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Interested committees:

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Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

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Full document details: 20/30416274 DC

Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
------------------	------------------------

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



62D/1759/CD

COMMITTEE DRAFT (CD)

PROJECT NUMBER:
IEC 80601-2-52 ED1

DATE OF CIRCULATION:
2020-03-27

CLOSING DATE FOR COMMENTS:
2020-06-19

SUPERSEDES DOCUMENTS:
62D/1740A/RR

IEC SC 62D : ELECTROMEDICAL EQUIPMENT

SECRETARIAT:
United States of America

SECRETARY:
Ms Hae Choe

OF INTEREST TO THE FOLLOWING COMMITTEES:

PROPOSED HORIZONTAL STANDARD:



Other TC/SCs are requested to indicate their interest, if any, in this CD to the secretary.

FUNCTIONS CONCERNED:

☐ EMC

☐ ENVIRONMENT

☐ QUALITY ASSURANCE

☒ SAFETY

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

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

NOTE FROM TC/SC OFFICERS:

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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This Consolidated version is not an official IEC Standard and has been prepared for user convenience. Only the current versions of the standard and its amendment(s) are to be considered the official documents.

This Consolidated version of IEC 60601-2-52 bears the edition number 1.1. It consists of the first edition (2009-12) [documents 62D/795/FDIS and 62D/815/RVD] and its amendment 1 (2015-03) [documents 62D/1186/FDIS and 62D/1232/RVD]. The technical content is identical to the base edition and its amendment.

This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted is available in this publication.

159 International standard IEC 80601-2-52 has been prepared by IEC subcommittee 62D:
160 Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical
161 practice, and by ISO technical committee 173: Assistive products for persons with disability.

162 It is published as double logo standard.

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

164 In this standard, the following print types are used:

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

171 In referring to the structure of this standard, the term

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

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

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

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

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

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

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

192

193 The committee has decided that the contents of the base publication and its amendment will
194 remain unchanged until the stability date indicated on the IEC web site under
195 "http://webstore.iec.ch" in the data related to the specific publication. At this date, the
196 publication will be

- 197 • reconfirmed,
198 • withdrawn,
199 • replaced by a revised edition, or
200 • amended.

201 The contents of the corrigendum of September 2010 have been included in this copy.

202

203

204

205

INTRODUCTION

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

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

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

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

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

231 The IEC 80601-2-52 is a continuation of the IEC 60601-2-52 standard. It will align with the
232 children version of the standard IEC 80601-2-89. The nomenclature was changed from IEC
233 60601-2-52 to IEC 80601-2-52 to indicate joint work between the ISO and the IEC.

234

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-52: Particular requirements for the basic safety and essential performance of adult 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 as defined in 201.3.212, intended for ADULTS as defined in 201.3.219. Included in scope are both electrical and non-electrical (manual) MEDICAL BEDS.

This standard does not apply for medical beds intended for children and adults with an atypical anatomy covered by IEC 80601-2-89 Medical electrical equipment – Particular requirements for the basic safety and essential performance of medical beds for children.

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, intended for ADULTS as defined in 201.3.219.

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 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*.

270 201.1.4 Particular standards**271 Replacement:**

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

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

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

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

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

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

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

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

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

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

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

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*

201.2 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:

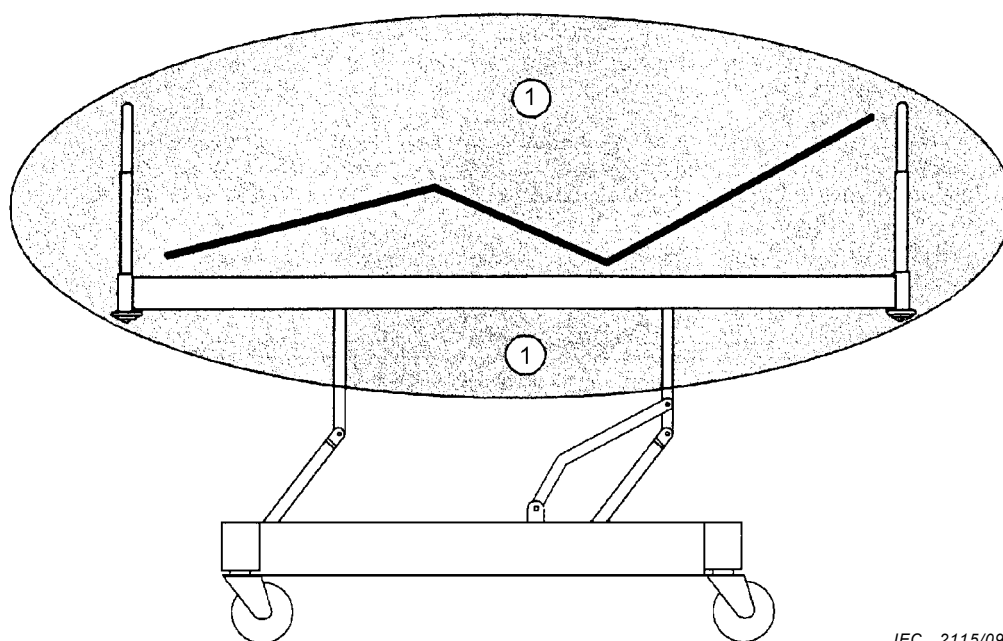
NOTE An index of defined terms is found beginning on page 82.

