



SLOVENSKI STANDARD
oSIST prEN IEC 80601-2-30:2025
01-april-2025

Medicinska električna oprema - 2-30. del: Posebne zahteve za osnovno varnost in bistvene lastnosti avtomatiziranih neinvazivnih sfigmomanometrov

Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

Medizinische elektrische Geräte - Teil 2-30: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von automatisierten nicht-invasiven Blutdruckmessgeräten

Appareils électromédicaux - Partie 2-30: Exigences particulières pour la sécurité de base et les performances essentielles des sphygmomanomètres non invasifs automatiques

Ta slovenski standard je istoveten z: prEN IEC 80601-2-30:2025

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62D/2201/CDV

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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:	HORIZONTAL FUNCTION(S):
ASPECTS CONCERNED: 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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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 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

PROPOSED STABILITY DATE: 2030

NOTE FROM TC/SC OFFICERS:

This edition includes the following significant technical changes with respect to the previous edition:

- a clarified definition of neonate and infant and associated modes;

- b) relabeling of some primary operating functions;
- c) additional requirements for monitoring equipment to avoid the misuse of misleading or “stale” data;
- d) updated normative references to the current versions where applicable.

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76 INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –**Part 2-30: Particular requirements for the basic safety
and essential performance of automated non-invasive
sphygmomanometers****FOREWORD**

- 86 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising
87 all national electrotechnical committees (IEC National Committees). The object of IEC is to promote
88 international co-operation on all questions concerning standardization in the electrical and electronic fields. To
89 this end and in addition to other activities, IEC publishes International Standards, Technical Specifications,
90 Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC
91 Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested
92 in the subject dealt with may participate in this preparatory work. International, governmental and non-
93 governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely
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97 consensus of opinion on the relevant subjects since each technical committee has representation from all
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101 Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any
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106 the latter.
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108 assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any
109 services carried out by independent certification bodies.
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112 members of its technical committees and IEC National Committees for any personal injury, property damage or
113 other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and
114 expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC
115 Publications.
- 116 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is
117 indispensable for the correct application of this publication.
- 118 9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a)
119 patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in
120 respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s),
121 which may be required to implement this document. However, implementers are cautioned that this may not
122 represent the latest information, which may be obtained from the patent database available at
123 <https://patents.iec.ch>. IEC shall not be held responsible for identifying any or all such patent rights.

124 International standard IEC 80601-2-30 has been prepared by a Joint Working Group of
125 subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical
126 equipment in medical practice, and of subcommittee SC3: Lung ventilators and related
127 equipment, of ISO technical committee 121: Anaesthetic and respiratory equipment.

128 This third edition cancels and replaces the second edition published in 2018. This edition
129 constitutes a technical revision.

130 This edition includes the following significant technical changes with respect to the previous
131 edition:

- 132 a) a clarified definition of neonate and infant and associated modes;
 133 b) relabeling of some primary operating functions;
 134 c) additional requirements for monitoring equipment to avoid the misuse of misleading or
 135 "stale" data;
 136 d) updated normative references to the current versions where applicable.

137 This publication is published as a double logo standard.

138 The text of this document is based on the following documents of IEC:

FDIS	Report on voting
62D/1548/FDIS	62D/1560/RVD

139
 140 Full information on the voting for the approval of this document can be found in the report on
 141 voting indicated in the above table. In ISO, the standard has been approved by 14 P members
 142 out of 15 having cast a vote.

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

144 In this document, the following print types are used:

- 145 – requirements and definitions: roman type;
- 146 – *test specifications*: *italic type*;
- 147 – informative material appearing outside of tables, such as notes, examples and references: in smaller type.
 148 Normative text of tables is also in a smaller type;
- 149 – TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS
 150 NOTED: SMALL CAPITALS.

151 In referring to the structure of this document, the term

- 152 – "clause" means one of the seventeen numbered divisions within the table of contents,
 153 inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- 154 – "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all
 155 subclauses of Clause 7).

156 References to clauses within this document are preceded by the term "Clause" followed by
 157 the clause number. References to subclauses within this particular standard are by number
 158 only.

159 In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any
 160 combination of the conditions is true.

161 The verbal forms used in this document conform to usage described in Clause 7 of the
 162 ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

- 163 – "shall" means that compliance with a requirement or a test is mandatory for compliance
 164 with this document;
- 165 – "should" means that compliance with a requirement or a test is recommended but is not
 166 mandatory for compliance with this document;
- 167 – "may" is used to describe a permissible way to achieve compliance with a requirement or
 168 test.

169 **An asterisk (*) as the first character of a title or at the beginning of a**
 170 **paragraph or table title indicates that there is guidance or rationale**
 171 **related to that item in Annex D**
 172 **(informative)**

173
 174

Application Programming Interface Framework

175 D.1 General guidance

176 This annex provides a minimal informative framework for Electronic Automated Blood Pressure device digital
 177 connectivity. It is common for health monitoring devices that are being used at all levels of patient acuity to be
 178 "connected" for the purpose of direct transmission of device data to a distant dashboard, electronic medical
 179 record and even from the patient's home to their health provider. In this annex, the term Application Programming
 180 Interface (API) is used in its most generic sense, representing the flow of data and commands to and from a
 181 device that provides connectivity and has NIBP determination capability. A conceptual API is presented without
 182 specifics of data structures or communication protocols. The annex is intended to serve as a starting point for
 183 discussion about the design of an API for an NIBP device. It is by no means a comprehensive or required
 184 framework but a starting point, listing basic functionality that an NIBP API should consider. There is no intention to
 185 provide a comprehensive model for an API that meets all the needs of all server/client interactions. Nor is there
 186 any intention to imply that the implementation of this API framework will provide any level of market acceptance or
 187 interoperability of NIBP devices.

188

189 The committee presents the following minimum set of API functionality for your consideration in the development
 190 of connected NIBP devices:

191 API shall include

- 192 - Start BP reading
- 193 - Stop BP reading
- 194 - Abort an NIBP cycle
- 195 - Get NIBP results - sys, dia, HR ,MAP, Error code
- 196 - Set BP mode to Neonate
- 197 - Set BP mode to Pediatric (if applicable)
- 198 - Set BP mode to Adult
- 199 - Set BP mode to special.
- 200 - Reset the API
- 201 - Set API Parameters (protocol, Baud ...)
- 202 - Control Pump
- 203 - Control valve
- 204 - Calibrate or cal-check pressure transducers
- 205 - Capability to support testing of single-fault failsafe components and controls

206 Annex AA.

207 A list of all parts of the 80601 International standard, published under the general title *Medical*
 208 *electrical equipment*, can be found on the IEC website.

209 The committee has decided that the contents of this publication will remain unchanged until
210 the stability date indicated on the IEC website under "<http://webstore.iec.ch>" in the data
211 related to the specific publication. At this date, the publication will be

- 212 • reconfirmed,
- 213 • withdrawn,
- 214 • replaced by a revised edition, or
- 215 • amended.

216

217 NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing
218 organizations may need a transitional period following publication of a new, amended or revised IEC publication in
219 which to make products in accordance with the new requirements and to equip themselves for conducting new or
220 revised tests. It is the recommendation of the committees that the content of this publication be adopted for
221 implementation nationally not earlier than 3 years from the date of publication.

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224

INTRODUCTION

225 The minimum safety requirements specified in this particular standard are considered to
226 provide for a practical degree of safety in the operation of an AUTOMATED SPHYGMOMANOMETER.

227 The requirements are followed by specifications for the relevant tests.

228 Following the decision taken by subcommittee 62D at the meeting in Washington DC in 1979,
229 a "General guidance and rationale" section giving some explanatory notes, where appropriate,
230 about the more important requirements is included in Annex AA. It is considered that
231 knowledge of the reasons for these requirements will not only facilitate the proper application
232 of the standard but will, in due course, expedite any revision necessitated by changes in
233 clinical practice or because of developments in technology. However, the Annex AA does not
234 form part of the requirements of this document.

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

244 **201.1 Scope, object and related standards**

245 Clause 1 of the general standard applies, except as follows:

246 **201.1.1 Scope**

247 *Replacement:*

248 This part of the 80601 International Standard applies to the BASIC SAFETY and ESSENTIAL
249 PERFORMANCE of AUTOMATED SPHYGMOMANOMETERS, hereafter referred to as ME EQUIPMENT,
250 which by means of an inflatable CUFF, are used for non-continuous indirect estimation of the
251 BLOOD PRESSURE without arterial puncture.

252 NOTE 1 Equipment that performs indirect DETERMINATION of the BLOOD PRESSURE without arterial puncture does
253 not directly measure the BLOOD PRESSURE. It only estimates the BLOOD PRESSURE.

254 This document specifies requirements for the BASIC SAFETY and ESSENTIAL PERFORMANCE for
255 this ME EQUIPMENT and its ACCESSORIES, including the requirements for the accuracy of BLOOD
256 PRESSURE DETERMINATION.

257 This document covers automatic electrically-powered ME EQUIPMENT used for the intermittent,
258 indirect estimation of the BLOOD PRESSURE without arterial puncture, including BLOOD
259 PRESSURE monitors for the HOME HEALTHCARE ENVIRONMENT.

260 Requirements for indirect estimation of the BLOOD PRESSURE without arterial puncture
261 ME EQUIPMENT with an electrically-powered PRESSURE TRANSDUCER and/or displays used in
262 conjunction with a stethoscope or other manual methods for determining BLOOD PRESSURE
263 (NON-AUTOMATED SPHYGMOMANOMETERS) are specified in document ISO 81060-1 [2].

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

267 HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS
268 within the scope of this document are not covered by specific requirements in this document
269 except in 201.11 and 201.105.3.3, as well as 7.2.13 and 8.4.1 of IEC 60601-1:2022.

270 **201.1.2 Object**

271 *Replacement:*

272 The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL
273 PERFORMANCE requirements for an AUTOMATED SPHYGMOMANOMETER as defined in 201.3.201.

274 **201.1.3 Collateral standards**

275 *Addition:*

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

278 IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 apply
279 as modified in Clauses 202, 206, 210, 211 and 212 respectively. IEC 60601-1-3 [3] does not
280 apply. All other published collateral standards in the IEC 60601-1 series apply as
281 published [1] [4].

282 **201.1.4 Particular standards**

283 *Replacement:*

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

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

289 For brevity, IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 are referred to in this
290 particular standard as the general standard. Collateral standards are referred to by their
291 document number.

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

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

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

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

306 Subclauses, figures or tables which are additional to those of the general standard are
307 numbered starting from 201.101. However, due to the fact that definitions in the general
308 standard are numbered 3.1 through 3.147, additional definitions in this document are
309 numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and
310 additional items aa), bb), etc.

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

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

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

321 201.2 Normative references

322 NOTE Informative references are listed in the bibliography beginning on page 56.

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

324 *Replacement:*

325 IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic*
326 *safety and essential performance – Collateral Standard: Electromagnetic disturbances –*
327 *Requirements and tests*
328 IEC 60601-1-2:2014/AMD 1:2020

329 IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic*
330 *safety and essential performance – Collateral standard: Usability*
331 IEC 60601-1-6:2010/AMD 1:2013
332 IEC 60601-1-6:2010/AMD 2:2020

333 *Addition:*

334 IEC 60068-2-27:2008, *Environmental testing – Part 2-27: Tests – Test Ea and guidance:*
335 *Shock*

336 IEC 60068-2-64:2008+AMD1:2019, *Environmental testing – Part 2-64: Tests – Test Fh:*
337 *Vibration, broad-band random and guidance*

338 IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic*
339 *safety and essential performance*
340 IEC 60601-1:2005/AMD 1:2012

341 IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for*
342 *basic safety and essential performance – Collateral Standard: Requirements for the*
343 *development of physiologic closed-loop controllers*
344 IEC 60601-1-10:2007/AMD1:2013
345 IEC 60601-1-10:2007/AMD2:2020

346 IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for*
347 *basic safety and essential performance – Collateral Standard: Requirements for medical*
348 *electrical equipment and medical electrical systems used in the home healthcare environment*
349 IEC 60601-1-11:2015/AMD1:2020

350 IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for*
351 *basic safety and essential performance – Collateral Standard: Requirements for medical*
352 *electrical equipment and medical electrical systems intended for use in the emergency*
353 *medical services environment*
354 IEC 60601-1-12:2014/AMD1:2020

355 IEC 60601-2-2:2017, *Medical electrical equipment – Part 2-2: Particular requirements for the*
356 *basic safety and essential performance of high frequency surgical equipment and high*
357 *frequency surgical accessories*
358 IEC 60601-2-2:2017/AMD1:2023

359 IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical*
360 *devices*
361 IEC 62366-1:2015/AMD1:2020

362 IEC 80369-5:2016, *Small-bore connectors for liquids and gases in healthcare applications –*
363 *Part 5: Connectors for limb cuff inflation applications*