



BSI Standards Publication

Medical electrical equipment

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

National foreword

This British Standard is the UK implementation of EN ISO 80601-2-70:2020. It is identical to ISO 80601-2-70:2020. It supersedes BS EN ISO 17510-1:2009, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121, Anaesthetic and respiratory equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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English Version

**Medical electrical equipment - Part 2-70: Particular
requirements for the basic safety and essential
performance of sleep apnoea breathing therapy equipment
(ISO 80601-2-70:2020)**

Appareils électromédicaux - Partie 2-70: Exigences
particulières pour la sécurité de base et les
performances essentielles de l'équipement de thérapie
respiratoire pour l'apnée du sommeil (ISO 80601-2-
70:2020)

Medizinische elektrische Geräte - Teil 2-70: Besondere
Festlegungen für die Sicherheit und die wesentlichen
Leistungsmerkmale von Schlafapnoe-
Atemtherapiegeräten (ISO 80601-2-70:2020)

This European Standard was approved by CEN on 19 October 2020.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

This document (EN ISO 80601-2-70:2020) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2021, and conflicting national standards shall be withdrawn at the latest by May 2021.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 17510-1:2009.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-70:2020 has been approved by CEN as EN ISO 80601-2-70:2020 without any modification.

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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 (see 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 (see 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.

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

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

This second edition cancels and replaces the first edition (ISO 80601-2-70:2015), which has been technically revised.

The main changes compared to the previous edition are as follows:

- modification of the bi-level positive airway pressure mode stability test method;
- modification of the *biocompatibility* requirements;
- reformatting to provide a unique identifier for each requirement;
- harmonization with the 'A2 project' of the general standard.

A list of all parts in the ISO 80601 series and the IEC 80601 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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^[22].

Hypopnoea refers to a transient reduction of airflow, often while the *patient* is asleep, that lasts for at least 10 s, shallow breathing. It also results in arousal or can cause oxygen saturation to drop. Hypopnoea is less severe than apnoea. It is commonly due to partial obstruction of the upper airway^[20].

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

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

This document 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.

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.

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 to 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.

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+AMD1:2012+AMD2:2020, Clause 1 applies, except as follows:

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

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 a *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.

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), which are given in ISO 80601-2-87^[13].

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.

This document does not specify the requirements for ventilators or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13^[8].

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^[9].

This document does not specify the requirements for ventilators or *accessories* intended for emergency and transport, which are given in ISO 80601-2-84^[12].

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^[10] and ISO 80601-2-80^[11].

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 201.3.215).

NOTE 1 This document has been prepared to address the relevant *essential principles*^[17] and labelling^[18] guidances of the International Medical Devices Regulators Forum (IMDRF) as indicated in Annex CC.

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

NOTE 3 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745^[16] as indicated in Annex EE.

201.1.3 Collateral standards

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

IEC 60601-1-2:2014+AMD1:2020 and IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 apply as modified in Clauses 202 and 206 respectively. IEC 60601-1-3:2008+AMD1:2013 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 define *basic safety* and *essential performance* requirements, and may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular *ME equipment* under consideration.

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

For brevity, IEC 60601-1+AMD1:2012+AMD2:2020 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, 211 for IEC 60601-1-11, 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 documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

Replacement:

ISO 7010:2019, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

Addition:

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

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

ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 16142-1:2016, *Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

ISO 17510:2015, *Medical devices — Sleep apnoea breathing therapy — Masks and application accessories*

ISO 17664:2017, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices*

ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 19223:2019, *Lung ventilators and related equipment — Vocabulary and semantics*

ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance*

ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects*

ISO 80369-1:2018, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80601-2-12:2020, *Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*

ISO 80601-2-74:2017, *Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

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

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 3744:2010, ISO 16142-1:2016, ISO 17510:2015, ISO 17664:2017, ISO 18562-1:2017, ISO 19223:2019, ISO 23328-2:2002, ISO 80601-2-12:2020, ISO 80601-2-74:2017,

IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014+AMD1:2020,
IEC 60601-1-6:2010+AMD1:2013+AMD2:2020, IEC 60601-1-8:2006+AMD1:2012+AMD2:2020,
IEC 60601-1-10:2007+AMD2:2020, IEC 60601-1-11:2015, IEC 62366-1:2015+AMD1:2020 and the following apply.

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

NOTE An index of defined terms is found in Annex FF.