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

331 **201.3.131**
332 *** TRAPPING ZONE**

333 *Addition:*

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

337 *Addition:*

338 **201.3.201**
339 *** APPLICATION ENVIRONMENT 1**

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

343 **201.3.202**
344 *** APPLICATION ENVIRONMENT 2**

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

348 **201.3.203**
349 *** APPLICATION ENVIRONMENT 3**

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

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

354 **201.3.204**
355 *** APPLICATION ENVIRONMENT 4**

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

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

360 **201.3.205**
361 *** APPLICATION ENVIRONMENT 5**

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

365 **201.3.206**
366 *** APPLICATION ENVIRONMENT 6**

367 Psychiatric (mental health) care environment where medical supervision is required, and
368 monitoring is provided. ME EQUIPMENT used in medical procedures may be provided to help
369 maintain, improve condition and protect the PATIENT. Environment when a patient may be a
370 harm to themselves or others.

Comment to National Committees: Please provide any national requirements or hazards related to Psychiatric (mental health / prison) medical beds in national comments. JWG4 is evaluating the need to include Application Environment 6.
--

371
372
373

374

375

376 **201.3.207**

377 **BED-LIFT**

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

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

381 **201.3.208**

382 **CHILD**

383 See definition in IEC 80601-2-89 (EN 50637)

384 **201.3.209**

385 **DISABLED PERSON**

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

388 [ISO 9999:2007]

389 **201.3.210**

390 **HEAD/FOOT BOARD**

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

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

394 **201.3.211**

395 **LIFTING POLE**

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

398 **201.3.212**

399 **MATTRESS OVERLAY**

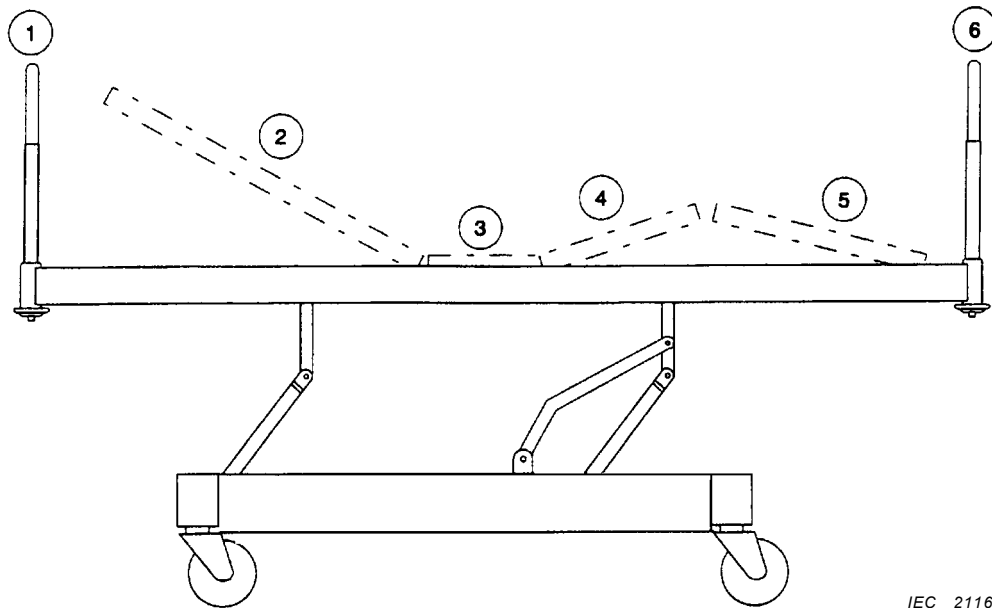
400 supplementary mattress (support surface), which is intended to be placed on an existing
401 mattress, and generally used for prophylactic or therapeutic effect

402 **201.3.213**

403 **MATTRESS SUPPORT PLATFORM**

404 structure which supports a PATIENT surface (for example mattress)

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



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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)**

201.3.214*** 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).

201.3.215**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 and/or movements

NOTE PENDANT CONTROLS may be wired, or wireless, and may integrate other functions, (e.g. 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

439 NOTE When a SIDE RAIL is located in the “up” position it provides a physical barrier, which is intended to reduce
440 the RISK of the PATIENT accidentally slipping or rolling off the mattress.

