SLOVENSKI STANDARD
SIST EN 60601-2-52:2010/A1:2015

01-september-2015

Medicinska električna oprema - 2-52. del: Posebne zahteve za osnovno varnost in bistvene lastnosti medicinskih postelj - Dopolnilo A1

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

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

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

Ta slovenski standard je istoveten z: **EN 60601-2-52:2010/A1:2015**

ICS:

11.140	Oprema bolnišnic	Hospital equipment

SIST EN 60601-2-52:2010/A1:2015 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 60601-2-52:2010/A1

May 2015

ICS 11.140

English Version

Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds (IEC 60601-2-52:2009/A1:2015)

Appareils électromédicaux -
Partie 2-52: Exigences particulières de sécurité de base et de performances essentielles des lits médicaux
(IEC 60601-2-52:2009/A1:2015)

Medizinische elektrische Geräte -
Teil 2-52: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von medizinischen Betten
(IEC 60601-2-52:2009/A1:2015)

This amendment A1 modifies the European Standard EN 60601-2-52:2010; it was approved by CENELEC on 2015-04-22. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment the status of a national standard without any alteration.

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CENELEC

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

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Ref. No. EN 60601-2-52:2010/A1:2015 E

Foreword

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• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-04-22

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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.

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

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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:

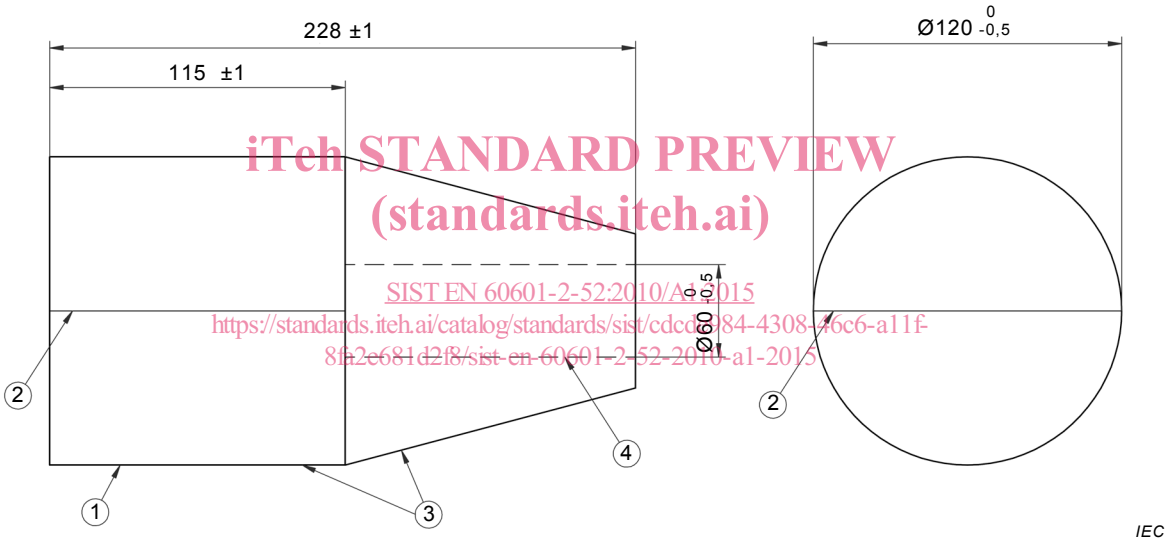
The MANUFACTURER shall include, in the RISK MANAGEMENT PROCESS, HAZARDS related to PATIENTS taller than 185 cm.

