

**SLOVENSKI STANDARD**  
**oSIST prEN IEC 60601-2-34:2023**  
**01-januar-2023**

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**Medicinska električna oprema - 2-34. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za invazivno nadzorovanje krvnega tlaka**

Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment

Medizinische elektrische Geräte - Teil 2-34: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von invasiven Blutdruck-Überwachungsgeräten

Amendement 1 - Appareils électromédicaux - Partie 2-34: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de surveillance de la pression sanguine prélevée directement

**Ta slovenski standard je istoveten z: prEN IEC 60601-2-34:2022**

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**ICS:**

11.040.55      Diagnostična oprema      Diagnostic equipment

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## 62D/1990/CDV

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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 <b>Attention IEC-CENELEC parallel voting</b> 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 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment**

PROPOSED STABILITY DATE: 2028

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

## MEDICAL ELECTRICAL EQUIPMENT –

**Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment**

## FOREWORD

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International standard IEC 60601-2-34 has been prepared by a Joint Working Group of IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice and ISO subcommittee SC3: Lung ventilators and related equipment, of ISO technical committee 121: Anaesthetic and respiratory equipment.

This fourth edition cancels and replaces the third edition of IEC 60601-2-34 published in 2011 and constitutes a technical revision. This edition was revised to align with Amendment 1:2012 and Amendment 2:2020 of IEC 60601-1:2005 as well as new versions of collateral standards and amendments thereto.

Further it includes the following technical changes:

- Expansion of the scope to the EMERGENCY MEDICAL SERVICE ENVIRONMENT
- Changed ESSENTIAL PERFORMANCE in Table 201.101
- Changed requirement for ingress protection

- 122 – Added PRIMARY OPERATING FUNCTIONS  
 123 – Added requirements for ALARM SYSTEM logging  
 124 – Deleted Annex BB (Alarm diagrams 208/IEC 60601-1-8:2006)

125 The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/XXX/FDIS	62D/XXX/RVD

126  
 127 Full information on the voting for the approval of this particular standard can be found in the  
 128 report on voting indicated in the above table.

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

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

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

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

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

142 References to clauses within this standard are preceded by the term “Clause” followed by the  
 143 clause number. References to subclauses within this particular standard are by number only.

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

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

- 148 – “shall” means that compliance with a requirement or a test is mandatory for compliance  
 149 with this standard;  
 150 – “should” means that compliance with a requirement or a test is recommended but is not  
 151 mandatory for compliance with this standard;  
 152 – “may” is used to describe a permissible way to achieve compliance with a requirement or  
 153 test.

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

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

158 The committee has decided that the contents of this publication will remain unchanged until  
 159 the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data  
 160 related to the specific publication. At this date, the publication will be

- 161 • reconfirmed,  
162 • withdrawn,  
163 • replaced by a revised edition, or  
164 • amended.

165 NOTE The attention of National Committees and Member Bodies is drawn to the fact that equipment  
166 manufacturers and testing organizations may need a transitional period following publication of a new, amended or  
167 revised IEC publication in which to make products in accordance with the new requirements and to equip  
168 themselves for conducting new or revised tests. It is the recommendation of the committees that the content of this  
169 publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

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## INTRODUCTION

173 This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of INVASIVE  
174 BLOOD PRESSURE MONITORING EQUIPMENT. It amends and supplements IEC 60601-1:2005,  
175 IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020: *Medical electrical*  
176 *equipment – Part 1: General requirements for basic safety and essential performance*,  
177 hereinafter referred to as the general standard.

178 The aim of this fourth edition is to bring this particular standard up to date with reference to  
179 Amendment 1:2012 and Amendment 2:2020 of the general standard and new versions of  
180 collateral standards and amendments thereto through technical changes.

181 The requirements of this particular standard take priority over those of the general standard  
182 and collateral standards.

183 A “General guidance and rationale” for the more important requirements of this particular  
184 standard is included in Annex AA. It is considered that knowledge of the reasons for these  
185 requirements will not only facilitate the proper application of the standard but will, in due  
186 course, expedite any revision necessitated by changes in clinical practice or as a result of  
187 developments in technology. However, Annex AA does not form part of the requirements of  
188 this standard.