441 **201.3.218**
442 **SPECIALTY MATTRESS**
443 mattress intended for prophylactic or therapeutic effect

444 **201.3.219**
445 **TEST BED BOARD**
446 flat, rigid loading board of dimensions as specified by the MANUFACTURER representing the
447 dimensions of the MEDICAL BED

448 **201.3.220**
449 **TRENDELENBURG**

450 A specific therapeutic position used in some medical procedures requiring greater than a 12°
451 head down tilt

452 Note: other mattress support platform tilt positions are permitted if trendelenburg position is
453 not indicated.

454 **201.3.221**
455 **UNDERCARRIAGE**
456 all components of the MEDICAL BED or BED-LIFT below the MATTRESS SUPPORT PLATFORM

457 **201.3.222**
458 *** ADULT**
459 PATIENT having a physical size equal to or more than 146 cm, a mass equal to or more than
460 40 kg and a body mass index (BMI) equal to or more than 17 or having a physical size, mass,
461 and body 14 index as defined by the MANUFACTURER’S RISK MANAGEMENT FILE.

462 **201.4 General requirements**

463 Clause 4 of the general standard applies.

464 **201.4.2.2 * General requirement for RISK MANAGEMENT**

465 *Addition:*

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

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

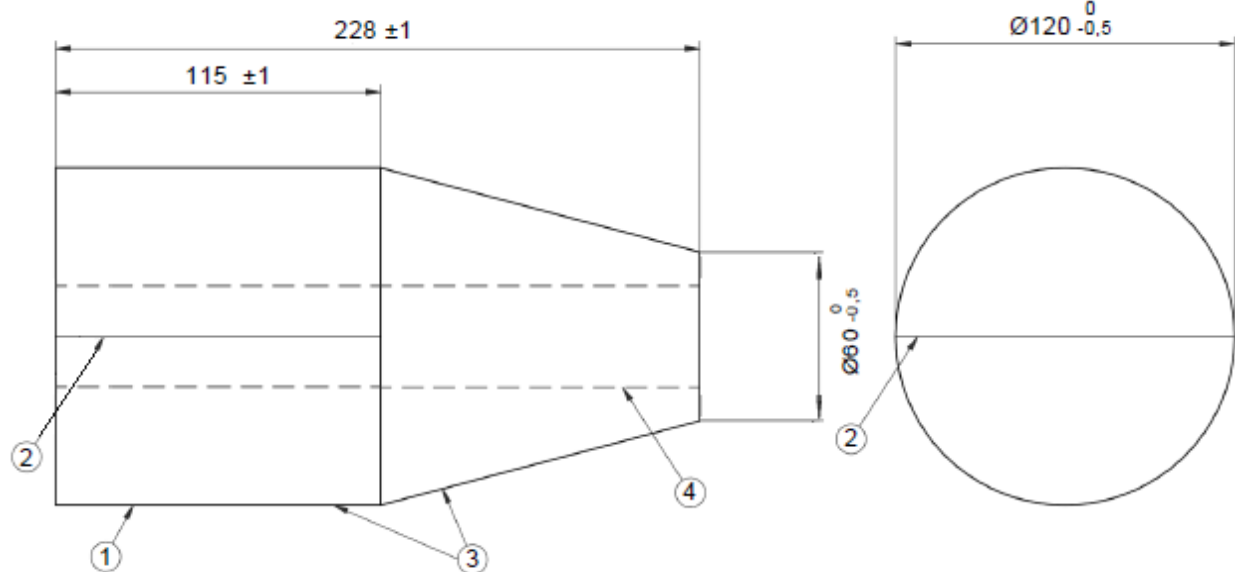
469 **201.5 General requirements for testing of ME EQUIPMENT**

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

471 *Additional subclauses:*

472 **201.5.101 * Entrapment test tools**

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



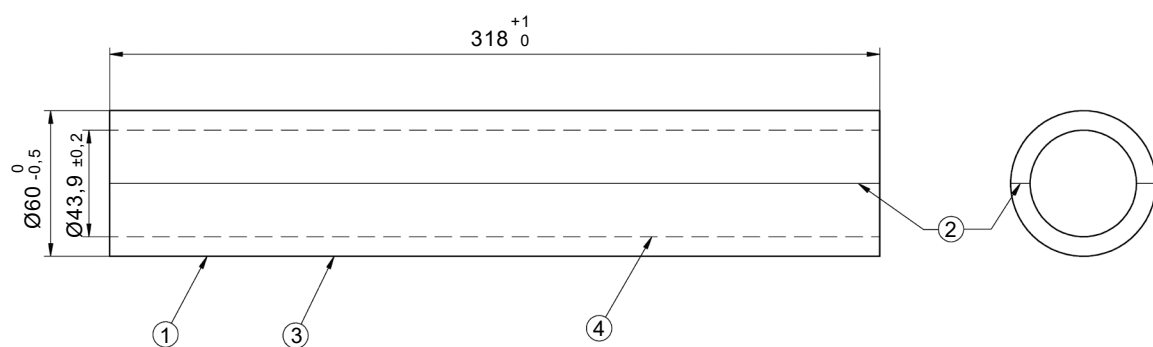
Dimensions in millimetres

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 (reference)

Figure 201.103 a) – Cone tool schematic

Dimensions in millimetres



IEC

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 (reference)

Figure 201.103 b) – Cylinder tool schematic**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.