Addition:

201.3.201

airway pressure accuracy

degree of correspondence between the pressure set on the *sleep apnoea breathing therapy equipment* and the actual (true) *airway pressure*

201.3.202

*** auto CPAP**

operating mode in which the *sleep apnoea breathing therapy equipment* automatically adjusts the applied gas pressure level within a clinically predetermined range to prevent disturbances of the *patient's* breathing at the lowest necessary pressure

Note 1 to entry: These disturbances are typically obstructive apnoea (cessation of air flow) or hypopnoea (shallow breathing) events.

Note 2 to entry: An *auto CPAP* mode may be bi-level.

201.3.203

*** automatic start/stop function**

feature by which the *sleep apnoea breathing therapy equipment* automatically starts or stops the therapy based on whether the *patient* is connected or disconnected from the equipment

Note 1 to entry: *Sleep apnoea breathing therapy equipment* may provide an *automatic start* function, an *automatic stop* function, or both.

201.3.204

breathing gas pathway

gas pathways through which gas flows at respiratory pressures between the *intake* and the *patient-connection port*

201.3.205

breathing tube

non-rigid tube used to convey gases between components of a breathing system

201.3.206

diagnostic apnoea

A_d

decrease in *airway* flow greater than ≥ 90 % of pre-event baseline for at least 10 s

Note 1 to entry: Airflow is typically measured by oronasal thermal airflow sensor or nasal pressure transducer normally determined using full polysomnography in an attended sleep study or home sleep test.

Note 2 to entry: Reference [19] was used to determine this definition.

201.3.207

diagnostic apnoea-hypopnoea index

AHI_d

average number of *diagnostic apnoea* events and *diagnostic hypopnoea* events occurring per hour of sleep

$$AHI_d = \frac{(A_d + H_d) \cdot 60}{t_s}$$

where

A_d is the total number of *diagnostic apnoea* events

H_d is the total number of *diagnostic hypopnoea* events

t_s is the total sleep time in minutes

Note 1 to entry: A *diagnostic apnoea-hypopnoea index* is normally determined using full polysomnography in an attended sleep study or home sleep test.

201.3.208

diagnostic hypopnoea

H_d

decrease in *airway* flow of at least 30 % of the pre-event baseline for at least 10 s; and at least 3 % oxygen desaturation from pre-event baseline or an arousal event, excluding *diagnostic apnoea*

Note 1 to entry: For monitoring oxygen saturation, a pulse oximeter should have a maximum signal averaging time of ≤ 3 s.

Note 2 to entry: An oxygen desaturation of 4 % from pre-event baseline is also used.

Note 3 to entry: Airflow is typically measured by oronasal thermal airflow sensor or nasal pressure transducer normally determined using full polysomnography in an attended sleep study or home sleep test.

Note 4 to entry: Reference [19] was used to determine this definition.

201.3.209

equipment apnoea

A_{flow}

diagnostic apnoea as estimated by *sleep apnoea breathing therapy equipment*

201.3.210

equipment apnoea-hypopnoea index

AHI_{flow}

average number of residual *equipment apnoea* and *equipment hypopnoea* events occurring per hour of the therapy session

Note 1 to entry: References [19] and [23] were used to determine this definition.

201.3.211 equipment hypopnoea

H_{flow}

diagnostic hypopnoea as estimated by *sleep apnoea breathing therapy equipment*

Note 1 to entry: *Sleep apnoea breathing therapy equipment* without oximetry cannot monitor oxygen saturation. Therefore, *sleep apnoea breathing therapy equipment* without the oxygen saturation information, can only provide an estimate of hypopnoea events.

201.3.212 flow-direction-sensitive component

component or *accessory* through which gas flow is in one direction only for proper functioning or *patient safety*

[SOURCE: ISO 4135:—^[1], definition 3.1.7, modified — Added 'or *accessory*' and replaced 'must be' with 'is'.]

201.3.213 gas output port

port through which gas is delivered at respiratory pressures through a tube to the *patient-connection port*

201.3.214 * ramp mode

operating mode in which the *sleep apnoea breathing therapy equipment* automatically increases the applied pressure level from an initial level to the clinically predetermined therapeutic level in a predetermined profile, or decreases the applied pressure level from the therapeutic level to a lower level in a predetermined profile

201.3.215 sleep apnoea breathing therapy equipment

ME equipment delivering a therapeutic breathing pressure to the *patient* intended to treat obstructive sleep apnoea by keeping the upper airways open

Note 1 to entry: *Sleep apnoea breathing therapy equipment* is primarily used in the *home healthcare environment* by a *lay operator* without direct professional supervision.

