



DPC: 24 / 30488536 DC

BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000

Fax: +44 (0)20 8996 7400

www.bsigroup.com

Date: 05 March 2024

Origin: International

Latest date for receipt of comments: 24 April 2024

Project No. 2020/00041

Responsible committee: CH/62/4 Particular medical equipment, software, and systems

Interested committees:

Title: BS EN IEC 80601-2-52 Medical electrical equipment

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

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

**WARNING: THIS IS A DRAFT AND MUST NOT BE REGARDED OR USED AS A BRITISH STANDARD.
THIS DRAFT IS NOT CURRENT BEYOND 24 April 2024**

This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

No copying is allowed, in any form, without prior written permission from BSI except as permitted under the Copyright, Designs and Patent Act 1988 or for circulation within a nominating organization for briefing purposes. Electronic circulation is limited to dissemination by e-mail within such an organization by committee members.

Further copies of this draft may be purchased from BSI Shop <http://shop.bsigroup.com> or from BSI Customer Services, Tel: +44(0) 20 8996 9001 or email cservices@bsigroup.com. British, International and foreign standards are also available from BSI Customer Services.

Information on the co-operating organizations represented on the committees referenced above may be obtained from <http://standardsdevelopment.bsigroup.com>

Responsible Committee Secretary: Ms Lindsey Ferrari (BSI)

Direct tel:

E-mail: lindsey.ferrari@bsigroup.com

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

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

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.	



DRAFT International Standard

IEC/DIS 80601-2-52

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

ICS: ISO ics

ISO/TC 173

Secretariat: **SIS**

Voting begins on:
2024-03-01

Voting terminates on:
2024-05-24

This document is circulated as received from the committee secretariat.

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

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENTS AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

Reference number
IEC/DIS 80601-2-52:2024(en)

Full document details: 24/30488536 DC

© IEC 2024
 **Documents**
Document Sharing Hub



COPYRIGHT PROTECTED DOCUMENT

© ISO 2024

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

© IEC 2024 – All rights reserved

1 CONTENTS

2	FOREWORD	5
3	INTRODUCTION	8
4	201.1 Scope, object and related standards	9
5	201.2 Normative references	11
6	201.3 Terms and definitions	11
7	201.4 General requirements	15
8	201.5 General requirements for testing of ME EQUIPMENT	15
9	201.6 Classification of ME EQUIPMENT and ME SYSTEMS	17
10	201.7 ME EQUIPMENT identification, marking and documents	18
11	201.8 Protection against electrical HAZARDS from ME EQUIPMENT	24
12	201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	25
13	201.10 Protection against unwanted and excessive radiation HAZARDS	50
14	201.11 Protection against excessive temperatures and other HAZARDS	50
15	201.12 Accuracy of controls and instruments and protection against hazardous	
16	outputs	53
17	201.13 HAZARDOUS SITUATIONS and fault conditions	54
18	201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	54
19	201.15 Construction of ME EQUIPMENT	55
20	201.16 ME SYSTEMS	59
21	201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	59
22	Annexes	59
23	Annex AA (informative) Particular guidance and rationale	60
24	Annex BB (normative) Design requirements and recommendations for MEDICAL BEDS	76
25	Annex CC (informative) Particular guidance for assessing risk of entrapment in v-	
26	shaped openings	80
27	Annex DD (informative) Guidance and recommendations for periodic inspection	86
28	Bibliography	88
29	Index of defined terms used in this particular standard	89

30

31 FIGURES

32	Figure 201.101 – MEDICAL BED, general arrangement	14
33	Figure 201.102 – Entrapment test tools	16
34	Figure 201.103 – Loading pad	17
35	Figure 201.104 – Impactor	17
36	Figure 201.105 – Ball chain loop and spherical mass	18
37	Figure 201.106 – Graphic symbol for maximum PATIENT weight and SAFE WORKING LOAD	19
38	Figure 201.107 – Graphic symbol for mass; weight	19
39	Figure 201.108 – Graphic symbol for machine washable MEDICAL BED	19
40	Figure 201.109 – Graphic symbol for jet stream washable MEDICAL BED	20
41	Figure 201.110 – Graphic symbol for manual cleaning only	20
42	Figure 201.111 – Physical description of an ADULT	21

