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Anaesthetic and respiratory equipment — Passive humidifiers

Matériel d'anesthésie et de réanimation respiratoire — Humidificateurs passifs

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Foreword

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

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

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

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

For an explanation on 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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

Introduction

This document specifies requirements for so called “cold bubble-through or cold pass-over” respiratory tract PASSIVE HUMIDIFIERS intended for use on PATIENTS in home care and in healthcare facilities. PASSIVE HUMIDIFIERS are used to raise the water content of gases delivered to PATIENTS. Gases available for medical use do not contain sufficient moisture and can damage or irritate the respiratory tract or desiccate secretions of PATIENTS whose upper airways have been bypassed. Inadequate humidity at the PATIENT-CONNECTION PORT can cause drying of the upper airway, or desiccation of tracheo-bronchial secretions in the tracheal or tracheostomy tube, which can cause narrowing or even obstruction of the airway[1][2][1)].

PASSIVE HUMIDIFIERS rely on moisture being transferred from a LIQUID RESERVOIR to the gas at room temperature, without heating of either the HUMIDIFICATION CHAMBER or BREATHING TUBES, to increase the water content of gases delivered to PATIENTS. Hence, such respiratory tract PASSIVE HUMIDIFIERS have a lower mg/l output than active humidifiers. Refer to ISO 80601-2-74 for BASIC SAFETY and ESSENTIAL PERFORMANCE of active humidifiers.

Since the safe use of a PASSIVE HUMIDIFIER depends on the interaction of the PASSIVE HUMIDIFIER with its ACCESSORIES, this document sets total system performance requirements up to the PATIENT-CONNECTION PORT. These requirements are applicable to ACCESSORIES such as BREATHING TUBES.

This document also constitutes a major technical revision of a portion of ISO 8185:2007[3], which it replaces in combination with ISO 80601-2-74. The most significant changes relative to ISO 8185:2007 for PASSIVE HUMIDIFIERS are the following modifications:

— extending the scope to include the PASSIVE HUMIDIFIER and its ACCESSORIES, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the PASSIVE HUMIDIFIER, and thus not only the PASSIVE HUMIDIFIER itself;

— modification of the humidification test PROCEDURE and the disclosure of humidification performance;

and the following additions:

— requirements for mechanical strength (via IEC 60601-1-11);

— new symbols;

— requirements for a PASSIVE HUMIDIFIER as a component of a system;

— requirements for CLEANING and DISINFECTION PROCEDURES;

— requirements for BIOCOMPATIBILITY;

— requirements for fire prevention;

— requirements for USABILITY.

PASSIVE HUMIDIFIERS are commonly used with air and air-oxygen mixtures and a PASSIVE HUMIDIFIER should be able to operate with these gases. Care should be taken if using other gas mixtures such as helium/oxygen mixtures as their physical properties are different from those of air and oxygen.

In this document, the following print types are used:

— requirements and definitions: roman type;

— *test specifications: 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;

1) Figures in square brackets refer to the Bibliography.

— TERMS DEFINED IN CLAUSE 3 OF THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

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

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

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

— "may" is used to describe a permissible way to achieve compliance with a requirement or test.

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 A.

Anaesthetic and respiratory equipment — Passive humidifiers

1 * Scope

This document specifies requirements for so-called "cold bubble-through" or "cold pass-over" humidifying equipment, hereafter referred to as a PASSIVE HUMIDIFIER. Figure 1 and Figure 2 illustrate these PASSIVE HUMIDIFIERS.

NOTE 1 PASSIVE HUMIDIFIER HUMIDIFICATION CHAMBERS are at room temperature so they have a lower HUMIDIFICATION OUTPUT than active humidifiers.

