



SLOVENSKI STANDARD
oSIST prEN IEC 80601-2-89:2024
01-maj-2024

Medicinska električna oprema - 2-89. del: Posebne zahteve za osnovno varnost in bistvene lastnosti medicinskih postelj za otroke

Medical electrical equipment - Part 2-89: Particular requirements for the basic safety and essential performance of medical beds for children

iTeh Standards
(<https://standards.iteh.ai>)

Ta slovenski standard je istoveten z: **prEN IEC 80601-2-89:2024**

<https://standards.iteh.ai/catalog/standards/sist/04c8f634-0c4c-42da-82c0-fe32445b6e39/osist-pren-iec-80601-2-89-2024>

ICS:

11.140 Oprema bolnišnic Hospital equipment

oSIST prEN IEC 80601-2-89:2024 **en**

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[oSIST prEN IEC 80601-2-89:2024](https://standards.iteh.ai/catalog/standards/sist/04c8f634-0c4c-42da-82c0-fe32445b6c39/osist-pren-iec-80601-2-89-2024)

<https://standards.iteh.ai/catalog/standards/sist/04c8f634-0c4c-42da-82c0-fe32445b6c39/osist-pren-iec-80601-2-89-2024>



62D/2113/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER:

IEC 80601-2-89 ED1

DATE OF CIRCULATION:

2024-03-01

CLOSING DATE FOR VOTING:

2024-05-24

SUPERSEDES DOCUMENTS:

62D/1758A/CD, 62D/1783A/CC

IEC SC 62D : PARTICULAR MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS	
SECRETARIAT: United States of America	SECRETARY: Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: <input type="checkbox"/> Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.
FUNCTIONS CONCERNED: <input type="checkbox"/> EMC <input type="checkbox"/> ENVIRONMENT <input type="checkbox"/> QUALITY ASSURANCE <input checked="" type="checkbox"/> SAFETY	
<input checked="" type="checkbox"/> SUBMITTED FOR CENELEC PARALLEL VOTING Attention IEC-CENELEC parallel voting The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.	<input type="checkbox"/> NOT SUBMITTED FOR CENELEC PARALLEL VOTING

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.

Recipients of this document are invited to submit, with their comments, notification of any relevant "In Some Countries" clauses to be included should this proposal proceed. Recipients are reminded that the CDV stage is the final stage for submitting ISC clauses. (SEE [AC/22/2007](#) OR [NEW GUIDANCE DOC](#)).

TITLE:

Medical electrical equipment - Part 2-89: Particular requirements for the basic safety and essential performance of medical beds for children

PROPOSED STABILITY DATE: 2030

NOTE FROM TC/SC OFFICERS:

Copyright © 2024 International Electrotechnical Commission, IEC. All rights reserved. It is permitted to download this electronic file, to make a copy and to print out the content for the sole purpose of preparing National Committee positions. You may not copy or "mirror" the file or printed version of the document, or any part of it, for any other purpose without permission in writing from IEC.

1 CONTENTS

2	FOREWORD.....	5
3	INTRODUCTION.....	7
4	201.1 Scope, object and related standards	7
5	201.2 Normative references	9
6	201.3 Terms and definitions	10
7	201.4 General requirements	15
8	201.5 General requirements for testing of ME EQUIPMENT.....	1616
9	201.6 Classification of ME EQUIPMENT and ME SYSTEMS	2020
10	201.7 ME EQUIPMENT identification, marking and documents	20
11	201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	27
12	201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS	28
13	201.10 Protection against unwanted and excessive radiation HAZARDS	5656
14	201.11 Protection against excessive temperatures and other HAZARDS	5656
15	201.12 Accuracy of controls and instruments and protection against hazardous outputs ..	5959
16	201.13 HAZARDOUS SITUATIONS and fault conditions	6060
17	201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	6060
18	201.15 Construction of ME EQUIPMENT	6060
19	201.16 ME SYSTEMS	6464
20	201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	6464
21	Annex AA (informative) Particular guidance and rationale	6565
22	AA.1 General guidance	6565
23	Annex BB (normative) Additional design requirements for Home Care and recommendations	
24	for all MEDICAL BEDS	7979
25	BB.1 General.....	7979
26	BB.2 Human factors (ergonomic)	7979
27	BB.3 Functionality	8080
28	Annex CC (informative) Particular guidance for assessing risk of entrapment in V-shaped	
29	openings.....	8383
30	Annex DD (informative) Guidance and recommendations for periodic inspection.....	8989
31	DD.1 Inspection Intervals	8989
32	DD.2 Inspection scope	8989
33	DD.3 Qualification of personnel	8989
34	DD.4 Inspection results.....	8989
35	DD.5 Inspection record	9090
36	Bibliography.....	9191
37	Index of defined terms used in this particular standard.....	9292

