

DRAFT INTERNATIONAL STANDARD

ISO/DIS 80601-2-70

ISO/TC 121/SC 3

Secretariat: ANSI

Voting begins on:
2019-09-27

Voting terminates on:
2019-12-20

Medical electrical equipment —

Part 2-70:

Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment

Appareils électromédicaux —

Partie 2-70: Exigences particulières pour la sécurité de base et les performances essentielles du matériel de traitement respiratoire de l'apnée du sommeil

ICS: 11.040.10

ITeH STANDARD PREVIEW
(standards.iteh.ai)
Full standard:
<https://standards.iteh.ai/catalog/standards/sist/79be123f-c3ec-475f-87e8-19ef223de22e/iso-dis-80601-2-70>

Member bodies are requested to consult relevant national interests in IEC/SC 62D before casting their ballot to the e-Balloting application.

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.

This document is circulated as received from the committee secretariat.

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.

ISO/CEN PARALLEL PROCESSING

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.



Reference number
ISO/DIS 80601-2-70:2019(E)

© ISO 2019

iTeh STANDARD PREVIEW
(standards.iteh.ai)
Full standard:
<https://standards.iteh.ai/catalog/standards/sist/79be123f-c3ec-475f-87e8-19ef223de22e/iso-dis-80601-2-70>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2019

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
Website: www.iso.org

Published in Switzerland

CONTENTS

1		
2	CONTENTS	3
3	FOREWORD	5
4	INTRODUCTION.....	7
5	201.1 Scope, object and related standards.....	9
6	201.2 Normative references.....	11
7	201.3 Terms and definitions	14
8	201.4 General requirements	16
9	201.5 General requirements for testing of ME equipment.....	17
10	201.6 Classification of <i>ME equipment</i> and <i>ME systems</i>	17
11	201.7 <i>ME equipment</i> identification, marking and documents.....	17
12	201.8 Protection against electrical <i>hazards</i> from <i>ME equipment</i>	22
13	201.9 Protection against <i>mechanical hazards</i> of <i>ME equipment</i> and <i>ME systems</i>	23
14	201.10 Protection against unwanted and excessive radiation <i>hazards</i>	24
15	201.11 Protection against excessive temperatures and other <i>hazards</i>	25
16	201.12 Accuracy of controls and instruments and protection against hazardous	
17	outputs.....	27
18	201.13 <i>Hazardous situations</i> and fault conditions.....	34
19	201.14 <i>Programmable electrical medical systems (pems)</i>	34
20	201.15 Construction of <i>ME equipment</i>	34
21	201.16 <i>ME systems</i>	34
22	201.17 Electromagnetic compatibility of <i>ME equipment</i> and <i>ME systems</i>	34
23	201.101 <i>Breathing gas pathway</i> connectors.....	35
24	201.102 Requirements for the <i>breathing gas pathway</i> and <i>accessories</i>	36
25	201.103 <i>Functional connection</i>	37
26	201.104 Training.....	37
27	202 Electromagnetic disturbances – Requirements and tests.....	37
28	206 Usability	38
29	211 Requirements for medical electrical equipment and medical electrical systems	
30	used in the home healthcare environment.....	39
31	Annex C (informative) Guide to marking and labelling requirements for <i>ME equipment</i>	
32	and <i>ME systems</i>	40
33	Annex D (informative) Symbols on marking.....	44
34	Annex AA (informative) Particular guidance and rationale.....	45
35	Annex BB (informative) Data interface requirements	51
36	Annex CC (informative) Reference to the <i>essential principles</i>	55