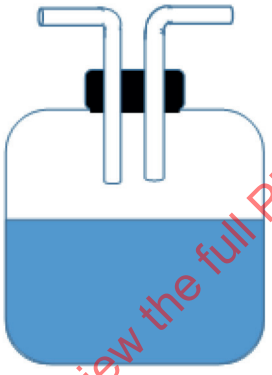

Figure 1 — Cold pass-over PASSIVE HUMIDIFIER

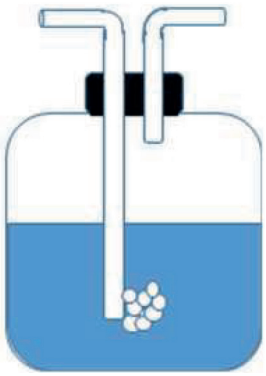

Figure 2 — Cold bubble-through PASSIVE HUMIDIFIER

This document is also applicable to those ACCESSORIES intended by their MANUFACTURER to be connected to a PASSIVE HUMIDIFIER.

A PASSIVE HUMIDIFIER integrated into another MEDICAL DEVICE is subject to the requirements of the standard of the other MEDICAL DEVICE.

EXAMPLE 1 The requirements in ISO 80601-2-69[4] also apply to a PASSIVE HUMIDIFIER integrated into an oxygen concentrator.

EXAMPLE 2 The requirements in ISO 80601-2-70[5] also apply a PASSIVE HUMIDIFIER integrated into sleep apnoea therapy equipment.

This document does not specify the requirements for active heated humidifiers, heated BREATHING TUBES, or active heat and moisture exchangers (HMEs), the requirements for which are given in ISO 80601-2-74.

NOTE 2 ISO 5367 specifies other safety and performance requirements for BREATHING TUBES.

This document is not applicable to a passive HME, which returns a portion of the expired moisture and heat of the PATIENT to the respiratory tract during inspiration without adding heat or moisture, the requirements for which are given in ISO 9360-1[6] and ISO 9360-2[7].

This document is not applicable to nebulizers used for the delivery of liquids to PATIENTS, the requirements for which are given in ISO 27427[8].

This document is not applicable to equipment commonly referred to as "room humidifiers" or humidifiers used in heating, ventilation and air conditioning systems, or humidifiers incorporated into infant incubators.

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 A.

This document has been prepared to support the ESSENTIAL PRINCIPLES OF SAFETY AND PERFORMANCE of a PASSIVE HUMIDIFIER and related ACCESSORIES as MEDICAL DEVICES in accordance with ISO 16142-1:2016. Annex D maps the clauses and subclauses of this document with the ESSENTIAL PRINCIPLES of ISO 16142-1:2016.

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.

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

NOTE 2 Informative references are listed in the Bibliography.

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 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

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

ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 10993-1:2009, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 13485:2016, *Medical devices — Quality management systems — Requirements for regulatory purposes*

EN 13544-2:2002+AMD1:2009, *Respiratory therapy equipment — Part 2: Tubing and connectors*

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 14971:2007, *Medical devices — Application of risk management to medical devices*

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

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

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

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

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

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

ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO 80601-2-12:2011, *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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135:2001, ISO 7396-1:2016, ISO 13485:2016, ISO 14971:2007, ISO 16142-1:2016, ISO 17664:2017, ISO 18562-1:2017, ISO 23328-2:2002, IEC 60601-1:2005+AMD1:2012, IEC 60601-1-11:2015, IEC 62366-1:2015, ISO 80601-2-12:2011, ISO 80601-2-74:2017 and the following apply.

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

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

NOTE For convenience, the sources of all defined terms used in this document are given in Annex E.

3.1
ACCOMPANYING DOCUMENTATION
materials accompanying a MEDICAL DEVICE and containing information for the user or those accountable for the installation, use and maintenance of the MEDICAL DEVICE, particularly regarding safe use

Note 1 to entry: The ACCOMPANYING DOCUMENTATION can consist of the instructions for use, technical description, installation manual, quick reference guide, etc.

Note 2 to entry: ACCOMPANYING DOCUMENTATION is not necessarily a written or printed document but could involve auditory, visual or tactile materials and multiple media types.

Note 3 to entry: MEDICAL DEVICES that can be used safely without instructions for use are exempted from having instructions for use by some authorities with jurisdiction.