38

39

40

FIGURES

41	Figure 201.101 – MEDICAL BED, general arrangement (example, schematic presentation only)	
42	14
43	Figure 201.102 – Small finger probe \varnothing 5,6	1616
44	Figure 201.103 – Entrapment test TOOLS.....	17
45	Figure 201.104 – Loading pad	18
46	Figure 201.105 – Impactor	19
47	Figure 201.106 – Side impactor TOOL.....	19
48	Figure 201.107 – Graphical symbol for maximum PATIENT weight and SAFE WORKING LOAD	20
49	Figure 201.108 – Graphic symbol for machine washable MEDICAL BED	2020
50	Figure 201.109 – Graphic symbol for jet stream washable MEDICAL BED	21
51	Figure 201.110 – Graphic symbol for manual cleaning only.....	21
52	Figure 201.111 – Description of allowed length of PATIENT	22
53	Figure 201.112 – Example of equivalent marking for positioning PATIENT in MEDICAL BED	23
54	Figure 201.113 – MEDICAL BED function controls and/or actuators: guidelines for creating	
55	graphical symbols.....	
56	Figure 201.114 – Examples of marking on the MEDICAL BED of storage location for wired and	
57	wireless PENDANT CONTROLS	25
58	Figure 201.115 – Example of MEDICAL BED with segmented or split SIDE RAIL	2929
59	Figure 201.116 – Example of MEDICAL BED with single piece SIDE RAIL and PROTECTION PANEL	
60	3030
61	Figure 201.117 – Dimension of handle for LIFTING POLE.....	3434
62	Figure 201.118 – Allowable spacing for fingers in areas of normal reach around the perimeter	
63	of the MATTRESS SUPPORT PLATFORM	3535
64	Figure 201.119 – Example using barriers for clearance measurement around the perimeter of	
65	the MATTRESS SUPPORT PLATFORM to mitigate patient-finger entrapment.....	3636
66	Figure 201.120 – Clearance areas	3737
67	Figure 201.121 – Required minimum radii of edges and corners	3838
68	Figure 201.122 – Retention of loop and mass	3939
69	Figure 201.123 – Lateral stability test along the side of the MEDICAL BED	4242
70	Figure 201.124 – Longitudinal stability test with removable FOOT BOARD	4242
71	Figure 201.125 – Longitudinal stability test with fixed HEAD/FOOT BOARDS.....	4343
72	Figure 201.126 – Distribution of SAFE WORKING LOAD for tests.....	4646
73	Figure 201.127 – Position of loading pad and impactor	4949
74	Figure 201.128 – Impact to slats and solid elements of MEDICAL BEDS	5151
75	Figure 201.129 – Application of forces for test of SIDE RAIL.....	5353
76	Figure 201.130 – Height of SIDE RAIL / PROTECTION PANELS	5555
77	Figure 201.131 – Configurations of the MATTRESS SUPPORT PLATFORM	63
78	Figure AA.1 – Example of marking for compatible mattresses specified by the MANUFACTURER	
79	6767
80	Figure AA.2 – Example of marking for detachable SIDE RAILS specified by the MANUFACTURER ..	
81	67	
82	Figure AA.3 – Resultant forces without mattress	7070
83	Figure AA.4 – Resultant forces with mattress	7070
84	Figure AA.5 – Example of 40 mm gap measurement of B	7070