201.4 General requirements

IEC 60601-1:2005+AMD1:2012, Clause 4 applies, except as follows:

201.4.3 Essential performance

IEC 60601-1:2005+AMD1:2012, 4.3 applies, except as follows:

Additional subclause:

201.4.3.101 * Additional requirements for essential performance

For the purposes of this document, *sleep apnoea breathing therapy equipment* is considered to not have *essential performance*.

- a) Notwithstanding this fact, when this document refers to *essential performance* as acceptance criteria, the static pressure shall be evaluated.
- b) The method of 202.8.1.101 may be used to evaluate static pressure as an acceptance criterion following specific tests required by this document.

201.4.6 * *ME equipment or ME system parts that contact the patient*

Amendment (add at end of 4.6 prior to the compliance check):

- aa) The *sleep apnoea breathing therapy equipment* parts or *accessories* that can come into contact with the *patient* shall be subject to the requirements for *applied parts* according to this subclause (i.e., 4.6 of the general standard).

NOTE See ISO 17510:2015 for additional requirements for *accessories* that can come into contact with the *patient*.

201.5 General requirements for testing of *ME equipment*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 5 applies, except as follows:

Addition:

201.5.101 Additional requirements for general requirements for testing of *ME equipment*

201.5.101.1 Gas flowrate and pressure specifications

In this document, requirements for the flowrate and pressure are expressed as if tested under *STPD* (*standard temperature and pressure dry*) conditions.

NOTE For the purposes of this document, *STPD* is 101,3 kPa at an operating temperature of 20 °C, dry.

Correct all test measurements to STPD, as appropriate.

201.5.101.2 * *Sleep apnoea breathing therapy equipment* testing errors

For the purposes of this document, tolerances declared in the *accompanying documents* shall include the uncertainty of the measurement used to determine the specification.

201.6 Classification of *ME equipment* and *ME systems*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 6 applies.

201.7 *ME equipment* identification, marking and documents

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 7 applies, except as follows:

201.7.1.2 * Legibility of markings

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.1.2 applies, except as follows:

Replacement (at the end of the second sentence of the second paragraph of the compliance check):

Replace '1 m' with '0,4 m'

Additional subclauses:

201.7.2.4.101 Additional requirements for accessories

- a) *Accessories* supplied separately shall:
 - 1) fulfil the requirements of 201.102;
 - 2) fulfil the requirements of 201.201.7.2.101; and
 - 3) be marked with an indication of any limitations or adverse effects of the *accessory* on the *basic safety* of the *sleep apnoea breathing therapy equipment*, if applicable.
- b) If marking the *accessory* is not practicable, this information may be placed in the instructions for use.

Check conformance by inspection and inspection of the risk management file for any limitations or adverse effects of the accessory.

201.7.2.13.101 Additional requirements for physiological effects

- a) Any natural rubber latex-containing components in the *gas pathways* or *accessories* shall be marked as containing latex.
- b) Such marking shall be *clearly legible*.
- c) The symbol ISO 7000-2725 or symbol 5.4.5 from ISO 15223-1:— (Table 201.D.1.101, symbol 4) may be used.
- d) The instructions for use shall disclose all natural rubber latex-containing components.

Check conformance by inspection.

201.7.2.17.101 * Additional requirements for protective packaging

- a) * The indication of single use shall be consistent for a *model or type reference*.
- b) The packaging for a *model or type reference* that is for single use shall be marked accordingly.
- c) Packages shall be *clearly legible* and shall be marked as follows:
 - 1) with a description of the contents;
 - 2) with an identification reference to the batch, type or serial number;
 - i) Symbol ISO 7000-2492 or symbol 5.1.5 from ISO 15223-1:— (Table 201.D.1.101, symbol 1) may be used for batch.
 - ii) Symbol ISO 7000-2493 or symbol 5.1.6 from ISO 15223-1:— (Table 201.D.1.101, symbol 2) may be used for batch.

iii) Symbol ISO 7000-2498 or symbol 5.1.7 from ISO 15223-1:— (Table 201.D.1.101, symbol 3) may be used for batch.

3) with, for packages containing natural rubber latex,

i) the word "LATEX", or

ii) the symbol ISO 7000-2725 or symbol 5.4.5 from ISO 15223-1:— (Table 201.D.1.101, symbol 4).

Check conformance by inspection.