[SOURCE: IEC 62366-1:2015, 3.2]

3.2
BASIC SAFETY
freedom from unacceptable RISK directly caused by physical HAZARDS when the MEDICAL DEVICE is used under NORMAL CONDITION and SINGLE FAULT CONDITION

[SOURCE: IEC 60601-1:2005, 3.10, modified: replaced “me equipment” with “the MEDICAL DEVICE”]

3.3
CLEARLY LEGIBLE
capable of being read by a person with normal vision

Note 1 to entry: See the test in 6.1.1.

[SOURCE: IEC 60601-1:2005+A1:2012, 3.15, modified: replaced “7.1.2” with “6.1.1”]

3.4
EXPECTED SERVICE LIFE
time period specified by the MANUFACTURER during which the MEDICAL DEVICE or ACCESSORY is expected to remain safe for use

Note 1 to entry: Maintenance can be necessary during the EXPECTED SERVICE LIFE.

[SOURCE: IEC 60601-1:2005+AMD1:2012, 3.28, modified: replaced “me equipment or me system” with “the MEDICAL DEVICE or ACCESSORY” and deleted parenthetical]

3.5
FLOW-DIRECTION-SENSITIVE COMPONENT
component or ACCESSORY through which gas flow must be in one direction only for proper functioning or PATIENT safety

[SOURCE: ISO 4135:2001, 3.1.7, modified: added “or ACCESSORY”]

3.6
HUMIDIFICATION CHAMBER
part of the PASSIVE HUMIDIFIER in which vaporization or nebulization takes place

3.7
HUMIDIFICATION OUTPUT
total mass of water vapour per unit volume of gas at the PATIENT-CONNECTION PORT

Note 1 to entry: HUMIDIFICATION OUTPUT shall be expressed under BODY TEMPERATURE AND PRESSURE, SATURATED (BTPS) conditions.

Note 2 to entry: Physiology lung volumes and flows are standardized to barometric pressure at sea level, body temperature, and saturated with water vapour (BTPS).

3.8
LIQUID CONTAINER
part of the PASSIVE HUMIDIFIER which holds the liquid

Note 1 to entry: The LIQUID CONTAINER can be accessible to the breathing gas.

Note 2 to entry: The LIQUID CONTAINER can also be part of the HUMIDIFICATION CHAMBER.

Note 3 to entry: The LIQUID CONTAINER can be detachable for filling.

3.9
LIQUID RESERVOIR
part of the PASSIVE HUMIDIFIER which replenishes the LIQUID CONTAINER

3.10
MAXIMUM LIMITED PRESSURE
$P_{LIM\ max}$
highest AIRWAY PRESSURE during NORMAL USE under NORMAL CONDITION or SINGLE FAULT CONDITION

3.11
PASSIVE HUMIDIFIER
bubble–through or pass-over MEDICAL DEVICE that creates vapour or droplets from water at room temperature to moisten the inspired gas

Note 1 to entry: PASSIVE HUMIDIFIER HUMIDIFICATION CHAMBERS are at room temperature so they have a lower HUMIDIFICATION OUTPUT than an active humidifier.

Note 2 to entry: PASSIVE HUMIDIFIERS do not use heat to increase the temperature of either the HUMIDIFICATION CHAMBER or the BREATHING TUBES.

Note 3 to entry: Figure 1 and Figure 2 illustrate PASSIVE HUMIDIFIERS.

3.12
PATIENT-CONNECTION PORT
port at the PATIENT end of the BREATHING TUBES intended for connection to an airway device

EXAMPLE A tracheal tube, tracheostomy tube, face mask and supralaryngeal airway are all airway devices.

