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ISO/TC **173**

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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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This draft is submitted to a parallel vote in ISO and in IEC.

Reference number
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

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

It is published as double logo standard.

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

Draft	Report on voting
62D/XX/FDIS	62D/XX/RVD

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

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

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

In this document, the following print types are used:

– requirements and definitions: roman type.
– *test specifications: italic type.*
– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
– TERMS DEFINED IN CLAUSE 3 OF IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, in this document or as noted: SMALL CAPITALS.

In referring to the structure of this document, the term

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

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

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

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

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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

A list of all parts of the IEC 80601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

– reconfirmed,

– withdrawn, or

– revised.

INTRODUCTION

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

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

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

As work began on the integration, the IEC adjusted its stance on BASIC SAFETY and ESSENTIAL PERFORMANCE, integrating them into the third edition of IEC 60601-1 published in 2005. It therefore became necessary to align the new standard with the third edition. The particular standard was given a new number, IEC 60601-2-52, and work began on alignment to third edition.

This particular standard, therefore, is the realization of much work in alignment, and scope adjustment between IEC 60601-2-38, EN 1970, and IEC 60601-1:2005. It represents the current thinking in BASIC SAFETY and ESSENTIAL PERFORMANCE of the MEDICAL BED as used to alleviate illness of PATIENTS and disability of PERSONS WITH DISABILITY. This is the effort of a joint working group of the IEC and the ISO.

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

201.1 Scope, object and related standards

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

201.1.1 * Scope

Replacement:

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

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

This document does not apply to:

- MEDICAL BEDS for CHILDREN and ADULTS with atypical anatomies (ADULTS ranging outside the definition for ADULTS in 202.3.222) covered by IEC 80601-2-89[1][1];
- SPECIALITY MATTRESS covered by ISO 20342 series[2];
- devices for which the INTENDED USE is mainly for examination or transportation under medical supervision (e.g. stretcher, examination table);
- all requirements for MEDICAL BEDS with special functionality.

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

HAZARDS inherent in the intended physiological function of MEDICAL BED or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in 7.2.13 and 8.4.1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

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

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

201.1.2 Object

Replacement:

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

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1 Numbers in square brackets refer to the Bibliography.

201.1.3 Collateral standards

Addition:

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

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

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

201.1.4 Particular standards

Addition:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, including the collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020

The numbering of clauses and subclauses of this particular standard corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

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

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

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

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

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

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

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE Informative references are listed in the Bibliography.

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

Replacement:

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

Addition:

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

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

EN 597-1, *Furniture - Assessment of the ignitability of mattresses and upholstered bed bases - Part 1: Ignition source smouldering cigarette*

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

201.3 Terms and definitions

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

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

– IEC Electropedia: available at https://www.electropedia.org/

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

201.3.8
APPLIED PART

Addition:

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

201.3.76
PATIENT

Replacement:

living person undergoing a medical PROCEDURE or PERSON WITH DISABILITY

201.3.109
SAFE WORKING LOAD
SWL

Replacement:

sum of:

1) the PATIENT;
2) the mattress;
3) the ACCESSORIES of the MEDICAL BED, only if they are supported by the support system of the MEDICAL BED; and
4) the SAFE WORKING LOADS supported by those ACCESSORIES, excluding PATIENT weight

201.3.131
*** TRAPPING ZONE**

Replacement:

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

Additional terms and definitions:

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

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

201.3.203
*** APPLICATION ENVIRONMENT 3**
long-term care in a medical area where medical supervision is required and monitoring is provided if necessary and MEDICAL BED used in medical PROCEDURES may be provided to help maintain or improve the condition of the PATIENT

Note 1 to entry: This includes use in nursing homes and in rehabilitation and geriatric facilities.

201.3.204
*** APPLICATION ENVIRONMENT 4**
care provided in a domestic area where MEDICAL BED is used to alleviate or compensate for an injury, disability or disease

Note 1 to entry: This excludes use in all other APPLICATION ENVIRONMENTs (e.g. nursing homes, rehabilitation and geriatric facilities) when a MEDICAL BED is purely designed for APPLICATION ENVIRONMENT 4.

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

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

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

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

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

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

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

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

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

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

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

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

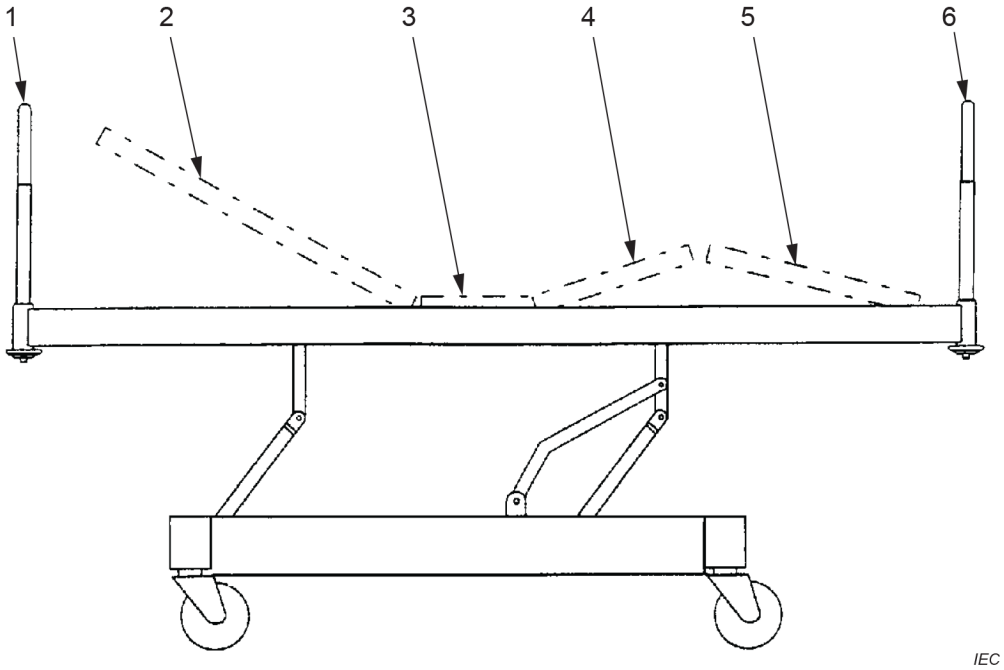
Note 1 to entry: It can be used as handles to push a MEDICAL BED intended to transport PATIENTS.

