



SLOVENSKI STANDARD
oSIST prEN ISO 80601-2-55:2016
01-december-2016

Medicinska električna oprema - 2-55. del: Posebne zahteve za osnovno varnost in bistvene lastnosti monitorjev dihalnih plinov (ISO/DIS 80601-2-55:2016)

Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO/DIS 80601-2-55:2016)

Medizinische elektrische Geräte - Teil 2-55: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Überwachungsgeräten für Atemgase (ISO/DIS 80601-2-55:2016)

Appareils électromédicaux -- Partie 2-55: Exigences particulières relatives à la sécurité de base et aux performances essentielles des moniteurs de gaz respiratoires (ISO/DIS 80601-2-55:2016)

Ta slovenski standard je istoveten z: prEN ISO 80601-2-55

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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oSIST prEN ISO 80601-2-55:2016 **en**

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ISO/DIS 80601-2-55

ISO/TC 121/SC 1

Secretariat: DIN

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Medical electrical equipment —

Part 2-55:

Particular requirements for the basic safety and essential performance of respiratory gas monitors

*Appareils électromédicaux —**Partie 2-55: Exigences particulières relatives à la sécurité de base et aux performances essentielles des moniteurs de gaz respiratoires*

ICS: 11.040.10

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This document is circulated as received from the committee secretariat.

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

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Reference number
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134 Foreword

135 ISO (the International Organization for Standardization) is a worldwide federation of national standards
136 bodies (ISO member bodies). The work of preparing International Standards is normally carried out through
137 ISO technical committees. Each member body interested in a subject for which a technical committee has
138 been established has the right to be represented on that committee. International organizations,
139 governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely
140 with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

141 The procedures used to develop this document and those intended for its further maintenance are described
142 in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of
143 ISO documents should be noted. This document was drafted in accordance with the editorial rules of the
144 ISO/IEC Directives, Part 2 (see www.iso.org/directives).

145 Attention is drawn to the possibility that some of the elements of this document may be the subject of patent
146 rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent
147 rights identified during the development of the document will be in the Introduction and/or on the ISO list of
148 patent declarations received (see www.iso.org/patents).

149 Any trade name used in this document is information given for the convenience of users and does not
150 constitute an endorsement.

151 For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment,
152 as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the
153 Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

154 The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*,
155 Subcommittee SC 1, *Breathing attachments and anaesthetic machines*, and Technical Committee IEC/TC 62,
156 *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*.

157 This second edition of ISO 80601-2-55 cancels and replaces the first edition of ISO 80601-2-55:2011. This
158 edition of ISO 80601-2-55 constitutes a technical revision of ISO 80601-2-55:2011 and includes the
159 following technical modifications:

160 — amendments following the publication of IEC 60601-1-12 (Collateral Standard: Requirements for
161 medical electrical equipment and medical electrical systems used in the emergency medical services
162 environment) that resulted in the deletion of additional requirements on respiratory gas monitors for
163 use during professional transport of a patient outside a healthcare facility because these are now
164 covered by IEC 60601-1-12;

165 — amendment of requirements on marking, warning and safety notices as well as accompanying
166 documents, in part due to the publication of the amendment 1:2012 to IEC 60601-1:2005;

167 — revision of 201.11.6.5 – ingress of water or particulate matter into equipment – and 201.15.3.5 - shock
168 and vibration – in order to distinguish between requirements on stand-alone respiratory gas monitors
169 and requirements on respiratory gas monitors that are incorporated into another medical electrical
170 equipment;

171 — inclusion of ISO 80369-2 - Connectors for breathing systems and driving gases applications – as the
172 normative reference for the port connector for diverting respiratory gas monitors;

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- 173 — addition of a new subclause 201.106 on functional connection accompanied by the related rationale and
174 informative annex on data interface requirements;
- 175 — revision of Clause 202 on electromagnetic disturbances based on the new edition of
176 IEC 60601-1-2:2014;
- 177 — revision of Clause 208 on alarms by taking into consideration the amendment 1:2012 to IEC
178 60601-1-8:2006;
- 179 — exclusion of IEC 60601-1-9 - Collateral Standard: Requirements for environmentally conscious design;
- 180 — deletion of the informative Annex BB on environmental aspects
- 181 — addition of requirements on calibration/zeoring.
- 182 ISO 80601 consists of the following parts, under the general title *Medical electrical equipment*:
- 183 — *Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*
- 184 — *Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic*
185 *workstation*
- 186 — *Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas*
187 *monitors*
- 188 — *Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for*
189 *body temperature measurement*
- 190 — *Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment*
191 *for medical use*
- 192 — *Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving*
193 *equipment*
- 194 — *Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator*
195 *equipment*
- 196 — *Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing*
197 *therapy equipment*
- 198 — *Part 2-72: Particular requirements for basic safety and essential performance of home healthcare*
199 *environment ventilators for ventilator-dependent patients*
- 200 IEC 80601 consists of the following parts, under the general title *Medical electrical equipment*:
- 201 — *Part 2-30: Particular requirements for the basic safety and essential performance of automated non-*
202 *invasive sphygmomanometers*
- 203 — *Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using*
204 *blankets, pads and mattresses and intended for heating in medical use*
- 205 — *Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices*
206 *and vitrectomy devices for ophthalmic surgery*
- 207 — *Part 2-59: Particular requirements for the basic safety and essential performance of screening*
208 *thermographs for human febrile temperature screening*

- 209 — *Part 2-60: Particular requirements for basic safety and essential performance of dental equipment*
- 210 — *Part 2-71: Particular requirements for the basic safety and essential performance of functional Near-*
- 211 *Infrared Spectroscopy (NIRS) equipment*

212 The ISO and IEC 80601 family of standards are also parts of the IEC 60601 family of standards.

213 European foreword

214 The following referenced documents are indispensable for the application of this document. For undated
215 references, the latest edition of the referenced document (including any amendments) applies. For dated
216 references, only the edition cited applies. However, for any use of this standard within the meaning of
217 Annex ZA, the user should always check that any referenced document has not been superseded and that its
218 relevant contents can still be considered the generally acknowledged state-of-art.

219 When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative
220 reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC
221 standard, as listed below.

222 NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in
223 whole or in part) to which they apply.

224 **Table 1 — Correlation between normative references and dated EN and ISO standards**

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 7000:2014	-	ISO 7000:2014
ISO 7010:2011	EN ISO 7010:2012	ISO 7010:2011
ISO 14937:2009	EN ISO 14937:2009	ISO 14937:2009
ISO 15223-1:2012	EN ISO 15223-1:2012	ISO 15223-1:2012
ISO 17664:2004	EN ISO 17664:2004	ISO 17664:2004
ISO 80601-2-13:2011+AMD1:2015	EN ISO 80601-2-13:2012 ^a	ISO 80601-2-13:2011
ISO 80369-2:- ^b	ISO 80369-2:- ^b	ISO 80369-2:- ^b
IEC 60601-1:2005+AMD1:2012	EN 60601-1:2006 + Cor.:2010+ A1:2013	IEC 60601-1:2005+AMD1:2012
IEC 60601-1-2:2014	EN 60601-1-2:2015	IEC 60601-1-2:2014
IEC 60601-1-6:2010+AMD1:2013	EN 60601-1-6:2010 + A1:2015	IEC 60601-1-6:2010+AMD1:2013
IEC 60601-1-8:2006+AMD1:2012	EN 60601-1-8:2007 + Cor.:2010 + A1:2013	IEC 60601-1-8:2006+AMD1:2012
IEC 60601-1-11:2015	EN 60601-1-11:2015	IEC 60601-1-11:2015
IEC 60601-1-12:2014	EN 60601-1-12:2015	IEC 60601-1-12:2014
IEC 60068-2-27:2008	EN 60068-2-27:2009	IEC 60068-2-27:2008
IEC 60068-2-64:2008	EN 60068-2-64:2008	IEC 60068-2-64:2008
IEC 60529:1989+AMD1:1999 +AMD2:2013	EN 60529:1991+A1:2000 +A2:2013	IEC 60529:2001
^a AMD1:2015 to ISO 80601-2-13 has not yet been adopted at European level. ^b To be published.		

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225 **Introduction**

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

227 — Requirements and definitions: roman type.

228 — *Test specifications: italic type.*

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

231 — TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

232 In referring to the structure of this document,

233 — “clause” means one of the 17 numbered divisions within the table of contents, inclusive of all
234 subdivisions (e.g. Clause 7 includes 7.1, 7.2, etc.), and

235 — “subclause” means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are all
236 subclauses of Clause 201.7).

237 References to clauses within this document are preceded by the term “Clause” followed by the clause
238 number. References to subclauses within this document are by number only.

239 In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of
240 the conditions is true.

241 The verbal forms used in this document conform to usage described in Annex H of the ISO/IEC Directives,
242 Part 2. For the purposes of this document, the auxiliary verb

243 — “shall” means that compliance with a requirement or a test is mandatory for compliance with document,

244 — “should” means that compliance with a requirement or a test is recommended but is not mandatory for
245 compliance with this document, and

246 — “may” is used to describe a permissible way to achieve compliance with a requirement or test.

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

249 The attention of Member Bodies and National Committees is drawn to the fact that equipment
250 manufacturers and testing organizations might need a transitional period following publication of a new,
251 amended, or revised ISO or IEC publication in which to make products in accordance with the new
252 requirements and to equip them for conducting new or revised tests. It is the recommendation of the
253 committee that the content of this document not be adopted for mandatory implementation nationally
254 earlier than three years from the date of publication for equipment newly designed and not earlier than five
255 years from the date of publication for equipment already in production.

256 **Medical electrical equipment — Part 2-55: Particular**
257 **requirements for the basic safety and essential performance of**
258 **respiratory gas monitors**

259 **201.1 Scope, object, and related standards**

260 IEC 60601-1:2005+AMD1:2012, Clause 1 applies, except as follows:

261 **201.1.1 * Scope**

262 IEC 60601-1:2005+AMD1:2012, 1.1 is replaced by:

263 This document specifies particular requirements for the BASIC SAFETY and ESSENTIAL PERFORMANCE of a
264 RESPIRATORY GAS MONITOR (RGM), hereafter referred to as ME EQUIPMENT, intended for CONTINUOUS OPERATION for
265 use with a PATIENT.

266 This document specifies requirements for

267 — anaesthetic gas monitoring,

268 — carbon dioxide monitoring, and

269 — oxygen monitoring.

270 NOTE 1 An RGM can be either stand-alone ME EQUIPMENT or integrated into other equipment, e.g. an anaesthetic
271 workstation or a ventilator.

272 This document is not applicable to an RGM intended for use with flammable anaesthetic agents.

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

276 HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of
277 this document are not covered by specific requirements in this document except in
278 IEC 60601-1:2005+AMD1:2012, 7.2.13 and 8.4.1.

279 NOTE 2 Additional information can be found in IEC 60601-1:2005+AMD1:2012, 4.2.

280 **201.1.2 Object**

281 IEC 60601-1:2005+AMD1:2012, 1.2 is replaced by:

282 The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements
283 for an RGM (as defined in 201.3.210) and its ACCESSORIES.

284 NOTE ACCESSORIES are included because the combination of the RGM and the ACCESSORIES needs to be safe.
285 ACCESSORIES can have a significant impact on the BASIC SAFETY and ESSENTIAL PERFORMANCE of an RGM.

ISO/DIS 80601-2-55:2016(E)286 **201.1.3 Collateral standards**

287 IEC 60601-1:2005+AMD1:2012, 1.3 applies with the following addition:

288 This document refers to those applicable collateral standards that are listed in
289 IEC 60601-1:2005+AMD1:2012, Clause 2, as well as those listed in 201.2 of this document and to the
290 following exceptions:

291 IEC 60601-1-3:2008 and IEC 60601-1-9:2007+AMD1:2013 do not apply.

292 **201.1.4 Particular standards**

293 IEC 60601-1:2005+AMD1:2012, 1.4 is replaced by:

294 In the IEC 60601 series, particular standards can modify, replace, or delete requirements contained in the
295 general standard, including the collateral standards, as appropriate for the particular ME EQUIPMENT under
296 consideration, and may add other BASIC SAFETY or ESSENTIAL PERFORMANCE requirements.

297 A requirement of a particular standard takes priority over IEC 60601-1:2005+AMD1:2012 or the collateral
298 standards.

299 For brevity, IEC 60601-1:2005+AMD1:2012 is referred to in this document as the general standard.
300 Collateral standards are referred to by their document number.

301 The numbering of clauses and subclauses of this document corresponds to those of the general standard
302 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard)
303 or applicable collateral standard with the prefix "2xx" where xx is the final digits of the collateral standard
304 document number (e.g. 202.4 addresses the content of IEC 60601-1-2, Clause 4 collateral standard, 208.4
305 addresses the content of IEC 60601-1-8, Clause 4 collateral standard, etc.). The changes to the text of the
306 general standard are specified by the use of the following words:

307 — "Replacement" means that the clause or subclause of IEC 60601-1:2005+AMD1:2012 or the applicable
308 collateral standard is replaced completely by the text of this document.

309 — "Addition" means that the text of this document is additional to the requirements of
310 IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard.

311 — "Amendment" means that the clause or subclause of IEC 60601-1:2005+AMD1:2012 or the applicable
312 collateral standard is amended as indicated by the text of this document.

313 Subclauses or figures that are additional to those of the general standard are numbered starting from
314 201.101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

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

317 The term "this standard" is used to make reference to IEC 60601-1:2005+AMD1:2012, any applicable
318 collateral standards, and this document taken together.

319 Where there is no corresponding clause or subclause in this document, the clause or subclause of
320 IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard, although possibly not relevant, applies
321 without modification; where it is intended that any part of IEC 60601-1:2005+AMD1:2012 or the applicable
322 collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this
323 document.

324 **201.2 Normative references**

325 The following documents are referred to in the text in such a way that some or all of their content constitutes
 326 requirements of this document. For dated references, only the edition cited applies. For undated references,
 327 the latest edition of the referenced document (including any amendments) applies.

328 NOTE Informative references are listed in the bibliography beginning on page 60.

329 IEC 60601-1:2005+AMD1:2012¹⁾, *Clause 2* applies, except as follows:

330 *Replacement:*

331 IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and*
 332 *essential performance — Collateral standard: Electromagnetic disturbances — Requirements and tests*

333 IEC 60601-1-6:2010²⁾, *Medical electrical equipment — Part 1-6: General requirements for basic safety and*
 334 *essential performance — Collateral standard: Usability*
 335 +Amendment 1:2013

336 IEC 60601-1-8:2006³⁾, *Medical electrical equipment — Part 1-8: General requirements for basic safety and*
 337 *essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in*
 338 *medical electrical equipment and medical electrical systems*
 339 +Amendment 1:2012

340 *Addition:*

341 ISO 7000:2014, *Graphical symbols for use on equipment — Registered symbols*

342 ISO 7010:2011, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

343 ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a*
 344 *sterilizing agent and the development, validation and routine control of a sterilization process for medical*
 345 *devices*

346 ISO 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information*
 347 *to be supplied — Part 1: General requirements*

348 ISO 17664:2004, *Sterilization of medical devices — Information to be provided by the manufacturer for the*
 349 *processing of resterilizable medical devices*

350 ISO 80601-2-13:2011, *Medical electrical equipment — Part 2-13: Particular requirements for basic safety and*
 351 *essential performance of an anaesthetic workstation*
 352 +Amendment 1:2015

353 ISO 80369-2:-⁴⁾ *Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors*
 354 *for breathing systems and driving gas applications*

355 IEC 60068-2-27:2008, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

1) There exists a consolidated edition 3.1(2012) including IEC 60601-1:2005 and its Amendment 1:2012.

2) There exists a consolidated edition 3.1(2013) including IEC 60601-1-6:2010 and its Amendment 1:2013.

3) There exists a consolidated edition 2.1(2012) including IEC 60601-1-8:2006 and its Amendment 1:2012.

4) To be published.