3.13
PROTECTION DEVICE
part or function of MEDICAL DEVICE or ACCESSORY that, without intervention by the USER, protects the PATIENT from hazardous output due to incorrect delivery of energy or substances

[SOURCE: ISO 80601-2-12:2011, 203.3.220, modified: replaced “me equipment” with “MEDICAL DEVICE or ACCESSORY” and “operator” with “USER”]

3.14
RELATIVE HUMIDITY
water vapour pressure, expressed as a percentage of the saturation vapour pressure, at a particular temperature

3.15
SINGLE FAULT CONDITION
condition of MEDICAL DEVICE in which a single means for reducing a RISK is defective or a single abnormal condition is present

[SOURCE: IEC 60601-1:2005, 3.116, modified: “me equipment” was replaced by “MEDICAL DEVICE”]

4 General requirements for testing

4.1 Water level

Unless otherwise specified, the LIQUID CONTAINER and LIQUID RESERVOIR shall be filled to maximum capacity, as indicated in the instructions for use, at the beginning of a test with distilled water at the ambient test temperature.

4.2 PASSIVE HUMIDIFIER test conditions

a) For testing, the PASSIVE HUMIDIFIER

   1) shall be connected to gas supplies as specified for NORMAL USE,

   2) except that industrial-grade oxygen and air may be substituted for the equivalent medical gas, as appropriate, unless otherwise stated.

b) When using substitute gases, care should be taken to ensure that the test gases are oil-free and appropriately dry.

The moisture content of all gas supplies shall be less than 1 mg/l.

4.3 * Gas flowrate and leakage specifications

In this document, requirements for the flowrate, volume and leakage are expressed at STANDARD TEMPERATURE AND PRESSURE, DRY (STPD), except for those associated with the BREATHING SYSTEM, which are expressed at BODY TEMPERATURE AND PRESSURE, SATURATED (BTPS).

NOTE 1 For the purposes of this standard, STPD is 101,325 kPa at an operating temperature of 20 °C.

NOTE 2 For the purposes of this standard, BTPS is local atmospheric pressure and a RELATIVE HUMIDITY of 100 % at an operating temperature of 37 °C.

Correct all test measurements to STPD or BTPS, as appropriate.

4.4 * PASSIVE HUMIDIFIER testing errors

a) For the purposes of this document, declared tolerances shall be adjusted by the measurement uncertainty.

b) The MANUFACTURER shall disclose the measurement uncertainty or each disclosed tolerance in the technical description.

Check compliance by inspection of the instructions for use and the technical description.

5 General requirements

5.1 Mechanical BASIC SAFETY for all PASSIVE HUMIDIFIERS

5.1.1 General

A PASSIVE HUMIDIFIER shall be free of rough surfaces, sharp corners and edges that can cause injury or damage.

Check compliance by inspection.

5.1.2 * Requirements for instability from unwanted lateral movement

a) A TRANSIT-OPERABLE PASSIVE HUMIDIFIER shall include a means by which the PASSIVE HUMIDIFIER can be easily attached to prevent unwanted movement during transport while in use.

b) The means shall allow the PASSIVE HUMIDIFIER to withstand accelerations or decelerations of 1,0 g longitudinal (forward, backward), 1,0 g transverse (left, right) for at least 5 s each.

EXAMPLES Means to be physically restrained during transport in a personal vehicle, in an ambulance or on a wheelchair.

Check compliance by functional testing.

5.1.3 * Requirements for audible acoustic energy

The A-weighted sound pressure level emitted by the PASSIVE HUMIDIFIER shall be less than 50 dB as determined by the following test method.

Check compliance with the following test.

a) *Place the PASSIVE HUMIDIFIER on a sound-reflecting plane, fill the liquid container to the least favourable level and attach the least favourable set of accessories from those indicated in the instructions for use.*

b) *Configure the test lung with the compliance and resistance components whose values are indicated in Table 1.*

— *Connect the PATIENT-CONNECTION PORT to the test lung.*

— *Connect a ventilator or other appropriate flow source to the input of the PASSIVE HUMIDIFIER.*

NOTE The ventilator or other appropriate flow source is being used as a driving source for the PASSIVE HUMIDIFIER.