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## MEDICAL ELECTRICAL EQUIPMENT –

### Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment

#### 198 **201.1 Scope, object and related standards**

199 Clause 1 of the general standard<sup>1</sup> applies, except as follows:

##### 200 **201.1.1 \*Scope**

201 *Replacement:*

202 This particular standard applies to BASIC SAFETY and ESSENTIAL PERFORMANCE of INVASIVE  
203 BLOOD PRESSURE MONITORING EQUIPMENT as defined in 201.3.63, hereinafter also referred to as  
204 ME EQUIPMENT.

205 This document applies to INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT intended for use  
206 in professional healthcare facilities and in the EMERGENCY MEDICAL SERVICE ENVIRONMENT.

207 This particular standard does not apply to catheter tubing, catheter needles, Luer locks, taps  
208 and tap tables that connect to the DOME.

209 This particular standard does not apply to non-invasive blood pressure monitoring equipment.

210 If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to  
211 ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the  
212 case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as follows:

213 The clause or subclause applies to ME EQUIPMENT, as default. For ME EQUIPMENT with the  
214 corresponding safety measure or function not completely integrated into the ME EQUIPMENT but  
215 instead implemented in an ME SYSTEM, the ME EQUIPMENT MANUFACTURER shall specify in the  
216 ACCOMPANYING DOCUMENTS which functionality and safety requirements shall be provided by  
217 the ME SYSTEM to comply with this standard. The ME SYSTEM has to be verified accordingly.

##### 218 **201.1.2 Object**

219 *Replacement:*

220 The object of this particular standard is to establish BASIC SAFETY and ESSENTIAL PERFORMANCE  
221 requirements for INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT, as defined in 201.3.63.

##### 222 **201.1.3 Collateral standards**

223 *Addition:*

224 This particular standard refers to those applicable collateral standards that are listed in  
225 Clause 2 of the general standard and Clause 201.2 of this particular standard.

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<sup>1</sup> The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-2:2005/AMD2:2020  
*Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

226 IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010, IEC 60601-1-  
227 6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020, IEC 60601-1-8:2006, IEC 60601-1-  
228 8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD1:2020 apply as modified in Clauses 202,  
229 206 and 208 respectively. IEC 60601-1-3, IEC 60601-1-9 and IEC 60601-1-10 do not apply.  
230 All other published collateral standards in the IEC 60601-1 series apply as published.

#### 231 **201.1.4 Particular standards**

232 *Replacement:*

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

237 A requirement of a particular standard takes priority over the general standard and collateral  
238 standards.

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

241 The numbering of clauses and subclauses of this particular standard corresponds to that of  
242 the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content  
243 of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x"  
244 where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this  
245 particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard,  
246 208.4 in this particular standard addresses the content of Clause 4 of the 60601-1-8 collateral  
247 standard, etc.). The changes to the text of the general standard are specified by the use of  
248 the following words:

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

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

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

255 Subclauses, figures or tables which are additional to those of the general standard are  
256 numbered starting from 201.101. However due to the fact that definitions in the general  
257 standard are numbered 3.1 through 3.154, additional definitions in this standard are  
258 numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and  
259 additional items aa), bb), etc.

260 Subclauses, figures or tables which are additional to those of a collateral standard are  
261 numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for  
262 IEC 60601-1-2, 208 for IEC 60601-1-8, etc.

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

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

## 270 **201.2 Normative references**

271 Clause 2 of the general standard applies, except as follows:

272 *Replacement:*

273 IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic*  
 274 *safety and essential performance – Collateral standard: Electromagnetic disturbances –*  
 275 *Requirements and tests*

276 IEC 60601-1-2:2014/AMD1:2020

277 IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic*  
 278 *safety and essential performance – Collateral standard: Usability*

279 IEC 60601-1-6:2010/AMD1:2013

280 IEC 60601-1-6:2010/AMD2:2020

281 IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic*  
 282 *safety and essential performance – Collateral standard: General requirements, tests and*  
 283 *guidance for alarm systems in medical electrical equipment and medical electrical systems*

