# IEC 60601-2-52

Edition 1.0 2015-03

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

**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 60601-2-52:2009-12/AMD1:2015-03(en-fr)

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# FOREWORD

This amendment has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

| FDIS | Report on voting |
|---|---|
| 62D/1186/FDIS | 62D/1232/RVD |

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

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability 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- withdrawn,
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### 201.1.1 * Scope

*Replace the existing text of the first paragraph with the following:*

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.

### 201.1.2 Object

*Replace the existing text of the replacement with the following:*

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.

### 201.3 Terms and definitions

*Add the following new term and definition:*

**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

### 201.4 General requirements

*Replace the existing text of the clause by the following:*

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

### 201.4.2.2 * General requirement for RISK MANAGEMENT

*Addition:*

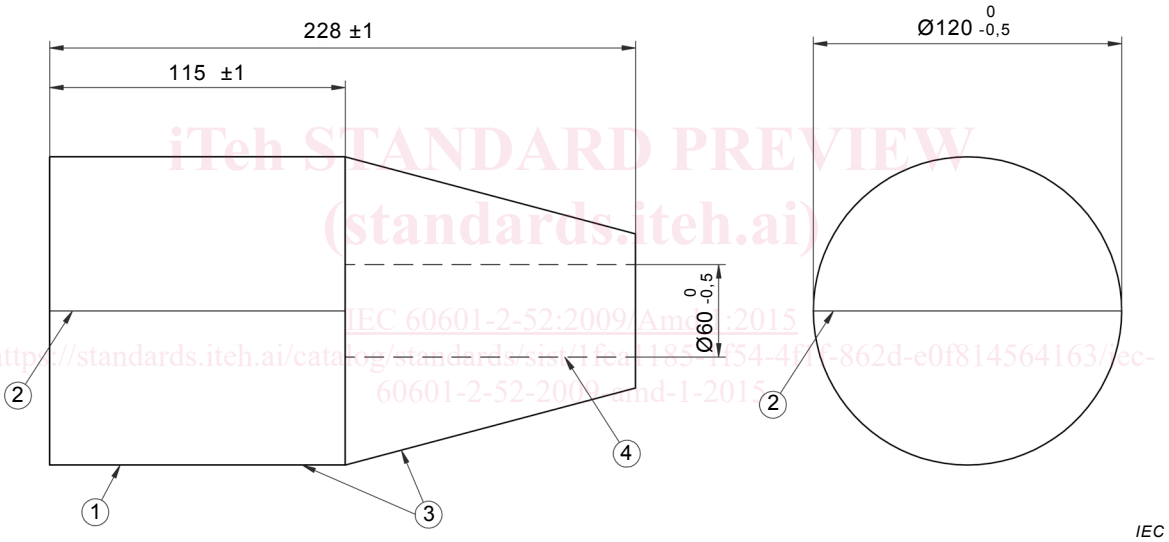
The MANUFACTURER shall include, in the RISK MANAGEMENT PROCESS, HAZARDS related to PATIENTS taller than 185 cm.