43	Figure 201.112 – MEDICAL BED function controls and/or actuators: guidelines for	
44	creating graphical symbols.....	22
45	Figure 201.113 – Example of MEDICAL BED with segmented or split SIDE RAIL	26
46	Figure 201.114 – Example of MEDICAL BED with single piece SIDE RAIL	27
47	Figure 201.115 – Allowable spacing for fingers in areas of normal reach around the	
48	perimeter of the MATTRESS SUPPORT PLATFORM	32
49	Figure 201.116 – Example using barriers for clearance measurement around the	
50	perimeter of the MATTRESS SUPPORT PLATFORM to mitigate PATIENT finger entrapment	33
51	Figure 201.117 – Clearance areas	34
52	Figure 201.118 – Retention of loop and mass	36
53	Figure 201.119 – Lateral stability test along the side of the MEDICAL BED	38
54	Figure 201.120 – Longitudinal stability test with removable FOOT BOARD.....	38
55	Figure 201.121 – Longitudinal stability test with fixed HEAD/FOOT BOARD.....	39
56	Figure 201.122 – Distribution of SAFE WORKING LOAD / maximum PATIENT weight for tests.....	42
57	Figure 201.123 – Position of Dynamic loading (see Figure 201.103 for loading pad)	45
58	Figure 201.124 – Application of forces for test of SIDE RAIL.....	46
59	Figure 201.125 – Height of SIDE RAIL	49
60	Figure 201.126 Direction of movement for rough handling test	55
61	Figure 201.127 – Configurations of the MATTRESS SUPPORT PLATFORM	57
62	Figure AA.1 – Example of marking to select recommended mattresses specified by the	
63	MANUFACTURER	62
64	Figure AA.2 – Example of marking for detachable SIDE RAILS specified by the	
65	MANUFACTURER	63
66	Figure AA.3 – Examples of marking on the MEDICAL BED of storage location for wired	
67	and wireless PENDANT CONTROLS	63
68	Figure AA.4 – Resultant forces without mattress	66
69	Figure AA.5 – Resultant forces with mattress	66
70	Figure AA.6 – Example of 60 mm gap measurement of B	66
71	Figure AA.7 – Angle measurement example of B	66
72	Figure AA.8 – Placement of measurement TOOL for measurement of D	68
73	Figure AA.9 – Example of area D measurement that passes	68
74	Figure AA.10 – Example of area D measurement that fails (on limit)	68
75	Figure AA.11 – Example of area D measurement that fails.....	68
76	Figure AA.12 – Example of potential PATIENT entrapment in area A within the SIDE RAIL	69
77	Figure AA.13 – Example of potential PATIENT entrapment in area A below the SIDE RAIL	69
78	Figure AA.14 – Example of potential PATIENT entrapment in area B	69
79	Figure AA.15 – Example of potential PATIENT entrapment in area C between split SIDE	
80	RAIL.....	69
81	Figure AA.16 – Example of potential PATIENT entrapment in area C between SIDE RAIL	
82	and HEAD BOARD	69
83	Figure AA.17 – Example of potential PATIENT entrapment in area D.....	69
84	Figure AA.18 – Example of potential PATIENT entrapment in area A below a single piece	
85	SIDE RAIL	69
86	Figure AA.19 – Concept of potential PATIENT foot-first entrapment tool for area A below	
87	a single piece SIDE RAIL	70
88	Figure BB.1 – Schematic presentation of under MEDICAL BED clearance.....	78

89	Figure BB.2 – Recommendations and requirements regarding angles for different	
90	sections of the MATTRESS SUPPORT PLATFORM	79
91	Figure CC.1 – Wedge tool	81
92	Figure CC.2 – V-shaped opening in relation to B	82
93	Figure CC.3 – Pass/fail in relation to area B	83
94	Figure CC.4 – Positioning of wedge tool	84
95	Figure CC.5 – Pass/fail in relation to area C between HEAD BOARD and FOOT BOARD	84
96	Figure CC.6 – Pass/fail in relation to area C between split SIDE RAILS	85
97		

98 TABLES

99	Table 201.101 – Protection against PATIENT entrapment.....	28
100	Table 201.102 – Protection against inadvertent PATIENT falls	50
101	Table 24 – Allowable maximum temperatures for skin contact with MEDICAL BED APPLIED	
102	PARTS.....	51
103		

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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

152 It is published as double logo standard.

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

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

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

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

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

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

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

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

- 172 – “shall” means that compliance with a requirement or a test is mandatory for compliance
173 with this standard;
- 174 – “should” means that compliance with a requirement or a test is recommended but is not
175 mandatory for compliance with this standard;
- 176 – “may” is used to describe a permissible way to achieve compliance with a requirement or
177 test.

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

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

182

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

- 187 • reconfirmed,
188 • withdrawn,
189 • replaced by a revised edition, or
190 • amended.
191

192 INTRODUCTION

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

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

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

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

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

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

221

MEDICAL ELECTRICAL EQUIPMENT –

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

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 201.3.214, intended for ADULTS as defined in 201.3.222. Included in scope are both electrical and non-electrical (manual) MEDICAL BEDS with or without adjustable features.

This standard does not apply for MEDICAL BEDS intended for CHILDREN covered by IEC 80601-2-89 Medical electrical equipment – Particular requirements for the basic safety and essential performance of medical beds for children.

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.

Excluded are devices for which the intended use is mainly for examination or transportation under medical supervision (e.g. stretcher, examination table).

This standard does not apply in all requirements to MEDICAL BEDS with special functionality.

Beds that are intended to be used for ADULTS with atypical anatomy shall state what atypical anatomies are meant. Additional requirements for the stated atypical anatomies shall be determined in the product RISK MANAGEMENT process and implemented as appropriate in the bed design.

EXAMPLE A bed intended for bariatric PATIENTS would require consideration of the differences in anthropomorphic ranges, and having implemented those ranges would label appropriately for the intended PATIENT population.

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:

¹⁾ The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

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

262 **201.1.3 Collateral standards**

263 *Addition:*

264 This particular standard refers to those applicable collateral standards that are listed in
 265 Clause 2 of the general standard and Clause 2 of this particular standard.

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

268 Some IEC 60601-1-8 requirements may be excluded if they don't affect PATIENT safety, could
 269 lead to user confusion, or are inappropriate to MEDICAL BED usage.

