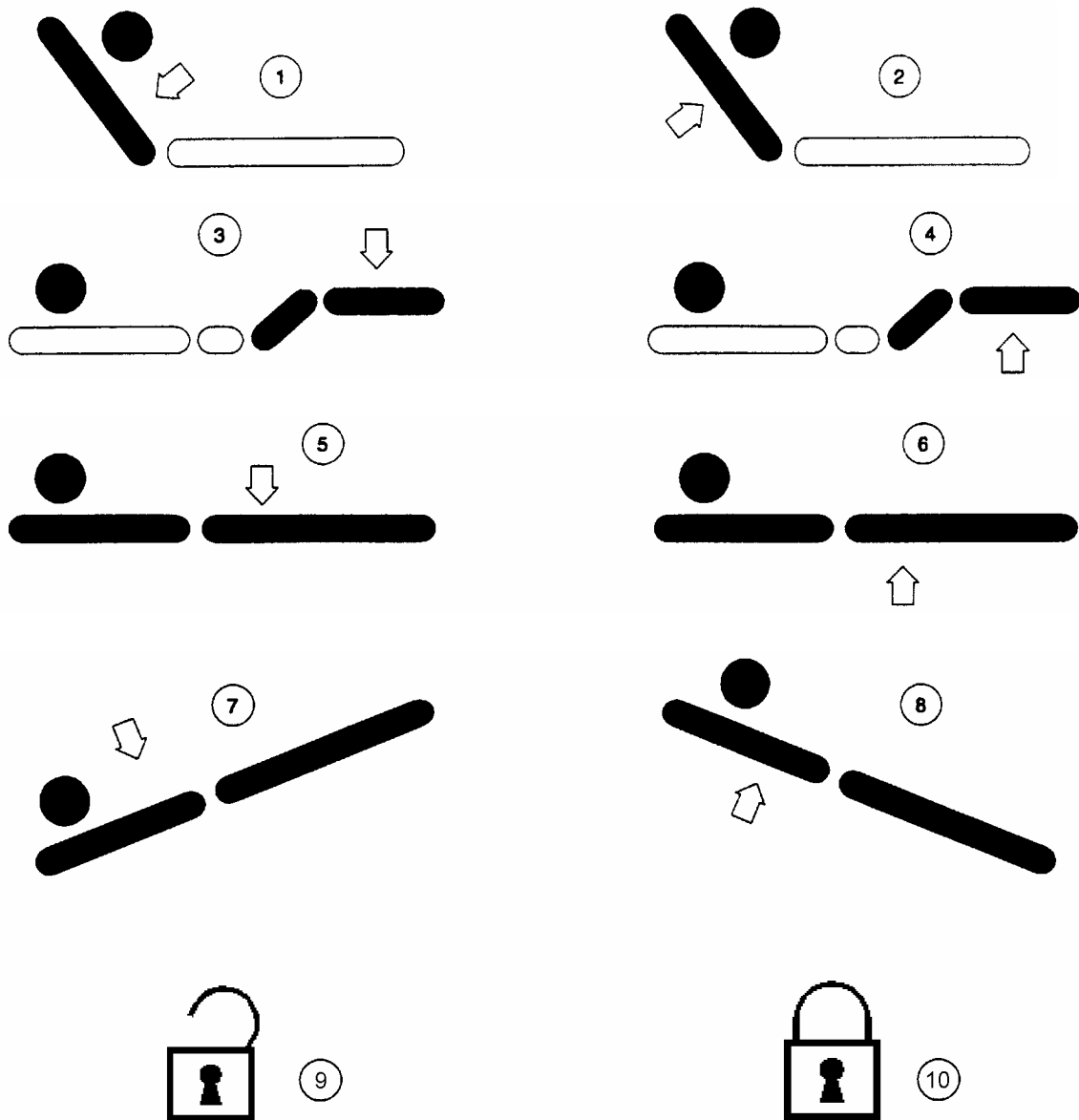
Compliance is checked by inspection of the MEDICAL BED.

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.

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

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.
-  e) The instructions for use shall provide a warning if a MEDICAL BED is limited to a specific group of PATIENTS.
- f) The instructions for use shall provide a warning that incompatible SIDE RAILS and mattresses can cause an entrapment hazard. 

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.

³⁾ Figures in square brackets refer to the bibliography.

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

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 (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 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.



A_x represents the different areas A_1 , A_2 , A_3 , A_4 , A_5 and A_6

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

