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Medical electrical equipment —

Part 2-84:

Particular requirements for basic safety and essential performance of emergency and transport ventilators

Appareils électromédicaux —

Partie 2-84: Titre manque

ICS: 11.040.10

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Full standard:
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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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78 **Foreword**

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

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

92 Attention is drawn to the possibility that some of the elements of this document may be
93 the subject of patent rights. ISO shall not be held responsible for identifying any or all such
94 patent rights. Details of any patent rights identified during the development of the
95 document will be in the Introduction and/or on the ISO list of patent declarations received.
96 www.iso.org/patents

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

99 Document ISO 80601-2-84 has been prepared by Technical Committee ISO/TC 121,
100 *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related*
101 *equipment* and IEC Technical Committee 62: *Electrical equipment in medical practice*,
102 Subcommittee 62D: *Electric equipment*.

103 This first edition cancels and replaces the first edition of ISO 10651-3 (1997) ^[1]¹. This
104 document constitutes a major technical revision and includes an alignment with the third
105 edition of IEC 60601-1, the second edition of IEC 60601-1-8, IEC 60601-1-12 as well as the
106 fourth edition of IEC 60601-1-2. This document is also intended to cancel and replace
107 EN 794-3 ^[2].

108 This document includes the following significant technical changes with respect to
109 ISO 10651-3:

- 110 – extending the scope to include the EMS VENTILATOR and its ACCESSORIES, where the
111 characteristics of those ACCESSORIES can affect the BASIC SAFETY or ESSENTIAL
112 PERFORMANCE of the VENTILATOR FOR THE EMERGENCY MEDICAL SERVICES ENVIRONMENT, and
113 thus not only the VENTILATOR FOR THE EMERGENCY MEDICAL SERVICES ENVIRONMENT itself;
- 114 – identification of ESSENTIAL PERFORMANCE for VENTILATOR FOR THE EMERGENCY MEDICAL
115 SERVICES ENVIRONMENT and its ACCESSORIES;
- 116 – modifying the tests for environmental conditions (via IEC 60601-1-12);
- 117 – modifying the tests for ALARM CONDITIONS (via IEC 60601-1-8); and
- 118 – modifying the tests for electromagnetic disturbances (via IEC 60601-1-2).

¹ Numbers in square brackets refer to the Bibliography.

- 119 This document includes the following significant technical additions:
- 120 – tests for ventilation performance;
 - 121 – test for instability from unwanted lateral movement;
 - 122 – test for audible acoustic energy;
 - 123 – tests for mechanical strength (via IEC 60601-1-12);
 - 124 – tests for environmental conditions (via IEC 60601-1-12);
 - 125 – tests for ALARM CONDITIONS (via IEC 60601-1-8);
 - 126 – tests for electromagnetic disturbances (via IEC 60601-1-2);
 - 127 – inclusion of the usability engineering process (via IEC 60601-1-6);
 - 128 – new symbols;
 - 129 – requirements for VENTILATOR FOR THE EMERGENCY MEDICAL SERVICES ENVIRONMENT as a
 - 130 component of an ME SYSTEM;
 - 131 – tests for ENCLOSURE integrity (water ingress via IEC 60601-1-12);
 - 132 – tests for CLEANING and DISINFECTION; and
 - 133 – consideration of contamination of the breathing gas delivered to the PATIENT from the
 - 134 GAS PATHWAYS.
- 135

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136 Introduction

137 This document is a major update of the requirements for a VENTILATOR FOR THE EMERGENCY
 138 MEDICAL SERVICES ENVIRONMENT. It includes harmonizing the requirements from
 139 ISO 10651-3, which it replaces, with the third edition of IEC 60601-1 including its first
 140 amendment, the fourth edition of IEC 60601-1-2, the second edition of IEC 60601-1-6
 141 including its first amendment, the third edition of IEC 60601-1-8 including its first
 142 amendment and the first edition of IEC 60601-1-12.

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. Normative
 148 text of tables is also in a smaller type
- 149 – TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR DOCUMENT OR AS
 150 NOTED: SMALL CAPITALS

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

- 152 – “clause” means one of the five numbered divisions within the table of contents,
 153 inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);
- 154 – “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are
 155 all subclauses of Clause 201).

