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### Medical electrical equipment —

Part 2-87:

### Particular requirements for basic safety and essential performance of high-frequency ventilators

ICS: 11.040.10

**ITEH STANDARD PREVIEW**  
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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](http://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](http://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 This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and*  
100 *respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and  
101 Technical Committee IEC/TC62, *Electrical equipment in medical practice*, Subcommittee  
102 62D: *Electric equipment*.

103 This is the first edition of ISO 80601-2-87.

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

105

106 **Introduction**

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

- 108 – Requirements and definitions: roman type
- 109 – *Instructions, test specifications and terms defined in Clause 3 of the general standard, in*  
110 *this document or as noted: italic type*
- 111 – Informative material appearing outside of tables, such as notes, examples and references: in  
112 smaller type. Normative text of tables is also in a smaller type

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

- 114 – “clause” means one of the four numbered divisions within the table of contents,  
115 inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);
- 116 – “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are  
117 all subclauses of Clause 201).

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

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

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

- 124 – “shall” means that conformance with a requirement or a test is mandatory for  
125 conformance with this document;
- 126 – “should” means that conformance with a requirement or a test is recommended but is  
127 not mandatory for conformance with this document;
- 128 – “may” is used to describe permission (e.g. a permissible way to achieve conformance  
129 with a requirement or test);
- 130 – “can” is used to describe a possibility or capability; and
- 131 – “must” is used to express an external constraint.

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

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

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

136 **Medical Electrical Equipment — Part 2-87: Particular**  
 137 **requirements for basic safety and essential performance**  
 138 **of high-frequency critical care ventilators**

139 **201.1 Scope, object and related standards**

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

141 **201.1.1 \* Scope**

142 *Replacement:*

143 This document applies to the *basic safety* and *essential performance* of a *high-frequency*  
 144 *ventilator (HFV)* in combination with its *accessories*, hereafter referred to as *ME equipment*:

145 — intended for use in an environment that provides specialized care for *patients* whose  
 146 conditions can be life-threatening and who can require comprehensive care and  
 147 constant monitoring in a *professional healthcare facility*;

148 NOTE 1 For the purposes of this document, such an environment is referred to as a critical care  
 149 environment. *High-frequency ventilators* for this environment are considered life-sustaining.

150 NOTE 2 For the purposes of this document, such a *high-frequency ventilator* can provide transport  
 151 within a *professional healthcare facility* (i.e. be a *transit-operable ventilator*).

152 NOTE 3 A *high-frequency ventilator* intended for use in transport within a *professional healthcare*  
 153 *facility* is not considered as an *ventilator* intended for the *emergency medical services environment*.

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

155 — intended for those *patients* who need differing levels of support from *artificial*  
 156 *ventilation* including *ventilator-dependent patients*; and

157 — capable of providing more than 150 *inflations/min*.

158 There are three principal designations of *HFV*:

159 — high frequency percussive *ventilation* (HFPV, with a typical *HFV frequency* of (60 to  
 160 1 000) *HFV inflations/min*);

161 — high frequency jet *ventilation* (HFJV, with a typical *HFV frequency* of (100 to 1 500)  
 162 *HFV inflations/min*); and

163 — high frequency oscillatory *ventilation* (HFOV, with a typical *HFV frequency* of (180 to  
 164 1200) *HFV inflations/min* and typically having an active *expiratory phase*).

165 Additionally, *HFV* designations can be combined together or with *ventilation* at *rates* less  
 166 than 150 *inflations/min*.

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

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167 \* A *high-frequency ventilator* is not considered to utilize *physiologic closed loop-control*  
168 *system* unless it uses a *physiological patient* variable to adjust the *ventilation* therapy  
169 settings.

170 This document is also applicable to those *accessories* intended by their *manufacturer* to be  
171 connected to an *HFV breathing system*, or to a *high-frequency ventilator*, where the  
172 characteristics of those *accessories* can affect the *basic safety* or *essential performance* of  
173 the *high-frequency ventilator*.

174 If a clause or subclause is specifically intended to be applicable to *ME equipment* only, or  
175 to *ME systems* only, the title and content of that clause or subclause will say so. If that is  
176 not the case, the clause or subclause applies both to *ME equipment* and to *ME systems*, as  
177 relevant.

178 *Hazards* inherent in the intended physiological function of *ME equipment* or *ME systems*  
179 within the scope of this document are not covered by specific requirements in this  
180 document except in 7.2.13 and 8.4.1 of IEC 60601-1:2005.

