



SLOVENSKI STANDARD
oSIST prEN IEC 80601-2-52:2024
01-maj-2024

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

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

Appareil électromédicaux - Partie 2-52: Exigences particulières de sécurité de base et de performances essentielles des lits médicaux

Ta slovenski standard je istoveten z: prEN IEC 80601-2-52:2024

<https://standards.iteh.ai/catalog/standards/sist/df180246-66e0-48d8-80fb-8a8db78b7050/osist-pren-iec-80601-2-52-2024>

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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

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TITLE:

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

PROPOSED STABILITY DATE: 2030

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104 **INTERNATIONAL ELECTROTECHNICAL COMMISSION**

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MEDICAL ELECTRICAL EQUIPMENT –**Part 2-52: Particular requirements for the basic safety
and essential performance of medical beds for adults****FOREWORD**

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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.
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MEDICAL ELECTRICAL EQUIPMENT –

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

228 **201.1 Scope, object and related standards**

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

230 **201.1.1 * Scope**

231 *Replacement:*

232 This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of
233 MEDICAL BEDS as defined in 201.3.214, intended for ADULTS as defined in 201.3.222. Included
234 in scope are both electrical and non-electrical (manual) MEDICAL BEDS with or without
235 adjustable features.

236 This standard does not apply for MEDICAL BEDS intended for CHILDREN covered by IEC 80601-
237 2-89 Medical electrical equipment – Particular requirements for the basic safety and essential
238 performance of medical beds for children.

239 A BED-LIFT and/or a detachable MATTRESS SUPPORT PLATFORM in combination with a compatible
240 non-MEDICAL BED as specified by the MANUFACTURER is also considered a MEDICAL BED.

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

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

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

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

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

253 HAZARDS inherent in the intended physiological function of MEDICAL BED or ME SYSTEMS within
254 the scope of this standard are not covered by specific requirements in this standard except in
255 7.2.13 and 8.4.1 of the general standard.

256 NOTE See also 4.2 of the general standard.

257 **201.1.2 Object**

258 *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.