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Medicinska električna oprema - 2-70. del: Posebne zahteve za osnovno varnost in bistvene lastnosti opreme za zdravljenje prenehanja dihanja v spanju (ISO/DIS 80601-2-70:2019)

Medical electrical equipment - Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment (ISO/DIS 80601-2-70:2019)

Medizinische elektrische Geräte - Teil 2-70: Besondere Festlegungen für die Sicherheit und die wesentlichen Leistungsmerkmale von Schlafapnoe-Atemtherapiegeräten (ISO/DIS 80601-2-70:2019)

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 (ISO/DIS 80601-2-70:2019)

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11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
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DRAFT INTERNATIONAL STANDARD

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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

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INTERNATIONAL ORGANIZATION for STANDARDISATION

MEDICAL ELECTRICAL EQUIPMENT –

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

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.

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

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

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

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.

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,

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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

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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.

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- 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.

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MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 * Scope, object and related standards

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

201.1.1 Scope

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

This document is applicable to the *basic safety* and *essential performance* of *sleep apnoea breathing therapy equipment*, hereafter referred to as *ME equipment*, intended to alleviate the symptoms of *patients* who suffer from obstructive sleep apnoea by delivering a therapeutic breathing pressure to the respiratory tract of the *patient*. *Sleep apnoea breathing therapy equipment* is intended for use in the *home healthcare environment* by *lay operators* as well as in professional healthcare institutions.

* *Sleep apnoea breathing therapy equipment* is not considered to utilize *physiologic closed-loop-control system* unless it uses a physiological *patient* variable to adjust the therapy settings.

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

This document is applicable to *ME equipment* or an *ME system* intended for those *patients* who are not dependent on mechanical ventilation.

This document is not applicable to *ME equipment* or an *ME system* intended for those *patients* who are dependent on mechanical ventilation such as *patients* with central sleep apnoea.

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

Masks and application *accessories* intended for use during sleep apnoea breathing therapy are additionally addressed by ISO 17510. Refer to Figure AA.1 for items covered further under this document.

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.

¹ 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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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 60601-1-3, 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.

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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.