181 NOTE 4 Additional information can be found in 4.2 of IEC 60601-1:2005+AMD1:2012.

182 This document is not applicable to *ME equipment* that is intended solely to augment the  
183 *ventilation* of spontaneously breathing *patients* within a *professional healthcare facility*.

184 This document does not specify the requirements for:

185 — *non-high-frequency ventilators* or *accessories* which provide conventional *ventilation*  
186 for use in critical care environments, which are given in ISO 80601-2-12;

187 NOTE 5 An *HFV* can incorporate conventional critical care *ventilator operational modes*, in which case  
188 ISO 80601-2-12 is applicable to those modes.

189 — *ventilators* or *accessories* intended for anaesthetic applications, which are given in  
190 ISO 80601-2-13 <sup>[3]</sup> <sup>2</sup>;

191 — *ventilators* or *accessories* intended for the *emergency medical services environment*,  
192 which are given in ISO 80601-2-84, the future replacement for ISO 10651-3 <sup>[4]</sup>;

193 NOTE 6 An *HFV* can incorporate *EMS ventilator* capability.

194 — *ventilators* or *accessories* intended for *ventilator-dependent patients* in the *home*  
195 *healthcare environment*, which are given in ISO 80601-2-72 <sup>[5]</sup>;

196 — *ventilators* or *accessories* intended for home-care ventilatory support devices, which  
197 are given in ISO 80601-2-79 <sup>[6]</sup> and ISO 80601-2-80 <sup>[7]</sup>, the replacements for  
198 ISO 10651-6 <sup>[8]</sup>;

199 — sleep apnoea breathing therapy *ME equipment*, which are given in ISO 80601-2-70 <sup>[9]</sup>;

200 — *continuous positive airway pressure (CPAP) ME equipment*;

201 — oxygen therapy constant flow *ME equipment*; and

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<sup>2</sup> Figures in square brackets refer to the Bibliography.



202 — cuirass or “iron-lung” *ventilation* equipment.

203 This document is a particular standard in the IEC 60601 and IEC/ISO 80601 series of  
204 documents.

### 205 **201.1.2 Object**

206 *Replacement:*

207 The object of this document is to establish particular *basic safety* and *essential performance*  
208 requirements for a *high-frequency ventilator*, as defined in 201.3.201, and its *accessories*.

209 NOTE 1 *Accessories* are included because the combination of the *high-frequency ventilator* and the  
210 *accessories* needs to be adequately safe. *Accessories* can have a significant impact on the *basic safety* or  
211 *essential performance* of a *high-frequency ventilator*.

212 NOTE 2 This document has been prepared to address the relevant *essential principles of safety and*  
213 *performance* of ISO 16142-1:2016 as indicated in Annex CC.

214 NOTE 3 This document has been prepared to address the relevant general safety and performance  
215 requirements of European regulation (EU) 2017/745 <sup>[10]</sup> as indicated in Annex DD.

### 216 **201.1.3 Collateral standards**

217 *Amendment (add after existing text):*

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

220 IEC 60601-1-2, IEC 60601-1-6 and IEC 60601-1-8 apply as modified in Clauses 202, 206  
221 and 208 respectively. IEC 60601-1-3 <sup>[11]</sup>, IEC 60601-1-9 <sup>[12]</sup>, IEC 60601-1-11 and  
222 IEC 60601-1-12 <sup>[13]</sup> do not apply. All other published collateral standards in the  
223 IEC 60601-1 series apply as published.

### 224 **201.1.4 Particular standards**

225 *Replacement:*

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

230 A requirement of a particular standard takes priority over IEC 60601-1:2005 or the  
231 collateral standards.

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

234 The numbering of clauses and subclauses of this document corresponds to those of the  
235 general standard with the prefix “201” (e.g. 201.1 in this document addresses the content  
236 of Clause 1 of the general standard) or applicable collateral standard with the prefix “2xx”  
237 where xx is the final digits of the collateral standard document number (e.g. 202.4 in this  
238 document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard,  
239 208.4 in this document addresses the content of Clause 4 of the IEC 60601-1-8 collateral  
240 standard, etc.). The changes to the text of the general standard are specified by the use of  
241 the following words:

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

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

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

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

253 Subclauses or figures that are additional to those of a collateral standard are numbered  
254 starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for  
255 IEC 60601-1-2, 203 for IEC 60601-1-3 <sup>[11]</sup>, etc.