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

**Figure 201.103 – Entrapment test tools**

*Replace the existing figure by the following new figure:*

Dimensions in millimetres

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**Key**

1 Total weight 5,1 kg ±0,05 kg

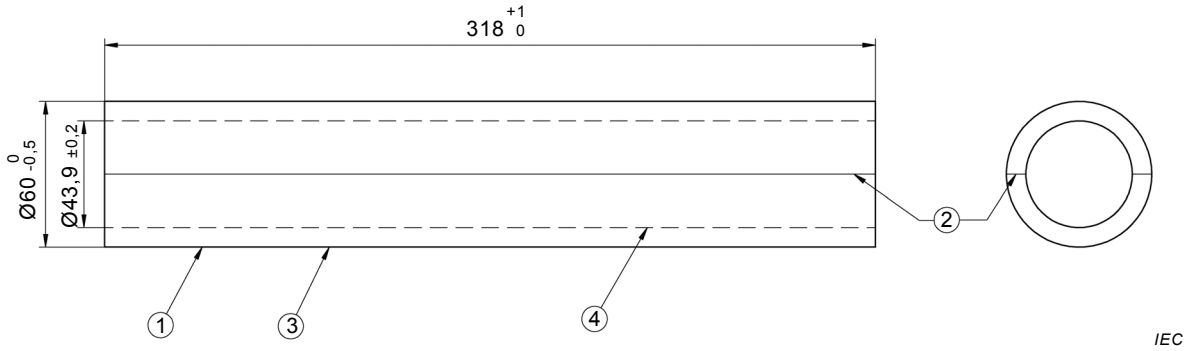
2 Marked centre line

3 Surface roughness 1,6

4 Drilling hole for weight adjustment

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

Dimensions in millimetres




**Key**

1 Total weight 3,34 kg ±0,05 kg

2 Marked centre line

3 Surface roughness 1,6

4 Drilling hole for weight adjustment

**Figure 201.103b) – Cylinder tool schematic**

**Figure 201.103 – Entrapment test tools**

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### 201.7 ME EQUIPMENT identification, marking and documents

#### 201.7.2.2 Identification

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*Add, after 201.7.2.2.106, the following new subclause:*

#### 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.

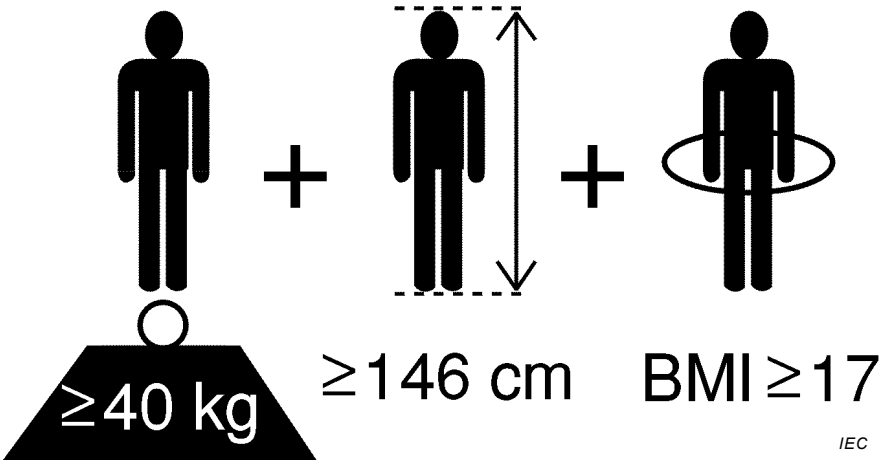


**Figure 201.120 – Physical description of an ADULT**

### 201.7.9.2 Instructions for use

#### 201.7.9.2.1 General

*Add the following new item:*

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

#### 201.7.9.2.2 Warning and safety notices

*Add the following new items:*

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

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

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

*Replace the existing figure with the following:*

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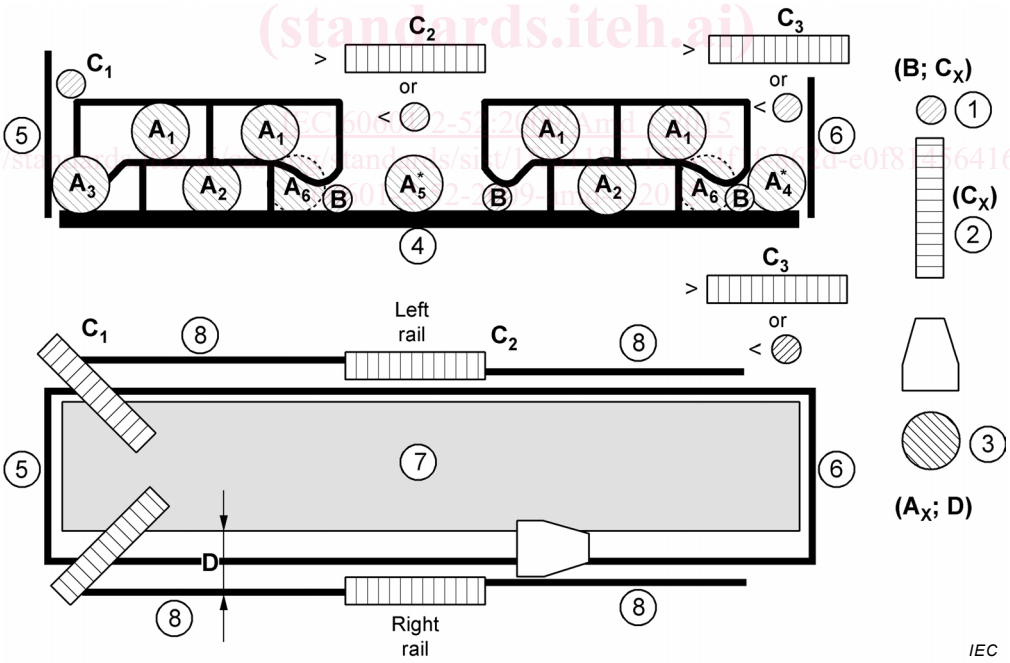