270 *Compliance is checked by inspection of the RISK MANAGEMENT FILE and USABILITY ENGINEERING*
 271 *FILE.*

272 **201.1.4 Particular standards**

273 *Replacement:*

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

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

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

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

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

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

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

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

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

303 The term “this standard” is used to make reference to the general standard, any applicable
 304 collateral standards and this particular standard taken together.

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

310 **201.2 Normative references**

311 NOTE Informative references are listed in the bibliography on page 86.

312 Clause 2 of the general standard applies except as follows:

313 *Replacement:*

314 *Change IEC 60529 reference from Amendment 1 to Amendment 2:*

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

317 *Additions:*

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

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

322 IEC 60068-2-31 *Environmental testing – Part 2-31: Tests – Test Ec: Rough handling shocks,*
 323 *primarily for equipment-type specimens*

324 **201.3 Terms and definitions**

325 For the purposes of this document, the terms and definitions given in the general standard
 326 apply, except as follows:

327 NOTE An index of defined terms is found beginning on page 89.

328 **201.3.76**

329 **PATIENT**

330 *Replacement:*

331 person undergoing a medical procedure or PERSON WITH DISABILITY

332 **201.3.109**

333 **SAFE WORKING LOAD**

334 **SWL**

335 *Replacement:*

336 The SAFE WORKING LOAD is the sum of:

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

342 **201.3.131**
 343 *** TRAPPING ZONE**

344 *Addition:*

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

348 *Addition:*

349 **201.3.201**
 350 *** APPLICATION ENVIRONMENT 1**

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

354 **201.3.202**
 355 *** APPLICATION ENVIRONMENT 2**

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

359 **201.3.203**
 360 *** APPLICATION ENVIRONMENT 3**

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

364 NOTE 1 to entry This includes use in nursing homes and in rehabilitation and geriatric facilities.

365 **201.3.204**
 366 *** APPLICATION ENVIRONMENT 4**

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

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

371 **201.3.205**
 372 *** APPLICATION ENVIRONMENT 5**

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

376 **201.3.206**
 377 *** APPLICATION ENVIRONMENT 6**

378 Psychiatric (mental health) care environment where medical supervision is required, and
 379 monitoring is provided. ME EQUIPMENT used in medical procedures may be provided to help
 380 maintain, improve condition and protect the PATIENT. Environment where a PATIENT may be a
 381 harm to themselves or others.

382 NOTE 1 to entry: Includes prisons, jails, correctional facilities.

- 383 **201.3.207**
 384 **BED-LIFT**
 385 height adjustable mechanism on which a MATTRESS SUPPORT PLATFORM can be mounted
- 386 NOTE 1 to entry The combination of a BED LIFT and a compatible non-MEDICAL BED as specified by the
 387 MANUFACTURER is considered to be a MEDICAL BED.
- 388 **201.3.208**
 389 **CHILD**
 390 PATIENT having a body length equal to or less than 155 cm and a mass equal to or less than
 391 70 kg and may display cognitive immaturity, exploratory behaviours and/or risk-taking
 392 tendencies
- 393 [IEC 80601-2-89, 201.3.207]
- 394 **201.3.209**
 395 **PERSON WITH DISABILITY**
 396 person with one or more impairments, one or more activity limitations, one or more
 397 participation restrictions or a combination thereof
- 398 [ISO 9999:2016]
- 399 **201.3.210**
 400 **HEAD/FOOT BOARD**
 401 assembly/assemblies mounted to MEDICAL BED, which identifies for the PATIENT the edge of the
 402 head or foot end of the MEDICAL BED and/or MATTRESS SUPPORT PLATFORM
- 403 NOTE 1 to entry: It may be used as handles to push a MEDICAL BED intended to transport PATIENTS.
- 404 **201.3.211**
 405 **LIFTING POLE**
 406 ACCESSORY attached to a MEDICAL BED and intended to assist support of a PATIENT when
 407 changing position by providing a gripping support above the PATIENT
- 408 **201.3.212**
 409 **MATTRESS OVERLAY**
 410 supplementary mattress (support surface), which is intended to be placed on an existing
 411 mattress, and generally used for prophylactic or therapeutic effect
- 412 **201.3.213**
 413 **MATTRESS SUPPORT PLATFORM**
 414 structure which supports a PATIENT surface (for example mattress)
- 415 NOTE 1 to entry: It can articulate or change positions to facilitate various therapeutic, diagnostic and convenience
 416 positions (See Figures 201.101 and 201.127 a) to 201.127 d)).