85	Figure AA.6 – Angle measurement example of B	7070
86	Figure AA.7 – Placement of measurement TOOL for measurement of D _x	7171
87	Figure AA.8 – Example of area D _x measurement that passes	7272
88	Figure AA.9 – Example of area D _x measurement that fails (on limit)	7272
89	Figure AA.10 – Example of area D _x measurement that fails	7272
90	Figure AA.11 – Example of potential PATIENT entrapment in area A within the SIDE RAIL	7373
91	Figure AA.12 – Example of potential PATIENT entrapment in area A below the SIDE RAIL	7373
92	Figure AA.13 – Example of potential PATIENT entrapment in area B.....	7373
93	Figure AA.14 – Example of potential PATIENT entrapment in area C between split SIDE RAIL	
94	7373
95	Figure AA.15 – Example of potential PATIENT entrapment in area C between SIDE RAIL and	
96	HEAD BOARD.....	7373
97	Figure AA.16 – Example of potential PATIENT entrapment in area D.....	7373
98	Figure AA.17 – Example of potential PATIENT entrapment in area A below a single piece SIDE	
99	RAIL.....	7474
100	Figure BB.1 – Schematic presentation of under MEDICAL BED clearance.....	8181
101	Figure BB.2 – Recommendations and requirements regarding angles for different sections of	
102	the MATTRESS SUPPORT PLATFORM	8282
103	Figure CC.1 – Wedge TOOL.....	8484
104	Figure CC.2 – V-shaped opening in relation to B.....	8585
105	Figure CC.3 – Pass/fail in relation to area B	8686
106	Figure CC.4 – Positioning of wedge TOOL.....	8787
107	Figure CC.5 – Pass/fail in relation to area C between HEAD BOARD and FOOT BOARD	8787
108	Figure CC.6 – Pass/fail in relation to area C between split SIDE RAILS	8888

109

TABLES

110	*Table 201.101 – Protection against PATIENT entrapment	3031
111	Table 201.102 – Minimum SAFE WORKING LOADS	4545
112	Table 201.103 – Protection against inadvertent PATIENT falls and climbing out of MEDICAL BED	
113	5656
114	Table 201.104 – Allowable maximum temperatures for skin contact with MEDICAL BED APPLIED	
115	PARTS.....	5757
116	Table AA.1 – Protection against PATIENT entrapment in non-moving parts	6969
117	Table AA.2 – Height of protective barriers according to age	7777

118

119

INTERNATIONAL ELECTROTECHNICAL COMMISSION

120

121

122

MEDICAL ELECTRICAL EQUIPMENT –

123

124

**Part 2-89: Particular requirements for the basic safety
and essential performance of medical beds for children**

125

126

127

128

FOREWORD

129

130

131

132

133

134

135

136

137

138

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.

139

140

141

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.

142

143

144

145

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.

146

147

148

149

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.

150

151

152

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.

153

6) All users should ensure that they have the latest edition of this publication.

154

155

156

157

158

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.

159

160

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.

161

162

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.

163

164

165

International standard IEC 80601-2-89 has been prepared by IEC subcommittee 62D: Electrical equipment in medical practice, and by ISO technical committee 173: Assistive products for persons with disability. It is published as double logo standard.

166

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

167

In this standard, the following print types are used:

168

– Requirements and definitions: roman type.

169

– *Test specifications: italic type.*

170

171

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

172

173

– Terms defined in clause 3 of the general standard, in this particular standard or as noted: SMALL CAPITALS.