37	Annex DD (informative) Reference to the general safety and performance requirements.....	58
38	Annex EE (informative) Terminology — alphabetized index of defined terms	62
39		
40	Figure 201.101 – Standard resistance.....	24
41	Figure 201.102 – Test set-up for static <i>airway pressure accuracy</i> in <i>normal use</i>	28
42	Figure 201.103 – Test set-up for dynamic <i>airway pressure accuracy</i> in <i>normal use</i>	30
43	Figure AA.1 – Relationship of the components of <i>sleep apnoea breathing therapy</i>	
44	<i>equipment</i> and <i>masks</i> and application <i>accessories</i> and the related standards	45
45		
46	Table 201.101 — Examples of permissible combinations of temperature and	
47	<i>relative humidity</i>	25
48	Table BB.101 – Parameters and units of measurement	52
49	Table BB.102 – Equipment identification.....	52
50	Table BB.103 – Session compliance monitoring	53
51	Table BB.104 – Session efficacy monitoring	53
52	Table BB.105 – Equipment therapy settings.....	54
53	Table BB.106 – Service monitoring.....	54
54	Table CC.1 — Correspondence between this document and the <i>essential principles</i>	55
55	Table DD.1 — Correspondence between this document and the general safety and	
56	performance requirements.....	58
57		

Full Standard Preview
https://standards.iteh.ai/catalog/standards/sist/79be123f-c3ec-475f-87ee-154223622c22/iso-dis-80601-2-70

58 INTERNATIONAL ORGANIZATION for STANDARDISATION

59

60

61

MEDICAL ELECTRICAL EQUIPMENT –

62

63

64

Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment

65

66

67

FOREWORD

68

69

70

71

72

73

74

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

75

76

77

78

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

79

80

81

82

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

83

84

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

85

86

87

88

ISO 80601-2-70 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*, and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

89

90

91

This second edition of ISO 80601-2-70 cancels and replaces the first edition of ISO 80601-2-70:2015. This edition of ISO 80601-2-70 constitutes a technical revision of ISO 80601-2-70:2015 and includes an alignment with the third edition of IEC 60601-1-6,

92 including its Amendment 2, the second edition of IEC 60601-1-8, including its Amendment 2, and
93 the second edition of IEC 60601-1-11.

94 The most significant changes are the following modifications:

- 95 – modified the *bi-level positive airway pressure* mode stability test method;
- 96 – modified the *biocompatibility* requirements
- 97 – added additional defined terms.

98

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Full standard:
<https://standards.iteh.ai/catalog/standards/sist/79be123f-c3ec-475f-87e8-19ef223de22e/iso-dis-80601-2-70>

99

INTRODUCTION

100 Sleep apnoea is a chronic medical condition where the *patient* repeatedly stops breathing during
 101 sleep. These episodes typically last 10 s or more and cause the oxygen levels in the blood to drop.
 102 It can be caused by obstruction of the upper airway (obstructive sleep apnoea or OSA) or by a
 103 failure of the brain to initiate a breath (central sleep apnoea).

104 NOTE *Sleep apnoea breathing therapy equipment* is intended for the treatment of obstructive sleep
 105 apnoea and not central sleep apnoea.

106 Sleep apnoea, if untreated, can cause and worsen other medical conditions, including
 107 hypertension, heart failure and diabetes ^[1].

108 Hypopnoea refers to a transient reduction of airflow, often while the *patient* is asleep, that lasts
 109 for at least 10 s, shallow breathing, or an abnormally low respiratory rate. Hypopnoea is less
 110 severe than apnoea. It also results in decreased air movement into the lungs and can cause oxygen
 111 levels in the blood to drop. It is commonly due to partial obstruction of the upper airway ^[2].

112 Awareness of the *risks* associated with sleep apnoea has grown significantly. As a result, the use
 113 of *sleep apnoea breathing therapy equipment* to treat both sleep apnoea and hypopnoea has
 114 become common.

115 This document covers *basic safety* and *essential performance* requirements needed to protect
 116 *patients* in the use of this *ME equipment*.

117 ISO 80601-2-70 covers *sleep apnoea breathing therapy equipment* for *patient* use. ISO 17510
 118 applies to *masks* and *accessories* used to connect *sleep apnoea breathing therapy equipment* to the
 119 *patient*. Figure AA.1 shows this diagrammatically.