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



Key

1 Total weight 5,1 kg ±0,05 kg

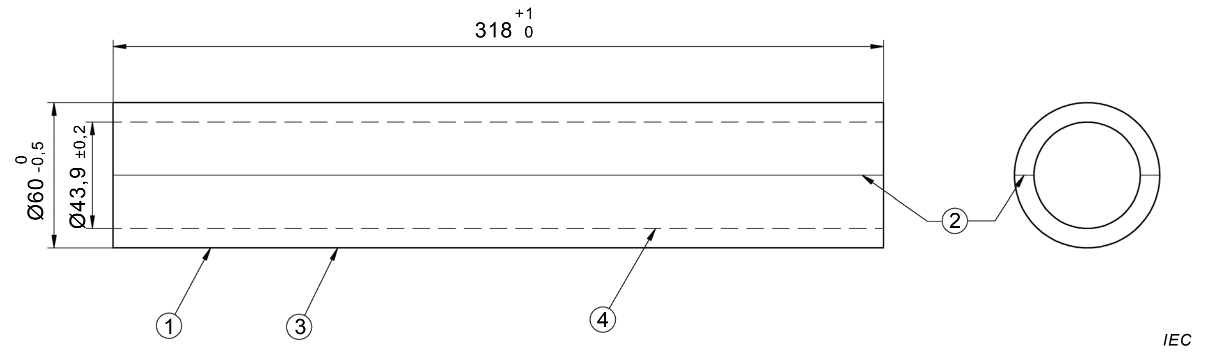
2 Marked centre line

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

201.7 ME EQUIPMENT identification, marking and documents

201.7.2.2 Identification

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.

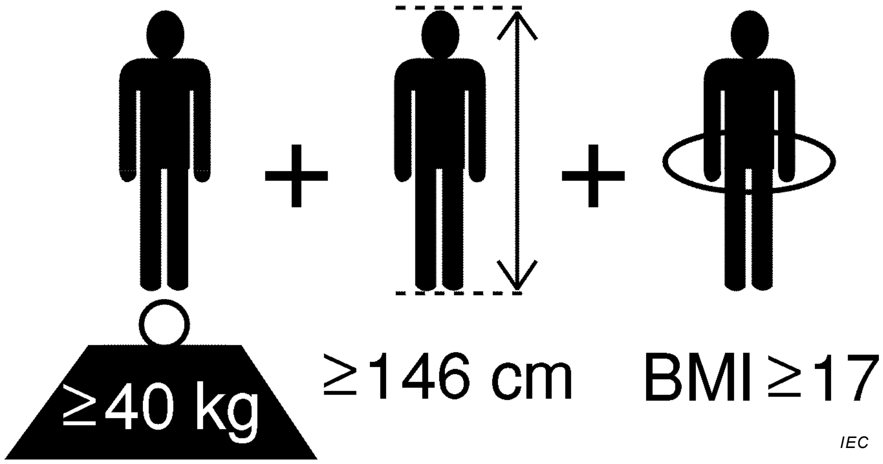


Figure 201.120 – Physical description of an ADULT

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:

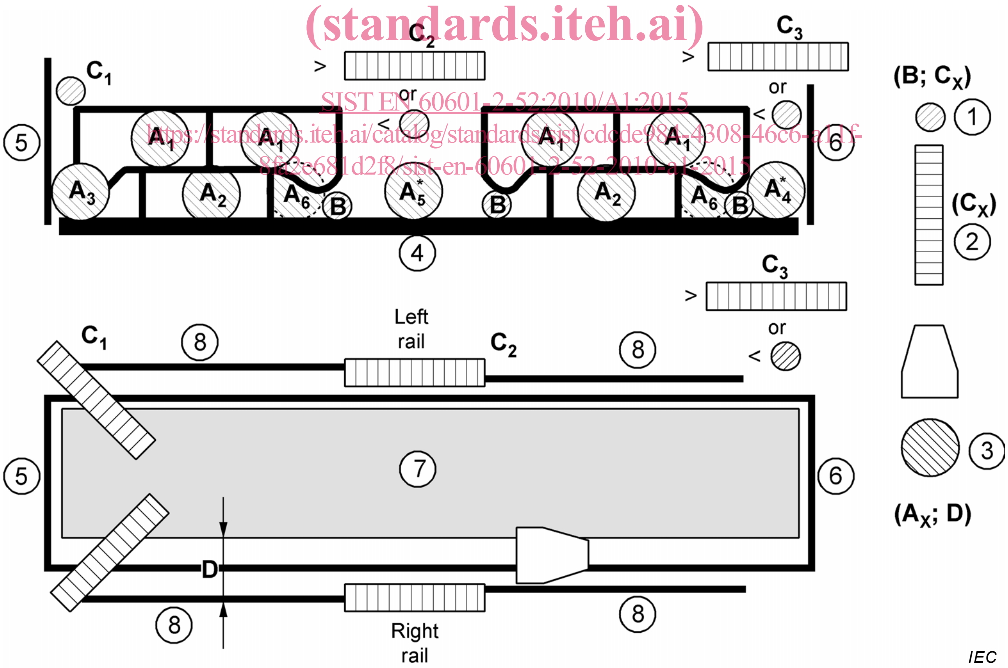
e) The instructions for use shall provide a warning if a MEDICAL BED is limited to a specific group of PATIENTS.

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:



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).