

---

**Medicinska električna oprema - 2-90. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za respiratorno terapijo z velikim pretokom (ISO/DIS 80601-2-90:2020)**

Medical electrical equipment - Part 2-90: Particular requirements for basic safety and essential performance of ventilatory high-flow therapy equipment (ISO/DIS 80601-2-90:2020)

Medizinische elektrische Geräte - Teil 2-90: Besondere Festlegungen für die Sicherheit und die wesentlichen Leistungsmerkmale von Geräten für die Beatmungstherapie mit hohem Durchfluss (ISO/DIS 80601-2-90:2020)

<https://standards.iteh.ai/catalog/standards/sist/d8debfaa-2569-49be-a90d-4e0d07c16b27/osist-pr-en-iso-80601-2-90-2020>

Appareils électromédicaux - Partie 2-90: Exigences particulières pour la sécurité de base et les performances essentielles des équipements de thérapie respiratoire à haut débit (ISO/DIS 80601-2-90:2020)

**Ta slovenski standard je istoveten z: prEN ISO 80601-2-90**

**ICS:**

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
-----------	--	--

**oSIST prEN ISO 80601-2-90:2020**      **en,fr,de**

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[oSIST prEN ISO 80601-2-90:2020](https://standards.iteh.ai/catalog/standards/sist/d8debf8a-2569-49be-a90d-4e0d07c16b27/osist-pren-iso-80601-2-90-2020)

<https://standards.iteh.ai/catalog/standards/sist/d8debf8a-2569-49be-a90d-4e0d07c16b27/osist-pren-iso-80601-2-90-2020>

# DRAFT INTERNATIONAL STANDARD

## ISO/DIS 80601-2-90

ISO/TC 121/SC 3

Secretariat: ANSI

Voting begins on:  
2020-10-07

Voting terminates on:  
2020-12-30

---

---

### Medical electrical equipment —

Part 2-90:

### Particular requirements for basic safety and essential performance of ventilatory high-flow therapy equipment

ICS: 11.040.10

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[oSIST prEN ISO 80601-2-90:2020](https://standards.iteh.ai/catalog/standards/sist/d8debf8a-2569-49be-a90d-4e0d07c16b27/osist-pren-iso-80601-2-90-2020)

<https://standards.iteh.ai/catalog/standards/sist/d8debf8a-2569-49be-a90d-4e0d07c16b27/osist-pren-iso-80601-2-90-2020>

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

This document is circulated as received from the committee secretariat.

**ISO/CEN PARALLEL PROCESSING**



Reference number  
ISO/DIS 80601-2-90:2020(E)

© ISO 2020

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[oSIST prEN ISO 80601-2-90:2020](https://standards.iteh.ai/catalog/standards/sist/d8debf8a-2569-49be-a90d-4e0d07c16b27/osist-pren-iso-80601-2-90-2020)  
<https://standards.iteh.ai/catalog/standards/sist/d8debf8a-2569-49be-a90d-4e0d07c16b27/osist-pren-iso-80601-2-90-2020>



### **COPYRIGHT PROTECTED DOCUMENT**

© ISO 2020

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Fax: +41 22 749 09 47  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