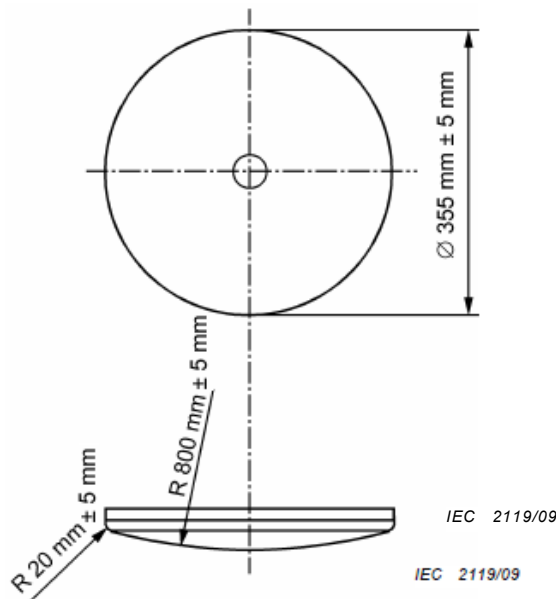


Figure 201.104 – Loading pad

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:

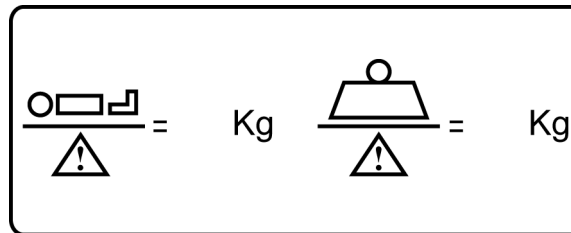
The MEDICAL BED shall be marked with the name or trademark and address of the MANUFACTURER, MODEL OR TYPE REFERENCE and means to allow traceability.

511 The detachable components shall be marked with the name or trademark and address of the
 512 MANUFACTURER, MODEL OR TYPE REFERENCE and means to allow traceability unless mis-
 513 identification does not present an unacceptable RISK.

514 *Additional subclauses:*

515 **201.7.2.2.101 * Marking of maximum PATIENT weight and SAFE WORKING LOAD**

516 a) The MEDICAL BED shall be marked with the corresponding maximum PATIENT weight
 517 (see 201.9.8.3.1) and SAFE WORKING LOAD (for symbol see Figure 201.105).



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

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

522 **201.7.2.2.102 Marking for machine washable MEDICAL BEDS by an automatic washing**
 523 **system**

524 MEDICAL BEDS intended for use with an automatic washing system shall be marked with the
 525 following text to distinguish them from MEDICAL BEDS which cannot tolerate such cleaning
 526 methods: “Caution, for cleaning purposes this bed can be used with automatic washing
 527 systems.” Or be marked with the corresponding symbol (see figure 201.121)



528

529 **Figure 201.121 – Graphic symbol for machine washable MEDICAL BED**
 530 **Marking for MEDICAL BEDS intended for jet stream washing**

531 MEDICAL BEDS intended for use with jet stream washing shall be marked with the following
 532 text: “Caution, for cleaning purposes this bed can be used with jet stream washing.” Or be
 533 marked with the corresponding symbol (see figure 201.122)



Figure 201.122 – Graphic symbol for jet stream washable MEDICAL BED

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).

