INTERNATIONAL STANDARD

ISO 80601-2-70

Second edition
2020-11

Medical electrical equipment —

Part 2-70: Particular requirements for the 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 de l'équipement de thérapie respiratoire pour l'apnée du sommeil

Reference number
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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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* ($P_{LIM\ max}$);

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:

Additional subclauses:

201.9.6.2.1.101 * Additional requirements for audible acoustic energy

a) The A-weighted *sound pressure level* emitted by the *sleep apnoea breathing therapy equipment*, when tested in accordance with the method in this subclause, shall be disclosed in the instructions for use.

b) The instructions for use shall disclose the *sound power level*.

Check conformance with the following test:

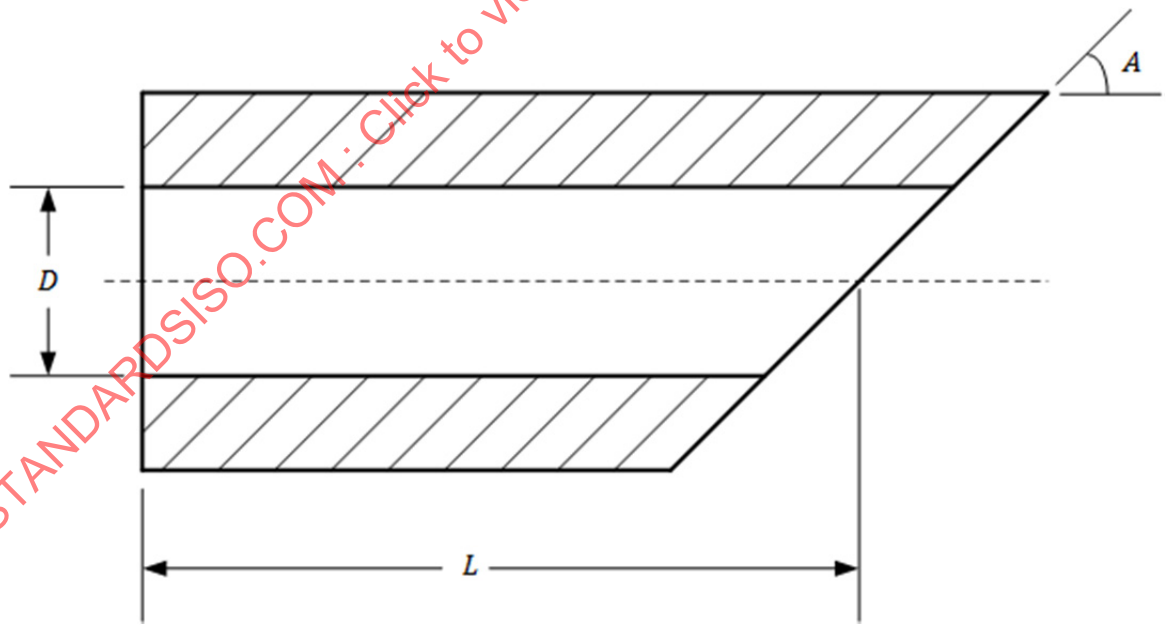
c) Place the sleep apnoea breathing therapy equipment on a sound-reflecting plane and attach the least favourable breathing gas pathway from those indicated in the instructions for use.

NOTE 1 The least favourable breathing gas pathway configuration can vary by mode, as applicable.

d) If a humidifier is provided with or specified in the accompanying documents of the sleep apnoea breathing therapy equipment, include the humidifier in the test. Fill the humidifier to the least favourable level.

e) Connect the standard resistance as indicated in Figure 201.101 to the patient-connection port.

f) Acoustically isolate the breathing tubes and the gas leaving at the resistance placed at the patient-connection port by a suitable means out of the testing area so that the noise caused by the breathing tube and the gas flow does not interfere with the sound measurement of the sleep apnoea breathing therapy equipment.



Key

D is the internal diameter: (4 ± 0,1) mm

L is the length: (40 ± 1) mm

A is the angle (45 ± 1)°

Break all edges with 0,15 mm to 0,20 mm radius or 45° chamfer. Drawing not to scale.

Figure 201.101 — Standard resistance

g) Set the sleep apnoea breathing therapy equipment to the least favourable mode and flow pattern, as applicable, that generates a continuous pressure of (10 ± 1) hPa ((10 ± 1) cmH_2O) at the patient-connection port.

NOTE 2 The least favourable mode, breath type and flow pattern can vary by breathing gas pathway configuration.

h) Using a microphone of the sound level meter conforming with the requirements of type 1 instruments specified in IEC 61672-1:2013, measure the sound pressure levels at 10 positions in a hemisphere with a radius from the geometric centre of the sleep apnoea breathing therapy equipment as specified in 7.2.3 and 8.1.1 of ISO 3744:2010.

i) Calculate the A-weighted sound pressure level averaged over the measurement surface according to 8.2.2 of ISO 3744:2010.

j) Confirm that the A-weighted background level of extraneous noise is at least 6 dB below that measured during the test.

k) Calculate the A-weighted sound power level according to 8.2.5 of ISO 3744:2010.

l) Confirm that the sound pressure level and the sound power level do not exceed those disclosed in the instructions for use.

m) Repeat steps b) to l) for each humidifier provided with or specified in the accompanying documents.

201.10 Protection against unwanted and excessive radiation *hazards*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 10 applies.

201.11 Protection against excessive temperatures and other *hazards*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 11 applies, except as follows:

201.11.1.2.2 *Applied parts* not intended to supply heat to a *patient*

Amendment (add between the existing paragraphs):

In *normal use* and *single fault condition*, over the *rated* flowrate range and at the maximum *rated* operating temperature, the temperature of the delivered gas of *sleep apnoea breathing therapy equipment* measured at the *patient connection port,* both with and without a humidifier, shall not exceed an energy equivalent to 43 °C and 100 % *relative humidity* (a specific enthalpy not to exceed 197 kJ/m^3 dry gas) when averaged over 120 s.

NOTE For additional information on the calculation of specific enthalpy, see ISO 80601-2-74:2017, Annex DD.

Table 201.101 contains examples of combinations of temperature and *relative humidity* with such a specific enthalpy.

Table 201.101 — Examples of permissible combinations of temperature and *relative humidity*

Temperature °C	***Relative humidity*** %
43	100
44	95
45	90
48	76
50	69
55	52
60	40
65	30
70	23

201.11.6.6 * *Cleaning* and *disinfection* of *ME equipment* or *ME system*

Amendment (replace the compliance check with the following):

aa) *Sleep apnoea breathing therapy equipment* and its *accessories* not intended for single use that can become contaminated with body fluids or expired gases during *normal condition* or *single fault condition* shall be designed to allow dismantling:

1) for *cleaning* and *disinfection*; or

2) *cleaning* and *sterilization*.

NOTE 1 Additional requirements are found in 11.6.7 of IEC 60601-1:2005+AMD1:2012.

bb) *Sleep apnoea breathing therapy equipment enclosures* shall be designed to allow for surface *cleaning* and *disinfection* to reduce to acceptable levels the *risk* of cross infection of the next *patient*.

cc) Instructions for *processing* the *sleep apnoea breathing therapy equipment* and its *accessories* shall

1) conform with ISO 17664:2017 and ISO 14937:2009, as appropriate, and

2) be disclosed in the instructions for use.

NOTE 2 ISO 14159[5] provides guidance for the design of *enclosures*.

Check conformance by inspection of the risk management file. When conformance with this document could be affected by the cleaning or the disinfecting of the sleep apnoea breathing therapy equipment or its parts or accessories, clean and disinfect them for the number of cycles determined by the expected service life in accordance with the methods indicated in the instruction for use, including any cooling or drying period. Confirm that basic safety and essential performance are maintained after these procedures. Confirm that the manufacturer has evaluated the effects of multiple process cycles and the effectiveness of those cycles.

201.11.7 *Biocompatibility* of *ME equipment* and *ME systems*

Amendment (add after existing text prior to the compliance statement):

aa) The *manufacturer* of any *sleep apnoea breathing therapy equipment*, its parts and *accessories* shall address in the *risk management process* the *risks* associated with the *biocompatibility* and potential contamination of the gas stream arising from the *gas pathways*.

bb) The *gas pathways* shall be evaluated for *biocompatibility* according to ISO 18562-1:2017.

NOTE The testing for particle emissions over the *expected service life* is required by ISO 18562-2[6].

cc) Special attention shall be given to substances that are endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction.

dd) An *sleep apnoea breathing therapy equipment*, its parts and *accessories* that contain phthalates or other substances, in a concentration that is above 0,1 % weight by weight, which are classified as endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction, shall be marked as containing such substances:

1) on the device itself; or

2) on the packaging.

ee) The symbol of ISO 7000-3723 or symbol 5.4.10 of ISO 15223-1:— (Table 201.D.2.101, symbol 5) may be used for such hazardous substances.

ff) A specific justification for the use of these substances shall be included in the *risk management file*.

gg) The instructions for use of a *sleep apnoea breathing therapy equipment*, its parts or *accessories* that contain endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction or that could result in sensitisation or an allergic reaction by the *patient* or *operator* shall contain information:

1) on *residual risks*; and

2) if applicable, on appropriate precautionary measures.

Check conformance by confirming conformity to ISO 18562-1:2017, inspection of the instructions for use and inspection of the risk management file for identification of the presence of substances that are endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction and the justification for their use.

201.11.8 Additional requirements for interruption of the power supply/*supply mains* to *ME equipment*

Amendment (add after existing text):

aa) *Sleep apnoea breathing therapy equipment* shall incorporate a means to allow spontaneous breathing by the *patient* when the electrical or pneumatic power supply fails or falls outside the range for normal operation. This means may be provided by a *mask* or *accessory.*

EXAMPLES A nasal *mask* or an anti-asphyxiation valve in a full face *mask* that conforms with ISO 17510.

bb) If this means is provided by the *mask* or other *accessory*, the instructions for use shall include a warning to the effect that “Warning: Failure to use a *mask* or *accessory* that permits spontaneous breathing can cause asphyxiation.”

201.12 Accuracy of controls and instruments and protection against hazardous outputs

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 12 applies, except as follows:

201.12.1 * Accuracy of controls and instruments

Amendment (add after existing sentence):

aa) The controls of *sleep apnoea breathing therapy equipment* shall be *clearly legible* under the conditions specified in 201.7.1.2 of this document.

Check conformance by application of the tests of 201.7.1.2.