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 document are by
 158 number only.

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

161 The verbal forms used in this document conform to usage described in ISO/IEC Directives,
 162 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
 164 compliance with this document;
- 165 – “should” means that compliance with a requirement or a test is recommended but is
 166 not mandatory for compliance with this document;
- 167 – “may” is used to describe permission (e.g. a permissible way to achieve compliance
 168 with a requirement or test);
- 169 – “can” is used to describe a possibility or capability; and
- 170 – “must” is used express an external constraint.

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

173 The attention of users of this standard are drawn to the fact that equipment manufacturers
 174 and testing organizations may need a transitional period following publication of a new,

175 amended or revised ISO or IEC publication in which to make products in accordance with
176 the new requirements and to equip themselves for conducting new or revised tests. It is
177 the recommendation of the committees that the content of this publication be adopted for
178 implementation nationally not earlier than 3 years from the date of publication for
179 equipment newly designed and not earlier than 5 years from the date of publication for
180 equipment already in production.

181

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182 **Medical Electrical Equipment — Part 2-84: Particular**
 183 **requirements for basic safety and essential performance**
 184 **of ventilators for the emergency medical services**
 185 **environment**

186 **201.1 Scope, object and related standards**

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

188 **201.1.1 Scope**

189 *Replacement:*

190 This document applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of an EMS VENTILATOR
 191 in combination with its ACCESSORIES, hereafter also referred to as ME EQUIPMENT, intended:

- 192 — for PATIENTS who need differing levels of support from artificial ventilation including
 193 for VENTILATOR-DEPENDENT PATIENTS;
- 194 — for use in the EMS ENVIRONMENT; and
- 195 — for invasive or non-invasive ventilation.

196 NOTE 1 An EMS VENTILATOR can also be used for transport within a PROFESSIONAL HEALTHCARE FACILITIES.

197 This document is also applicable to those ACCESSORIES intended by their MANUFACTURER to
 198 be connected to a BREATHING SYSTEM of an EMS VENTILATOR, or to an EMS VENTILATOR, where
 199 the characteristics of those ACCESSORIES can affect the BASIC SAFETY or ESSENTIAL
 200 PERFORMANCE of the EMS VENTILATOR.

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

205 HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS
 206 within the scope of this document are not covered by specific requirements in this
 207 document except in IEC 60601-1:2005, 7.2.13 and 8.4.1.

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

209 This part of ISO 80601 does not specify the requirements for

- 210 — VENTILATORS or ACCESSORIES intended for VENTILATOR-DEPENDENT PATIENTS in critical care
 211 applications, which are given in ISO 80601-2-12 [3].
- 212 — VENTILATORS or ACCESSORIES intended for VENTILATOR-DEPENDENT PATIENTS in the HOME
 213 HEALTHCARE ENVIRONMENT, which are given in ISO 80601-2-72 [4].
- 214 — VENTILATORS or ACCESSORIES intended for anaesthetic applications, which are given in
 215 ISO 80601-2-13 [5].
- 216 — VENTILATORS or ACCESSORIES intended for ventilatory support equipment (intended only to
 217 augment the ventilation of spontaneously breathing PATIENTS), which are given in
 218 ISO 80601-2-79 [6] and ISO 80601-2-80 [7].

- 219 — obstructive sleep apnoea therapy ME EQUIPMENT, which are given in ISO 80601-2-70 ^[8].
- 220 — OPERATOR-powered resuscitators, which are given in ISO 10651-4 ^[9].
- 221 — gas-powered emergency resuscitators, which are given in ISO 10651-5 ^[10].
- 222 — continuous positive AIRWAY PRESSURE (CPAP) ME EQUIPMENT.
- 223 — high-frequency jet VENTILATORS (HFJVs).
- 224 — high-frequency oscillatory VENTILATORS (HFOVs) ^[11].
- 225 — cuirass or “iron-lung” VENTILATORS.

226 This part of ISO 80601 is a particular **standard** in the IEC 60601-1 and ISO/IEC 80601 series of
227 documents.

228 **201.1.2 Object**

229 *Replacement:*

230 The object of this particular document is to establish particular BASIC SAFETY and ESSENTIAL
231 PERFORMANCE requirements for an EMS VENTILATOR, as defined in 201.3.205, and its
232 ACCESSORIES.

