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

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

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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,

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

INTRODUCTION

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

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

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

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

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

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

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

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

In this document, the following print types are used:

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

In referring to the structure of this document, the term

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

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

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

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

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

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

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

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

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

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+A1:2012[1], 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*

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 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the General Standard.

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

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

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

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

This document does not specify the requirements for ventilators or *accessories* intended for emergency and transport, which are given in ISO 10651-3[2]. [7]

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

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

201.1.2 Object

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

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

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

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

201.1.3 Collateral standards

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

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

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements 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.

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

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

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

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

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

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

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

Subclauses, figures or tables which 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 3.139, 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, figures or tables which 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, 203 for IEC 6060-1-3, etc.

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

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

201.2 Normative references

The following referenced documents, in whole or in part, are normatively referenced in this document and are indispensable for the application 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.

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

NOTE 2 Informative references are listed in the Bibliography.

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

Replacement:

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

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
+Amendment 1:2013[3)]
+Amendment 2:—[4)]

IEC 60601-1-8:2006, *Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
+Amendment 1:2012[5)]
+Amendment 2:—[6)]

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

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

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

ISO 7010:2011, *Graphical symbols -- Safety colours and safety signs -- Registered safety signs*
+Amendment 1:2012
+Amendment 2:2012
+Amendment 3:2012
+Amendment 4:2013
+Amendment 5:2013
+Amendment 6:2014

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

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.