- 174 In referring to the structure of this standard, the term
- 175 – “clause” means one of the seventeen numbered divisions within the table of contents,
176 inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- 177 – “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all
178 subclauses of Clause 7).
- 179 References to clauses within this standard are preceded by the term “Clause” followed by the
180 clause number. References to subclauses within this collateral standard are by number only.
- 181 In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any
182 combination of the conditions is true.
- 183 The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC
184 Directives, Part 2. For the purposes of this standard, the auxiliary verb:
- 185 – “shall” means that compliance with a requirement or a test is mandatory for compliance with
186 this standard;
- 187 – “should” means that compliance with a requirement or a test is recommended but is not
188 mandatory for compliance with this standard;
- 189 – “may” is used to describe a permissible way to achieve compliance with a requirement or
190 test.
- 191 An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title
192 indicates that there is guidance or rationale related to that item in Annex AA.
- 193 A list of all parts of the IEC 60601 series, published under the general title *Medical electrical
194 equipment*, can be found on the IEC website.
- 195 The committee has decided that the contents of the base publication and its amendment will
196 remain unchanged until the stability date indicated on the IEC web site under
197 "http://webstore.iec.ch" in the data related to the specific publication. At this date, the
198 publication will be
- 199 • reconfirmed,
200 • withdrawn,
201 • replaced by a revised edition, or
202 • amended.

203 INTRODUCTION

204 IEC 80601-2-52 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL BEDS for
 205 ADULTS, hence not covering requirement for beds for CHILDREN and ADULTS with atypical
 206 anatomy. This particular standard is based on EN 50637, which was created pursuant to
 207 Mandate M/467 Medical beds issued by the European Commission with the following
 208 background information:

209 It appears, from a first analysis undertaken by EU Competent Authorities, that the current set
 210 of standards is not adapted to the needs of CHILDREN or ADULTS with an atypical anatomy. IEC
 211 80601-2-52 does not foresee a maximum distance for the bars that is small enough to prevent
 212 accidents.

213 According to the EU Competent Authorities' representatives, a part of the safety problem is due
 214 to the fact that medical beds for ADULTS are not appropriately labelled as being designed only
 215 for ADULTS with a normal anatomy. Users are therefore not always aware of the risk of medical
 216 beds for young PATIENTS or for ADULTS with an atypical anatomy. Hospital administrations do
 217 not always see a need to buy medical beds which are appropriate for CHILDREN or for ADULTS
 218 with an atypical anatomy. Therefore, clear labelling of the targeted PATIENT groups for medical
 219 beds complying with IEC 80601-2-52 could reduce the risk of inappropriate use of this kind of
 220 medical beds for CHILDREN or for ADULTS with an atypical anatomy.

221 EU Competent Authorities' representatives also stated that there is a need for the development
 222 of requirements for MEDICAL BEDS and COTS for CHILDREN and ADULTS with an atypical anatomy.

223 In order to prevent IEC 80601-2-52 from being extraordinarily complex to use, CLC/TC 62
 224 decided to develop this particular standard rather than further amending IEC 80601-2-52 in
 225 relation to use for CHILDREN and ADULTS with an atypical anatomy.

226 This standard is based on EN50637 and IEC 80601-2-52 with input from the following standards
 227 and reports:

- 228 • EN 716-1, Furniture — Children's cots and folding cots for domestic use — Part 1: Safety
 229 requirements
- 230 • EN 716-2, Furniture — Children's cots and folding cots for domestic use — Part 2: Test
 231 methods
- 232 • EN 1130-2, Furniture — Cribs and cradles for domestic use — Part 2: Test methods
- 233 • EN 747-1, Furniture — Bunk beds and high beds — Part 1: Safety, strength and durability
 234 requirements
- 235 • EN 747-2, Furniture — Bunk beds and high beds — Part 2: Test methods
- 236 • CEN/TR 13387 (all parts), Child use and care articles — General safety guidelines
- 237 • DIN 32623, Hospital children's cots made from metal and plastic — Safety requirements and
 238 testing
- 239 • Nordic Requirements specification for Adjustable beds for disabled children

240 **201.1. Scope, object and related standards**

241 Clause 1 of the general standard¹ applies, except as follows:

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*.