1	<b>Contents</b>	
2	Contents.....	iii
3	Introduction.....	vi
4	201.1 Scope, object and related standards.....	1
5	201.2 Normative references.....	3
6	201.3 Terms and definitions.....	5
7	201.4 General requirements.....	9
8	201.5 General requirements for testing of <i>ME equipment</i> .....	11
9	201.6 Classification of <i>ME equipment</i> and <i>ME systems</i> .....	11
10	201.7 <i>ME equipment</i> identification, <i>marking</i> and documents.....	11
11	201.8 Protection against electrical <i>hazards</i> from <i>ME equipment</i> .....	18
12	201.9 Protection against <i>mechanical hazards</i> of <i>ME equipment</i> and <i>ME systems</i> .....	18
13	201.10 Protection against unwanted and excessive radiation <i>hazards</i> .....	20
14	201.11 Protection against excessive temperatures and other <i>hazards</i> .....	20
15	201.12 Accuracy of controls and instruments and protection against hazardous outputs.....	23
16	201.13 <i>Hazardous situations</i> and fault conditions for <i>ME equipment</i> .....	30
17	201.14 <i>Programmable electrical medical systems (PEMS)</i> .....	31
18	201.15 Construction of <i>ME equipment</i> .....	31
19	201.16 <i>ME systems</i> .....	32
20	201.17 Electromagnetic compatibility of <i>ME equipment</i> and <i>ME systems</i> .....	32
21	201.101 Gas connections.....	33
22	201.102 Requirements for the <i>breathing system</i> and <i>accessories</i> .....	35
23	201.103 * Indication of duration of operation.....	36
24	201.104 <i>Functional connection</i> .....	37
25	201.105 <i>Power supply cords</i> .....	37
26	201.106 <i>Respiratory high-flow therapy equipment</i> security.....	37
27	202 Electromagnetic disturbances — Requirements and tests.....	38
28	206 Usability.....	38
29	208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.....	40
31	211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.....	42
33	Annex C (informative) Guide to <i>marking</i> and labelling requirements for <i>ME equipment</i> and <i>ME systems</i> .....	43
35	Annex D (informative) <i>Symbols on marking</i> .....	49
36	Annex AA (informative) Particular guidance and rationale.....	50
37	Annex BB (informative) Data interface requirements.....	63

## ISO 80601-2-90:2020(E)

38	<b>Annex CC (informative) Reference to the IMDRF essential principles and labelling guidances ....</b>	<b>67</b>
39	<b>Annex DD (informative) Reference to the essential principles.....</b>	<b>70</b>
40	<b>Annex EE (informative) Reference to the general safety and performance requirements.....</b>	<b>73</b>
41	<b>Annex FF (informative) Terminology — Alphabetized index of defined terms.....</b>	<b>76</b>
42		
43	<b>Tables</b>	
44	<b>Table 201.101 — Distributed essential performance requirements.....</b>	<b>9</b>
45	<b>Table 201.102 — Examples of permissible combinations of temperature and</b>	
46	<b>relative humidity .....</b>	<b>20</b>
47	<b>Table 201.103 — STPD and BTPS conversion factor for altitude.....</b>	<b>25</b>
48	<b>Table 201.104 — Test conditions for oxygen concentration tests.....</b>	<b>27</b>
49	<b>Table 201.C.101 — Marking on the outside of respiratory high-flow therapy equipment,</b>	
50	<b>its parts or accessories .....</b>	<b>43</b>
51	<b>Table 201.C.102 — Accompanying documents, general.....</b>	<b>43</b>
52	<b>Table 201.C.103 — Instructions for use.....</b>	<b>44</b>
53	<b>Table 201.C.104 — Technical description .....</b>	<b>48</b>
54	<b>Table 201.D.2.101 — Additional symbols on marking.....</b>	<b>49</b>
55	<b>Table BB.101 — Parameters and units of measurement.....</b>	<b>64</b>
56	<b>Table BB.102 — Equipment Identification .....</b>	<b>64</b>
57	<b>Table BB.103 — Usage monitoring.....</b>	<b>65</b>
58	<b>Table BB.104 — Equipment settings.....</b>	<b>65</b>
59	<b>Table BB.105 — Therapy monitoring.....</b>	<b>65</b>
60	<b>Table BB.106 — Respiratory high-flow therapy equipment alarm limits.....</b>	<b>66</b>
61	<b>Table BB.107 — Event information.....</b>	<b>66</b>
62	<b>Table BB.108 — Service monitoring .....</b>	<b>66</b>
63	<b>Table CC.1 — Correspondence between this document and the essential principles .....</b>	<b>67</b>
64	<b>Table CC.2 — Correspondence between this document and the labelling principles.....</b>	<b>69</b>
65	<b>Table DD.1 — Correspondence between this document and the essential principles .....</b>	<b>70</b>
66	<b>Table EE.1 — Correspondence between this document and the general safety and</b>	
67	<b>performance requirements.....</b>	<b>73</b>
68		
69		

## 70 Foreword

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

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

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

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

87 For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions  
88 related to conformity assessment, as well as information about ISO's adherence to the World Trade  
89 Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL:  
90 [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

91 This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*,  
92 Subcommittee SC 3, *Lung ventilators and related equipment*, and Technical Committee IEC/TC 62, *Electrical*  
93 *equipment in medical practice*, Subcommittee SC D, *Electrical equipment*. The draft was circulated for voting to  
94 the national bodies of both ISO and IEC.