233 NOTE ACCESSORIES are included because the combination of the EMS VENTILATOR and the ACCESSORIES needs
234 to have acceptable RISK. ACCESSORIES can have a significant impact on the BASIC SAFETY or ESSENTIAL
235 PERFORMANCE of an EMS VENTILATOR.

236 **201.1.3 Collateral standards**

237 *Amendment (add at the end of the subclause):*

238 This document refers to those applicable collateral standards that are listed in Clause 2 of
239 the general standard² and Clause 201.2 of this document.

240 IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8 and IEC 60601-1-12 apply as modified in
241 Clauses 202, 206, 208 and 212 respectively. IEC 60601-1-3 ^[12] and IEC 60601-1-11 ^[13] do
242 not apply. All other published collateral standards in the IEC 60601-1 series apply as
243 published.

244 **201.1.4 Particular standards**

245 *Replacement:*

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

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

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

² The general standard is IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

254 The numbering of clauses and subclauses of this particular document corresponds to those
 255 of the general standard with the prefix “201” (e.g. 201.1 in this document addresses the
 256 content of Clause 1 of the general standard) or applicable collateral standard with the
 257 prefix “2xx” where xx is the final digits of the collateral standard document number (e.g.
 258 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral
 259 standard, 208.4 in this document addresses the content of Clause 4 of the IEC 60601-1-8
 260 collateral standard, etc.). The changes to the text of the general standard are specified by
 261 the use of the following words:

262 “Replacement” means that the clause or subclause of IEC 60601-1:2005 or the applicable
 263 collateral standard is replaced completely by the text of this particular document.

264 “Addition” means that the text of this document is additional to the requirements of
 265 IEC 60601-1:2005 or the applicable collateral standard.

266 “Amendment” means that the clause or subclause of IEC 60601-1:2005 or the applicable
 267 collateral standard is amended as indicated by the text of this document.

268 Subclauses, figures or tables that are additional to those of the general standard are
 269 numbered starting from 201.101. However, due to the fact that definitions in the general
 270 standard are numbered 3.1 through 3.147, additional definitions in this document are
 271 numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and
 272 additional items aa), bb), etc.

273 Subclauses or figures that are additional to those of a collateral standard are numbered
 274 starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for
 275 IEC 60601-1-2, 208 for IEC 60601-1-8, etc.

276 The term “this document” is used to make reference to the general standard, any
 277 applicable collateral standards and this particular document taken together.

278 Where there is no corresponding clause or subclause in this document, the clause or
 279 subclause of IEC 60601-1:2005 or the applicable collateral standard, although possibly not
 280 relevant, applies without modification; where it is intended that any part of IEC 60601-
 281 1:2005 or the applicable collateral standard, although possibly relevant, is not to be
 282 applied, a statement to that effect is given in this particular document.

283 201.2 Normative references

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

288 NOTE 1 The way in which these referenced documents are cited in normative requirements determines
 289 the extent (in whole or in part) to which they apply.

290 NOTE 2 Informative references are listed in the Bibliography.

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

292 *Replacement:*

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

294 ISO 7010:2011+AMD1:2012+AMD2:2012+AMD3:2012+AMD4:2013+AMD5:2014
 295 +AMD6:2014+AMD7:2016, *Graphical symbols — Safety colours and safety signs —*
 296 *Registered safety signs*