242 201.1.1 * Scope**243 Replacement:**

244 This standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL BEDS,
245 hereafter referred to as MEDICAL BEDS as defined in 201.3.219, intended for CHILDREN as defined
246 in 201.3.207, and ADULTS with atypical anatomy (ADULTS ranging outside the definition for
247 ADULTS in 201.3.201).

248 This standard applies to electrical or non-electrical MEDICAL BEDS with nonadjustable and
249 electrical / mechanical adjustable functions.

250 This standard applies to MEDICAL BEDS with an INTERNAL LENGTH of up to 180 cm suitable to a
251 body length of 155 cm.

252 NOTE 1 The limitation of 180 cm is in order to minimize the foreseeable misuse, of a parent sharing the bed with
253 the child or that the bed will be used by an ADULT.

254 If a manufacturer wishes to make a bed that can be used by both a child and an ADULT, e.g.
255 INTERNAL LENGTH of 180 cm or more, then it shall fulfil both IEC 80601-2-52 and this particular
256 standard.

257 This Standard does not apply to:

- 258 • ADULT *only* beds covered by IEC 80601-2-52
- 259 • incubators covered by IEC 60601-2-19;
- 260 • devices for which the INTENDED USE is mainly for examination or transportation under
261 medical supervision (e.g. stretcher, examination table).

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

265 HAZARDS inherent in the intended physiological function of MEDICAL BEDS or ME SYSTEMS within
266 the scope of this standard are not covered by specific requirements in this standard except in
267 7.2.13 and 8.4.1 of the general standard.

268 NOTE See also 4.2 of the general standard.

269 201.1.2 Object**270 Replacement:**

271 The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL
272 PERFORMANCE requirements and test methods for MEDICAL BEDS as defined in 201.3.219
273 intended for CHILDREN as defined in 201.3.207 and ADULTS with atypical anatomy.

274 201.1.3 Collateral standards**275 Addition:**

276 This particular standard refers to those applicable collateral standards that are listed in Clause
277 2 of the general standard and corrigenda and Clause 2 of this particular standard.

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

280 **201.1.4 Particular standards**

281 *Replacement:*

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

286 A requirement of this particular standard takes priority over the general standard.

287 The numbering of clauses and subclauses of this particular standard corresponds to that of the
288 general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of
289 Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where
290 x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular
291 standard addresses the content of Clause 4 of the IEC 60601-1-2:2015 collateral standard,
292 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3:2008
293 collateral standard, etc.). The changes to the text of the general standard are specified by the
294 use of the following words:

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

297 "Addition" means that the text of this particular standard is additional to the requirements of EN
298 60601-1:2006 or applicable collateral standard.

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

301 Subclauses, figures or tables which are additional to those of the general standard are
302 numbered starting from 201.101. However, due to the fact that definitions in the general
303 standard are numbered 3.1 through 3.147, additional definitions in this standard are numbered
304 beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items
305 aa), bb), etc.

306 Subclauses, figures or tables which are additional to those of a collateral standard are
307 numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC
308 60601-1-2, 203 for IEC 60601-1-3, etc.

309 The term "this standard" is used to make reference to EN 60601-1:2006, any applicable
310 collateral standards and this particular standard taken together.