95 This is the first edition of ISO 80601-2-90.

96

## ISO 80601-2-90:2020(E)

97 **Introduction**

98 *Respiratory high-flow therapy equipment* has been used successfully for years with neonatal *patients*. In recent  
 99 years there is more information about treating adults with *respiratory high-flow therapy equipment* when it is  
 100 used as an intermediate therapy to improve oxygenation in adult critical care *patients*, respiratory care units  
 101 and for palliative care. The use of *respiratory high-flow therapy equipment* continues to increase as it is easily  
 102 set up and is well tolerated by *patients*.

103 Since the outbreak of COVID-19 in China in January of 2020, its spread has been rapid and fierce. In hospitals  
 104 across the world, all kinds of *respiratory high-flow therapy equipment* have been widely used. More and more  
 105 new *manufacturers* of *respiratory high-flow therapy equipment* have rapidly emerged. Neither international nor  
 106 national standards are available for *respiratory high-flow therapy equipment*. With the spread of the epidemic  
 107 globally, the demand for this document is clear and very urgent.

108 The first *respiratory high-flow therapy equipment* was constructed by the connection of a *humidifier*, air/oxygen  
 109 mixer/blender, breathing tube and cannula. Based on the improvement in technical integration in recent years,  
 110 there are several technical routes for *respiratory high-flow therapy equipment* on the market. *Respiratory high-*  
 111 *flow therapy equipment* is not fully covered by the existing standards for *humidifiers*, gas mixers for medical use  
 112 or ventilators.

113 This document addresses the *basic safety* and *essential performance* requirements of *respiratory high-flow*  
 114 *therapy equipment*, including *risks* related to oxygen (e.g., fires, incorrect oxygen concentration, incorrect flow  
 115 delivery, etc.).

116 Specifically, the following *risks* and related requirements were considered in the development of this document.

- 117 — The air entering the *gas intake port* by the *respiratory high-flow therapy equipment* might be contaminated.  
 118 What measures are needed to avoid or reduce the contamination of the *gas pathways*.
- 119 — The input oxygen source pressure might be unstable.
- 120 — When the pressure of the oxygen source is insufficient, is there an additional gas source, such as adding an  
 121 additional oxygen input to maintain the delivered oxygen concentration?
- 122 — When the oxygen concentration of the *respiratory high-flow therapy equipment* does not reach the set value,  
 123 does the *respiratory high-flow therapy equipment* need to generate an *alarm condition*?
- 124 — Is the *respiratory high-flow therapy equipment* easy to install and adjust by *operators* wearing multiple  
 125 layers of protective clothing and gloves?
- 126 — Are the *markings* and displays of the *respiratory high-flow therapy equipment* clear enough for *operators*  
 127 whose vision is blurred due to aerosol on their goggles?
- 128 — To reduce unnecessary *risk* of infection and reduce the burden on the *operators*, *respiratory high-flow*  
 129 *therapy equipment* needs to remain stable, reducing the need for frequent *operator* adjustment.
- 130 — For the *respiratory high-flow therapy equipment* used in an infected area, after one *patient's* use, before the  
 131 next *patient's* use or before the *respiratory high-flow therapy equipment* is transferred to a non-infected  
 132 area, the *respiratory high-flow therapy equipment* needs *cleaning* and *disinfection*, including the surface of  
 133 the *enclosure* and the internal *gas pathways*.
- 134 — The risk of infectious exhaled gas.

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

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

- 137 — requirements and definitions: roman type;
- 138 — *test specifications*: italic type;
- 139 — informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative  
 140 text of tables is also in a smaller type.



- 141 — *terms defined in Clause 3 of the general standard<sup>1</sup>, in this document or as noted: small capitals.*
- 142 In referring to the structure of this document, the term
- 143 — “clause” means one of the five numbered divisions within the table of contents, inclusive of all subdivisions  
144 (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);
- 145 — “subclause” means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses of  
146 Clause 201).
- 147 References to clauses within this document are preceded by the term “Clause” followed by the clause number.  
148 References to subclauses within this particular document are by number only.
- 149 In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of  
150 the conditions is true.
- 151 The verbal forms used in this document conform to usage described in ISO/IEC Directives, Part 2. For the  
152 purposes of this document, the auxiliary verb:
- 153 — “shall” means that conformance with a requirement or a test is mandatory for conformance with this  
154 document;
- 155 — “should” means that conformance with a requirement or a test is recommended but is not mandatory for  
156 conformance with this document;
- 157 — “may” is used to describe permission (e.g. a permissible way to achieve conformance with a requirement or  
158 test);
- 159 — “can” is used to describe a possibility or capability;
- 160 — “must” is used express an external constraint.
- 161 An asterisk (\*) as the first character of a title or at the beginning of a paragraph or table title indicates that there  
162 is guidance or rationale related to that item in Annex AA.
- 163 The ISO and IEC 80601 family of documents are also parts of the IEC 60601 family of documents.

---

<sup>1</sup> The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.*

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[oSIST prEN ISO 80601-2-90:2020](https://standards.iteh.ai/catalog/standards/sist/d8debfaa-2569-49be-a90d-4e0d07c16b27/osist-pren-iso-80601-2-90-2020)

<https://standards.iteh.ai/catalog/standards/sist/d8debfaa-2569-49be-a90d-4e0d07c16b27/osist-pren-iso-80601-2-90-2020>

164 **Medical electrical equipment**

165 **Part 2-90:**  
 166 **Particular requirements for basic safety and essential**  
 167 **performance of respiratory high-flow therapy equipment**

168 **201.1 Scope, object and related standards**

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

170 **201.1.1 \* Scope**

171 *Replacement:*

172 This document applies to the *basic safety and essential performance of respiratory high-flow therapy equipment*,  
 173 as defined in 201.3.219, hereafter also referred to as *ME equipment*, in combination with its *accessories*:

- 174 — intended for use with *patients* who can breathe spontaneously; and
- 175 — intended for *patients* who would benefit from improved alveolar gas exchange; and who would benefit from  
 176 receiving high-flow humidified respiratory gases, including a *patient* whose upper airway is bypassed.

177 EXAMPLE 1 *Patients with Type 1 Respiratory Failure who exhibit a reduction in arterial blood oxygenation or*  
 178 *patients who would benefit from reduced work of breathing, as needed in Type 2 Respiratory Failure, where arterial*  
 179 *carbon dioxide is high.*

180 *Respiratory high-flow therapy equipment* can be intended for use in the *home healthcare environment* or  
 181 intended for use in professional healthcare facilities.

182 NOTE 1 In the *home healthcare environment*, the *supply mains* is often not reliable.

183 *Respiratory high-flow therapy equipment* can be *transit-operable*.

184 This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to the  
 185 *respiratory high-flow therapy equipment*, where the characteristics of those *accessories* can affect the *basic safety*  
 186 or *essential performance* of the *respiratory high-flow therapy equipment*.

187 EXAMPLE 2 Breathing sets, connectors, water traps, expiratory valve, *humidifier*, *breathing system filter*, external  
 188 electrical power source, *distributed alarm system*.

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

192 *Hazards* inherent in the intended physiological function of *ME equipment* or *ME systems* within the scope of this  
 193 document are not covered by specific requirements in this document except in IEC 60601-1:2005+AMD1:2012,  
 194 7.2.13 and 8.4.1.

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

196 This document does not specify the requirements for:

- 197 — *ventilators* or *accessories* for *ventilator-dependent patients* intended for critical care applications, which are  
 198 given in ISO 80601-2-12<sup>[15]</sup>;

## ISO 80601-2-90:2020(E)

- 199 — *ventilators* or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13<sup>[16]</sup>;
- 200 — *ventilators* or *accessories* intended for the emergency medical services environment, which are given in  
201 ISO 80601-2-84<sup>[21]2</sup>;
- 202 — *ventilators* or *accessories* intended for *ventilator-dependent patients* in the *home healthcare environment*,  
203 which are given in ISO 80601-2-72<sup>[18]</sup>;
- 204 — ventilatory support equipment or *accessories* intended for *patients* with ventilatory impairment, which are  
205 given in ISO 80601-2-79<sup>[19]</sup>;
- 206 — ventilatory support equipment or *accessories* intended for *patients* with ventilatory insufficiency, which  
207 are given in ISO 80601-2-80<sup>[20]</sup>;
- 208 — sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70<sup>[17]</sup>;
- 209 — continuous positive airway pressure (CPAP) *ME equipment*;
- 210 — high-frequency jet *ventilators* (HFJVs)<sup>[32]</sup>, which are given in ISO 80601-2-87<sup>[22]</sup>;
- 211 — gas mixers for medical use, which are given in ISO 11195<sup>[11]</sup>;
- 212 — high-frequency oscillatory *ventilators* (HFOVs), which are given in ISO 80601-2-87<sup>[22]</sup>; and
- 213 — cuirass or “iron-lung” ventilation equipment.

214 NOTE 3 *Respiratory high-flow therapy equipment* can be incorporated into any of the above equipment, in which case  
215 those standards would be applicable for those *ventilation-modes*.

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

### 217 201.1.2 Object

218 IEC 60601-1:2005, 1.2 is replaced by: [oSIST prEN ISO 80601-2-90:2020](https://standards.iteh.ai/catalog/standards/sist/d8debfaa-2569-49be-a90d-)  
<https://standards.iteh.ai/catalog/standards/sist/d8debfaa-2569-49be-a90d->

219 The object of this document is to establish particular *basic safety and essential performance* requirements for  
220 *respiratory high-flow therapy equipment*, as defined in 201.3.202, and its *accessories*.

221 NOTE 1 *Accessories* are included because the combination of the *respiratory high-flow therapy equipment* and the  
222 *accessories* needs to be adequately safe. *Accessories* can have a significant impact on the *basic safety* or *essential*  
223 *performance* of the *respiratory high-flow therapy equipment*.

224 NOTE 2 This document has been prepared to address the relevant International Medical Device Regulators Forum  
225 (IMDRF) *essential principles* and labelling guidances as indicated in Annex CC.

226 NOTE 3 This document has been prepared to address the relevant *essential principles of safety and performance* of  
227 ISO 16142-1:2016 as indicated in Annex DD.

228 NOTE 4 This document has been prepared to address the relevant general safety and performance requirements of European  
229 regulation (EU) 2017/745<sup>[27]</sup> as indicated in Annex EE.

### 230 201.1.3 Collateral standards

231 IEC 60601-1:2005+AMD1:2012+AMD2:2020, 1.3 applies with the following addition:

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

---

<sup>2</sup> Under preparation. Stage at the time of publication: ISO/DIS 80601-2-84:2017.

234 IEC 60601-1-2:2014+AMD1:2020+AMD2:2020, IEC 60601-1-6:2010+AMD1:2013+AMD2:2020,  
 235 IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 and IEC 60601-1-11:2015+AMD1:2020 apply as modified in  
 236 Clauses 202, 206, 208 and 211 respectively. IEC 60601-1-3<sup>[23]</sup> does not apply. All other published collateral  
 237 standards in the IEC 60601-1 series apply as published.

#### 238 **201.1.4 Particular standards**

239 IEC 60601-1:2005, 1.4 is replaced by:

240 In the IEC 60601 series, particular standards define *basic safety* and *essential performance* requirements, and  
 241 may modify, replace or delete requirements contained in the general standard, including the collateral  
 242 standards as appropriate for the particular *ME equipment* under consideration.

243 A requirement of a particular standard takes priority over the general standard.

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

246 The numbering of clauses and subclauses of this document corresponds to that of the general standard with  
 247 the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or  
 248 applicable collateral standard with the prefix "2xx", where xx is the final digits of the collateral standard  
 249 document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral  
 250 standard, 211.10 in this document addresses the content of Clause 10 of the IEC 60601-1-11 collateral  
 251 standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

252 "Replacement" means that the clause or subclause of the general standard or applicable collateral standard is  
 253 replaced completely by the text of this document.

254 "Addition" means that the text of this document is additional to the requirements of the general standard or  
 255 applicable collateral standard.

256 "Amendment" means that the clause or subclause of the general standard or applicable collateral standard is  
 257 amended as indicated by the text of this document.