- 297 ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels,*
298 *labelling and information to be supplied — Part 1: General requirements*
- 299 ISO 19054:2005+AMD1:2016, *Rail systems for supporting medical equipment*
- 300 IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for*
301 *basic safety and essential performance — Collateral standard: Electromagnetic*
302 *disturbances — Requirements and tests*
- 303 IEC 60601-1-6:2010+AMD1:2013, *Medical electrical equipment — Part 1-6: General*
304 *requirements for basic safety and essential performance — Collateral standard: Usability*
- 305 IEC 60601-1-8:2006+AMD1:2012, *Medical electrical equipment — Part 1-8: General*
306 *requirements for basic safety and essential performance — Collateral standard: General*
307 *requirements, tests and guidance for alarm systems in medical electrical equipment and*
308 *medical electrical systems*
- 309 IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*
- 310 IEC 62304:2006+AMD1:2015, *Medical device software — Software life cycle processes*
- 311 *Addition:*
- 312 ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content*
- 313 ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels*
314 *of noise sources using sound pressure — Engineering methods for an essentially free field*
315 *over a reflecting plane*
- 316 ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of*
317 *machinery and equipment*
- 318 ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1:*
319 *Cones and sockets*
- 320 ISO 5359:2014, *Anaesthetic and respiratory equipment -- Low-pressure hose assemblies for*
321 *use with medical gases*
- 322 ISO 5367:2014, *Anaesthetic and respiratory equipment -- Breathing sets and connectors*
- 323 ISO 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed*
324 *medical gases and vacuum*
- 325 ISO 9360-1:2000, *Anaesthetic and respiratory equipment — Heat and moisture exchangers*
326 *(HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum*
327 *tidal volumes of 250 ml*
- 328 ISO 9360-2:2001, *Anaesthetic and respiratory equipment — Heat and moisture exchangers*
329 *(HMEs) for humidifying respired gases in humans — Part 2: HMEs for use with*
330 *tracheostomized patients having minimum tidal volumes of 250 ml*
- 331 ISO 14937:2009, *Sterilization of health care products — General requirements for*
332 *characterization of a sterilizing agent and the development, validation and routine control*
333 *of a sterilization process for medical devices*
- 334 EN 15986:2011, *Symbols for medical devices containing phthalates*
- 335 ISO 17664:2017, *Processing of health care products -- Information to be provided by the*
336 *medical device manufacturer for the processing of medical devices*

- 337 ISO 18082:2014, *Anaesthetic and respiratory equipment -- Dimensions of non-*
 338 *interchangeable screw-threaded (NIST) low-pressure connectors for medical gases*
- 339 ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare*
 340 *applications-- Part 1: Evaluation and testing within a risk management process*
- 341 ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use: — Part 1:*
 342 *Salt test method to assess filtration performance*
- 343 ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use: — Part 2:*
 344 *Non-filtration aspects*
- 345 ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications -*
 346 *- Part 1: General requirements*
- 347 ISO 80601-2-55:— (Ed 2)³, *Medical electrical equipment — Part 2-55: Particular*
 348 *requirements for the basic safety and essential performance of respiratory gas monitors*
- 349 ISO 80601-2-74:2017, *Medical electrical equipment — Part 2-74: Particular requirements*
 350 *for the basic safety and essential performance of respiratory humidifying equipment*
- 351 IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment — Part 1: General*
 352 *requirements for basic safety and essential performance*
- 353 IEC 60601-1-12:2014, *Medical Electrical Equipment -- Part 1-12: General requirements for*
 354 *basic safety and essential performance - Collateral Standard: Requirements for medical*
 355 *electrical equipment and medical electrical systems used in the emergency medical services*
 356 *environment*
- 357 IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to*
 358 *medical devices*
- 359 IEC 62570:2014, *Standard practice for marking medical devices and other items for safety*
 360 *in the magnetic resonance environment*

361 **201.3 Terms and definitions**

362 For the purposes of this document, the terms and definitions given in ISO 4135:2001 ^[14],
 363 ISO 7010:2011, ISO 7396-1:2016, ISO 8836:2014 ^[15], ISO 9000:2015 ^[16],
 364 ISO 9360-1:2000, ISO 17510:2015 ^[17], ISO 17664:2017, IEC 60601-1:2005+AMD1:2012,
 365 IEC 60601-1-2:2014, IEC 60601-1-6:2010, IEC 60601-1-8:2006+AMD1:2012,
 366 IEC 62304:2006+AMD1:2015, IEC 62366-1:2015, ISO 80601-2-12:— ^[3],
 367 ISO 80601-2-55:— ⁴, ISO 80601-2-74:2017 and the following apply.

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

- 370 – IEC Electropedia: available at <http://www.electropedia.org/>
- 371 – ISO Online browsing platform: available at <http://www.iso.org/obp>

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

³ Under preparation. Stage at the time of publication: ISO FDIS 80601-2-55:2017.

⁴ Under preparation. Stage at the time of publication: ISO FDIS 80601-2-55:2017.