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

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

- 122 – Requirements and definitions: roman type
- 123 – *Test specifications and terms defined in clause 3 of the general standard, in this document or as*
 124 *noted: italic type*
- 125 – Informative material appearing outside of tables, such as notes, examples and references: in smaller type.
 126 Normative text of tables is also in a smaller type

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

- 128 – “clause” means one of the four numbered divisions within the table of contents, inclusive of all
 129 subdivisions (e.g. Clause 201 includes subclauses 201.1, 201.2, etc.);
- 130 – “subclause” means a numbered subdivision of a clause (e.g. 201.101, 201.102 and 201.102.1
 131 are all subclauses of Clause 201).

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

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

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

- 138 – “shall” means that conformance with a requirement or a test is mandatory for conformance
139 with this document;
- 140 – “should” means that conformance with a requirement or a test is recommended but is not
141 mandatory for conformance with this document;
- 142 – “may” is used to describe a permission (e.g. a permissible way to achieve conformance with a
143 requirement or test);
- 144 – “can” is used to describe a possibility or capability; and
- 145 – “must” is used express an external constraint.

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

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

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

150 The ISO and IEC 80601 family of standards are also parts of the IEC 60601 family of standards.

151

iTeh STANDARD PREVIEW
(standards.iteh.ai)
Full standard:
<https://standards.iteh.ai/catalog/standard/iso-dis-80601-2-70-2019/c3ec-475f-87e8-19ef223de22e/iso-dis-80601-2-70-2019>

152 **MEDICAL ELECTRICAL EQUIPMENT –**

153

154 **Part 2-70: Particular requirements for the basic safety and**

155 **essential performance of sleep apnoea breathing therapy equipment**

156 **201.1 * Scope, object and related standards**

157 IEC 60601-1:2005+A1:2012¹, Clause 1 applies, except as follows:

158 **201.1.1 Scope**

159 IEC 60601-1:2005+Amendment 1:2012, 1.1 is replaced by:

160 This document is applicable to the *basic safety* and *essential performance* of *sleep apnoea breathing*

161 *therapy equipment*, hereafter referred to as *ME equipment*, intended to alleviate the symptoms of

162 *patients* who suffer from obstructive sleep apnoea by delivering a therapeutic breathing pressure

163 to the respiratory tract of the *patient*. *Sleep apnoea breathing therapy equipment* is intended for

164 use in the *home healthcare environment* by *lay operators* as well as in professional healthcare

165 institutions.

166 * *Sleep apnoea breathing therapy equipment* is not considered to utilize *physiologic closed-loop-*

167 *control system* unless it uses a physiological *patient* variable to adjust the therapy settings.

168 This document excludes *sleep apnoea breathing therapy equipment* intended for use with

169 neonates.

170 This document is applicable to *ME equipment* or an *ME system* intended for those *patients* who are

171 not dependent on mechanical ventilation.

172 This document is not applicable to *ME equipment* or an *ME system* intended for those *patients* who

173 are dependent on mechanical ventilation such as *patients* with central sleep apnoea.

174 This document is also applicable to those *accessories* intended by their *manufacturer* to be

175 connected to *sleep apnoea breathing therapy equipment*, where the characteristics of those

176 *accessories* can affect the *basic safety* or *essential performance* of the *sleep apnoea breathing*

177 *therapy equipment*.

178 *Masks* and application *accessories* intended for use during sleep apnoea breathing therapy are

179 additionally addressed by ISO 17510. Refer to Figure AA.1 for items covered further under this

180 document.

181 If a clause or subclause is specifically intended to be applicable to *ME equipment* only, or to

182 *ME systems* only, the title and content of that clause or subclause will say so. If that is not the case,

183 the clause or subclause applies both to *ME equipment* and to *ME systems*, as relevant.

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

184 *Hazards* inherent in the intended physiological function of *ME equipment* or *ME systems* within the
185 scope of this document are not covered by specific requirements in this document except in 7.2.13
186 and 8.4.1 of the general standard.

187 NOTE See also 4.2 of the General Standard.

188 This document is not applicable to high-frequency jet ventilators (HFJVs) or high-frequency
189 oscillatory ventilators (HFOVs) [1], which are given in ISO 80601-2-87 [3].

190 This document does not specify the requirements for ventilators or *accessories* intended for
191 critical care ventilators for ventilator-dependent *patients*, which are given in ISO 80601-2-12. [4]

192 This document does not specify the requirements for ventilators or *accessories* intended for
193 anaesthetic applications, which are given in ISO 80601-2-13. [5]

194 This document does not specify the requirements for ventilators or *accessories* intended for home
195 care ventilators for ventilator-dependent *patients*, which are given in ISO 80601-2-72. [6]

196 This document does not specify the requirements for ventilators or *accessories* intended for
197 emergency and transport, which are given in ISO 10651-3²⁾. [7]

198 This document does not specify the requirements for ventilators or *accessories* intended for home-
199 care ventilatory support, which are given in ISO 80601-2-79 [8] and ISO 80601-2-80.

200 This document is a particular standard in the IEC 60601-1 and ISO/IEC 80601 series of standards.

201 **201.1.2 Object**

202 IEC 60601-1:2005, 1.2 is replaced by:

203 The object of this document is to establish particular *basic safety* and *essential performance*
204 requirements for *sleep apnoea breathing therapy equipment* [as defined in 201.3.222].

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

207 NOTE 2 This document has been prepared to address the relevant general safety and performance
208 requirements of European regulation (EU) 2017/745 ^[19] as indicated in Annex DD.

209 **201.1.3 Collateral standards**

210 IEC 60601-1:2005+AMD 1:2012, 1.3 applies with the following addition:

211 IEC 60601-1-2:2014 and IEC 60601-1-6:2010+AMD1:2013+AMD2:— apply as modified in
212 Clauses 202 and 206 respectively. IEC 60601-1-3:2008+AMD 1:2013 does not apply. All other
213 published collateral standards in the IEC 60601-1 series apply as published.

214 **201.1.4 Particular standards**

215 *Replacement:*

216 In the IEC 60601 series, particular standards may modify, replace or delete requirements
217 contained in the general standard and collateral standards as appropriate for the particular

2) In the future, this standard is expected to be harmonized with the IEC 60601-1:2005 at which time it will be replaced by ISO 80601-2-xx.

218 *ME equipment* under consideration, and may add other *basic safety* and *essential performance*
 219 requirements.

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

221 For brevity, IEC 60601-1 is referred to in this document as the general standard. Collateral
 222 standards are referred to by their document number.

223 The numbering of clauses and subclauses of this document corresponds to that of the general
 224 standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of
 225 the general standard) or applicable collateral standard with the prefix "20x", where x is the final
 226 digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the
 227 content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the
 228 content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the
 229 general standard are specified by the use of the following words:

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

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

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

236 Subclauses, figures or tables which are additional to those of the general standard are numbered
 237 starting from 201.101. However, due to the fact that definitions in the general standard are
 238 numbered 3.1 through 3.139, additional definitions in this document are numbered beginning
 239 from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

240 Subclauses, figures or tables which are additional to those of a collateral standard are numbered
 241 starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2,
 242 203 for IEC 6060-1-3, etc.

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

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

250 **201.2 Normative references**

251 The following referenced documents, in whole or in part, are normatively referenced in this
 252 document and are indispensable for the application of this document. For dated references, only
 253 the edition cited applies. For undated references, the latest edition of the referenced document
 254 (including any amendments) applies.

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

257 NOTE 2 Informative references are listed in the Bibliography.

258 IEC 60601-1:2005+AMD 1:2012, Clause 2 applies, except as follows:

259 *Replacement:*

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

263 IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic*
264 *safety and essential performance – Collateral standard: Usability*
265 *+Amendment 1:2013³⁾*
266 *+Amendment 2:—⁴⁾*

267 IEC 60601-1-8:2006, *Medical electrical equipment - Part 1-8: General requirements for basic*
268 *safety and essential performance - Collateral Standard: General requirements, tests and guidance*
269 *for alarm systems in medical electrical equipment and medical electrical systems*
270 *+Amendment 1:2012⁵⁾*
271 *+Amendment 2:—⁶⁾*

272 IEC 60601-1-10:2007, *Medical electrical equipment -- Part 1-10: General requirements for basic*
273 *safety and essential performance -- Collateral standard: Requirements for the development of*
274 *physiologic closed-loop controllers*

275 IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic*
276 *safety and essential performance – Collateral Standard: Requirements for medical electrical*
277 *equipment and medical electrical systems used in the home healthcare environment*

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

279 ISO 7010:2011, *Graphical symbols -- Safety colours and safety signs -- Registered safety signs*
280 *+Amendment 1:2012*
281 *+Amendment 2:2012*
282 *+Amendment 3:2012*
283 *+Amendment 4:2013*
284 *+Amendment 5:2013*
285 *+Amendment 6:2014*

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

288 *Addition:*

³⁾ There exists a consolidated edition 3.1(2013) including IEC 60601-1-6:2010 and its Amendment 1:2013.

⁴⁾ Under preparation. Stage at the time of publication: IEC DAMD2 80601-1-6:2019.

⁵⁾ There exists a consolidated edition 2.1(2012) including IEC 60601-1-8:2006 and its Amendment 1:2012.

⁶⁾ Under preparation. Stage at the time of publication: IEC DAMD2 80601-1-8:2019.

- 289 ISO 3744:2010, *Acoustics -- Determination of sound power levels and sound energy levels of noise*
 290 *sources using sound pressure -- Engineering methods for an essentially free field over a reflecting*
 291 *plane*
- 292 ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*
- 293 ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and*
 294 *equipment*
- 295 ISO 5356-1:2015, *Anaesthetic and respiratory equipment — Conical connectors — Cones and*
 296 *sockets*
- 297 ISO 16142-1:2016, *Medical devices -- Recognized essential principles of safety and performance of*
 298 *medical devices -- Part 1: General essential principles and additional specific essential principles for*
 299 *all non-IVD medical devices and guidance on the selection of standards*
- 300 ISO 17664:2017, *Processing of health care products -- Information to be provided by the medical*
 301 *device manufacturer for the processing of medical devices*
- 302 ISO 17510:2015, *Sleep apnoea breathing therapy masks and application accessories*
- 303 ISO 19223:2019, *Lung ventilators and related equipment -- Vocabulary and semantics*
- 304 ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test*
 305 *method to assess filtration performance*
- 306 ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-*
 307 *filtration aspects*
- 308 ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications — Part*
 309 *1: General requirements*
- 310 ISO 80601-2-12:⁷, *Medical electrical equipment -- Part 2-12: Particular requirements for basic*
 311 *safety and essential performance of critical care ventilators*
- 312 ISO 80601-2-74:2017, *Medical electrical equipment -- Part 2-74: Particular requirements for basic*
 313 *safety and essential performance of respiratory humidifying equipment*
- 314 ISO 80601-2-80:2018, *Medical electrical equipment -- Part 2-80: Particular requirements for basic*
 315 *safety and essential performance of ventilatory support equipment for ventilatory insufficiency*
- 316 IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety*
 317 *and essential performance*
 318 *Amendment 1:2012*
- 319 IEC 62366-1:2015, *Medical devices – Application of usability engineering to medical devices*
- 320 EN 15986:2011, *Symbol for use in the labelling of medical devices — Requirements for labelling of*
 321 *medical devices containing phthalates*

⁷ Under preparation. Stage at the time of publication: ISO FDIS 80601-2-12:2019.