Only applies when the area C above is < 60 mm.

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

**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

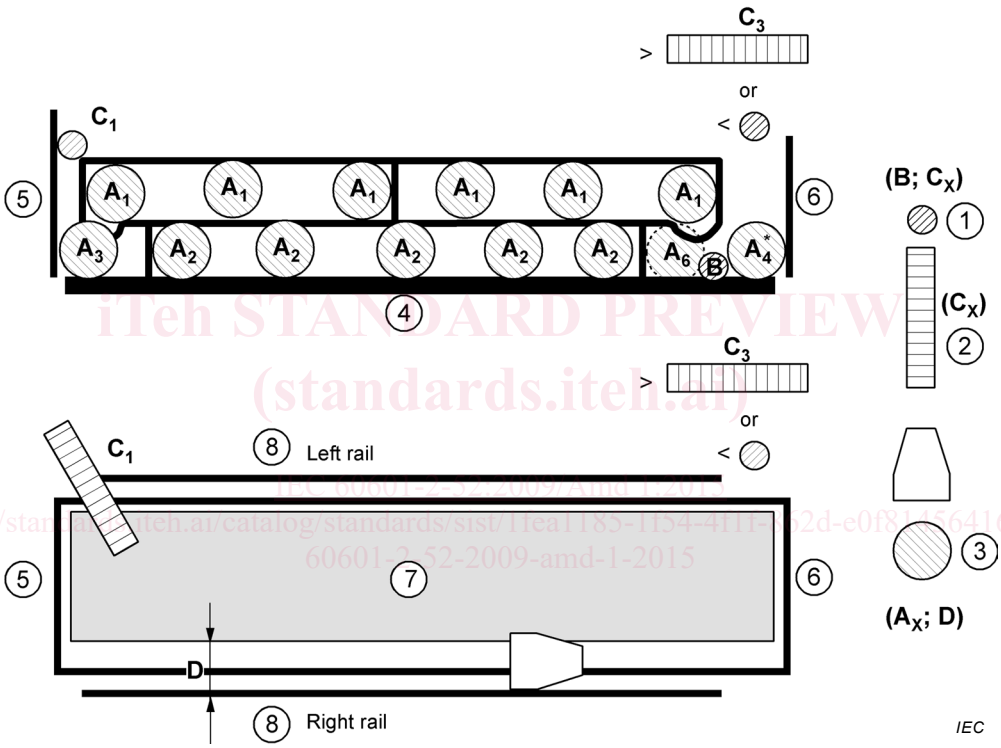
7 Mattress

8 SIDE RAIL

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

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

*Replace the existing figure with the following:*

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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**

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

*Add, after the existing second paragraph the following note:*

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

## Annex AA – Particular guidance and rationale

## AA.2 Rationale for particular clauses and subclauses

### Subclause 201.1.1 – Scope

*Add, at the end of the existing third sentence, the phrase: "*, a weight of equal to or more than 40 kg and a body mass index (BMI) equal to or more than 17.*"*

*Add the following new rationales:*

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**Definition 201.3.201 – ADULT**

The body mass index is calculated by the following formula:

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

Where:

$m$ in kg

$l$ in m

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

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

For an explanation see also 201.1.1.

### Subclause 201.4.2 – RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS

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

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

*Delete the existing fourth paragraph of this rationale.*

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