
Medicinska električna oprema - 2-12. del: Posebne zahteve za osnovno varnost in bistvene lastnosti ventilatorjev za intenzivno nego (ISO/DIS 80601-2-12:2021)

Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators (ISO/DIS 80601-2-12:2021)

Medizinische elektrische Geräte - Teil 2-12: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Beatmungsgeräten für die Intensivpflege (ISO/DIS 80601-2-12:2021)

Appareils électromédicaux - Partie 2-12: Exigences particulières relatives à la sécurité de base et aux performances essentielles des ventilateurs pulmonaires pour utilisation en soins intensifs (ISO/DIS 80601-2-12:2021)

Ta slovenski standard je istoveten z: prEN ISO 80601-2-12

ICS:

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|-----------|--|--|
| 11.040.10 | Anestezijska, respiratorna in reanimacijska oprema | Anaesthetic, respiratory and reanimation equipment |
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oSIST prEN ISO 80601-2-12:2021**en,fr,de**

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Part 2-12:

Particular requirements for basic safety and essential performance of critical care ventilators

Appareils électromédicaux —

Partie 2-12: Exigences particulières relatives à la sécurité de base et aux performances essentielles des ventilateurs pulmonaires pour utilisation en soins intensifs

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ISO/CEN PARALLEL PROCESSING



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91 **Foreword**

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

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

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

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

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

113 This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory*
 114 *equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care* and
 115 Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62D, *Electric*
 116 *equipment*, in collaboration with the European Committee for Standardization (CEN) Technical
 117 Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on
 118 technical cooperation between ISO and CEN (Vienna Agreement).

119 This third edition cancels and replaces the second edition (ISO 80601-2-12:2020), which has been
 120 technically revised. The main changes compared to the previous edition are as follows:

- 121 — alignment with IEC 60601-1:2005+AMD1:2012+AMD2:2020,
 122 IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014+AMD1:2020 and IEC 60601-
 123 1-6:2010+AMD1:2013+AMD2:2020.
- 124 — reformatted according to most recent Central Secretariat editing rules;
- 125 — added requirements for the display legibility for *operators* wearing personal protective equipment;
- 126 — added requirements for display during calibration of gas monitors;
- 127 — clarified *maximum limited pressure* requirements;
- 128 — clarified high *airway pressure alarm condition* requirements;
- 129 — added requirements for *ventilator system recovery*; and
- 130 — harmonization with ISO 20417, where appropriate.

- 131 A list of all parts in the ISO 80601 series and the IEC 80601 series can be found on the ISO website.
- 132 Any feedback or questions on this document should be directed to the user's national standards body. A
- 133 complete listing of these bodies can be found at www.iso.org/members.html.

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134 **Introduction**

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

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

138 — “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.12 are all
 139 subclauses of Clause 201).

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

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

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

145 — “shall” indicates a requirement;

146 — “should” indicates a recommendation;

147 — “may” indicates a permission;

148 — “can” is used to describe a possibility or capability.

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

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

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

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Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators

201.1 Scope, object and related standards

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

201.1.1 Scope

Replacement:

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

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

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

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

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

NOTE 3 A critical care *ventilator* intended for use in transport within a *professional healthcare facility* is not considered as an *emergency medical services environment ventilator*.

- intended to be operated by a *healthcare professional operator*; and

- intended for those *patients* who need differing levels of support from *artificial ventilation* including for *ventilator-dependent patients*.

A critical care *ventilator* is not considered to utilize a *physiologic closed-loop-control system* unless it uses a physiological *patient* variable to adjust the *ventilation* therapy settings.

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

NOTE 4 If a clause or subclause is specifically intended to be applicable to *ME equipment* only, or to *ME systems* only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to *ME equipment* and to *ME systems*, as relevant.

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

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186 NOTE 5 Additional information can be found in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 4.2.

187 This document is not applicable to *ME equipment* or *ME system* operating in a *ventilator-operational mode*
188 solely intended for *patients* who are not dependent on *artificial ventilation*.

189 NOTE 6 A critical care *ventilator*, when operating in such a *ventilator-operational mode*, is not considered life-
190 sustaining.

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

193 This document does not specify the requirements for:

194 — *ventilators* or *accessories* intended for anaesthetic applications, which are given in
195 ISO 80601-2-13^[19];

196 — *ventilators* or *accessories* intended for the *emergency medical services environment*, which are given
197 in ISO 80601-2-84^[24];

198 — *ventilators* or *accessories* intended for *ventilator-dependent patients* in the *home healthcare*
199 *environment*, which are given in ISO 80601-2-72^[21];

200 — *ventilators* or *accessories* intended for home-care ventilatory support devices, which are given in
201 ISO 80601-2-79^[22] and ISO 80601-2-80^[23];

202 — obstructive sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70^[20];

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

204 — high-frequency *ventilators*, which are given in ISO 80601-2-87^[25];

205 NOTE 7 A critical care *ventilator* can incorporate high-frequency jet or high-frequency oscillatory *ventilator-*
206 *operational modes*.

207 — respiratory high-flow therapy equipment, which are given in ISO 80601-2-90^[26];

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

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

210 201.1.2 Object

211 *Replacement:*

212 The object of this document is to establish *basic safety* and *essential performance* requirements for a
213 *ventilator* and its *accessories*.

214 *Accessories* are included because the combination of the *ventilator* and the *accessories* needs to be
215 adequately safe. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of a
216 *ventilator*.

217 NOTE 1 This document has been prepared to address the relevant *essential principles*^[39] and labelling^[40]
218 guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex CC.

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

221 NOTE 3 This document has been prepared to address the relevant general safety and performance requirements
222 of European regulation (EU) 2017/745 as indicated in Annex EE.

223 **201.1.3 Collateral standards**

224 *Amendment (add after existing text):*

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

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

228 IEC 60601-1-2:2014+AMD1:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 and
229 IEC 60601-1-8:2016+AMD1:2012+AMD2:2020 apply as modified in Clauses 202, 206 and 208
230 respectively. IEC 60601-1-3^[27], IEC 60601-1-9^[28], IEC 60601-1-11^[30] and IEC 60601-1-12^[31] do not
231 apply. All other published collateral standards in the IEC 60601-1 series apply as published.

232 **201.1.4 Particular standards**

233 *Replacement:*

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

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

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

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

247 “Replacement” means that the clause or subclause of IEC 60601-1:2005+AMD1:2012+AMD2:2020 or the
248 applicable collateral standard is replaced completely by the text of this document.

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

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

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

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

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

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

201.2 Normative references

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

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

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

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

Addition:

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

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

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

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

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

¹ Under preparation. Stage at the time of publication: ISO/FDIS 15223-1:2021.

- 285 ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors*
- 286 ISO 7396-1:2016+AMD1:2017, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed*
287 *medical gases and vacuum*
- 288 ISO 9360-1:2000, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for*
289 *humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml*
- 290 ISO 9360-2:2001, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for*
291 *humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having*
292 *minimum tidal volumes of 250 ml*
- 293 ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a*
294 *sterilizing agent and the development, validation and routine control of a sterilization process for medical*
295 *devices*
- 296 ISO 17664-1:—², *Processing of health care products — Information to be provided by the medical device*
297 *manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*
- 298 ISO 17664-2:2021, *Processing of health care products — Information to be provided by the medical device*
299 *manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*
- 300 ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications —*
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² Under preparation. Stage at the time of publication: ISO/FDIS 17664-1:2020.

³ Under preparation. Stage at the time of publication: ISO/FDIS 80601-2-74:2021.