201.3.211
LIFTING POLE
ACCESSORY attached to a MEDICAL BED and intended to assist support of a PATIENT when changing position by providing a gripping support above the PATIENT

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

201.3.213
MATTRESS SUPPORT PLATFORM
structure which supports a PATIENT surface

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



Key

1 HEAD BOARD

2 Back section (part of MATTRESS SUPPORT PLATFORM)

3 Seat section (part of MATTRESS SUPPORT PLATFORM)

4 Upper leg section (part of MATTRESS SUPPORT PLATFORM)

5 Lower leg section (part of MATTRESS SUPPORT PLATFORM)

6 FOOT BOARD

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

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

201.3.215
MOTION LOCKOUT CONTROL
auxiliary subsystem that deactivates motion controls

201.3.216
PENDANT CONTROL
handheld device, which has a FUNCTIONAL CONNECTION to the MEDICAL BED, controlling at least MEDICAL BED articulations or movements or both.

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

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

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

201.3.218
SPECIALTY MATTRESS
mattress intended for prophylactic or therapeutic effect

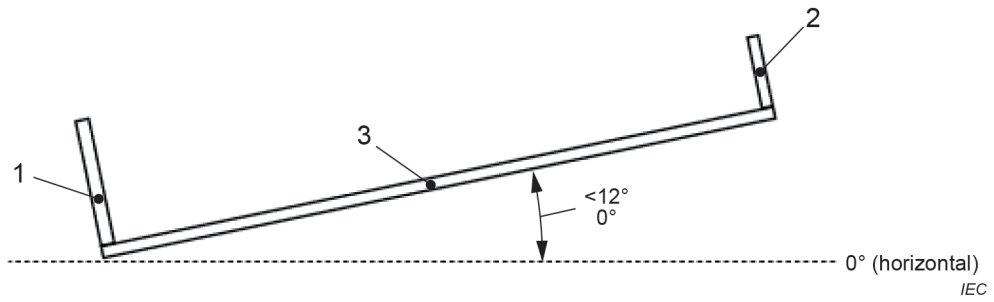
201.3.219
TEST BED BOARD
flat, rigid loading board of dimensions as specified by the MANUFACTURER representing the dimensions of the MEDICAL BED

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

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

201.3.222
*** ADULT**
PATIENT having a physical size equal to or more than 146 cm, a mass equal to or more than 40 kg and a body mass index (BMI) equal to or more than 17

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



Key

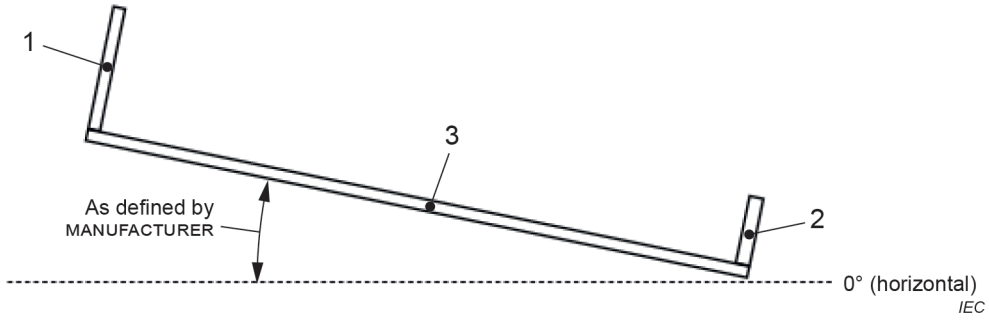
1 HEAD BOARD

2 FOOT BOARD

3 MATTRESS SUPPORT PLATFORM

Figure 201.102 – HEAD DOWN TILT, Example

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



Key

1 HEAD BOARD

2 FOOT BOARD

3 MATTRESS SUPPORT PLATFORM

Figure 201.103 – FOOT DOWN TILT, Example

201.4 General requirements

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

201.4.2.2 * General requirement for RISK MANAGEMENT

Addition:

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

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

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

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

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

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

201.4.6 ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

Addition:

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

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

201.5 General requirements for testing of ME EQUIPMENT

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

201.5.9.2 ACCESSIBLE PARTS

Addition:

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

Additional subclauses:

201.5.101 * Entrapment test tools

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