Additional subclauses:

201.12.1.101 Stability of static *airway pressure accuracy* (long-term accuracy)

a) The stability of the static *airway pressure accuracy* for any type of *sleep apnoea breathing therapy equipment* when operating in *normal condition* shall be disclosed in the instructions for use, as the maximum error from the set pressure.

NOTE Expressing this information in graphical or tabular form is useful for the *operator*.

b) The accuracy of the performance of the *sleep apnoea breathing therapy equipment* shall either be:

1) determined for each *breathing gas pathway* configuration indicated in the instructions for use; or

2) determined for the worst-case *breathing gas pathway* configuration indicated in the instructions for use.

c) If worst-case *breathing gas pathway* configurations are used, the rationale for their selection shall be documented in the *risk management file*.

Check conformance by inspection of the risk management file for the rationale, if applicable, and by inspection of the instructions for use with the following tests:

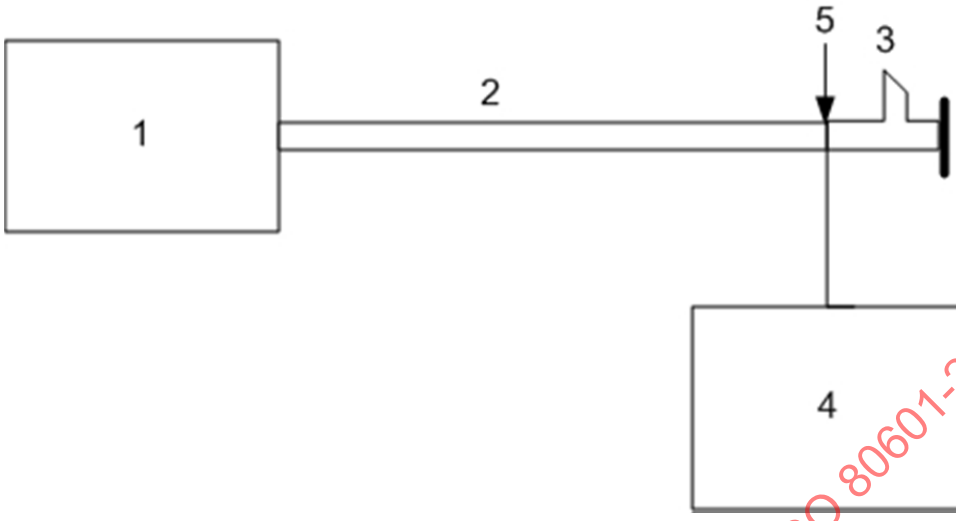
d) Set up the sleep apnoea breathing therapy equipment for normal use according to Figure 201.102 with the pressure set to 10 hPa (10 cm H_2O) in CPAP mode. For bi-level pap sleep apnoea breathing therapy equipment without a CPAP mode, adjust the inspiratory and expiratory pressures to the same value. Switch off all comfort features and auto bi-level modes of the ME equipment. Place the standard resistance (Figure 201.101) at the patient-connection port.

NOTE Comfort features include, e.g. automatic start/stop function, ramp modes, etc.

e) Measure the pressure at least once per second at the patient-connection port for the period of 8 h. Calculate the average pressure for each 1 min interval.

f) Determine the most positive and most negative pressure deviation of the calculated average pressures from the set pressure on the sleep apnoea breathing therapy equipment.

g) Confirm that the deviation is within the static airway pressure accuracy limit disclosed in the instructions for use.



Key

1 *sleep apnoea breathing therapy equipment*
2 *breathing gas pathway*
3 standard resistance (see Figure 201.101)
4 pressure meter
5 *patient-connection port*

Figure 201.102 — Test setup for static *airway pressure accuracy* in *normal use*

201.12.1.102 Stability of dynamic *airway pressure accuracy* (short-term accuracy)

201.12.1.102.1 *CPAP* mode

a) With the *sleep apnoea breathing therapy equipment* operating in *CPAP* mode in *normal condition*, the stability of the dynamic *airway pressure accuracy* shall be disclosed in the instructions for use, as the maximum error from set pressure.

b) The accuracy of the performance of the *sleep apnoea breathing therapy equipment* shall either be:

1) determined for each *breathing gas pathway* configuration indicated in the instructions for use; or

2) determined for the worst-case *breathing gas pathway* configuration indicated in the instructions for use.

c) If worst-case *breathing gas pathway* configurations are used, the rationale for their selection shall be documented in the *risk management file*.

Check conformance by inspection of the risk management file for the rationale, if applicable, and by inspection of the instructions for use with the following tests:

d) Connect the patient-connection port to a pressure-measuring device and a pump that produces a sinusoidal cycle with an I:E ratio of 1:1 and a breathing frequency of 10 breaths/min according to

Figure 201.103. Switch off all comfort features of the ME equipment. At the patient-connection port, monitor and measure the flowrate and pressure using a pressure- and flowrate-measuring device utilizing a 5 Hz low-pass filter with a minimum sample rate of 100 Hz. Include all measurement uncertainties of the test apparatus used for these tests [specified in a) and b)] in the calculation of the results (i.e. uncertainties are to be added to the differences measured). Ensure that the deadspace of the test lung is less than the tidal volume used.

e) Set the pressure to the minimum pressure setting.

f) Set lung parameters according to Table 201.102 with a tidal volume, V_t, of approximately 500 ml.

g) If necessary, adjust the settings until the breathing frequency and stroke volume match the desired settings. Record the pressure and flowrate waveforms for a duration of 5 min.

h) For each cycle, determine the most positive and the most negative pressure deviation from the set value.

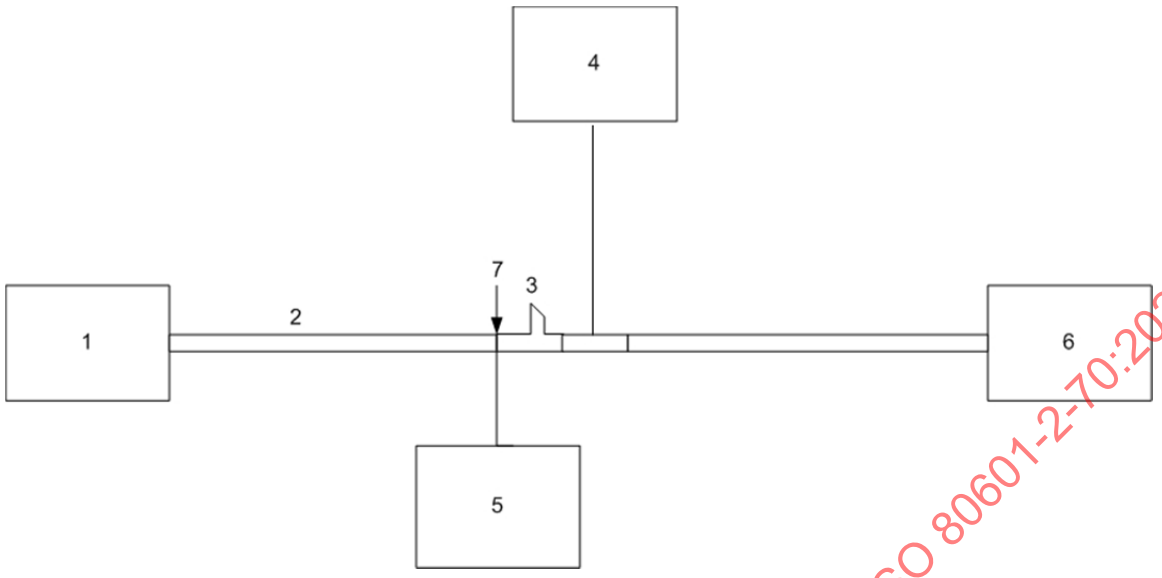
i) Calculate the average of the most positive pressure deviations over the period of 5 min.

j) Calculate the average of the most negative pressure deviations over the period of 5 min.

k) Confirm that the values determined in i) and j) are within the dynamic airway pressure accuracy limit disclosed in the instructions for use.

l) Repeat steps g) to k) for each set pressure indicated in Table 201.102.

m) Repeat steps e) to m) for each breath rate indicated in Table 201.102.



Key

1 *sleep apnoea breathing therapy equipment*
2 *breathing gas pathway*
3 standard resistance (see Figure 201.101)
4 flow meter
5 pressure-measuring device
6 pump that produces a sinusoidal cycle
7 *patient-connection port*

Figure 201.103 — Test setup for dynamic *airway pressure accuracy* in *normal use*

Table 201.102 — Parameters for dynamic *airway pressure accuracy* testing

	Fraction of the maximum adjustable pressure				
P^a (hPa) (cm H_2O)	P_{min}	P_{min} + ¼ (P_{max} – P_{min})	P_{min} + ½ (P_{max} – P_{min})	P_{min} + ¾ (P_{max} – P_{min})	P_{max}
f (breaths/min)	10, 15, and 20				
V_t (ml)	500				

[a] Set pressure rounded to the nearest whole integer.

Where
P_{min} is the minimum pressure setting;
P_{max} is the maximum pressure setting.

201.12.1.102.2 *Bi-level positive airway pressure* mode, pressure stability

a) With the *sleep apnoea breathing therapy equipment* operating in *normal condition*, the stability of the dynamic *airway pressure accuracy* shall be disclosed in the instructions for use, as the mean and standard deviation of the error between the set values and the delivered values for:

1) the inspiratory pressure level; and

2) the expiratory pressure level.

b) The technical description shall disclose the percentage used for the calculation determining the accuracy for:

1) the inspiratory phase;

2) the expiratory phase;

3) as well as where these time slots are located within:

i) the inspiratory phase.

ii) the expiratory phase.

c) The accuracy of the performance of the *sleep apnoea breathing therapy equipment* shall either be:

1) determined for each *breathing gas pathway* configuration indicated in the instructions for use; or

2) determined for the worst-case *breathing gas pathway* configuration indicated in the instructions for use.

d) If worst-case *breathing gas pathway* configurations are used, the rationale for their selection shall be documented in the *risk management file*.

Check conformance by inspection of the risk management file for the rationale, if applicable, and by inspection of the instructions for use with the following tests:

e) Connect the patient-connection port to a pressure-measuring device and a pump that produces a sinusoidal cycle with an I:E ratio of 1:1 and a breathing frequency of 10 breaths/min according to Figure 201.103. Set any adjustable rise time to the minimum value. Switch off all comfort features and auto CPAP modes of the ME equipment. Monitor and measure the flowrate and pressure at the patient-connection port using a pressure- and flowrate-measuring device utilizing a 5 Hz low-pass filter with a minimum sample rate of 100 Hz. Ensure that the deadspace of the test lung is less than the tidal volume used.

NOTE Comfort features include, e.g. automatic start/stop function, ramp modes, etc.

f) Set the inspiratory pressure and expiratory pressure to the minimum pressure setting.

g) Set lung parameters according to Table 201.103 with a tidal volume, $\boldsymbol{V}_t$, of approximately 500 ml.

To accommodate the different control mechanisms of different designs during the change from the inspiratory phase to the expiratory phase and vice versa, measure the inspiratory pressure and expiratory pressures as specified in the technical description.

h) Record the pressure and flowrate waveforms. If necessary, adjust the settings until the breathing frequency and tidal volume are approximately the desired settings.

i) For each cycle, determine the absolute inspiratory pressure difference from the inspiratory set value for each sample. Calculate the mean and standard deviation of these pressures over a period of 5 min.

j) For each cycle, determine the absolute expiratory pressure difference from the expiratory set value for each sample. Calculate the mean and standard deviation of these pressures over a period of 5 min.

k) Confirm that the mean and standard deviation of the dynamic inspiratory and expiratory pressure errors are within the accuracy disclosed in the instructions for use.

l) Repeat steps i) to k) for each set pressure indicated in Table 201.103.

m) Repeat steps f) to l) for each breath rate indicated in Table 201.103.

Table 201.103 — Parameters for dynamic *airway pressure accuracy* testing for *positive airway pressure* mode

	Fraction of the maximum adjustable pressure				
P^a, inspiratory (hPa) (cm H_2O)	P_{min} + 4	P_{min} + 2 + ¼ (P_{max} – P_{min})	P_{min} + 2 + ½ (P_{max} – P_{min})	P_{min} + 2 + ¾ (P_{max} – P_{min})	P_{max}
P^a, expiratory (hPa) (cm H_2O)	P_{min}	P_{min} – 2 + ¼ (P_{max} – P_{min})	P_{min} – 2 + ½ (P_{max} – P_{min})	P_{min} – 2 + ¾ (P_{max} – P_{min})	P_{max} – 4
f (breaths/min)	10, 15, and 20				
V_t (ml)	500				

[a] Set pressure rounded to the nearest whole integer.

Where
P_{min} is the minimum pressure setting;
P_{max} is the maximum pressure setting.

201.12.1.103 * Maximum flowrate

a) The flowrate capability of *sleep apnoea breathing therapy equipment* over the set pressure range shall be disclosed in the instructions for use.

b) The disclosure may be in tabular form.

Check conformance by inspection of the instructions for use and with the following tests:

c) Set up the sleep apnoea breathing therapy equipment with a 1,9 ± 0,15 m breathing tube. If the maximum length breathing tube is less than 1,9 m, use the maximum length breathing tube indicated in the instructions for use. Switch off all comfort features of the ME equipment.

*d) * Apply a pressure-measuring device and flowmeter to the patient-connection port. Ensure that the pressure-measuring device and flowmeter have a combined pressure drop that does not exceed 1 hPa at 40 l/min.*

e) Apply an adjustable valve at the patient-connection port.

f) Set the pressure to the minimum setting and adjust the valve to achieve (40 ± 2) l/min and measure the actual pressure delivered to the patient-connection port.

g) Adjust the valve until the actual measured pressure is reduced by 1 hPa ± 0,1 hPa (1 cm H_2O ± 0,1 cm H_2O). Read the corresponding measured pressure and flowrate value.

h) Repeat step e) 10 times and record the average value of these 10 measurements. Confirm that the sleep apnoea breathing therapy equipment can deliver at least as much flow as is indicated in the instructions for use.

i) Repeat step f) to i) with each pressure as indicated in Table 201.104.

Table 201.104 — *Sleep apnoea breathing therapy equipment* flowrate performance at set pressures

	Test pressures[a]				
	P_{min}	P_{min} + ¼ (P_{max} – P_{min})	P_{min} + ½ (P_{max} – P_{min})	P_{min} + ¾ (P_{max} – P_{min})	P_{max}
Measured pressure at the *patient-connection port* (hPa)					
Average flow at the *patient-connection port* (l/min)					

[a] Set pressure rounded to the nearest whole integer.

Where
P_{min} is the minimum pressure setting;
P_{max} is the maximum pressure setting.

201.12.4 Protection against hazardous output

Additional subclauses:

201.12.4.101 Measurement of *airway pressure*

a) If *sleep apnoea breathing therapy equipment* is equipped with *monitoring equipment* to indicate the *airway pressure* the accuracy under steady-state conditions shall not be worse than ±(2 % of the full scale reading +4 % of the actual reading).

b) The full-scale reading shall not exceed the maximum value that can be achieved under *single fault condition*.

c) The site of actual measurement may be anywhere in the *breathing gas pathway*, but the indicated value shall be referenced to the *patient-connection port*.

Check conformance by functional testing and inspection of the instructions for use.

201.12.4.102 * *Maximum limited pressure protection device*

A *protection device* shall be provided to prevent the *airway pressure* from exceeding the *maximum limited pressure* of:

a) 30 hPa (30 cm H_2O) in *normal condition;* and

b) 40 hPa (40 cm H_2O) in *single fault condition*.

Check conformance by functional testing in normal condition and single fault condition.

201.12.4.103 * CO_2 rebreathing

a) *Sleep apnoea breathing therapy equipment* shall be designed so that rebreathing of carbon dioxide is minimized to an acceptable level.

b) Use of *sleep apnoea breathing therapy equipment* with a designated *mask* or *accessory* that conforms with ISO 17510:2015 may be used to conform with this requirement.

1) In such a case, the *accompanying documents* shall include the:

i) list of designated *masks* or *accessories;* or

ii) the necessary information to locate such a list.

EXAMPLE The address of the list on a website.

NOTE The design of the *sleep apnoea breathing therapy equipment* can be such that this requirement is satisfied without a designated *mask* or *accessory*.

2) If this means is provided by the *mask* or other *accessory*, the instructions for use shall include a warning to the effect that "Warning: Failure to use a mask or accessory that minimizes rebreathing of carbon dioxide or permits spontaneous breathing can cause asphyxiation."

Check conformance by application of the tests of Annex F of ISO 17510:2015. If the sleep apnoea breathing therapy equipment provides the means of conformance, use it as the flow source for the test.

201.13 *Hazardous situations* and fault conditions

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 13 applies.

201.14 *Programmable electrical medical systems* (*PEMS*)

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 14 applies.

201.15 Construction of *ME equipment*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 15 applies, except as follows:

Additional subclause:

201.15.101 Mode of operation

Sleep apnoea breathing therapy equipment shall be suitable for *continuous operation*.

Check conformance by inspection.

201.16 *ME systems*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 16 applies.

201.17 Electromagnetic compatibility of *ME equipment* and *ME systems*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 17 applies.

Addition:

201.101 *Breathing gas pathway* connectors

201.101.1 General

a) A conical *breathing gas pathway* connector shall:

   1) be a 15 mm connector conforming with ISO 5356-1:2015;

   2) be a 22 mm connector conforming with ISO 5356-1:2015; or

   3) not engage with those connectors.

b) A non-conical connector shall:

   1) not engage with a conical connector conforming with ISO 5356-1:2015; or

   2) conform with the engagement, disengagement and leakage requirements of ISO 5356-1:2015.

c) The *small-bore* connectors of the *breathing gas pathway*, its parts or *accessories* shall conform with ISO 80369-1:2018.

Check conformance by application of the tests of ISO 5356-1:2015, ISO 80369-1:2018 and functional testing.

201.101.2 Other named ports

201.101.2.1 *Patient-connection port*

The *patient-connection port,* if conical, shall be one of the following:

a) a female 15 mm conical connector conforming with ISO 5356-1:2015;

b) a female 22 mm conical connector conforming with ISO 5356-1:2015.

Check conformance by application of the tests of ISO 5356-1:2015.

201.101.2.2 *Gas output port*

If provided, the *gas output port* shall:

a) be a male 15 mm conical connector conforming with ISO 5356-1:2015;

b) be a male 22 mm conical connector conforming with ISO 5356-1:2015; or

c) not engage with any of the connectors of ISO 5356-1:2015.

Check conformance by application of the tests of ISO 5356-1:2015.

201.101.2.3 *Flow-direction-sensitive components*

Any *operator*-detachable *flow-direction-sensitive component* of the *breathing gas pathway* shall be so designed that it cannot be fitted in such a way that it presents an unacceptable *risk* to the *patient*.

Check conformance by inspection of operator-detachable flow-direction-sensitive components and inspection of the risk management file.

201.101.2.4 Ancillary port

If an ancillary port is provided, it shall:

a) conform with ISO 80369-1:2018; and

b) be provided with a means to secure closure after removal of an *accessory* connected to the ancillary port.

NOTE 1 It is expected that the R1 connector of ISO 80369-2[7] will meet this criterion. The pressure range for this connector is specified for up to 125 hPa.

NOTE 2 An ancillary port connects to the *gas pathway* and is generally used for sampling of gases or for introduction of therapeutic aerosols.

Check conformance by inspection and application of the tests of ISO 80369-1:2018.

201.101.2.5 Monitoring probe port

If a port is provided for introducing a monitoring probe, it shall:

a) not be compatible with connectors specified in ISO 5356-1:2015;

b) be provided with a means to secure the probe in position; and

c) be provided with a means to secure closure after removal of the probe.

Check conformance by inspection and application of the tests of ISO 5356-1:2015.

201.101.2.6 Oxygen inlet port

If an oxygen inlet port is provided, it shall conform with ISO 80369-1:2018.

NOTE 1 It is expected that the female R1 connector of ISO 80369-2[7] will meet this criterion.

Check conformance by inspection and application of the tests of ISO 80369-1:2018.

201.102 Requirements for the *breathing gas pathway* and *accessories*

201.102.1 * General

All *breathing gas pathways*, their parts and *accessories* shall conform with the requirements of this document, whether they are produced by the *manufacturer* of the *sleep apnoea breathing therapy equipment* or by another entity ("third-party manufacturer" or healthcare provider).

Check conformance by the tests of this document.

201.102.2 Labelling

a) The *model or type reference* of at least one compatible *sleep apnoea breathing therapy equipment* shall be disclosed in the *accompanying document* provided with each *breathing gas pathway* and *accessory* conforming with 201.102.1.

b) Statements shall be included in the *accompanying document* of each *breathing gas pathway*, part and *accessory* to the effect that:

1) breathing gas pathways, their parts and accessories are validated for use with specific sleep apnoea breathing therapy equipment;

2) incompatible parts or accessories can result in degraded performance; and

3) the responsible organization is accountable for ensuring the compatibility of the sleep apnoea breathing therapy equipment and all of the parts or accessories used to connect to the patient before use.

Check conformance by inspection of the accompanying document.

201.102.3 Humidification

Any *humidifier*, including heated *breathing tubes*, either incorporated into the *sleep apnoea breathing therapy equipment* or recommended for use with the *sleep apnoea breathing therapy equipment* or its *breathing gas pathway*, shall conform with ISO 80601-2-74:2017.

Check conformance *by application of the tests of ISO 80601-2-74:2017.*

201.102.4 *Breathing system filter (BSF)*

Any *BSF*, either incorporated into the *sleep apnoea breathing therapy equipment* or recommended for use with the *sleep apnoea breathing therapy equipment* or its *breathing gas pathway*, shall conform with the relevant requirements of:

a) ISO 23328-1:2003; and

b) ISO 23328-2:2002.

Check conformance by application of the tests of ISO 23328-1:2003 and ISO 23328-2:2002.

201.103 *Functional connection*

201.103.1 General

Basic safety shall be maintained:

a) if a connection to the *functional connection* of a *sleep apnoea breathing therapy equipment* is disrupted; or

b) if the equipment connected to those parts fails.

Check conformance by functional testing.

201.103.2 * *Functional connection* to support remote supervision

a) *Sleep apnoea breathing therapy equipment* should be equipped with a *functional connection* that permits data transmission to and from the *sleep apnoea breathing therapy equipment* to support remote supervision of the equipment.

b) The data transmission should be capable of transmitting the information described in Annex BB.

Check conformance by inspection.

201.104 Training

In the application of the requirements of IEC 62366-1:2015+AMD1:2020, 5.6, 5.7.1 b), 5.7.3 d) and 5.8, training for the *lay operator* shall be considered necessary for the *lay operator*.

NOTE Requirements for training are found in IEC 62366-1:2015+AMD1:2020, 5.8.

Check conformance by inspection of the accompanying document.

202 Electromagnetic disturbances — Requirements and tests

IEC 60601-1-2:2014+AMD1:2020 applies, except as follows:

202.4.3.1 Configurations

Amendment (replace the second dash of 4.3.1 with):

— the *sleep apnoea breathing therapy equipment* operated using the conditions and test configuration of 201.12.1.101 d).

202.5.2.2.1 Requirements applicable to all *ME equipment* and *ME systems*

Amendment [add note to list element b)]:

NOTE The requirements of this document are not considered deviations or allowances.

Addition:

202.8.1.101 Additional general requirements

a) *Sleep apnoea breathing therapy equipment* shall be tested according to the requirements for the *home healthcare environment*.

b) The following degradations, if associated with *basic safety*, shall not be allowed:

1) component failures,

2) changes in programmable parameters or settings,

3) reset to default settings,

4) change of operating mode, and

EXAMPLE Change from a *bi-level positive airway pressure* to *CPAP* mode.

5) static or dynamic pressure deviation of more than twice the *airway pressure accuracy* limit disclosed in the instructions for use when measured at least once per second during the testing.

The *sleep apnoea breathing therapy equipment* may exhibit temporary degradation of performance (e.g. deviation from the performance indicated in the instructions for use) that does not affect *basic safety*.

206 Usability

IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 applies except as follows:

For *sleep apnoea breathing therapy equipment*, the following shall be considered *primary operating functions*:

a) if applicable, setting the *lay operator*-adjustable controls;

b) assembling the *breathing gas pathway,* including connection of the detachable parts of the *breathing gas pathway,* to the *sleep apnoea breathing therapy equipment*;

EXAMPLE *Humidifier*, nebulizer, water trap, tubing, *BSF*

c) starting the *sleep apnoea breathing therapy equipment* from power-off or standby; and

d) turning off or switching the *sleep apnoea breathing therapy equipment* to standby.

The following *operator* interactions associated with therapy also shall be considered *primary operating functions*:

NOTE For the purposes of this document the following functions are considered *primary operating functions* even though they are not performed on the *sleep apnoea breathing therapy equipment's operator- interface*.

e) setting up the *humidifier* to condition gases delivered through the *breathing gas pathway* into the *patient*; and

f) adding oxygen-enriched air to the gas flowing into the *patient*.

211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 60601-1-11:2015+AMD1:2020 applies except as follows:

211.4.2.3.1 Continuous operating conditions

Amendment (replace the second dash following Note 2 with):

– marked on the *ME equipment*, unless such marking is not practicable, in which case the more restricted range need only be disclosed in the instructions for use; and

aa) More than one range may be marked.

EXAMPLE *Sleep apnoea breathing therapy equipment* that can be operated over different operating ranges with or without a *humidifier* in use.

Subclause 8.4 does not apply.

Annexes of IEC 60601-1:2005+AMD1:2012+AMD2:2020 apply, except as follows.

Annex C
(informative)

Guide to marking and labelling requirements for *ME equipment* and *ME systems*

201.C.1 Marking on the outside of *ME equipment*, *ME systems* or their parts

Amendment:

Additional requirements for marking on the outside of a *sleep apnoea breathing therapy equipment*, its parts and *accessories* are found in Table 201.C.101.

Table 201.C.101 — Marking on the outside of a *sleep apnoea breathing therapy equipment*, its parts or *accessories*

Description of marking	Subclause
Any particular storage, handling and operating instructions	201.7.2.101 b) 1)
Any particular warnings and precautions relevant to the immediate operation of the *sleep apnoea breathing therapy equipment*	201.7.2.101 b)
For *accessories,* an indication of any limitations or adverse effects on the *basic safety* of the *sleep apnoea breathing therapy equipment*, if applicable	201.7.2.4.101 a) 3)
For *accessories* or *breathing gas pathways*, containing natural rubber latex, if applicable	201.7.2.13.101
For *accessories* supplied separately, the requirements of 201.7.2.101	201.7.2.4.101
For *sleep apnoea breathing therapy equipment*, part and accessory, contains phthalates or other substances, which are classified as endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction, if applicable	201.11.7 dd) 1)
For packages, description of the contents	201.7.2.17.101 c) 1)
For packages, identification reference to the batch, type or serial number	201.7.2.17.101 c) 2)
For packages containing natural rubber latex contents, if applicable	201.7.2.17.101 c) 3)
For packages containing single use contents, if applicable	201.7.2.17.101 b)
For packaging, contains phthalates or other substances, which are classified as endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction, if applicable	201.11.7 dd) 2)
Range of continuous operating conditions	211.4.2.3.1
Units of measurement for volumes, flows and leakages	201.7.4.3
Where appropriate, *operator*-accessible parts or *accessories*, an arrow indicating the direction of the flow for *flow-direction-sensitive components* that are *operator*-removable without the use of a *tool*	201.7.2.101 c) 1)
Where appropriate, *operator*-accessible *sleep apnoea breathing therapy equipment*, its parts or *accessories*, a warning not to obstruct the gas intake	201.7.2.101 c) 2)

Description of marking	Subclause
Where appropriate, *operator*-accessible *sleep apnoea breathing therapy equipment*, its parts or *accessories*, use of an appropriate air *intake* filter is required	201.7.2.101 c) 5)
Where appropriate, *operator*-accessible *sleep apnoea breathing therapy equipment*, its parts or *accessories*, use of an appropriate *breathing system filter* is required	201.7.2.101 c) 3)
Where appropriate, *operator*-accessible *sleep apnoea breathing therapy equipment*, its parts or *accessories*, methods of *cleaning* or replacing the air *intake* filter	201.7.2.101 c) 6)
Where appropriate, *operator*-accessible *sleep apnoea breathing therapy equipment*, its parts or *accessories*, methods of *cleaning* or replacing the *breathing system filter*	201.7.2.101 c) 4)

201.C.2 *Accompanying documents*, general

Amendment:

Additional requirements for general information to be included in the *accompanying documents* of a *sleep apnoea breathing therapy equipment* or its parts are found in Table 201.C.102.

Table 201.C.102 — *Accompanying documents*, general

Description of requirement	Subclause
Declared tolerances including the measurement uncertainty of the measurement used to determine the specification	201.5.101.2
For each *breathing gas pathway* or *accessory*, the *model or type reference* of at least one compatible *sleep apnoea breathing therapy equipment*	201.102.2 a)
For each *breathing gas pathway*, part or *accessory*, a statement to the effect that breathing gas pathways, their parts and accessories are validated for use with specific sleep apnoea breathing therapy equipment	201.102.2 b) 1)
For each *breathing gas pathway*, part or *accessory*, a statement to the effect that incompatible parts can result in degraded performance	201.102.2 b) 2)
For each *breathing gas pathway*, part or *accessory*, a statement to the effect that the responsible organization is responsible for ensuring the compatibility of the sleep apnoea breathing therapy equipment and all of the parts used to connect to the patient before use	201.102.2 b) 3)
List of designated *masks* or *accessories* needed to minimize rebreathing of carbon dioxide, if required	201.12.4.103 b) 1)
Name or trade name and address of the *manufacturer* to which the *responsible organization* can refer	201.7.9.1
Necessary information to locate a list of designated *masks* or *accessories* needed to minimize rebreathing of carbon dioxide, if required	201.12.4.103 b) ii)
Training is necessary for the *lay operator*	201.104
Where the *manufacturer* does not have an address within the locale, an authorized representative within the locale to which the *responsible organization* can refer	201.7.9.1

201.C.3 *Accompanying documents*, instructions for use

Amendment:

Additional requirements for information to be included in the instructions for use of a *sleep apnoea breathing therapy equipment* or its parts are found in Table 201.C.103.

Table 201.C.103 — Instructions for use

Description of requirement	Subclause
Any particular storage, handling and operating instructions	201.7.2.101 b) 1)
Any particular warnings and precautions relevant to the immediate operation of the *sleep apnoea breathing therapy equipment*	201.7.2.101 b) 2)
Any restrictions on the positioning of components within the *breathing gas pathway*, if applicable	201.7.9.2.14.101 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	201.7.9.2.9.101 c)
Details of any restrictions on the sequence of components within the *breathing gas pathway*, if applicable	201.7.9.2.14.101 c)
Diagram for the connection of *operator*-detachable parts either supplied or recommended	201.7.9.2.14.101 b)
Diagram of the *sleep apnoea breathing therapy equipment*, if applicable	201.7.9.2.14.101 b)
Dynamic *airway pressure accuracy* as the maximum error from the set pressure for *CPAP* mode, if applicable	201.12.1.102.1 a)
Dynamic *airway pressure accuracy* as the maximum error from the set pressure for *bi-level PAP* mode, if applicable	201.12.1.102.2 a)
For *accessories* supplied separately where marking the *accessory* is not practicable, the requirements of 201.7.2.4.101	201.7.2.4.101 b)
For *accessories* or *breathing gas pathways*, containing natural rubber latex, if applicable	201.7.2.13.101
For *sleep apnoea breathing therapy equipment*, its parts or *accessories* that contain phthalates or other substances, which are classified as endocrine disrupting, carcinogenic, mutagenic or toxic to reproduction, information on *residual risks* for children or treatment of pregnant or nursing women and, if applicable, on appropriate precautionary measures	201.11.7 gg)
For *sleep apnoea breathing therapy equipment*, its parts or *accessories* where marking is not practicable, the requirements of 7.2.101 b) and c)	201.7.2.101 d)
For the *sleep apnoea breathing therapy equipment*, dependent on a *mask* or *accessory* to allow spontaneous breathing, a warning to the effect that failure to use a mask or accessory that permits spontaneous breathing can cause asphyxiation.	201.11.8 bb)
For the *sleep apnoea breathing therapy equipment*, its parts or *accessories* intended for single use, information on known characteristics and technical factors known to the *manufacturer* that could pose a *risk* if reused	201.7.9.2.1.101 a)
Identification of portions of the *gas pathways* through the *conserving equipment* that can become contaminated with body fluids or expired gases during both *normal condition* and *single fault condition*	201.7.9.2.12
If applicable, the *procedure* necessary to determine the state of the *internal electrical power source*	201.7.9.2.9.101 b)
If a separate *healthcare professional operator* instructions for use is provided, it contains the *lay operator* instructions for use	201.7.9.2.1.101 2) i)
Instructions for *processing* the *sleep apnoea breathing therapy equipment* and its *accessories*	201.11.6.6 cc)
Maximum flowrate of *sleep apnoea breathing therapy equipment* over the set pressure range in tabular form	201.12.1.103 a)
Sound power level	201.9.6.2.1.101 b)

Description of requirement	Subclause
Sound pressure level	201.9.6.2.1.101 a)
Specification of the *intake* filter including the maximum duration of use and the details on how to replace this filter	201.7.9.2.14.101 d)
Specification of the *breathing system filter* including, but not limited to, the specifications of the filter, including the volume, the compliance, the resistance over the flow range, the maximum duration of use and the details on how to replace this filter	201.7.9.2.14.101 e)
Stability of the static *airway pressure accuracy* as the maximum error from the set pressure	201.12.1.101 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	201.7.9.2.5.101 a)
Statement to the effect that the proper placement and positioning of the patient interface is critical to the consistent operation of this equipment	201.7.9.2.5.101 b)
Summary of the *use specification*	201.7.9.2.9.101 a)
Warning statement to the effect that "WARNING: Humidification can increase the resistance of breathing system filters and that the operator must monitor the breathing system filter frequently for increased resistance and blockage to ensure the delivery of the therapeutic pressure."	201.7.9.2.2.101 c)
Warning statement to the effect that "WARNING: The equipment must not be covered or positioned in such a way that the operation or performance of the equipment is adversely affected, including applicable examples	201.7.9.2.2.101 a)
Warning to the effect that "WARNING: Failure to use a mask and accessory that minimizes CO_2 rebreathing or spontaneous breathing can cause asphyxiation", unless not applicable	201.12.4.103 b) 2)
Warning to the effect that "WARNING: Sleep Apnoea Breathing Equipment are not suitable for patient's requiring continuous ventilator support"	201.7.9.2.2.101 d)
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.", unless the sleep apnoea breathing therapy equipment is intended for use with an oxygen concentration above ambient	201.7.9.2.2.101 b)

201.C.4 *Accompanying documents*, technical description

Additional requirements for information to be included in the technical description of a *sleep apnoea breathing therapy equipment* or its parts are found in Table 201.C.104.

Table 201.C.104 — Technical description

Description of requirement	Subclause
Description of the comfort features and their range of adjustment (e.g. *automatic start/stop function*, *ramp modes*, automatic inspiratory pressure increase or automatic expiratory pressure decrease), if provided	201.7.9.3.1.101 h)
Description of the definitions used for efficacy monitoring of A_{flow}, H_{flow}, and AHI_{flow}	201.7.9.3.1.101 e)
For *ME equipment* without a respiratory pressure-measuring device, the stability of pressure control between recommended maintenance times, if applicable	201.7.9.3.1.101 f)
Maximum limited pressure	201.7.9.3.1.101 b) 1)
Means of transitioning between levels in *bi-level positive airway pressure* mode	201.7.9.3.1.101 g)

Description of requirement	Subclause
Percentage of each inspiratory and expiratory phase that is used for the calculation determining the accuracy as well as where within the inspiratory and expiratory phases the percentage slot is taken	201.12.1.102.2 b)
Pneumatic diagram of the *sleep apnoea breathing therapy equipment*	201.7.9.3.1.101 a)
Rated range of the set *airway pressure* during *normal use*, if adjustable	201.7.9.3.1.101 b) 2)
Specification of the *intake* filter	201.7.9.3.1.101 d)
Statement to the effect that combinations with other medical devices can alter the performance of the equipment, if applicable	201.7.9.3.1.101 i)
Statement to the effect that efficacy monitoring (A_{flow}, H_{flow}, and $AHI_{flow)}$ are an estimate provided by *sleep apnoea breathing therapy equipment* and not diagnostic parameters	201.7.9.3.1.101 e)
Statement to the effect that the responsible organization should ensure the compatibility of the equipment and all of the parts and accessories used to connect to the patient before use	201.7.9.3.1.101 c) 1)
Statement to the effect that the responsible organization should ensure that the therapeutic pressure setting were determined for the patient individually with the configuration of the equipment to be used, including accessories	201.7.9.3.1.101 c) 2)
Statement to the effect that the responsible organization should periodically reassess the setting(s) of the therapy for effectiveness	201.7.9.3.1.101 c) 3)

Annex D
(informative)

Symbols on marking

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

Addition:

Table 201.D.1.101 — Additional symbols on marking

No	Symbol	Reference	Title and description
1		ISO 7000-2492 Symbol 5.1.5 ISO 15223-1:— IEC 60878:2015[14]	Batch code To identify the *manufacturer's* batch or lot code, for example on a medical device or the corresponding packaging. The code shall be placed adjacent to the symbol.
2		ISO 7000-2493 Symbol 5.1.6 ISO 15223-1:— IEC 60878:2015[14]	Catalogue number To identify the *manufacturer's* catalogue number, for example on a medical device or the corresponding packaging. The catalogue number shall be placed adjacent to the symbol.
3		ISO 7000-2498 Symbol 5.1.7 ISO 15223-1:— IEC 60878:2015[14]	Serial number To identify the *manufacturer's* serial number, for example on a medical device or its packaging. The serial number shall be placed adjacent to the symbol.
4		ISO 7000-2725 Symbol 5.4.5 ISO 15223-1:— IEC 60878:2015[14]	Contains or presence of [natural rubber latex] On medical devices: to indicate that the equipment contains the identified product or substance.
5		ISO 7000-3723 Symbol 5.4.10 ISO 15223-1:—	Contains hazardous substances Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties.

Additional Annexes:

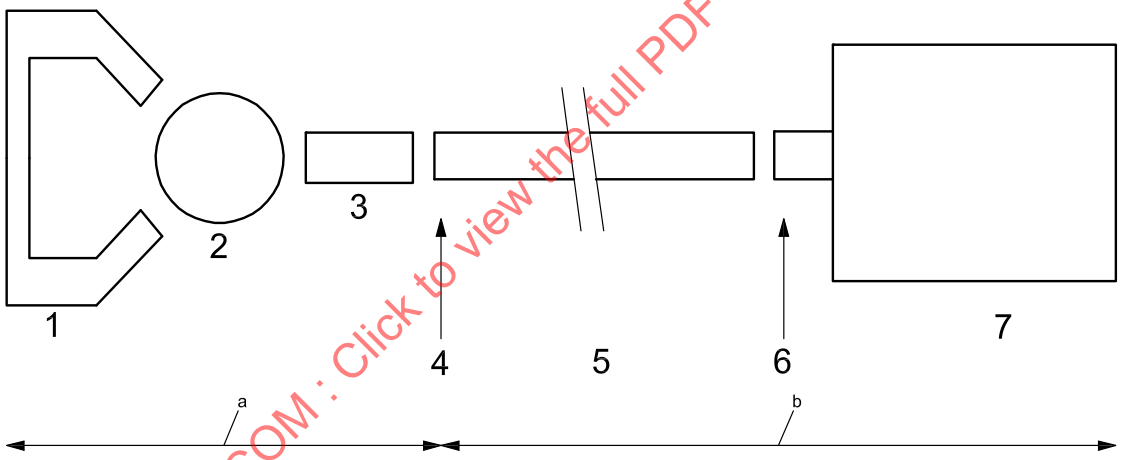
Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This Annex provides rationale for some requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the rationales underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this document necessitated by those developments.

Figure AA.1 is a typical example of a series of component arrangements of this document and ISO 17510. It is intended to enhance comprehension of the combination of *sleep apnoea breathing therapy equipment* and *masks* and application *accessories*, as well as to clarify the scope of the related standards.



Key

1 headgear
2 *mask*
3 connecting element (optional)
4 *patient-connection port*
5 *breathing tube*
6 *gas output port*
7 *sleep apnoea breathing therapy equipment*
[a] Scope of ISO 17510.
[b] Scope of this document.

NOTE 1 The *exhaust port* can be located in the connecting element (3), the *mask* (2) or the *sleep apnoea breathing therapy equipment* (7).

NOTE 2 A *humidifier* can be integral to the *sleep apnoea breathing therapy equipment* (7) or in series with the *breathing tube* (5).

NOTE 3 A *breathing system filter* can be placed in series with the *breathing tube* (5).

Figure AA.1 — Relationship of the components of *sleep apnoea breathing therapy equipment* and *masks* and application *accessories* and the related standards

AA.2 Rationale for particular clauses and subclauses

The numbering of the following rationales corresponds to the numbering of the terms, clauses and subclauses in this document. The numbering is, therefore, not consecutive.

Subclause 201.1.1 — Scope

The field of application encompasses *CPAP* equipment, *bi-level positive airway pressure equipment*, and *auto CPAP* equipment intended for sleep apnoea breathing therapy. *Sleep apnoea breathing therapy equipment* rely on both the design of the *sleep apnoea breathing therapy equipment* to minimize the *risk* of asphyxia and the defence mechanisms of the *patient* to respond to *single fault conditions* and arouse the *patient* from sleep, thereby allowing the *patient* to remove himself from potential *harm*. Therefore, this document deals extensively with the performance standard for *sleep apnoea breathing therapy equipment* to ensure the delivery of the therapeutic pressure and prevent asphyxia.

Sleep apnoea breathing therapy equipment can be used in healthcare facilities, at home, in ships, in aircraft or in other transport situations.

Sleep apnoea breathing therapy equipment is not considered a *physiologic closed-loop control system* due to the fact that parameters monitored during delivery of therapy that are also used to control the delivery of the gas are exclusively physical parameters of the delivered gas. Consequently, these parameters are considered equipment variables as specified in IEC 60601-1-10.

Sleep apnoea breathing therapy equipment that uses the breathing system pressure and flowrate as a feedback to control pressure is a closed-loop control system, but not a *physiologic closed-loop control system*. The pressure is considered both a 'variable' influenced by the *patient* physical conditions and at the same time a 'feedback variable', but it is not a quantity or condition measured from the *patient's* physical condition.

The *patient's* physical condition is a disturbance on the closed loop system but the *sleep apnoea breathing therapy equipment* does not adjust the therapy settings based on measurement of these *patient* parameters.

The requirements of this standard do not require the *sleep apnoea breathing therapy equipment* to adjust delivery parameters based on the detection in the change of physiological conditions of the *patient*. All automatic adjustments of *sleep apnoea breathing therapy equipment* parameters are only based on the measurement of physical variables related to the delivery of gas to the *patient-connection port*. In this sense the *sleep apnoea breathing therapy equipment* ends at the *patient-connection port*, (i.e. has no direct contact to the physiological parameters of the *patient*) and a change in the *patient's* physiological conditions is a disturbance to the *sleep apnoea breathing therapy equipment's* control system that does not act to control the physiological change but continues to control the physical variable(s) to their original objectives.

Term 201.3.202 — *Auto CPAP*

An *auto CPAP* mode is intended to apply sufficient gas pressure to support the patency of the *patient's* airway to treat obstructive sleep apnoea, while reducing pressure when appropriate for *patient* comfort. The *sleep apnoea breathing equipment* monitors respiratory events through the influence of the *patient's* breathing on the flow waveforms. The incidence of respiratory events can vary throughout sleep, for example with a *patient's* body position, sleep cycle and in response to the applied gas pressure. The appropriate gas pressure can also vary from day to day due to other influences or changes, for example diet, body weight, alcohol, medications, environment, stress and exercise.

The committees attempted to create a test method to assess the performance of *auto CPAP* modes. Unfortunately, that attempt was not clinically representative as none of the proposed mechanical models adequately represented the behaviour of a *patient's* airway. The committees concluded that a clinical study should be needed for either a new *auto CPAP* mode or modified *auto CPAP* mode that could change the clinical performance. Specifying the protocol for such a study is beyond the scope of this document. Nonetheless, the following general considerations can guide the development of such a study.

Clinical studies should conform to ISO 14155[4].

The study population should be representative of the population for which the *auto CPAP* mode is intended to be used. In particular, the age group and therapeutic environment of subjects should correspond to the desired labelling. The inclusion/exclusion criteria should be defined prior to initiating the study. The study should be adequately powered based on the study objective, performance measures and pre-specified performance goals. The pertinent demographics and baseline variables such as age, gender, BMI (body mass index), race, clinical diagnosis, comorbidities, indication for therapy, *use environment* (home, hospital, etc.) and all other pertinent baseline variables on a per-subject basis should be collected.

AHI_d is the commonly accepted primary endpoint. Secondary endpoints can include oxygen desaturation index (ODI), T90 (percentage of time, oxygen saturation is <90 %) and the validated *patient* reported outcomes. The evaluation of therapeutic medical devices involves comparison of the therapeutic capability of the test medical device to an authoritative standard, which is assumed to be correct. In the case of *sleep apnoea breathing therapy equipment*, the authoritative standard is clinical polysomnography (PSG) scored by a trained analyst on an epoch-by-epoch basis (the recommended epoch is 30 s) as per the current best practice guidelines (e.g. AASM scoring guidelines for PSG[19]). This can be achieved by having a blinded scorer analyse raw data to interpret the events (*diagnostic apnoea*, *diagnostic hypopnoea*) in an epoch and compare to PSG interpretation of events in that epoch. The study duration of each subject should include a minimum of 4 h of technically adequate data, obtained during a recording attempt that encompasses the habitual sleep period[21].

The statistical hypotheses should be consistent with the objective of the study and be clearly stated in the study protocol. The statistical hypotheses and the study success criteria are used to determine the sample size and statistical methodology that will be used to analyse the primary study endpoint. The data should be analysed for each mode (e.g. *auto CPAP*) on a per-subject basis.

The lab-to-lab variability in PSG data monitoring and differences between PSG scorers are well documented in the scientific literature. Therefore, this can be addressed by performing clinical testing at multiple sleep labs. The clinical testing should be scored by at least two scorers for consensus and in the case where there is disagreement, three scorers.

Term 201.3.203 — *Automatic start/stop function*

An *automatic start/stop function* can reduce discomfort and noise due to excessive flow levels that arise when the *sleep apnoea breathing therapy equipment* is activated prior to connection to the *patient* or remains active while the *mask* has been removed or disconnected.

Term 201.3.217 — *Ramp mode*

A *ramp mode* is intended to increase the pressure gradually while the *patient* falls asleep with a relatively low, comfortable pressure level. A *ramp mode* also can reduce the pressure prior to the *patient's* time to wake.

Subclause 201.4.3.101 — Additional requirements for *essential performance*

Sleep apnoea breathing equipment has no *essential performance*. *Patients* diagnosed with OSA are capable of spontaneously breathing and do not require additional ventilatory support. In the absence of treatment (e.g. power failure or loss of therapy or other likely/foreseeable events) where performance is lost or degraded beyond the limits specified by the *manufacturer*, the *patient* does not suffer any adverse effects requiring immediate medical intervention. This means that a loss in performance of *sleep apnoea breathing equipment* does not result in an unacceptable *risk*. This is why no *alarm conditions* are required when therapy is lost or degraded.

Nonetheless, *sleep apnoea breathing equipment* is expected to provide effective therapy in *normal condition* even though loss of that therapy is not considered an unacceptable *risk*. This is why pressure is evaluated in lieu of *essential performance* as an acceptance criterion (i.e., pressure does not change by more than twice the *airway pressure accuracy* limit disclosed in the instructions for use). The test method specified in 202.8.1.101, together with the configuration specified in 201.12.1.101.a) provide a method for evaluating pressure with a sampling period of one second. The duration of test should be at least twice the dwell time for the intervention that is being evaluated.

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

Since the *accessories* of *sleep apnoea breathing therapy equipment* are likely to be draped over or around the *patient*, they are likely to come into direct contact with the *patient* during *normal use*. Additionally, the *gas pathways* conduct fluids into or out of the *patient*. As such, the *gas pathways* of the *sleep apnoea breathing therapy equipment* and its *accessories* need to be investigated regarding *biocompatibility* and compatibility with substances that might pass into the *patient* via the *gas pathways*. Also of concern are electrical *hazards* should any circuitry be incorporated into the *accessories*.

Subclause 201.5.101.2 — *Sleep apnoea breathing therapy equipment* testing errors

When testing *sleep apnoea breathing therapy equipment* performance several of the test parameters cannot be measured without a significant degree of measurement uncertainty due to limitations of the accuracy that can be achieved, particularly when measuring volumes by the integration of rapidly changing flows.

Because of the relative significance of these uncertainties, it is important that *manufacturers* allow for them when declaring parameter accuracy.

Similarly, it is important for a third-party tester also to recognise the significance of the uncertainty in their own measurements when testing to this document.

In practice, this means that, for example, if a *manufacturer* determines that a parameter has a tolerance of ±7 % but that the measurement uncertainty is ±3 % then a parameter tolerance of ±10 % is declared. If a third-party tester subsequently obtains an error of the measured value for that parameter of ±15 %, with a measurement uncertainty of ±5 %, then the third-party tester has to accept the *manufacturer's* claim.

Furthermore, the *manufacturer* is required to disclose the measurement uncertainty for each declared value in order to provide both information to the *responsible organization* and guidance for a third-party tester as to the needed measurement accuracy when testing to this document.

Subclause 201.7.1.2 — Legibility of markings

In order to change the settings of *sleep apnoea breathing therapy equipment breathing therapy equipment*, the *operator* needs to be within an arm's length of the control.

Subclause 201.7.2.17.101 — Additional requirements for protective packaging

It is hazardous for the *patient* if a product, part or *accessory* is labelled as single use in one market and multi-use in another, using an identical *model or type reference* as it is reasonably foreseeable that it moves from one place to another.

Subclause 201.7.9.1 — Additional general requirements

Where the *manufacturer* of a *ME equipment* is not located in the same geographical locale as the *operator* or *responsible organization* of the *ME equipment*, it is important that contact details are provided for a representative within the locale who is available for post-market surveillance reporting and who can respond to enquiries. Where this is not the *manufacturer*, contact details for the *manufacturer* also are provided. In many jurisdictions, this is a requirement of authorities having jurisdiction.

Subclause 201.7.9.3.1.101 — Additional general requirements

In this document covering the treatment of obstructive sleep apnoea, control of the *CPAP* or *bi-level positive airway pressures* in response to the *patient's* breathing is achieved by a classical control loop where the *sleep apnoea breathing therapy equipment* responds when the desired treatment pressure does not equal the measured pressure. This is achieved by an increase or decrease in motor speed until the equilibrium (treatment = measured pressure) has been re-established. In the case of *sleep apnoea breathing therapy equipment* providing *bi-level positive airway pressure* there are two treatment pressures, inspiratory positive airway pressure (IPAP) and expiratory positive airway pressure (EPAP). The difference between these two values is referred to as the pressure support (PS) value expressed in hPa or cmH_2O. The PS value is set by the clinician and is typically 2 hPa (2 cmH_2O) to 3 hPa (3 cmH_2O). When the *patient* breathes, the *sleep apnoea breathing therapy equipment* responds in the same manner as the *CPAP* control loop in synchronisation with the *patient's* breathing pattern.

Subclause 201.9.6.2.1.101 — Additional requirements for audible acoustic energy

Noise emissions are especially disturbing if the noise includes tonal components. Therefore it is recommended that the tonal components of noise be determined additionally[15].

For undisturbed sleep, the World Health Organization recommends that the *sound pressure level* should not exceed 30 dB(A). *Manufacturers* are encouraged to strive for lower *sound pressure levels*.

Subclause 201.11.6 — *Cleaning* and *disinfection* of *ME equipment* or *ME system*

The essential principles of ISO 16142-1 require that medical devices are not to be operated or used if their condition could compromise the health and safety of the *patient* on whom they are being used or the employees or third parties interacting with them.

This means that *sleep apnoea breathing therapy equipment*, its *accessories* and parts cannot be used if there is a potential *risk* of the *patient*, *operator* or other person being infected as a result of contact with the *sleep apnoea breathing therapy equipment*, its *accessory* or part.

Therefore, a non-single use *sleep apnoea breathing therapy equipment*, its *accessories* and parts require an appropriate level of *disinfection*, depending on their use, but rarely need to be sterile.

Recommendations for hygienic *processing* of *sleep apnoea breathing therapy equipment*, its *accessories* and parts are based on the general hygiene requirements for the *processing* of medical devices and need to take into consideration the special requirements and needs of *patient* care in the clinical environment. The requirements for hygienic *processing* of this document are intended to

— make the *responsible organization* for *processing* the *sleep apnoea breathing therapy equipment* aware of how to implement these tasks in a responsible manner through appropriate delegation, and

— help all parties involved in the *processing* of *sleep apnoea breathing therapy equipment*, its *accessories* and parts to conform with the *manufacturer's* instructions.

The *cleaning* and *disinfection procedures* of the *manufacturer* are also intended to provide practical support to all those involved in *patient* care in the clinical environment with regard to implementing the hygiene measures required for the *patient's* safety.

It should be noted that *sleep apnoea breathing therapy equipment*, as all other medical devices that have been contaminated with human pathogenic microorganisms, are a potential source of infection for humans. Any *sleep apnoea breathing therapy equipment* that has already been used on another *patient* is potentially contaminated with contagious pathogenic microorganisms until proven otherwise. Appropriate handling and *processing procedures* are essential to protect the next person handling the device or the next *patient* on whom the device is used. Hence *sleep apnoea breathing therapy equipment*, its re-usable *accessories* and parts that have been used are required to undergo *processing*, following the *manufacturer's* instructions, prior to reuse by another *patient*.

The following basic considerations need to be addressed by the *manufacturer* when specifying the *processing* instructions of *sleep apnoea breathing therapy equipment*, its *accessories* or parts:

a) protecting the *patient*, the *operator* and the *responsible organization* (including personnel involved in performing the *processing*);

b) the limits of the *procedures* used for *processing* (such as the number of *processing* cycles);

c) the necessity to guarantee the proven standardized *procedures* in a consistently high and verifiable quality, based on an established quality management system.

The recommended *processing* should be determined by:

— the potential degree and type of contamination of the *sleep apnoea breathing therapy equipment*, its *accessories* or parts;

— the *risk* of infecting another *patient* resulting from their reuse and the type of application of the *sleep apnoea breathing therapy equipment*.

Special consideration of the possible *risk* associated with the contamination of gas-conducting components due to the *patient's* re-breathing under *single fault condition* should be considered.

On the basis of the above, a *verified* and *validated* documented *processing procedure* needs to be specified in such detail so that the outcome is reproducible. An acceptable *residual risk* from the *hazard* of infection for the next *patient* can be assumed if:

a) the documented *processing procedure's* effectiveness has been *verified* through appropriate scientific methods by the *manufacturer*;

b) the reliability of the documented *processing procedures* has been *verified* in practice through appropriate quality assurance measures by the *responsible organization* carrying out the *processing procedures*.

When selecting and evaluating the *processing procedures*, the *manufacturer* should consider:

— the amount and type of pathogenic microorganisms expected to contaminate the *sleep apnoea breathing therapy equipment*, its *accessories* or parts;

— the *risk* for the pathogenic microorganisms to be transmitted to the *patient*, *operator* or other persons;

— the microorganism's resistance to the recommended *processing procedures*.

The *risks* posed by a *processed sleep apnoea breathing therapy equipment*, its *accessories* or parts are determined by the following factors:

a) undesired effects, which can result from:

   — the previous use;

   — the previous *processing*;

   — transportation and storage;

b) the *risks* from subsequent uses, such as the following:

   — residues from the previous use (such as secretions, other body fluids, and drugs);

   — residues from the previous *processing* (such as *cleaning* agents, disinfectants and other substances, including their reaction products);

   — changes of physical, chemical or functional properties of the device;

   — changes in the condition of the material (such as accelerated wear and tear, embrittlement and changed surface conditions, connectors and adhesive joints);

c) the *risk* of transmission of any pathogenic microorganisms.

When considering the suitability of the *processing* and the feasibility of the *processing* for the *sleep apnoea breathing therapy equipment*, its *accessories* or parts, the *manufacturer* should consider the following points:

— the *risks* involved in the *processing*;

— the cost effectiveness of the *processing*;

— the practicability of the *processing*;

— the availability of the *cleaning* equipment and the *cleaning* agents specified in the *processing*;

— the efficiency of the *processing*;

— the reproducibility of the *processing*;

— quality management requirements of the *processing*;

— the environmental impact of the *processing* and the disposal of the *sleep apnoea breathing therapy equipment*, its *accessories* or parts.

The *manufacturer* should *verify* all *cleaning* agents and *processing procedures* used with regard to their suitability and repeatability with the *sleep apnoea breathing therapy equipment*, its *accessories* or parts, depending on the type of use.

The *responsible organization* should *verify* that manual *cleaning* and *disinfection* of the *sleep apnoea breathing therapy equipment*, its *accessories* or parts are always carried out in accordance with the *procedures* specified in the *accompanying document*.

The *manufacturer* should specify *validated* automated *cleaning* and *disinfection procedures*. If they are not followed, the effectiveness of the *cleaning* and *disinfection* cannot be guaranteed. Such parameters could include the volume of water used, water pressure, temperature, pH, dosage of *cleaning* agents and disinfectants and residence time.

To ensure the reproducibility of automated *processing procedures*, tests should be carried out on a regular basis.

The *manufacturer* should ensure that the specified *disinfection procedures* are *verified* to be bactericidal, fungicidal and virucidal so that the cleaned and disinfected *sleep apnoea breathing therapy equipment*, its *accessories* or parts do not pose an unacceptable *risk* of infection by reproductive pathogenic microorganisms when any of these elements, collectively or individually comes in contact with the next *patient*, *operator* or other person.

Effective *disinfection* requires that the instructions for the disinfectant, especially with regard to concentration and residence time, are followed.

Following any *processing procedure*, safety and functional testing of the *sleep apnoea breathing therapy equipment* and *accessories* (as specified by the *manufacturer's* instructions) needs to be carried out. If necessary, safety-relevant functional testing can be carried out directly before use of the *sleep apnoea breathing therapy equipment*.

The extent and type of the tests depends on the *sleep apnoea breathing therapy equipment*, *accessory* or part and these need to be defined in the *accompanying document*.

Subclause 201.12.1 — Accuracy of controls and instruments

The *patient* does not need to read the controls of *sleep apnoea breathing therapy equipment* while sleeping. The intended use of the equipment is to improve sleep. Not lighting the controls is not a relevant *hazard* for the use of *sleep apnoea breathing therapy equipment*.

Subclause 201.12.1.103 — Maximum flowrate

d)

To limit their interference on the measurement, the pressure-measuring device and flowmeter should have low impedance to flow. This is most significant at the lowest pressure setting of the *sleep apnoea breathing therapy equipment*, typically 3 hPa to 4 hPa.

When the test is configured at 40 l/min, the circuit impedance beyond the *patient-connection port* should be mostly due to the valve rather than the pressure-measuring device and flowmeter. When the valve is opened, if the pressure reduction of 1 hPa cannot be achieved, it can be due to the impedance in the pressure-measuring device and flowmeter.

Pressure-measuring devices and flowmeters with impedance below 1 hPa at 40 l/min are suitable to test typical *sleep apnoea breathing therapy equipment*. *Sleep apnoea breathing therapy equipment* with high maximum flowrate can need pressure-measuring devices and flowmeters with even lower impedance to demonstrate their maximum flowrate limit in this test.

Subclause 201.12.4.102 — *Maximum limited pressure protection device*

Nowadays a great number of *sleep apnoea breathing therapy equipment* includes *CPAP* as well as *bi-level positive airway pressure* modes. Sometimes even modes with more than 2 pressure levels are utilized. Considering the fact that the *risks* related to the supply of high breathing system pressures for all *patients* is similar and independent of the mode in which the *sleep apnoea breathing therapy equipment* is used and considering the fact that all *sleep apnoea breathing therapy equipment* are used with open application systems (i.e. leaky *masks*), the committee considered that only one set of maximum pressure limitation for *normal* and *single fault condition* should be specified. The higher of the two previous limits was chosen.

Subclause 201.12.4.103 — CO_2 rebreathing

Sleep apnoea therapy equipment breathing gas pathways differ from most other *breathing gas pathways* in the design of the inspiratory and expiratory breathing pathways in that they share a common conduit, namely the *breathing tube* connecting the sleep apnoea flow generator to the *patient-connection port*. The *breathing tube* contains a mixture of fresh and expired gases. This design has important consequences for the potential for rebreathing of carbon dioxide and thereby the inspired oxygen concentration. Therefore the design and configuration of *sleep apnoea breathing therapy equipment* and its *masks* and *accessories* have a major impact on the potential for rebreathing of carbon dioxide and thereby the inspired oxygen concentration.

Subclause 201.102.1 — General

It is the responsibility of the *manufacturer* of *sleep apnoea breathing therapy equipment accessories* to *verify* that their product conforms with the requirements of this document.

Subclause 201.103.2 — *Functional connection* to support remote supervision

See Annex BB for definitions of data that *sleep apnoea breathing therapy equipment* should provide.

Annex BB
(informative)

Data interface requirements

BB.1 Background and purpose

Heightened interest in monitoring and controlling of *sleep apnoea breathing therapy equipment*, as well as accountability and responsiveness of the parties involved has become evident on an international scale. Consequently, *patients*, caregivers, clinicians, service providers, and payers have begun the systematic definition and collection of information with regard to monitoring the performance of *sleep apnoea breathing therapy equipment*. This trend is also concomitantly driven by an enhanced data infrastructure. In order to establish a common definition for monitoring the sleep apnoea therapy performance, explicit criteria need be applied to choosing and defining parameters. This framework is intended to inform about a common definition of sleep apnoea therapy parameters. The selection is based on some agreement about what is to be monitored, and for what purpose.

It is important to note that any data collection be carried out according to privacy and confidentiality legislation and ethical principles.

A harmonized effort to develop internationally accepted sleep apnoea therapy indicators will not only foster increasingly robust cross-national analyses, but can also facilitate the development of comparable data that can be used as a basis for the setting of international benchmarks.

The standardization of data available from *sleep apnoea breathing therapy equipment* is intended to help to eliminate the current shortcomings and significantly contribute to the improvement of the therapy. This approach seeks to provide a definition that will be used across *sleep apnoea breathing therapy equipment* for providing therapy data independent of the *manufacturer* or what mechanisms are used to transport the data, either locally or remotely, to a *healthcare professional*. This approach ensures comparability between data regardless of the transport mechanism chosen to be most appropriate for a *patient* situation, it also provides for flexible and cost-effective integration into disparate systems that *healthcare professionals* can be using for *patient* data management. This approach also maintains comparability between data while allowing advancement in data transport technology to provide solutions that better meet *patient*, caregiver, clinician, service provider and payer needs. As such, the definition of specific communication interface hardware or software considerations such as protocols or transport mediums is outside of the scope of this document.

A number of monitoring requirements exist for sleep apnoea therapy, depending upon the *patient*, caregiver, clinician, service provider, and payer needs, which require various levels of data. This document seeks to define the data that *sleep apnoea breathing therapy equipment* are required to provide to meet the objectives of these users.

The following categories of data are defined:

— **Parameters and units of measurement:** Parameters and units of measurement used within the *sleep apnoea breathing therapy equipment*

— **Equipment identification:** Information identifying the *sleep apnoea breathing therapy equipment*

— **Session compliance monitoring:** Data providing evidence of *patient* compliance to therapy

— **Session efficacy monitoring:** Data providing parameters related to the effectiveness of the treatment

NOTE This is in addition to compliance monitoring.

— **Equipment therapy settings:** Therapy settings provided by *sleep apnoea breathing therapy equipment*

— **Service monitoring:** Indicators relating to preventative or corrective maintenance of the *sleep apnoea breathing therapy equipment* and its *accessories*

All *sleep apnoea breathing therapy equipment* should provide the information to enable identification of the *sleep apnoea breathing therapy equipment*. Implementation of any further data levels is optional.

NOTE ISO/IEEE 11073-10424[3] provides a means of communicating this information.

BB.2 Data definition

Table BB.101 defines the information, which identifies the pressure and flowrate units and the pressure and leakage percentiles, used in the data set.

Table BB.101 — Parameters and units of measurement

Parameter	Description	Type
Pressure units	Specification of the units of measurement for pressure-related data	Units of measurement selected: (cmH_2O or hPa)
Flowrate units	Specification of the units of measurement for flowrate-related data	Value selected: (l/min or l/s)
Pressure / Leakage percentile	Specification of the percentile used for flowrate and leakage percentile calculation	Value selected: (90 or 95)

Table BB.102 defines *sleep apnoea breathing therapy equipment* identification data.

Table BB.102 — Equipment identification

Parameter	Description	Type
Equipment *manufacturer*	Identification of the *manufacturer* of the equipment	Text string
Equipment model	Identification of the product or model number of the equipment	Text string
Equipment serial number	The identification number of the equipment	Text string
Equipment software version	Identification of the software version implemented in the equipment	Text string
NOTE More than one software version can need to be communicated from the equipment.		

Table BB.103 defines data required for compliance monitoring.

A set of data should be provided for a therapy session.

Table BB.103 — Session compliance monitoring

Parameter	Description	Type
Therapy stop date / time	The current UTC (Universal Time Coordinated) date and time when the usage session was stopped	ISO 8601(all parts)[2] Date Time: (YYYY-MM-DDThh:mm:ssZ)
Hours of flow generation	Number of hours the equipment is powered on and providing flow for the usage session	Value: (h)
Hours of *patient* use	Number of hours the equipment is providing therapy to the *patient* for the usage session	Value: (h)

Table BB.104 defines data required for efficacy monitoring.

A set of measured and calculated values should be provided for each therapy session.

Table BB.104 — Session efficacy monitoring

Parameter	Description	Type
AHI_{flow} (*equipment apnoea hypopnoea index*)	The average number of *equipment apnoea* and *equipment hypopnoea* events occurring per hour of the therapy session.	Value: (events/h)
Percentile pressure	The 90th or 95th percentile *airway pressure*	Value: (cmH_2O or hPa)
Percentile leakage	The 90th or 95th percentile leakage flowrate	Value: (l/min or l/s)
Average pressure	The average pressure for the therapy session	Value: (cmH_2O or hPa)
Average leakage	The average system leakage flowrate for the therapy session	Value: (l/min or l/s)
***Sleep apnoea breathing therapy equipment* supporting detailed event recording**		
Equipment apnoea event	List of the date time of each *equipment apnoea* event stop and the length of each apnoea event	List of: ISO 8601(all parts)[2] Date Time (YYYY-MM-DDThh:mm:ssZ) Value: (s)
Equipment hypopnoea event	List of the date time of each *equipment hypopnoea* event stop and the length of each hypopnoea event	List Of: ISO 8601(all parts)[2] Date Time (YYYY-MM-DDThh:mm:ssZ) Value: (s)
NOTE In a *bi-level pap* mode, the average pressure is the time-weighted average of the measured *airway pressure*.		

Table BB.105 defines applicable device settings for each mode of operation.

Table BB.105 — Equipment therapy settings

Parameter	Description	Type
Mode of operation	Selected *ventilation-mode* systematic code as defined in ISO 19223:2019, Annex E: — CPAP — BPAP — any additional code, if applicable.	Type selected
***Sleep apnoea breathing therapy equipment* operating in *CPAP* mode**		
CPAP pressure	Delivered pressure setting	Value: (cmH_2O or hPa)
***Sleep apnoea breathing therapy equipment* operating in *self-adjusting* positive *airway pressure* mode**		
Minimum pressure	Minimum delivered pressure setting	Value: (cmH_2O or hPa)
Maximum pressure	Maximum delivered pressure setting	Value: (cmH_2O or hPa)
***Sleep apnoea breathing therapy equipment* operating in *bi-level pap* mode**		
Inspiratory pressure	Inspiratory pressure setting	Value: (cmH_2O or hPa)
Expiratory pressure	Expiratory pressure setting	Value: (cmH_2O or hPa)

Table BB.106 defines applicable service and maintenance parameters.

Table BB.106 — Service monitoring

Parameter	Description	Type
Maintenance needed	A *manufacturer*-specific list of any items requiring maintenance, e.g. filter, *mask*, tubing	List of text strings: (*manufacturer*-defined)
Equipment service indicator	An indication that service is required	Text string: (*manufacturer*-defined)
Hours of flow generation	Number of hours the equipment has provided flow	Value: (h)

Annex CC
(informative)

Reference to the IMDRF *essential principles* and labelling guidances

This document has been prepared to support the *essential principles* and labelling requirements of *sleep apnoea breathing therapy equipment*, its *accessories* or parts as a medical device according to the International Medical Device Regulators Forum (IMDRF). This document is intended to be acceptable for conformity assessment purposes.

Conformance with this document provides one means of demonstrating conformance with the specific *essential principles* of IMDRF/GRRP WG/N47:2018[17] and labelling principles IMDRF/GRRP WG/N52:2019[18]. Other means are possible. Table CC.1 maps the clauses and subclauses of this document with the essential principles of IMDRF/GRRP WG/ N47:2018. Table BB.2 maps the clauses and subclauses of this document with the labelling principles of IMDRF/GRRP WG/N52:2019.

NOTE 1 When an *essential principle* does not appear in Table CC.1, it means that it is not addressed by this document.

Table CC.1 — Correspondence between this document and the *essential principles*

***Essential principle* of IMDRF/GRRP WG/N47:2018[17]**	**Corresponding clause(s)/ sub-clause(s) of this document**	**Qualifying remarks/Notes**
5.1.1	All	The part relating to manufacturing is not addressed
5.1.3	201.4, 201.4.3.101	The part relating to manufacturing is not addressed
5.1.3 a)	201.4, 201.4.3.101	
5.1.3 b)	201.4.3.101, 201.7, 201.11.8, 201.12.4	
5.1.4	201.7	
5.1.5 a)	201.12.1, 206	
5.1.5 b)	206	
5.1.6	All	
5.17	201.4, 201.15	
5.19	201.4	
5.3.1 a)	201.7.2.13.101, 201.11.7	Only the requirements related to toxicity are covered.
5.3.1 b)	201.11.6.6, 201.11.7	Covered for *normal use* including *cleaning*, *disinfection* and *sterilization*.
5.3.1 e)	201.11.6.6 bb)	Covered for *normal use* including *cleaning* and *disinfection*.
5.3.1 f)	201.11.7, 201.12.1.101,	Covered for *biocompatibility* and

Essential principle of IMDRF/GRRP WG/N47:2018[17]	Corresponding clause(s)/ sub-clause(s) of this document	Qualifying remarks/Notes
	201.12.1.102.1, 201.12.1.102.2, 201.12.1.103	accuracy.
5.3.2	201.11.6.6, 201.11.7	
5.3.3	201.11.7	Only the requirements related to design are addressed
5.3.5	201.11.6	
5.3.5 a)	201.11.6.6	
5.3.5 b)	201.11.6.6, 201.11.6.7	
5.3.5 c)	201.11.7	
5.4.1	201.11.6.6	
5.5.1	201.7.2.4.101, 201.7.2.13.101, 201.7.9.2.5.101 b), 201.7.9.2.14.101, 201.16, 201.101, 201.102	Covered with respect to use with the listed *accessories*, latex-containing components, connecting *accessories* and *operator*-detachable components and positioning of the *patient*-interface
5.5.2 a)	201.9	
5.5.2 b)	201.12.1, 201.12.4, 206	
5.5.2 c)	202	Covered with respect to magnetic fields, external electrical and electromagnetic effects and electrostatic discharge.
5.5.2 h)	202	Covered with respect to electromagnetic disturbances.
5.5.3	201.11	
5.5.5	201.7.2.4.101, 201.7.2.13.101, 201.7.9.2.5.101 b), 201.7.9.2.14.101, 201.101, 201.102.1	Covered with respect to use with the listed *accessories*, connecting *accessories* and *operator*-detachable components and positioning of the *patient*-interface.
5.5.7	201.12.1, 206	
5.6.1	201.9, 201.11, 211	
5.6.3	201.9.6.2.1.101	
5.6.4	201.7.9.2.5.101 b), 201.101	
5.6.5	201.11	
5.7.1	201.13	
5.7.5	202	
5.7.6	202	
5.7.7	201.8, 201.13	
5.8.1	201.14	