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

316 **201.2 Normative references**

317 NOTE Informative references are listed in the Bibliography.

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

319 *Addition:*

320 EN 71-3, *Safety of toys — Part 3: Migration of certain elements*

- 321 EN 716-2, *Furniture — Children's cots and folding cots for domestic use — Part 2: Test methods*
- 322 EN 597-1 *Furniture – Assessment of the ignitability of mattresses and upholstered bed bases*
- 323 – *Part 1: Ignition Source: Smouldering Cigarette*
- 324 EN 597-2 *Furniture — Assessment of ignitability of mattresses and upholstered bed bases —*
- 325 *Part 2: Ignition source: match-flame equivalent*
- 326 ISO 7619-2, *Rubber, vulcanized or thermoplastic - Determination of indentation hardness - Part*
- 327 *2: IRHD pocket meter method*
- 328 IEC 50525-2-21, *Electric cables — Low voltage energy cables of rated voltages up to and*
- 329 *including 450/750 V (U_o/U) — Part 2-21: Cables for general applications — Flexible cables with*
- 330 *crosslinked elastomeric insulation*
- 331 IEC 60068-2-31, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks,*
- 332 *primarily for equipment-type specimens (IEC 60068-2-31)*
- 333 *Replacement of the references to IEC 60227-1:1993 and IEC 60245-1:2003 (not to be dated*
- 334 *anymore):*
- 335 IEC 60227-1, *Polyvinyl chloride insulated cables of rated voltages up to and including 450/750*
- 336 *V — Part 1: General requirements*
- 337 IEC 60245-1, *Rubber insulated cables — Rated voltages up to and including 450/750 V — Part*
- 338 *1: General requirements*
- 339 *Deletion:*
- 340 ISO 9614-1, *Acoustics — Determination of sound power levels of noise sources using sound*
- 341 *intensity — Part 1: Measurement at discrete points*

342 **201.3 Terms and definitions**

343 For the purposes of this document, the terms and definitions given in Clause 3 of the general

344 standard apply, except as follows.

345 NOTE An index of defined terms is found at the end of this document.

346 **201.3.67**

347 **MULTIPLE SOCKET-OUTLET**

348 **MSO**

349 *Replacement:* <http://standards.iteh.ai/catalog/standards/sist/04c8f634-0c4c-42da-82c0-fe32445b6c39/osist-pren-iec-80601-2-89-2024>

350 one or more socket-outlets intended to be connected to, or integral with, flexible cables or cords

351 or ME EQUIPMENT for SUPPLY MAINS or equivalent voltage

352 NOTE 1 to entry: A MULTIPLE SOCKET-OUTLET can be a separate item or an integral part of equipment.

353 **201.3.76**

354 **PATIENT**

355 *Replacement:*

356 person undergoing a medical procedure or PERSON WITH DISABILITY

357 NOTE 1 to entry: Whenever the term PATIENT is used, it comprises both ADULTS with an atypical anatomy and

358 CHILDREN.

359 **201.3.109**

360 **SAFE WORKING LOAD**

361 **SWL**

362 *Replacement:*

363 The SAFE WORKING LOAD is the sum of:

- 364 1) the PATIENT;
- 365 2) the mattress;

366 3) the ACCESSORIES of the MEDICAL BED, only if they are supported by the support system
367 of the MEDICAL BED; and

368 4) the SAFE WORKING LOADS supported by those ACCESSORIES, excluding PATIENT weight.

369 **201.3.131**
370 *** TRAPPING ZONE**

371 *Addition:*

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

375 *Addition:*

376 **201.3.201**
377 **ADULT**

378 PATIENT having a physical size equal to or more than 146 cm, a mass equal to or more than 40
379 kg and a body mass index (BMI) equal to or more than 17, or having a physical size, mass, and
380 body index as defined by the MANUFACTURER'S RISK MANAGEMENT FILE

381 [Source: IEC 80601-2-52, 201.3.222]

382 **201.3.202**
383 *** APPLICATION ENVIRONMENT 1**

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

387 **201.3.203**
388 *** APPLICATION ENVIRONMENT 2**

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

392 **201.3.204**
393 *** APPLICATION ENVIRONMENT 3**

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

397 NOTE 1 to entry: This includes use in CHILDREN'S nursing homes and in rehabilitation facilities.

398 **201.3.205**
399 *** APPLICATION ENVIRONMENT 4**

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

402 NOTE 1 to entry: This excludes use in all other application environments (e.g. CHILDREN'S nursing homes and
403 rehabilitation facilities) when a MEDICAL BED is purely designed for APPLICATION ENVIRONMENT 4.