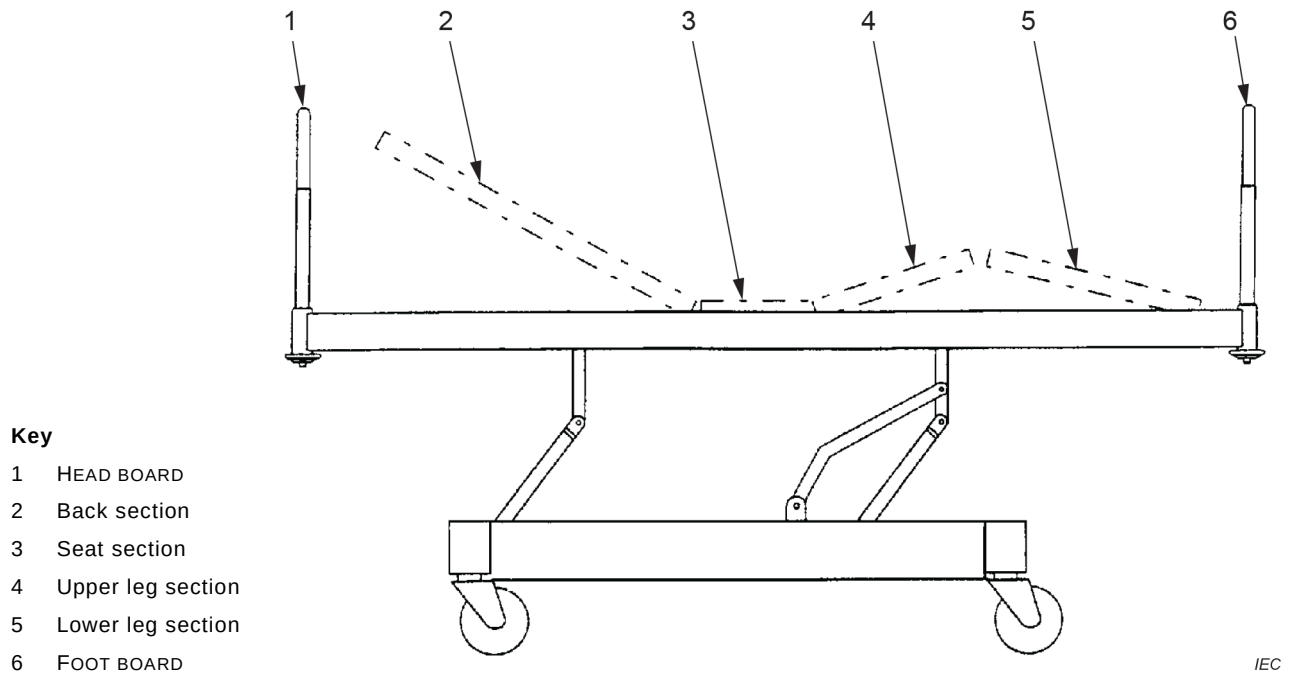


**Figure 201.101 – MEDICAL BED, general arrangement
(example, schematic presentation only)**

201.3.214

* MEDICAL BED

device for which the INTENDED USE is sleeping/resting 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

201.3.215

MOTION LOCKOUT CONTROL

auxiliary subsystem that deactivates motion controls

201.3.216

PENDANT CONTROL

handheld device provided by the MANUFACTURER, which has a FUNCTIONAL CONNECTION to the MEDICAL BED, controlling at least MEDICAL BED articulations and/or movements

NOTE 1 to entry: 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

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

446 **201.3.220**
 447 **TRENDELENBURG**
 448 A specific therapeutic position used in some medical procedures requiring a minimum 12°
 449 head down angle of the entire mattress support platform with respect to horizontal.

450 **201.3.221**
 451 **UNDERCARRIAGE**
 452 all components of the MEDICAL BED or BED-LIFT below the MATTRESS SUPPORT PLATFORM

453 **201.3.222**
 454 *** ADULT**
 455 PATIENT having a physical size equal to or more than 146 cm, a mass equal to or more than 40
 456 kg and a body mass index (BMI) equal to or more than 17, or having a physical size, mass,
 457 and body index as defined by the MANUFACTURER'S RISK MANAGEMENT FILE

458 **201.4 General requirements**

459 Clause 4 of the general standard applies.

460 **201.4.2.2 * General requirement for RISK MANAGEMENT**

461 *Addition:*

462 The MANUFACTURER shall include, in the RISK MANAGEMENT process, HAZARDS related to
 463 PATIENTS taller than 185 cm, or having a physical size, mass and body mass index (BMI)
 464 outside the definition of ADULT.

465 Any alternative means not described in this standard to ensure an equivalent level of BASIC
 466 SAFETY and ESSENTIAL PERFORMANCE shall be justified by the MANUFACTURER in the RISK
 467 MANAGEMENT FILE.

468 For medical beds intended for application environment 6 the risk management shall include:

- 469 • Strangulation hazards
- 470 • Snagging hazards
- 471 • Disassembly resulting in choking and /or ingestion
- 472 • Material flammability

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

474 **201.4.6 ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT**

475 *Addition:*

476 All parts within the reach of the PATIENT, even if they are underneath the MATTRESS SUPPORT
 477 SURFACE (see Figure 201.116) shall be included in the RISK MANAGEMENT process for
 478 determination if they should be treated as APPLIED PARTS.

479 For APPLICATION ENVIRONMENT 4 and APPLICATION ENVIRONMENT 6, APPLIED PARTS shall include
 480 all parts of the MEDICAL BED (the entire bed).