201.7.2.2.107 Marking on the MEDICAL BED for ADULTS

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

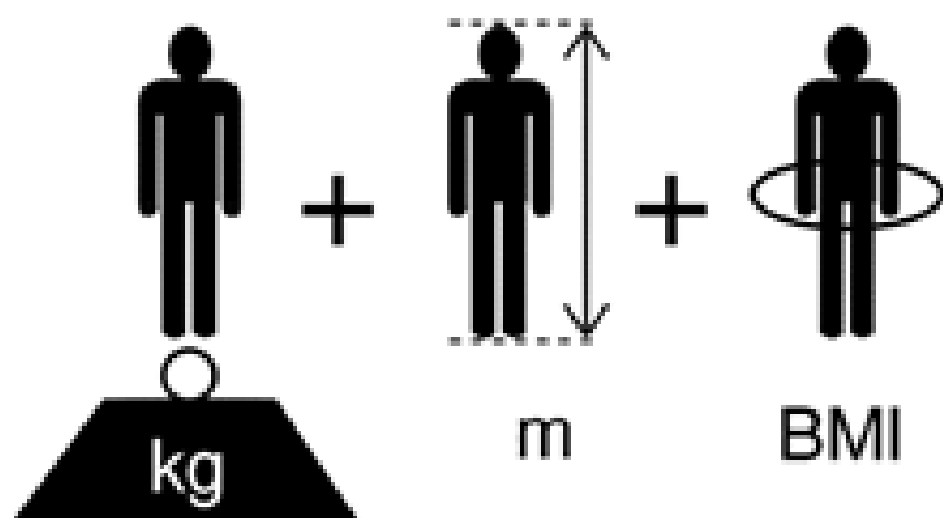


Figure 201.120 – Physical description of an ADULT

201.7.2.4 ACCESSORIES

Addition:

556 Where an overload on an ACCESSORY that is intended to support loads can create an
557 unacceptable RISK, the corresponding SAFE WORKING LOAD shall be marked on the ACCESSORY.

558 *Compliance is checked by inspection.*

559 **201.7.4.2 Control devices**

560 *Addition:*

561 Where reliance to prevent unintended movement of the MATTRESS SUPPORT PLATFORM is based
562 on a MOTION LOCKOUT CONTROL which requires activation by the OPERATOR, this shall be
563 disclosed by markings or symbols as appropriate on the outside of the MEDICAL BED and which
564 are visible from a position of NORMAL USE (see Figure 201.106).

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

567 *Compliance is checked by inspection of the MEDICAL BED.*

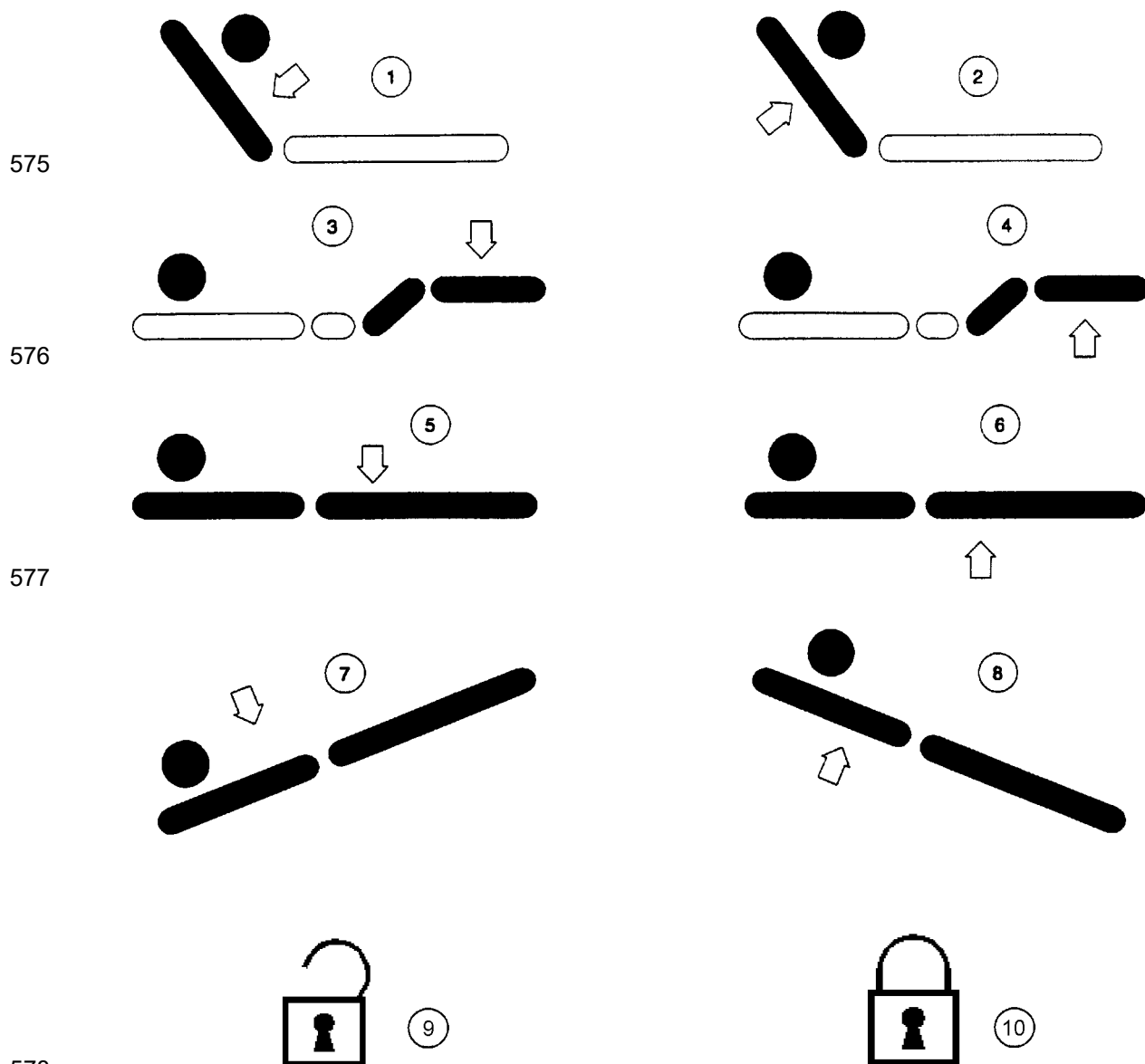
568 **201.7.6.3 Symbols for controls and performance**