— *Acoustically isolate the test lung and ventilator or other appropriate flow source by a suitable means so that any noise caused by the test lung and ventilator does not interfere with the sound measurement of the PASSIVE HUMIDIFIER.*

c) *If the flow source is a ventilator, set the ventilator to volume control mode that generates ventilation as indicated in Table 1. Otherwise, configure the flow source to the worst-case flow.*

Table 1 — Test conditions for acoustic tests

Adjustable parameter	Test condition		
	For a PASSIVE HUMIDIFIER intended to provide an inspired volume		
	$V_{del} \geq 300$ ml	300 ml $\geq V_{del} \geq$ 50 ml	$V_{del} \leq 50$ ml
Delivered volume, V_{del}[a]	500 ml	150 ml	30 ml
Ventilatory frequency, f	10 min^{-1}	20 min^{-1}	30 min^{-1}
I:E ratio	1:2	1:2	1:2
PEEP	5 hPa	5 hPa	5 hPa
Resistance, R[b][9][10][11]	5 hPa$(l/s)^{-1}$ ± 10 %	20 hPa$(l/s)^{-1}$ ± 10 %	50 hPa$(l/s)^{-1}$ ± 10 %
Isothermal Compliance, C[b]	50 ml hPa^{-1} ± 5 %	20 ml hPa^{-1} ± 5 %	1 ml hPa^{-1} ± 5 %

[a] V_{del} is measured by means of a pressure sensor on the test lung, where $V_T = C \times P_{max}$, and
V_t is the volume delivered to the test lung
C is the Isothermal Compliance of the test lung
P_{max} is the maximum pressure measured in the test lung

[b] The accuracy for C and R applies over the ranges of the measured parameters.

d) *Using the microphone of a sound level meter complying 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 PASSIVE HUMIDIFIER as specified in ISO 3744:2010, 7.2.*

e) *Calculate the A-weighted sound pressure level averaged over the measurement surface according to ISO 3744:2010, 8.1.*

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

g) *Take measurements using the frequency-weighting characteristic A and the time-weighting characteristic F on the sound level meter in a free field over a reflecting plane as specified in ISO 3744:2010. Average the values in accordance with ISO 3744:2010, 8.1.*

h) *Ensure that the measured sound pressure level is less than 50 dB.*

5.1.4 * Overflow

a) In NORMAL CONDITION and SINGLE FAULT CONDITION, a PASSIVE HUMIDIFIER shall be so constructed that the following HAZARDOUS SITUATIONS shall not occur:

1) the volume of liquid exiting the HUMIDIFICATION CHAMBER outlet and the PATIENT-CONNECTION PORT exceeding:

i) 1,0 ml in 1 min or 2,0 ml in 1 h when intended for use with PATIENTS weighing less than 5 kg; and

ii) 5 ml in 1 min or 20 ml in 1 h for all other PATIENTS.

b) When a PASSIVE HUMIDIFIER is operated under NORMAL CONDITION at the maximum flowrate of NORMAL USE, a HAZARDOUS SITUATION or unacceptable RISK due to overflow shall not occur:

1) if the LIQUID CONTAINER or LIQUID RESERVOIR is filled to its maximum capacity;

2) for a PORTABLE PASSIVE HUMIDIFIER (e.g. table top), if the PASSIVE HUMIDIFIER is tilted through an angle of 10° from any position of NORMAL USE when operated under NORMAL CONDITION at the maximum flowrate of NORMAL USE; and

3) for a TRANSIT-OPERABLE (e.g. pole-mounted or carried) PASSIVE HUMIDIFIER, if the PASSIVE HUMIDIFIER is tilted through an angle of 20° from any position of NORMAL USE; and then moved over a 10 mm threshold, if MOBILE.

Check compliance by the following test:

c) *Fill the LIQUID CONTAINER and LIQUID RESERVOIR to the indicated maximum level. Operate the PASSIVE HUMIDIFIER at its maximum RATED flowrate.*

d) *Subsequently tilt the PASSIVE HUMIDIFIER through an angle of 10° in the least favourable direction(s) (if necessary with refilling) starting from the position of NORMAL USE.*

e) *Subsequently tilt the MOBILE PASSIVE HUMIDIFIER through an angle of 20° in the least favourable direction(s) (if necessary with refilling) starting from the position of NORMAL USE and move it over a threshold that is 10 mm ± 0,5 mm high and at least 80 mm wide at a rate of 0,8 m/s ± 0,1 m/s.*

f) *Return the PASSIVE HUMIDIFIER to normal orientation and subsequently add a further quantity equal to 15 % of the capacity of the LIQUID CONTAINER and LIQUID RESERVOIR, poured in steadily over a period of 1 min.*

g) *Confirm that no more liquid than is specified exits the HUMIDIFICATION CHAMBER outlet.*