284 IEC 60601-1-8:2006/AMD1:2012

285 IEC 60601-1-8:2006/AMD2:2020

286 ISO 15223-1:2021 *Medical devices – Symbols to be used with information to be supplied by*  
 287 *the manufacturer – Part 1: General requirements*

288 *Addition:*

289 IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic*  
 290 *safety and essential performance*

291 Amendment 1:2012

292 Amendment 2:2020

293

294 IEC 60601-2-2, *Medical electrical equipment – Part 2-2: Particular requirements for the basic*  
 295 *safety and essential performance of high frequency surgical equipment and high frequency*  
 296 *surgical accessories*

297 NOTE Informative references are listed in the bibliography.

## 298 **201.3 Terms and definitions**

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

300 For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC  
 301 60601-1:2005/AMD1:2012 and IEC 60601-2:2005/AMD2:2020, IEC 60601-1-2:2014 and  
 302 IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and  
 303 IEC 60601-1-6:2010/AMD2:2020, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and  
 304 IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-12:2014 and IEC 60601-1-12:2015/AMD1:2020  
 305 apply, except as follows:

306 ISO and IEC maintain terminological databases for use in standardization at the following  
 307 addresses:

- 308 • IEC Electropedia: available at <http://www.electropedia.org/>
- 309 • ISO Online browsing platform: available at <http://www.iso.org/obp>

310 *Replacement:*

311 **201.3.63**  
 312 **MEDICAL ELECTRICAL EQUIPMENT**  
 313 **ME EQUIPMENT**  
 314 **INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT (ME EQUIPMENT)**  
 315 device including associated PRESSURE TRANSDUCERS, that is used for internal measurement or  
 316 monitoring of circulatory system pressures

317 *Replacement:*

318 **201.3.8**  
 319 **APPLIED PART**  
 320 PRESSURE TRANSDUCER, including its associated catheter and any fluid-filled system

321 *Additional definitions:*

322 **201.3.201**  
 323 **CATHETER**  
 324 tubular device, single or multi-lumen, designed to be partially or totally inserted into the  
 325 cardiovascular system for diagnostic purposes

326 **201.3.202**  
 327 **CATHETER TIP PRESSURE TRANSDUCER**  
 328 PRESSURE TRANSDUCER mounted at, or close to, the tip of a CATHETER

329 **201.3.203**  
 330 **DOME**  
 331 means for hydraulically coupling the PATIENT'S blood pressure to a PRESSURE TRANSDUCER  
 332 external to the PATIENT

333 **201.3.204**  
 334 **NOMINAL SENSITIVITY**  
 335 ratio of the change in PRESSURE TRANSDUCER output to a change of the value of the pressure  
 336 at any selected pressure range

337 **201.3.205**  
 338 **PRESSURE TRANSDUCER**  
 339 device for converting pressure into an electrical signal

## 340 **201.4 General requirements**

341 Clause 4 of the general standard applies, except as follows:

### 342 **201.4.3 ESSENTIAL PERFORMANCE**

343 *Addition:*

#### 344 **201.4.3.101 Additional ESSENTIAL PERFORMANCE requirements**

345 Additional ESSENTIAL PERFORMANCE requirements for INVASIVE BLOOD PRESSURE MONITORING  
 346 EQUIPMENT are found in subclauses listed in Table 201.101.

347 **Table 201.101 – ESSENTIAL PERFORMANCE requirements**

Requirement	Subclause
Defibrillator protection	201.8.5.5.1
Accuracy of pressure measurements	201.12.1.101

Electrosurgery interference	202.8.101
<b>PHYSIOLOGICAL ALARM CONDITIONS</b>	208.6.1.2.101
PRESSURE TRANSDUCER disconnect ALARM CONDITION	208.6.1.2.102
PRESSURE TRANSDUCER fault ALARM CONDITION	208.6.1.2.103
Catheter disconnect ALARM CONDITION	208.6.1.2.104
ALARM SYSTEM delays for PHYSIOLOGICAL ALARM CONDITIONS	208.6.4.1.101
ALARM SYSTEM delays for TECHNICAL ALARM CONDITIONS	208.6.4.1.102
Delays to or from a DISTRIBUTED INFORMATION SYSTEM ABOUT ALARM CONDITIONS (DIS) or a DISTRIBUTED ALARM SYSTEM (DAS)	208.6.4.2

## 348 **201.5 General requirements for testing of ME EQUIPMENT**

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

### 350 **201.5.4 Other conditions**

351 *Addition:*

352 If necessary for the purpose of conducting the test, the INTERNAL ELECTRICAL POWER SOURCE  
353 may be replaced by an external battery or d.c. power supply to provide the necessary test  
354 voltage.