569 *Addition:*

570 Controls and/or indicators, when possible, shall be marked using symbols that convey the
571 intended function of those controls or indicators without the need for additional text.

572 NOTE Figure 201.106 is intended as a guideline when designing these symbols. In all cases where standard
573 international symbols exist, they should be used.

574



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578

579 **Key**

- 580 1 Back section down function
- 581 2 Back section up function
- 582 3 Leg down function
- 583 4 Leg up function
- 584 5 MATTRESS SUPPORT PLATFORM down
- 585 6 MATTRESS SUPPORT PLATFORM up
- 586 7 Trendelenburg and/ or head down tilt
- 587 8 Anti-Trendelenburg/reverse Trendelenburg and/ or foot down tilt
- 588 9 Padlock-symbol (unlocked) for MOTION LOCKOUT CONTROL
- 589 10 Padlock-symbol (locked) for MOTION LOCKOUT CONTROL

590

591

**Figure 201.106 – MEDICAL BED function controls and/or actuators:
guidelines for creating graphic symbols**

592 201.7.9.2 Instructions for use**593 201.7.9.2.1 General**

594 *Addition:*

595 The instructions for use shall include:

- 596 a) a description according to 201.3. of the intended APPLICATION ENVIRONMENT(S);
- 597 b) the maximum PATIENT weight and SAFE WORKING LOAD. The SAFE WORKING LOAD is the sum
598 of:
- 599 – the PATIENT;
- 600 – the mattress;
- 601 – the ACCESSORIES of the MEDICAL BED (only if they are supported by the support system
602 of the MEDICAL BED); and
- 603 – the load supported by those ACCESSORIES (excluding PATIENT weight);
- 604 c) an explanation of how to deactivate any MEDICAL BED function if movement caused by that
605 function could cause injury to the PATIENT;
- 606 d) for APPLICATION ENVIRONMENT 4 intended MEDICAL BEDS, the result of the measurement of
607 auditable acoustic energy in accordance with ISO 3746.
- 608 e) a description of the intended PATIENT group(s).

609 201.7.9.2.2 Warning and safety notices

610 *Addition:*

- 611 a) The instructions for use shall provide a warning that the MEDICAL BED should be left in
612 its lowest position when the PATIENT is unattended in order to reduce RISK of injury due
613 to falls.
- 614 b) The instructions for use shall provide a warning on HAZARDS caused by inappropriate
615 handling of the POWER SUPPLY CORD, e. g. by kinking, shearing or other mechanical
616 damages.
- 617 c) The instructions for use shall provide a warning, stating that when routing cables from
618 other equipment in the MEDICAL BED, precautions shall be taken to avoid squeezing
619 those between parts of the MEDICAL BED.
- 620 d) The instructions for use shall provide a warning if a MEDICAL BED shall only be used
621 with certain hoists, because of the limited space underneath the MEDICAL BED.
- 622 e) The instructions for use shall provide a warning if a MEDICAL BED is limited to a specific
623 group of PATIENTS.
- 624 f) The instructions for use shall provide a warning that incompatible side rails and
625 mattresses can cause an entrapment hazard
- 626

627 201.7.9.2.5 ME EQUIPMENT description

628 *Addition:*

629 201.7.9.2.5.101 Selection of mattress

630 The instructions for use shall contain information on the selection of mattress(es), including
631 mattress dimensions and mattress characteristics (e.g. to reduce the RISK of entrapment and
632 falls (see also 201.7.2.2.105)).

633 **201.7.9.2.5.102 Selection of SIDE RAILS**

634 The instructions for use shall contain information on the selection of SIDE RAILS, including
635 SIDE RAIL dimensions and SIDE RAIL characteristics (e.g. to reduce the RISK of entrapment and
636 falls (see also 201.7.2.2.106)).