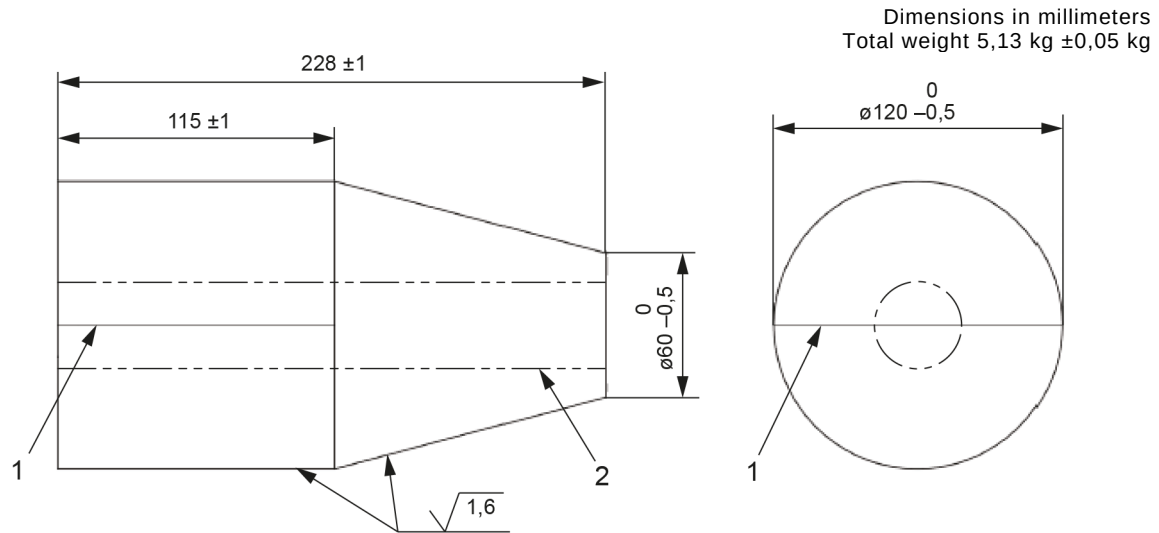
481 **201.5 General requirements for testing of ME EQUIPMENT**

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

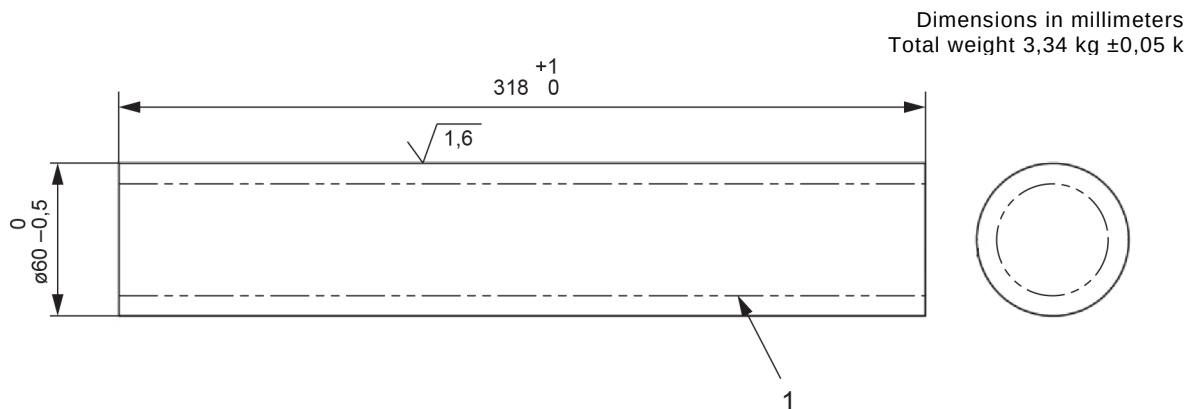
483 *Additional subclauses:*

*** Entrapment test tools**

Figures 201.102 a) and 201.102 b) illustrate entrapment test tools (a cone tool and a cylinder tool respectively).

**Key**

- 1 Marked centre line
- 2 Drilling hole for weight adjustment, if necessary

Figure 201.102 a) – Cone tool schematic**Key**

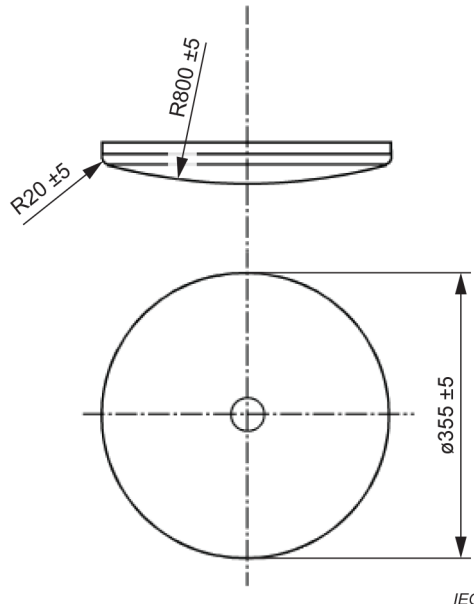
- 1 Drilling hole for weight adjustment, if necessary

Figure 201.102 b) – Cylinder tool schematic**Figure 201.102 – Entrapment test tools**

501 **201.5.102 Loading pad**

502 The loading pad (see Figure 201.103) is a rigid circular object, (355 $\pm$ 5) mm in diameter,
 503 the face of which has a convex spherical curvature of 800 mm radius with a 20 mm front edge
 504 radius.