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

258 Where there is no corresponding clause or subclause in this document, the clause or  
259 subclause of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard,  
260 although possibly not relevant, applies without modification, where it is intended that any  
261 part of IEC 60601-1:2005+AMD1:2012 or the applicable collateral standard, although  
262 possibly relevant, is not to be applied, a statement to that effect is given in this particular  
263 document.

### 264 **201.2 Normative references**

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

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

271 NOTE 2 Informative references are listed in the Bibliography.

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

273 *Replacement:*

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

275 ISO 7010:2011+AMD1:2012+AMD2:2012+AMD3:2012+AMD4:2013+AMD5:2014  
276 +AMD6:2014+AMD7:2016+AMD8:2017, *Graphical symbols — Safety colours and safety  
277 signs — Registered safety signs*

278 ISO 15223-1:2016, *Medical devices — Symbols to be used with medical device labels,  
279 labelling and information to be supplied — Part 1: General requirements*

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

- 283 IEC 60601-1-6:2010+AMD1:2013, *Medical electrical equipment — Part 1-6: General*  
 284 *requirements for basic safety and essential performance — Collateral standard: Usability*
- 285 IEC 60601-1-8:2006+AMD1:2012, *Medical electrical equipment — Part 1-8: General*  
 286 *requirements for basic safety and essential performance — Collateral standard: General*  
 287 *requirements, tests and guidance for alarm systems in medical electrical equipment and*  
 288 *medical electrical systems*
- 289 IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*
- 290 IEC 62304:2006+AMD1:2015, *Medical device software — Software life cycle processes*
- 291 *Addition:*
- 292 ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content*
- 293 ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels*  
 294 *of noise sources using sound pressure — Engineering methods for an essentially free field*  
 295 *over a reflecting plane*
- 296 ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of*  
 297 *machinery and equipment*
- 298 ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1:*  
 299 *Cones and sockets*
- 300 ISO 5359:2014, *Anaesthetic and respiratory equipment -- Low-pressure hose assemblies for*  
 301 *use with medical gases*
- 302 ISO 5367:2014, *Anaesthetic and respiratory equipment -- Breathing sets and connectors*
- 303 ISO 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed*  
 304 *medical gases and vacuum*
- 305 ISO 8836:2014, *Suction catheters for use in the respiratory tract*
- 306 ISO 9000:2015, *Quality management systems -- Fundamentals and vocabulary*
- 307 ISO 14937:2009, *Sterilization of health care products — General requirements for*  
 308 *characterization of a sterilizing agent and the development, validation and routine control*  
 309 *of a sterilization process for medical devices*
- 310 ISO 16142-1:2016, *Medical devices — Recognized essential principles of safety and*  
 311 *performance of medical devices — Part 1: General essential principles and additional specific*  
 312 *essential principles for all non-IVD medical devices and guidance on the selection of*  
 313 *standards*
- 314 ISO 17510:2015, *Medical devices -- Sleep apnoea breathing therapy -- Masks and application*  
 315 *accessories*
- 316 ISO 17664:2017, *Processing of health care products -- Information to be provided by the*  
 317 *medical device manufacturer for the processing of medical devices*
- 318 ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare*  
 319 *applications-- Part 1: Evaluation and testing within a risk management process*
- 320 ISO 19223:2019, *Lung ventilators and related equipment -- Vocabulary and semantics*

## ISO/DIS 80601-2-87:2020(E)

- 321 ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use: — Part 1:*  
322 *Salt test method to assess filtration performance*
- 323 ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use: — Part 2:*  
324 *Non-filtration aspects*
- 325 ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications -*  
326 *- Part 1: General requirements*
- 327 ISO 80601-2-12:—<sup>3</sup> (Ed 2), *Medical electrical equipment — Part 2-12: Particular*  
328 *requirements for the basic safety and essential performance of critical care ventilators*
- 329 ISO 80601-2-55:2018 (Ed 2), *Medical electrical equipment — Part 2-55: Particular*  
330 *requirements for the basic safety and essential performance of respiratory gas monitors*
- 331 ISO 80601-2-74:2017, *Medical electrical equipment — Part 2-74: Particular requirements*  
332 *for the basic safety and essential performance of respiratory humidifying equipment*
- 333 ISO 80601-2-84:—<sup>4</sup>, *Medical electrical equipment — Part 2-84: Particular requirements for*  
334 *basic safety and essential performance of emergency and transport ventilators*
- 335 IEC 60068-2-27:2008, *Environmental testing — Part 2-27: Tests — Test Ea and guidance:*  
336 *Shock*
- 337 IEC 60068-2-31:2008, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling*  
338 *shocks, primarily for equipment-type specimens*
- 339 IEC 60068-2-64:2008, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration,*  
340 *broadband random and guidance*
- 341 IEC 60529:1989+AMD1:1999+AMD2:2013, *Degrees of protection provided by enclosures*  
342 *(IP Code)*
- 343 IEC 60601-1:2005+AMD1:2012, *Medical electrical equipment — Part 1: General*  
344 *requirements for basic safety and essential performance*
- 345 IEC 60601-1-10:2007, *Medical electrical equipment - Part 1-10: General requirements for*  
346 *basic safety and essential performance - Collateral Standard: Requirements for the*  
347 *development of physiologic closed-loop controllers*
- 348 IEC 60601-1-11:2015, *Medical electrical equipment - Part 1-11: General requirements for*  
349 *basic safety and essential performance - Collateral Standard: Requirements for medical*  
350 *electrical equipment and medical electrical systems used in the home healthcare*  
351 *environment*
- 352 IEC 60601-1-12:2014, *Medical electrical equipment - Part 1-12: General requirements for*  
353 *basic safety and essential performance - Collateral Standard: Requirements for medical*  
354 *electrical equipment and medical electrical systems intended for use in the emergency*  
355 *medical services environment*
- 356 IEC 60601-2-2:2009, *Medical electrical equipment — Part 2-2: Particular requirements for*  
357 *the basic safety and essential performance of high frequency surgical equipment and high*  
358 *frequency surgical accessories*

<sup>3</sup> Under preparation. Stage at the time of publication: ISO FDIS 80601-2-12:2019.

<sup>4</sup> Under preparation. Stage at the time of publication: ISO FDIS 80601-2-84:2019.

359 IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to*  
360 *medical devices*

361 IEC 62570:2014, *Standard practice for marking medical devices and other items for safety*  
362 *in the magnetic resonance environment*

363 EN 15986:2011, *Symbols for medical devices containing phthalates*

### 364 **201.3 Terms and definitions**

365 For the purposes of this document, the terms and definitions given in ISO 7010:2011,  
366 ISO 7396-1:2016, ISO 8836:2014, ISO 9000:2015, ISO 16142-1:2016, ISO 17510:2015,  
367 ISO 17664:2017, ISO 18562-1:2017, ISO 19223:2019, ISO 23328-2:2002,  
368 IEC 60601-1:2005+AMD1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010,  
369 IEC 60601-1-8:2006+AMD1:2012, IEC 60601-1-10:2007, IEC 60601-1-11:2015,  
370 IEC 60601-1-12:2014, IEC 60601-2-2:2009, IEC 62304:2006+AMD1:2015,  
371 IEC 62366-1:2015, ISO 80601-2-12:—, ISO 80601-2-74:2017, ISO 80601-2-84:— and the  
372 following apply.

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

375 – IEC Electropedia: available at <http://www.electropedia.org/>

376 – ISO Online browsing platform: available at <http://www.iso.org/obp>

377 NOTE An alphabetized index of defined terms is found Annex EE.

#### 378 **201.3.201**

##### 379 ***high-frequency ventilator***

##### 380 ***HFV***

381 *ME equipment* intended to provide *ventilation* of the *lungs* of the *patient* when connected  
382 to the airway of the *patient* using a *rate* greater than 150 *inflations/min*

383 Note 1 to entry: Inflation rates are specified as per minute solely when differentiating from conventional-  
384 rate *ventilation*. All normative requirements regarding HFV are written using inflation rates per second.

#### 385 **201.3.202**

##### 386 ***HFV breathing system***

387 pathways through which gas flows to or from the *HFV* and to or from the *patient*

#### 388 **201.3.203**

##### 389 ***HFV inflation***

390 periodic *ventilator* action intended to increase the volume of gas in the *lungs*

#### 391 **201.3.204**

##### 392 ***HFV volume***

393 volume of gas delivered through the *patient-connection port* or at the distal outlet of the  
394 jet system during an *HFV inflation*

395 Note 1 to entry: The effective volume delivered to the *lung* can be significantly smaller than the *HFV volume*.  
396 The leakage of uncuffed tracheal tubes and even small changes in resistance or compliance of the  
397 respiratory system (e.g. by secretion in the airways, through the use of a different *HFV breathing system* or  
398 tracheal tube) can change the volume delivered to the *lung*.

399 Note 2 to entry: The achievable *HFV volume* depends characteristically on the *HFV frequency*. In general,  
400 lower *HFV frequencies* permit higher *HFV volumes*.