637 **201.7.9.2.5.103 * Angles and height of MEDICAL BED**

638 The instructions for use shall identify the maximum angles, which can be achieved in NORMAL
639 USE by each part of the MATTRESS SUPPORT PLATFORM with reference to horizontal. They shall
640 also identify the maximum and minimum heights from the floor which can be achieved by the
641 MATTRESS SUPPORT PLATFORM in NORMAL USE. They shall also identify any emergency
642 position(s) and the controls by which such position(s) are obtained.

643 **201.7.9.2.5.104 * Maximum mass of MEDICAL BED**

644 The instructions for use shall identify the maximum mass (in kg) of the MEDICAL BED. If the
645 MEDICAL BED is intended to be disassembled into parts, the maximum mass (in kg) of any parts
646 shall be stated in the instructions for use.

647 **201.7.9.2.13 Maintenance**

648 *Replacement:*

649 The instruction for use shall instruct the OPERATOR or RESPONSIBLE ORGANIZATION in sufficient
650 detail concerning preventive inspection, maintenance and calibration to be performed by
651 them, including the frequency of such maintenance.

652 The instruction for use shall provide information for the safe performance of such routine
653 maintenance necessary to ensure the continued safe use of the MEDICAL BED.

654 Additionally, the instructions for use shall identify the parts on which preventive inspection
655 and maintenance shall be performed by SERVICE PERSONNEL, including the periods to be
656 applied and details about the actual performance of such maintenance.

657 For MEDICAL BEDS containing rechargeable batteries that are intended to be maintained by
658 anyone other than SERVICE PERSONNEL, the instruction for use shall contain instructions to
659 ensure adequate maintenance.

660 Additional information regarding periodic inspections can be found in in Annex DD

661 **201.8 Protection against electrical HAZARDS from ME EQUIPMENT**

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

663 **201.8.5.2.1 * F-TYPE APPLIED PARTS**

664
665 Addition:

666
667 A type BF applied part shall have no conductive connection to accessible metal parts.
668

669 **201.8.5.2.2 *TYPE B APPLIED PARTS**

670
671 This subclause does not apply.
672

673 Note: Type B applied parts are allowed for medical beds. This revision only removes this 1 subclause.

674

675 **201.8.11.3.2 Types**676 *Replacement:*

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

679 POWER SUPPLY CORDS and other external flexible mains cables and cords on MEDICAL BEDS
680 shall be type EN 50525-2-21 H05-BQ-F [1]³⁾ or equivalent quality for mechanical robustness.

681 POWER SUPPLY CORDS shall be equipped with appropriate strain relief and bend protection.

682 POWER SUPPLY CORD sets shall have a moulded-on plug or other means to withstand the
683 ingress of water during the cleaning PROCESS for which the MEDICAL BED is intended.

684 The MEDICAL BED shall be equipped with a means to keep the POWER SUPPLY CORD clear of any
685 moving MEDICAL BED part or mechanism, when the MEDICAL BED is in use, transport or not in
686 use to avoid a damage of the POWER SUPPLY CORD.

687 POWER SUPPLY CORDS shall be adequately protected against damages from contact with
688 moving part(s) or from friction at sharp corners and edges within the MEDICAL BED.

689 *Compliance is checked by inspection.*

690 **201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS**

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

692 **201.9.1 * MECHANICAL HAZARDS of ME EQUIPMENT**693 *Addition:*694 **201.9.1.101 * Protection against PATIENT entrapment in non-moving parts**

695 Any openings or areas (A₁, A₂, A₃, A₄, A₅, A₆, B, C and D) within the MEDICAL BED system and
696 which are above the MATTRESS SUPPORT PLATFORM shall meet the dimensional and
697 constructional requirements of Figures 201.107, 201.108 and Table 201.101. Where a RISK of
698 PATIENT entrapment exists and is addressed in another way this shall be justified by the
699 MANUFACTURER in the RISK MANAGEMENT FILE.

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

702 *Compliance is checked with the MATTRESS SUPPORT PLATFORM in the flat and lowest position*
703 *as allowed by design unless otherwise noted as indicated in Table 201.101. The test shall be*
704 *performed with the SIDE RAIL in its raised and locked positions which are not intended to be*
705 *used primarily for patient ingress and / or egress. The instructions for use shall state which*
706 *side rail locking positions are intended to be used primarily for patient ingress and / or egress.*

³⁾ Figures in square brackets refer to the bibliography.