505 Dimensions in millimeters

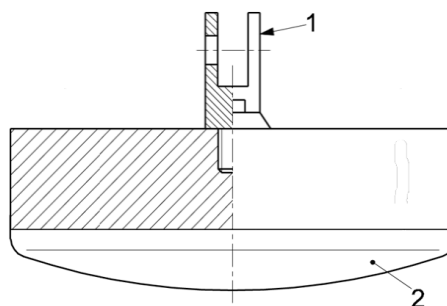


506
 507 **Figure 201.103 – Loading pad**

508 **201.5.103 Impactor**

509 The impactor body is approximately 200 mm in diameter and is mounted to the striking
 510 surface. The total mass of the assembly shall be 25 kg $\pm$ 0,1 kg.

511 The striking surface shall be a rigid circular object, (200 $\pm$ 5) mm in diameter, the face of
 512 which has a convex spherical curvature of 300 mm radius with a 12 mm front edge radius.



513
 514 Key

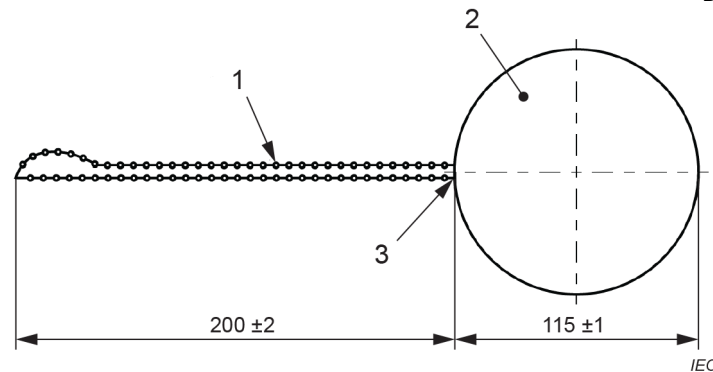
515 1 connecting part of the lifting device which shall not restrain the free fall

516 2 striking surface

517 **Figure 201.104 – Impactor**

518

Dimensions in millimeters



519

520 Key

521 1 ball chain loop with a length of 200 ± 2 mm522 2 spherical mass, weight $2,5 \pm 0,05$ kg and diameter 115 ± 1 mm

523 3 fixing point

524 NOTE The ball chain loop is formed by the ball chain entering the spherical mass at a common fixing point.

525 **Figure 201.105 – Ball chain loop and spherical mass**526 **201.6 Classification of ME EQUIPMENT and ME SYSTEMS**

527 Clause 6 of the general standard applies, except as follows:

528 **201.6.2 * Protection against electrical shock**529 *Addition:*

530 For APPLICATION ENVIRONMENT 4, the MEDICAL BED shall be CLASS II.

531 **201.7 ME EQUIPMENT identification, marking and documents**

532 Clause 7 of the general standard applies, except as follows:

533 **201.7.2.2 Identification**534 *Replacement of the first paragraph:*

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

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

540 *Additional subclauses:*541 **201.7.2.2.101 * Marking of maximum PATIENT weight and SAFE WORKING LOAD**

542 a) The MEDICAL BED shall be marked with the corresponding maximum PATIENT weight
 543 (see 201.9.8.3.1) and SAFE WORKING LOAD (for symbol see Figure 201.106).

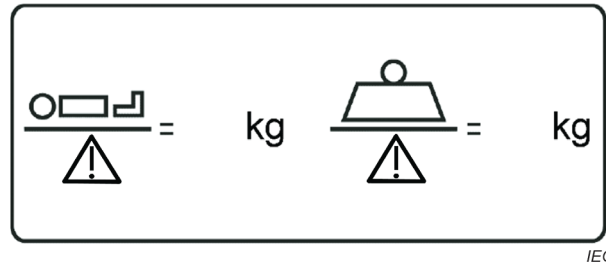


Figure 201.106 – Graphic symbol for maximum PATIENT weight and SAFE WORKING LOAD

- b) Detachable parts of a MEDICAL BED of a mass of more than 20 kg shall be marked with symbol ISO 7000-1321B¹, including the actual mass, at least in kg, as in Figure 201.107.



Figure 201.107 – Graphic symbol for mass; weight

201.7.2.2.102 Marking for MEDICAL BED washing systems

- a) 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: “For cleaning purposes this bed can be used with automatic washing systems.” or be marked with the corresponding symbol (see Figure 201.108).



Symbol ISO 700-3897

Figure 201.108 – Graphic symbol for machine washable MEDICAL BED

- b) MEDICAL BEDS intended for use with jet stream washing shall be
- marked with the following text: “For cleaning purposes this bed can be used with jet stream washing.” or be marked with the corresponding symbol for IPX9 in accordance with IEC 60529; and
 - provide a minimum protection of IPX5 per IEC 60529.



Symbol ISO 700-3890

Figure 201.109 – Graphic symbol for jet stream washable MEDICAL BED

- c) For MEDICAL BEDS which are limited to only manual wipe down methods, the manufacturer shall mark the medical bed with suitable cautionary text or symbol ISO 7000-0423 (see Figure 201.110).



Symbol ISO 7000-0423

Figure 201.110 – Graphic symbol for manual cleaning only

- d) For all other wash systems the manufacturer shall mark the medical bed with suitable cautionary text or the appropriate symbol.

201.7.2.2.103 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.