201.7.2.101 Additional requirements for marking on the outside of ME equipment or ME equipment parts

a) The marking of *sleep apnoea breathing therapy equipment*, its parts or *accessories* shall be *clearly legible*.

b) The marking of *sleep apnoea breathing therapy equipment*, its parts or *accessories* shall include the following:

1) any particular storage, handling and operating instructions; and

2) any particular warnings and precautions relevant to the immediate operation of the *sleep apnoea breathing therapy equipment*.

c) If applicable, the marking of *operator-accessible sleep apnoea breathing therapy equipment*, its parts or *accessories* shall have *clearly legible* markings of the following,

1) an arrow indicating the direction of the flow for *flow-direction-sensitive components* that are *operator-removable* without the use of a *tool*;

2) a caution not to obstruct the *intake*;

EXAMPLE Caution: Gas Intake — Do not obstruct

3) an indication as to whether use of an appropriate *breathing system filter* is required;

4) if required, the *cleaning* or replacement interval of the *breathing system filter*;

5) an indication as to whether the use of an appropriate air *intake* filter is required; and

6) if required, the *cleaning* or the replacement interval of the air *intake* filter.

d) Notwithstanding requirement b) and c), if the size of *ME equipment*, its parts or *accessory*, or the nature of its *enclosure*, does not allow affixation of these markings, the remaining markings shall be included in the instructions for use.

Check conformance by inspection.

201.7.4.3 Units of measurement

IEC 60601-1:2005+AMD1:2012, 7.4.3 applies, except as follows:

Amendment (add to the bottom as a new row in Table 1):

All gas volume, flow and leakage specifications shall be expressed at *STPD* (*standard temperature and pressure, dry*).

NOTE For the purposes of this document, *STPD* is 101,3 kPa at an operating temperature of 20 °C, dry.

201.7.9.1 * Additional general requirements

IEC 60601-1:2005+AMD1:2012, 7.9.1 applies, except as follows:

Amendment (replace the first dash with):

- name or trade name and address of
 - the *manufacturer*; and
 - where the *manufacturer* does not have an address within the locale, an authorized representative within the locale,
- to which the *responsible organization* can refer;

201.7.9.2 Instructions for use

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 7.9.2 applies, except as follows:

Additional subclauses:

201.7.9.2.1.101 Additional general requirements

- a) The instructions for use shall disclose if the *sleep apnoea breathing therapy equipment*, its parts or *accessories* are intended for single use, information on known characteristics and technical factors known to the *manufacturer* that could pose a risk if the *sleep apnoea breathing therapy equipment*, its parts or *accessories* would be reused.
- b) Separate instructions for use may be provided for:
 - 1) the *lay operator*; and
 - 2) the *healthcare professional operator*.
 - i) The *healthcare professional operator* instructions for use, if provided, shall include the information contained in the *lay operator* instructions for use.
- c) The *manufacturer* may choose in which instructions for use to place the information required by this based on *risk management* and *usability* considerations document unless otherwise indicated in this document.

Check conformance by inspection of the instructions for use.

201.7.9.2.2.101 Additional requirements for warnings and safety notices

The instructions for use shall include

- a) a caution statement to the effect that “CAUTION: The equipment must not be covered or positioned in such a way that the operation or performance of the equipment is adversely affected”. The caution shall be accompanied by applicable examples.

EXAMPLE 1 Do not position next to a curtain that blocks the flow of cooling air, thereby causing the equipment to overheat.

EXAMPLE 2 Do not block the gas intake, thereby interfering with therapy.

- b) unless the *sleep apnoea breathing therapy equipment* is intended for use with an oxygen concentration above ambient, a warning to the effect that “WARNING: Sources of oxygen must be located more than 1 m from the equipment to avoid the risk of fire and burns.”
- c) a warning statement to the effect that “WARNING: Humidification can increase the resistance of breathing system filters and the operator must monitor the breathing system filter frequently for increased resistance and blockage to ensure the delivery of the therapeutic pressure.”

Unless not applicable, the instructions for use shall include the following:

- d) a warning to the effect that “WARNING: Sleep Apnoea Breathing Equipment are not suitable for patient’s requiring continuous ventilator support.”

Check conformance by inspection of the instructions for use.

201.7.9.2.5.101 Additional requirements for *ME equipment* description

The instructions for use shall include

- a) a statement to the effect that the patient should use the therapeutic pressure setting, as individually determined with the configuration of the equipment and accessories, being used.
- b) a statement to the effect that the proper placement and positioning of the patient interface is critical to the consistent operation of this equipment.