Question 1: JWG4 would like specific recommendations from National committees regarding the text in the paragraphs above and below this text box. Please include in your commenting if you would prefer

- a) Text not changed (will remain as written in 60601-2-52)
- b) Text changed as red lined
- c) Text changed with modification, please recommend text

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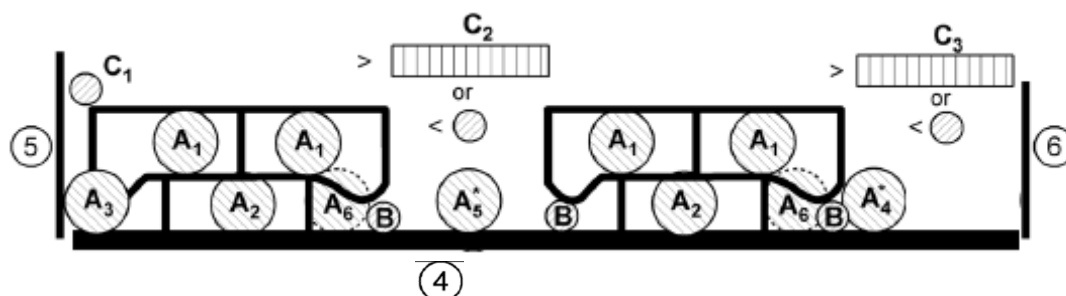
711 Requirements involving the MATTRESS SUPPORT PLATFORM and mattress are checked
712 with the mattress(es) meeting dimensional and characteristic requirements (i.e. thickness,
713 width, length, ILD) as specified by the MANUFACTURER (see 201.7.9.2.5.101)..
714 Requirements of Figures 201.107, 201.108 and Table 201.101 involving the mattress are
715 excluded for SPECIALTY MATTRESSES.

716 A RISK ASSESSMENT shall be performed to evaluate:

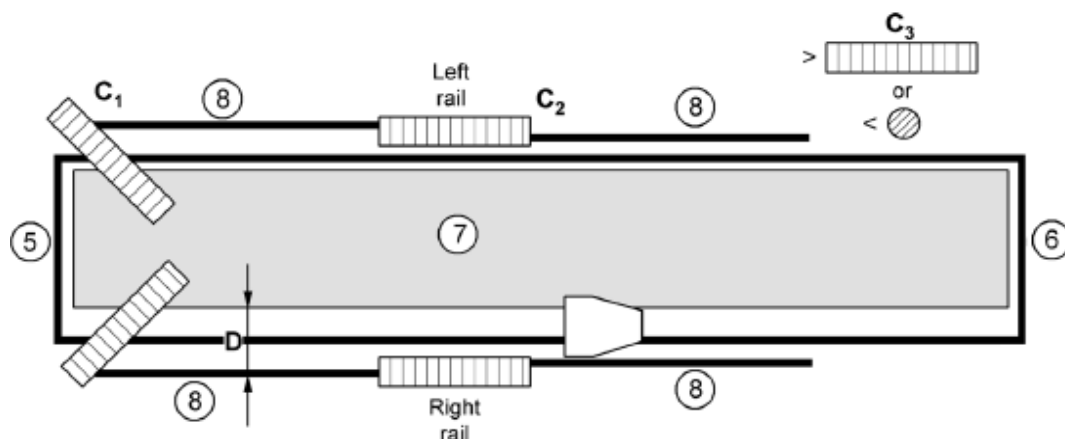
- 717 – SPECIALTY MATTRESSES;
- 718 – MATTRESS OVERLAYS;
- 719 – ACCESSORIES;
- 720 – articulated MATTRESS SUPPORT PLATFORM positions.
- 721 – PATIENTS taller than 1.85 m..
- 722 – Mattress support platform positions other than lowest

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

724



725



726

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

728 A_x represents the different areas A_1 , A_2 , A_3 , A_4 , A_5 and A_6 729 **Key**

730 1 Area of TOOL representing neck diameter (60 mm).

731 2 Area of TOOL representing chest breadth (318 mm).

732 3 Area of TOOL representing head breadth (120 mm).

733 4 MATTRESS SUPPORT PLATFORM

734 5 HEAD BOARD

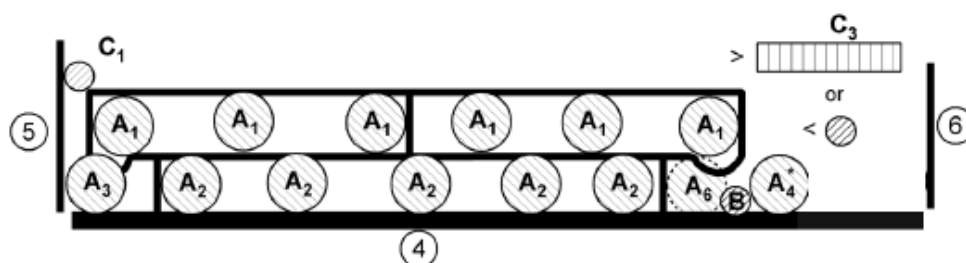
735 6 FOOT BOARD

736 7 Mattress

737 8 SIDE RAIL

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

739



740