355 The values used in test circuits, unless otherwise specified, shall have at least an accuracy as  
356 given below:

- 357 – resistors:  $\pm 1\%$ ;
- 358 – capacitors:  $\pm 10\%$ ;
- 359 – inductors:  $\pm 10\%$ ;
- 360 – test voltages:  $\pm 1\%$

### 361 **201.5.8 \* Sequence of tests**

362 *Amendment:*

363 Tests called for in 201.8.5.5.1 of this particular standard and in 8.5.5 of the general standard  
364 shall be carried out prior to the LEAKAGE CURRENT and dielectric strength tests described in  
365 subclauses 8.7 and 8.8 of the general standard and prior to the tests specified in subclause  
366 201.12.1.101.

## 367 **201.6 Classification of ME EQUIPMENT and ME SYSTEMS**

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

### 369 **201.6.2 \* Protection against electric shock**

370 *Replacement of the last paragraph:*

371 APPLIED PARTS shall be classified as TYPE CF APPLIED PARTS (see 7.2.10 and 8.3 of the general  
372 standard). APPLIED PARTS shall be classified as DEFIBRILLATION-PROOF APPLIED PARTS (see  
373 8.5.5 of the general standard).

### 374 **201.6.6 Mode of operation**

375 *Replacement:*

376 ME EQUIPMENT shall be classified for CONTINUOUS OPERATION (see 7.2.11).

### 377 **201.7 ME EQUIPMENT identification, marking and documents**

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

#### 379 **201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT** 380 **parts**

##### 381 **201.7.2.10 APPLIED PARTS**

382 *Addition:*

383 If fulfilment of TYPE CF APPLIED PART isolation depends on the PRESSURE TRANSDUCER, then  
384 symbol 27, Table D.1 of the general standard, shall be marked on the PRESSURE TRANSDUCER.

##### 385 **201.7.2.17 \* Protective packaging**

386 *Addition:*

387 The packaging of PRESSURE TRANSDUCER and DOMES supplied in sterile condition shall be  
388 marked with symbol 5.2.1, 5.2.2, 5.2.3, 5.2.4 or 5.2.5 of ISO 15223-1:2021 and the time limit  
389 for safe use, expressed as the year and month by which these ACCESSORIES should be used  
390 (symbol 5.1.4).

391 The packaging of PRESSURE TRANSDUCER and DOMES that are for single use shall be marked  
392 with symbol 28 in Table D.1 of the general standard.

##### 393 **201.7.9.2.2 Warning and safety notices**

394 *Addition:*

395 The instructions for use shall include a warning that defibrillator protection requires the use of  
396 MANUFACTURER specified ACCESSORIES including PRESSURE TRANSDUCERS and adapter cables.

##### 397 **201.7.9.2.9 Operating instructions**

398 *Addition:*

##### 399 **201.7.9.2.9.101 Additional instructions for use**

400 The operating instructions shall include the following:

- 401 a) the INTENDED USE including the environment of use;
- 402 b) for ME EQUIPMENT a list of the specified ACCESSORIES such as PRESSURE TRANSDUCER(S)  
403 and DOME(S);
- 404 c) for PRESSURE TRANSDUCERS, a list of ME EQUIPMENT that complies with the requirements of  
405 this standard when used with these PRESSURE TRANSDUCERS;
- 406 d) descriptions of how to connect the PRESSURE TRANSDUCERS and ACCESSORIES, how to  
407 calibrate and zero the PRESSURE TRANSDUCERS and suggested means for removing  
408 entrapped air from the hydraulic system;
- 409 e) recommended frequency of zeroing

410 EXAMPLE 1: Every 8 hours.

411 EXAMPLE 2: After moving the patient.

412 EXAMPLE 3: Following changes in ambient conditions (pressure, temperature)