404 **201.3.206**
405 *** APPLICATION ENVIRONMENT 5**

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

409 **201.3.207**
410 **CHILD**

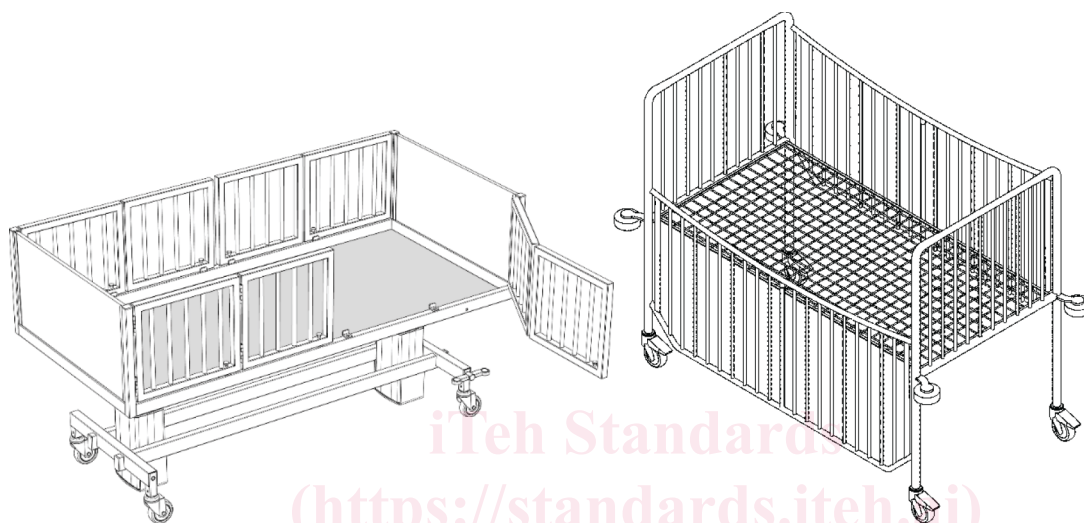
411 PATIENT having a body length equal to or less than 155 cm and a mass equal to or less than 70
412 kg and may display cognitive immaturity, exploratory behaviours and/or risk taking tendencies

413 NOTE 1 to entry: Body length is measured from crown to sole.

414 **201.3.208**
415 **COT**

416 MEDICAL BED with an INTERNAL LENGTH ≥ 90 cm and < 140 cm provided with PROTECTION PANELS
417 also intended for CHILDREN able to stand up in bed

418 NOTE 1 to entry: In other countries this may be referred to as other terms (e.g. crib).



419

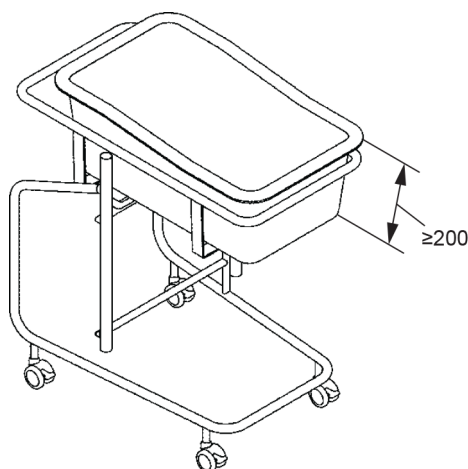
IEC

420 **201.3.209**
421 **CRIB**

422 MEDICAL BED with an INTERNAL LENGTH < 90 cm provided with PROTECTION PERIMETER, intended
423 for CHILDREN until they are able to sit, kneel or to pull themselves up

424 NOTE 1 to entry: Excluded are MEDICAL BEDS with a swinging or rocking function.

425 NOTE 2 to entry In other countries this may be referred to as other terms (e.g. bassinet).



426

IEC

427 **201.3.210**
428 **PERSON WITH DISABILITY**