258 Subclauses, figures or tables that are additional to those of the general standard are numbered starting from  
 259 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147,  
 260 additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are  
 261 lettered AA, BB, etc., and additional items aa), bb), etc.

262 Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from  
 263 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

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

266 Where there is no corresponding clause or subclause in this particular document, the clause or subclause of the  
 267 general standard or applicable collateral standard, although possibly not relevant, applies without  
 268 modification; where it is intended that any part of the general standard or applicable collateral standard,  
 269 although possibly relevant, is not to be applied, a statement to that effect is given in this document.

#### 270 **201.2 Normative references**

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

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

276 NOTE 2 Informative references are listed in the Bibliography.

**ISO 80601-2-90:2020(E)**

- 277 IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 2, applies, except as follows:
- 278 *Replacement:*
- 279 IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*
- 280 *Addition:*
- 281 ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using*  
282 *sound pressure — Engineering methods for an essentially free field over a reflecting plane*
- 283 ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and equipment*
- 284 ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*
- 285 ISO 5359:2014, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical*  
286 *gases*
- 287 ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors*
- 288 ISO 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and*  
289 *vacuum*
- 290 ISO 16142-1:2016, *Medical devices — Recognized essential principles of safety and performance of medical*  
291 *devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical*  
292 *devices and guidance on the selection of standards*
- 293 ISO 17664:2017, *Processing of health care products — Information to be provided by the medical device*  
294 *manufacturer for the processing of medical devices*
- 295 ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1:*  
296 *Evaluation and testing within a risk management process*
- 297 ISO 19223:2019, *Lung ventilators and related equipment — Vocabulary and semantics*
- 298 ISO 20417:2020, *Medical devices — Information to be supplied by the manufacturer*
- 299 ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to*  
300 *assess filtration performance*
- 301 ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects*
- 302 ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General*  
303 *requirements*
- 304 ISO 80369-7:2020, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors*  
305 *for intravascular or hypodermic applications*
- 306 ISO 80601-2-55:2018, *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and*  
307 *essential performance of respiratory gas monitors*

308 ISO 80601-2-74:—<sup>3</sup>, *Medical electrical equipment — Part 2-74: Particular requirements for basic safety and*  
 309 *essential performance of respiratory humidifying equipment*

310 IEC 62366-1:2015+AMD1:2020, *Medical devices — Part 1: Application of usability engineering to medical*  
 311 *devices*

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

### 314 **201.3 Terms and definitions**

315 For the purposes of this document, the terms and definitions given in ISO 7396-1:2016, ISO 8836:2014,  
 316 ISO 16142-1:2016, ISO 17664:2017, ISO 18562-1:2017, ISO 19223:2019, ISO 20417:2020, ISO 23328-2:2002,  
 317 IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014,  
 318 IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020,  
 319 IEC 60601-1-11:2015, IEC 60601-1-12:2014, IEC 62366-1:2015 as indicated in Annex FF and the following  
 320 apply.

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

322 — IEC Electropedia: available at <http://www.electropedia.org/>

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

324 NOTE An alphabetized index of defined terms is found Annex FF.

325 IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 3 applies, except as follows:

326 *Addition:*

oSIST prEN ISO 80601-2-90:2020  
<https://standards.iteh.ai/catalog/standards/sist/d8debfaa-2569-49be-a90d-4e0d07c16b27/osist-pren-iso-80601-2-90-2020>

#### 327 **201.3.201**

##### 328 ***airway device***

329 device intended to provide a *gas pathway* to and from the *patient's* trachea

330 [SOURCE: ISO 4135:—<sup>[5]</sup>, 3.8.1.1]

#### 331 **201.3.202**

##### 332 ***airway pressure***

333 ***P<sub>aw</sub>***

334 pressure at the *patient-connection port*

335 [SOURCE: ISO 4135:—<sup>[5]</sup>, 3.1.4.39.1]

#### 336 **201.3.203**

##### 337 ***body temperature pressure, saturated***

338 ***BTPS***

339 ambient atmospheric pressure, at a temperature of 37 °C, and a relative humidity (201.3.220) of 100 %

340 [SOURCE: ISO 4135:—<sup>[5]</sup>, 3.1.1.7]

<sup>3</sup> Under preparation. Stage at the time of publication: ISO/DIS 80601-2-74:2020