201.7.2.2.104 * Marking of replacement mattresses

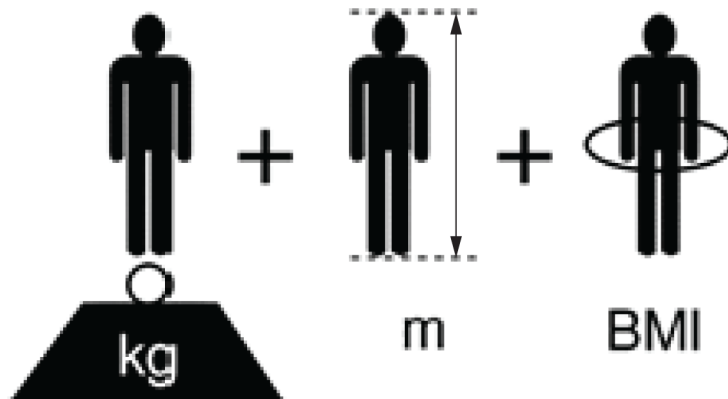
MEDICAL BEDS designed to have replacement mattresses shall be marked with the general warning sign ISO 7010:2003-W001 placed together with the text: "Incompatible mattresses can create hazards. Read instructions for use" or a symbol as appropriate on a prominent place on the MEDICAL BED indicating the compatible mattresses (see example in AA.1).

201.7.2.2.105 * Marking of detachable SIDE RAILS

MEDICAL BEDS designed to have detachable SIDE RAILS shall be marked with the general caution sign ISO 7000-0434A placed together with the text: "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).

201.7.2.2.106 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 201.111.



IEC

Figure 201.111 – Physical description of an ADULT

201.7.2.2.107* Marking on the MEDICAL BED for PENDANT CONTROL STORAGE

MEDICAL BEDS intended for APPLICATION ENVIRONMENT 6 shall be marked at the designated location of storage of the PENDANT CONTROL.

NOTE See Annex AA for examples of this marking.

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 201.112).

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 201.112 is intended as a guideline when designing these symbols. In all cases where standard international symbols exist, they can be used.

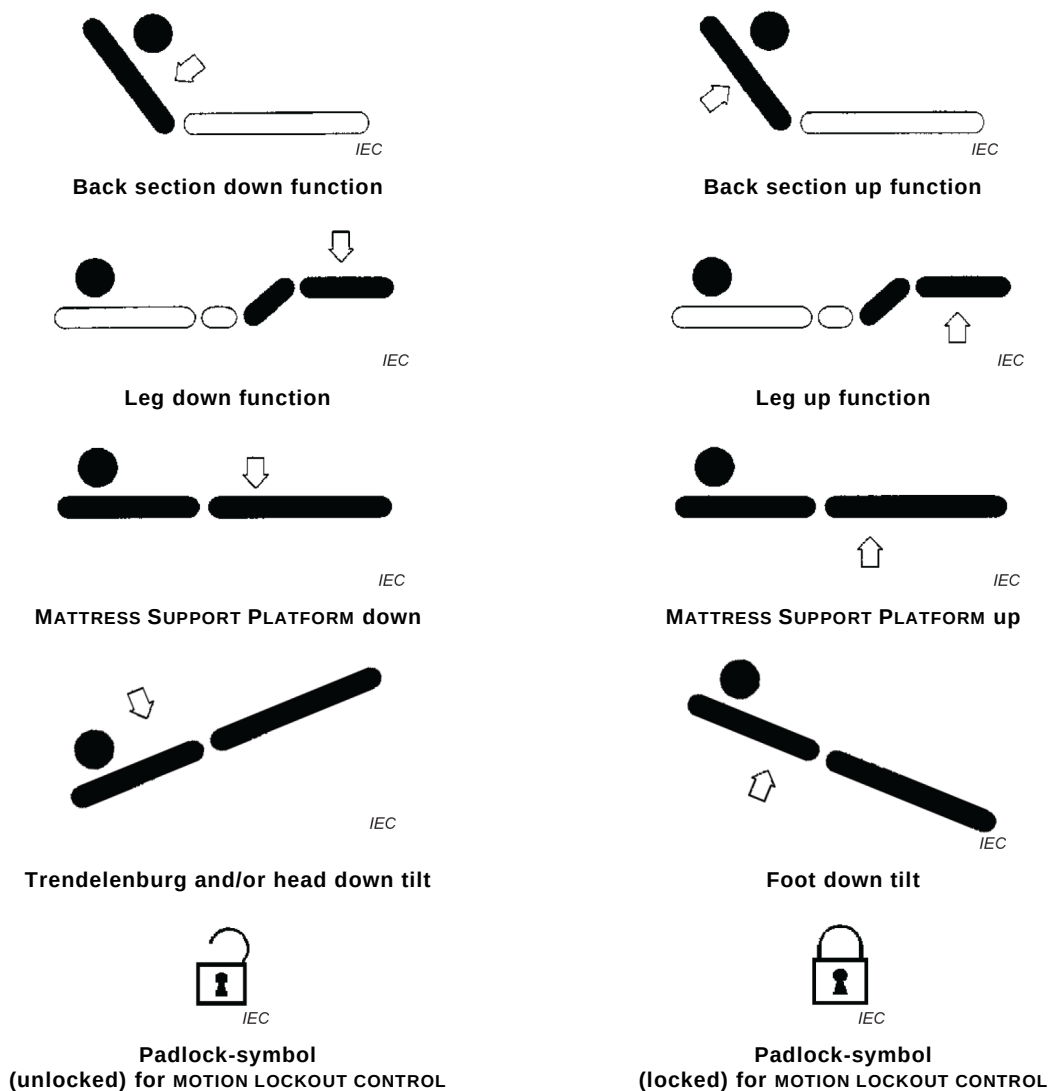


**Figure 201.112 – MEDICAL BED function controls and/or actuators:
guidelines for creating graphical symbols**

201.7.9.2 Instructions for use

201.7.9.2.1 General

Addition:

The instructions for use shall include:

- a description according to 201.3. of the intended APPLICATION ENVIRONMENT(S);
- the maximum PATIENT weight and SAFE WORKING LOAD.
- an explanation of how to deactivate any MEDICAL BED function if movement caused by that function could cause injury to the PATIENT;
- the result of the measurement of audible acoustic energy measured in accordance with subclause 9.6.2.1 of the general standard, except only using ISO 3746.
- 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.
- g) The instructions for use shall provide a warning for equipment in close proximity or attached to the MEDICAL BED can cause a HAZARD, e.g. entrapment or tipping over.
- h) For MEDICAL BEDS intended for use in APPLICATION ENVIRONMENT 6, The instructions for use shall provide a warning that the PENDANT control, and its cable if applicable, shall be stored in a secured location out of reach of the PATIENT when not in use.

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 201.7.2.2.104)).

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 201.7.2.2.105)).

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:

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

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

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

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

689 NOTE Additional information regarding periodic inspections can be found in in Annex DD.

690 **201.8 Protection against electrical HAZARDS from ME EQUIPMENT**

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

692 **201.8.11.2 Multiple Socket Outlets**

693 *Addition:*

694 For APPLICATION ENVIRONMENT 6, if MULTIPLE SOCKET OUTLETS are supplied, they shall be out of
 695 reach of the patient, e.g. in a lockable box.

696 **201.8.11.3.2 * Types**

697 *Replacement:*

698 For APPLICATION ENVIRONMENTS 1 through 5 POWER SUPPLY CORDS shall be a minimum 2,5 m
 699 measured from the plug to the outside perimeter of the MEDICAL BED.

700 For APPLICATION ENVIRONMENT 6 any cords shall be as short as possible in order to minimize
 701 the RISK of strangulation. This shall be part of the RISK ANALYSIS of the MANUFACTURER.

702 POWER SUPPLY CORDS and other external flexible mains cables and cords on MEDICAL BEDS
 703 shall be medium or heavy-duty use rating. Light-duty cords are not adequate.

704 A polyvinyl chloride insulated POWER SUPPLY CORD shall not be used for ME EQUIPMENT having
 705 external metal parts with a temperature exceeding 75 °C and which can be touched in NORMAL
 706 USE by the cord, unless it is RATED for that temperature. See also Table 22.

707 POWER SUPPLY CORDS shall be equipped with appropriate strain relief and bend protection.
 708 POWER SUPPLY CORD sets shall have a moulded-on plug or other means to withstand the
 709 ingress of water during the cleaning PROCESS for which the MEDICAL BED is intended.

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

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

715 *Compliance is checked by inspection.*

716 **201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS**

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

718 NOTE SIDE RAILS are not required on MEDICAL BEDS. Clauses including SIDE RAIL requirements are only applicable
719 if SIDE RAILS are provided.

720 **201.9.1 * MECHANICAL HAZARDS of ME EQUIPMENT**

721 *Addition:*

722 **201.9.1.101 * Protection against PATIENT entrapment in non-moving parts**

723 Any openings or areas (A₁, A₂, A₃, A₄, A₅, A₆, B, C and D) within the MEDICAL BED system and
724 which are above the MATTRESS SUPPORT PLATFORM shall meet the dimensional and
725 constructional requirements of Figures 201.113, 201.114 and Table 201.101. Where a RISK of
726 PATIENT entrapment exists and is addressed in another way this shall be justified by the
727 MANUFACTURER in the RISK MANAGEMENT FILE.

728 For APPLICATION ENVIRONMENT 6 any opening or area within the MEDICAL BED system shall meet the
729 dimensional and constructional requirements of Figures 201.112, 201.113, Table 201.101.

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

732 *Compliance is checked with the MATTRESS SUPPORT PLATFORM in the flat position unless*
733 *otherwise noted as indicated in Table 201.101. The test shall be performed with the SIDE RAIL*
734 *in all raised and locked positions.*

735 All the tests are performed without the mattress except the test for Dimension D.
736 Requirements involving the mattress are checked with the mattress(es) as specified by the
737 MANUFACTURER. Requirements of Figures 201.113, 201.114 and Table 201.101 involving the
738 mattress are excluded for SPECIALTY MATTRESSES.

739 A RISK ASSESSMENT shall be performed to evaluate:

- 740 – SPECIALTY MATTRESSES;
- 741 – MATTRESS OVERLAYS, e.g. PATIENT being trapped between mattresses and MATTRESS
742 OVERLAYS.
- 743 – ACCESSORIES;
- 744 – articulated MATTRESS SUPPORT PLATFORM positions.

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