EXAMPLE The proper placement and positioning of the *mask* on the face is critical to the consistent operation of this equipment.

Check conformance by inspection of the instructions for use.

201.7.9.2.9.101 Additional requirements for operating instructions

The instructions for use shall include

- a) a summary of the *use specification* (see IEC 62366-1:2015, 5.1).
- b) if applicable, the instructions for use shall include the *procedure* necessary to determine the state of the *internal electrical power source*.
- c) a cross reference between the *manufacturer-specific* naming of the *ventilator’s ventilation-modes* and the *ventilation-mode* systematic coding scheme in Annex E of ISO 19223:2019.

Check conformance by inspection of the instructions for use.

201.7.9.2.12 *Cleaning, disinfection, and sterilization*

IEC 60601-1:2005+AMD1:2012, 7.9.2.12 applies, except as follows:

Amendment: (add after normal use)

and *single fault condition*

Amendment: (add after bulleted list)

aa) The instructions for use shall identify the portions of the *gas pathways* through the *sleep apnoea breathing therapy equipment* that can become contaminated with body fluids or expired gases during both:

- 1) *normal condition*; and
- 2) *single fault condition*.

EXAMPLE A fault that causes loss of airflow.

201.7.9.2.14.101 Additional requirements for *accessories, supplementary equipment, used material*

If applicable, the instructions for use shall disclose

a) any restrictions on the positioning of components within the *breathing gas pathway*.

EXAMPLE 1 Where such components are *flow-direction-sensitive components*.

b) a diagram of the *sleep apnoea breathing therapy equipment*, including a diagram for *operator-detachable parts* of the *breathing gas pathway* either supplied or recommended in the instructions for use.

c) details of any restrictions on the sequence of components within the *breathing gas pathway*.

EXAMPLE 2 Proper location of *flow-direction sensitive components*.

d) for the *intake filter*, the maximum duration of use and the details on how to replace this filter.

e) the specification of the *breathing system filter* including, but not limited to, the volume, the compliance, the resistance over the flow range, the maximum duration of use and the details on how to replace this filter.

Check conformance by inspection of the instructions for use and inspection of the risk management file for any adverse effect of any recommended accessory.

201.7.9.3.1.101 * Additional general requirements

The technical description shall disclose

- a) a pneumatic diagram of the *sleep apnoea breathing therapy equipment*, including a diagram for *operator-detachable parts* of the *breathing gas pathway* either supplied or recommended in the instructions for use.
- b) a listing of the following pressures:

- 1) *maximum limited pressure* ($P_{\text{LIM max}}$);
- 2) if adjustable, the *rated* range of the set *airway pressure* during *normal use*;

NOTE There can be more than one set *airway pressure*.

- c) a statement to the effect that the *responsible organization*
 - 1) should ensure the compatibility of the equipment and all of the parts and accessories used to connect to the patient before use;
 - 2) should ensure that the therapeutic pressure settings were determined for the patient individually with the configuration of the equipment to be used, including accessories; and
 - 3) should periodically reassess the setting(s) of the therapy for effectiveness; and
- d) the specification of the *intake* filter including, but not limited to, the most penetrating particle size and the penetration value for that particle size.
- e) the description of the definitions used for efficacy monitoring, including a statement to the effect that they are an estimate provided by *sleep apnoea breathing therapy equipment* and not diagnostic parameters:
 - 1) *equipment apnoea* (A_{flow});
 - 2) *equipment hypopnoea* (H_{flow}); and
 - 3) *equipment apnoea hypopnoea index* (AHI_{flow}).

If applicable, the technical description shall disclose

- f) for *ME equipment* without a respiratory pressure-measuring device, the stability of pressure control between recommended maintenance times.
- g) the means of alternating between levels in *bi-level positive airway pressure* mode.
- h) a description of the comfort features (e.g. *automatic start/stop functions*, *ramp modes*, automatic inspiratory pressure increase or automatic expiratory pressure decrease) and their range of adjustment.
- i) a statement to the effect that combinations with medical devices other than recommended can alter the performance of the equipment (e.g. combinations with a *humidifier*, filter, *breathing system filter*, or *exhaust port*).

Check conformance by inspection of the technical description.

201.8 Protection against electrical hazards from ME equipment

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 8 applies.

201.9 Protection against mechanical hazards of ME equipment and ME systems

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 9 applies, except as follows: