
Medicinska električna oprema - 2-84. del: Posebne zahteve za osnovno varnost in bistvene lastnosti ventilatorjev v okolju nujne medicinske pomoči (ISO/DIS 80601-2-84:2022)

Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment (ISO/DIS 80601-2-84:2022)

Medizinische elektrische Geräte - Teil 2-84: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Notfall- und Transportbeatmungsgeräten (ISO/DIS 80601-2-84:2022)

Appareils électromédicaux - Partie 2-84: Exigences particulières relatives à la sécurité de base et aux performances essentielles des ventilateurs utilisés dans l'environnement des services médicaux d'urgence (ISO/DIS 80601-2-84:2022)

Ta slovenski standard je istoveten z: prEN ISO 80601-2-84

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
11.160	Prva pomoč	First aid

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DRAFT INTERNATIONAL STANDARD

ISO/DIS 80601-2-84

ISO/TC 121/SC 3

Secretariat: ANSI

Voting begins on:
2022-01-25Voting terminates on:
2022-04-19

Medical electrical equipment —

Part 2-84:

Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

*Appareils électromédicaux —**Partie 2-84: Exigences particulières relatives à la sécurité de base et aux performances essentielles des ventilateurs utilisés dans l'environnement des services médicaux d'urgence*

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Published in Switzerland

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160 **Foreword**

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

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

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

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

178 For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and
 179 expressions related to conformity assessment, as well as information about ISO's adherence to the
 180 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see
 181 www.iso.org/iso/foreword.html.

182 This document was prepared jointly by Technical Committee ISO/TC 121, Anaesthetic and
 183 respiratory equipment, Subcommittee SC 3, Respiratory devices and related equipment used for
 184 patient care, and Technical Committee IEC/TC 62, Electrical equipment in medical practice,
 185 Subcommittee 62D, Electromedical equipment, in collaboration with the European Committee for
 186 Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*,
 187 in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna
 188 Agreement).

189 This second edition cancels and replaces the first edition (ISO 80601-2-84:2020), which has been
 190 technically revised. The main changes compared to the previous edition are as follows:

- 191 — alignment with IEC 60601-1:2005+AMD1:2012+AMD2:2020,
 192 IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020,
 193 IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, and IEC 60601-1-12:2014+AMD1:2020.
- 194 — reformatted according to most recent Central Secretariat editing rules;
- 195 — clarified *maximum limited pressure* requirements;
- 196 — added requirements for a *responsible organization* log.

197 A list of all parts in the ISO 80601 series and the IEC 80601 series can be found on the ISO website.

198 Any feedback or questions on this document should be directed to the user's national standards
 199 body. A complete listing of these bodies can be found at www.iso.org/members.html.

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200 **Introduction**

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

202 — “clause” means one of the five numbered divisions within the table of contents, inclusive of all
203 subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);

204 — “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all
205 subclauses of Clause 201).

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

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

210 In this document, the following verbal forms are used:

211 — “shall” indicates a requirement;

212 — “should” indicates a recommendation;

213 — “may” indicates a permission;

214 — “can” is used to describe a possibility or capability; and

215 — “must” indicates an external constraint.

216 Annex C contains a guide to the *marking* and labelling requirements in this document.

217 Annex D contains a summary of the *symbols* referenced in this document.

218 Requirements in this document have been decomposed so that each requirement is uniquely
219 delineated. This is done to support automated requirements tracking.

220

221 **Medical electrical equipment —**
 222 **Part 2-84:**
 223 **Particular requirements for the basic safety and essential**
 224 **performance of ventilators for the emergency medical services**
 225 **environment**

226 **201.1 Scope, object and related standards**

227 IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 1 applies, except as follows:

228 **201.1.1 Scope**

229 *Replacement:*

230 NOTE 1 There is guidance or rationale for this subclause contained in Clause AA.2.

231 This document applies to the *basic safety and essential performance* of an *EMS ventilator* in combination
 232 with its *accessories*, hereafter also referred to as *ME equipment*:

233 — intended for *patients* who need differing levels of support from *artificial ventilation* including
 234 *ventilator-dependent patients*;

235 — intended to be operated by a *healthcare professional operator*;

236 — intended for use in the *EMS environment*; and

237 — intended for *invasive or non-invasive ventilation*.

238 NOTE 2 An *EMS ventilator* can also be used for transport within a *professional healthcare facility*.

239 An *EMS ventilator* is not considered to utilize a *physiologic closed loop-control system* unless it uses a
 240 physiological *patient* variable to adjust the *ventilation* therapy settings.

241 This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to
 242 the *ventilator breathing system*, or to an *EMS ventilator*, where the characteristics of those *accessories* can
 243 affect the *basic safety* or *essential performance* of the *EMS ventilator*.

244 NOTE 3 If a clause or subclause is specifically intended to be applicable to *ME equipment* only, or to *ME systems*
 245 only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies
 246 both to *ME equipment* and to *ME systems*, as relevant.

247 *Hazards* inherent in the intended physiological function of *ME equipment* or *ME systems* within the scope
 248 of this document are not covered by specific requirements in this document except in IEC 60601-
 249 1:2005+AMD2:2020, 7.2.13 and 8.4.1.

250 NOTE 4 Additional information can be found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 4.2.

251 This document does not specify the requirements for the following:

252 — *ventilators* or *accessories* intended for *ventilator-dependent patients* in critical care applications,
 253 which are given in ISO 80601-2-12^[17].

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- 254 — *ventilators* or *accessories* intended for *ventilator-dependent patients* in the *home healthcare*
255 *environment*, which are given in ISO 80601-2-72^[20].
- 256 — *ventilators* or *accessories* intended for anaesthetic applications, which are given in
257 ISO 80601-2-13^[18].
- 258 — *ventilators* or *accessories* intended for ventilatory support equipment (intended only to augment the
259 *ventilation* of spontaneously breathing *patients*), which are given in ISO 80601-2-79^[21] and
260 ISO 80601-2-80^[22]¹.
- 261 — obstructive sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70^[19].
- 262 — user-powered resuscitators, which are given in ISO 10651-4^[8].
- 263 — gas-powered emergency resuscitators, which are given in ISO 10651-5^[9].
- 264 — *continuous positive airway pressure (CPAP) ME equipment*.
- 265 — high-frequency jet *ventilators* (HFJVs), which are given in ISO 80601-2-87^[23].
- 266 — high-frequency oscillatory *ventilators* (HFOVs)^[43], which are given in ISO 80601-2-87^[23].
- 267 NOTE 5 An *EMS ventilator* can incorporate high-frequency jet or high-frequency oscillatory *ventilation-*
268 *modes*.
- 269 — cuirass or “iron-lung” *ventilators*.

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270 **201.1.2 Object**271 *Replacement:*

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272 The object of this particular document is to establish *basic safety* and *essential performance* requirements
273 for an *EMS ventilator*, as defined in 201.3.201, and its *accessories*.

274 *Accessories* are included because the combination of the *EMS ventilator* and the *accessories* needs to have
275 acceptable *risk*. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of
276 an *EMS ventilator*.

277 NOTE 1 This document has been prepared to address the relevant *essential principles*^[37] and labelling^[38]
278 guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex CC.

279 NOTE 2 This document has been prepared to address the relevant *essential principles of safety and performance* of
280 ISO 16142-1:2016^[13] as indicated in Annex DD.

281 NOTE 3 This document has been prepared to address the relevant general safety and performance requirements
282 of European regulation (EU) 2017/745^[39].

283 **201.1.3 Collateral standards**284 *Amendment (add at the end of the subclause):*

285 This document refers to those applicable collateral standards that are listed in Clause 2 of the general
286 standard and in 201.2 of this document.

¹ ISO 80601-2-79 and ISO 80601-2-80 replace ISO 10651-6, which has been withdrawn.

287 NOTE The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020.

288 IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020,
289 IEC 60601-1-8:2016+AMD1:2012+AMD2:2020 and IEC 60601-1-12:2014+AMD1:2020 apply as
290 modified in Clauses 202, 206, 208 and 212 respectively. IEC 60601-1-3^[24], IEC 60601-1-9^[25], and
291 IEC 60601-1-11^[27] do not apply. All other published collateral standards in the IEC 60601-1 series apply
292 as published.

293 **201.1.4 Particular standards**

294 *Replacement:*

295 In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in
296 the general standard, including the collateral standards, as appropriate for the particular *ME equipment*
297 under consideration, and may add other *basic safety* or *essential performance* requirements.

298 A requirement of a particular standard takes priority over IEC 60601-1:2005+AMD1:2012+AMD2:2020
299 or the collateral standards.

300 For brevity, IEC 60601-1:2005+AMD1:2012+AMD2:2020 is referred to in this particular document as the
301 general standard. Collateral standards are referred to by their document number.

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

309 "Replacement" means that the clause or subclause of IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the
310 applicable collateral standard is replaced completely by the text of this particular document.

311 "Addition" means that the text of this document is additional to the requirements of
312 IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the applicable collateral standard.

313 "Amendment" means that the clause or subclause of IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the
314 applicable collateral standard is amended as indicated by the text of this document.

315 Subclauses, figures or tables that are additional to those of the general standard are numbered starting
316 from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through
317 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional
318 annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

319 Subclauses or figures that are additional to those of a collateral standard are numbered starting from 20x,
320 where "x" is the number of the collateral standard (e.g. 202 for IEC 60601-1-2, 208 for IEC 60601-1-8,
321 etc.).

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

324 Where there is no corresponding clause or subclause in this document, the clause or subclause of
325 IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the applicable collateral standard, although possibly not
326 relevant, applies without modification; where it is intended that any part of
327 IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the applicable collateral standard, although possibly
328 relevant, is not to be applied, a statement to that effect is given in this particular document.

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329 **201.2 Normative references**

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

333 IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 2 applies, except as follows:

334 Replacement:

335 ISO 19054:2005+AMD1:2016, *Rail systems for supporting medical equipment*

336 IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

337 Addition:

338 ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content*

339 ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources
340 using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

341 ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and
342 equipment*

343 ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and
344 sockets*

345 ISO 5359:2014+AMD1:2017, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for
346 use with medical gases*

347 ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

348 ISO 7396-1:2016+AMD1:2017, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed
349 medical gases and vacuum*

350 ISO 9360-1:2000, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for
351 humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml*

352 ISO 9360-2:2001, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for
353 humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having
354 minimum tidal volumes of 250 ml*

355 ISO 10524-1:2018, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and
356 pressure regulators with flow-metering devices*

357 ISO 10524-3:2019, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated
358 with cylinder valves (VIPRS)*

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

362 ISO 17664-1:2021, *Processing of health care products — Information to be provided by the medical device
363 manufacturer for the processing of medical devices*

364 ISO 17664-2:2021, *Processing of health care products — Information to be provided by the medical device
365 manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

- 366 ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications —*
367 *Part 1: Evaluation and testing within a risk management process*
- 368 ISO 19223:2019, *Lung ventilators and related equipment — Vocabulary and semantics*
- 369 ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*
- 370 ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use: — Part 1: Salt test method*
371 *to assess filtration performance*
- 372 ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use: — Part 2: Non-filtration*
373 *aspects*
- 374 ISO 80369-1:2021, *Small-bore connectors for liquids and gases in healthcare applications — Part 1:*
375 *General requirements*
- 376 ISO 80601-2-55:2018, *Medical electrical equipment — Part 2-55: Particular requirements for the basic*
377 *safety and essential performance of respiratory gas monitors*
- 378 ISO 80601-2-74:2021, *Medical electrical equipment — Part 2-74: Particular requirements for the basic*
379 *safety and essential performance of respiratory humidifying equipment*
- 380 IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General*
381 *requirements for basic safety and essential performance*
- 382 IEC 60601-1-12:2014+AMD1:2020, *Medical Electrical Equipment — Part 1-12: General requirements for*
383 *basic safety and essential performance — Collateral Standard: Requirements for medical electrical*
384 *equipment and medical electrical systems used in the emergency medical services environment*
- 385 IEC 62366-1:2015+AMD1:2020, *Medical devices — Part 1: Application of usability engineering to medical*
386 *devices*
- 387 IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic*
388 *resonance environment*
- 389 IEC Guide 115:2021, *Application of uncertainty of measurement to conformity assessment activities in the*
390 *electrotechnical sector*

391 **201.3 Terms and definitions**

392 For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+AMD1:2012,
393 and the following apply.

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

- 395 — ISO Online browsing platform: available at <https://www.iso.org/obp>
- 396 — IEC Electropedia: available at <http://www.electropedia.org/>

397 NOTE An alphabetized index of defined terms is found in Annex DD.

398 **201.3.201**

399 **accompanying information**

400 information accompanying or *marked* on a medical device or *accessory* for the user or those accountable
401 for the installation, use, *processing*, maintenance, decommissioning and disposal of the medical device or
402 *accessory*, particularly regarding safe use

403 Note 1 to entry: The *accompanying information* shall be regarded as part of the medical device or *accessory*.