5.1.5 * Overpressure requirement

a) If the PASSIVE HUMIDIFIER is intended to be directly connected to a MEDICAL GAS PIPELINE SYSTEM complying with ISO 7396-1:2016 then it:

1) shall operate and meet the requirements of this document throughout its RATED range of input pressure; and

2) shall not cause an unacceptable RISK under the SINGLE FAULT CONDITION of 1 000 kPa.

NOTE 1 An internal pressure regulator can be required to accommodate the SINGLE FAULT CONDITION of maximum input pressure as well as the RATED range of input pressure.

NOTE 2 Under the SINGLE FAULT CONDITION of overpressure, it is desirable for gas to continue to flow to the BREATHING SYSTEM. Under this condition, the flowrate from the PASSIVE HUMIDIFIER is likely to be outside of its specification.

b) If the PASSIVE HUMIDIFIER has a maximum RATED input pressure in excess of 600 kPa, the PASSIVE HUMIDIFIER shall not cause an unacceptable RISK under the SINGLE FAULT CONDITION of twice the maximum RATED input pressure.

Check compliance by functional testing in NORMAL USE and under NORMAL CONDITION with the most adverse operating settings, by functional testing in SINGLE FAULT CONDITION and inspection of the RISK MANAGEMENT FILE.

5.2 Compatibility requirement

If the PASSIVE HUMIDIFIER is intended to be directly connected to a MEDICAL GAS PIPELINE SYSTEM complying with ISO 7396-1:2016 then:

a) the RATED range of input pressure shall cover the range specified in ISO 7396-1:2016; and

b) under NORMAL CONDITION,

1) the maximum 10 s average input flow required by the PASSIVE HUMIDIFIER for each gas shall not exceed 60 l/min at a pressure of 280 kPa, measured at the gas input port; and

2) the transient input flow shall not exceed 200 l/min averaged for 3 s;

or

3) the ACCOMPANYING DOCUMENTATION shall disclose

i) the maximum 10 s average input flow required by the PASSIVE HUMIDIFIER for each gas at a pressure of 280 kPa, measured at the gas input port;

ii) the maximum transient input flow averaged for 3 s required by the PASSIVE HUMIDIFIER for each gas at a pressure of 280 kPa, measured at the gas input port; and

iii) a warning to the effect that this PASSIVE HUMIDIFIER is a high flow device and should only be connected to a pipeline installation designed using a diversity factor that allows for the indicated high flow at a specified number of terminal outlets, in order to avoid exceeding the pipeline design flow, thereby minimising the RISK that the PASSIVE HUMIDIFIER interferes with the operation of adjacent equipment.

Check compliance by functional testing in NORMAL USE and under NORMAL CONDITION with the most adverse operating settings and by inspection of the ACCOMPANYING DOCUMENTATION.

EXAMPLE Highest driving gas consumption, highest gas delivery and, if provided, the highest RATED gas consumption at any gas power supply output.

5.3 General requirements for mechanical strength

a) The tests of Clause 10 of IEC 60601-1-11:2015 shall be performed on the same sample of the PASSIVE HUMIDIFIER after the tests of Clause 10 of this document.

b) If more than one PROCEDURE is specified in the instructions for use, each PROCEDURE shall be so tested.

c) A separate sample of the PASSIVE HUMIDIFIER may be used for each specified PROCEDURE.

Check compliance by application of the tests of IEC 60601-1-11:2015, Clause 10.

6 Identification, marking and ACCOMPANYING DOCUMENTATION

6.1 Legibility and durability of markings

6.1.1 Legibility

The markings required by 6.2 shall be CLEARLY LEGIBLE under the following conditions:

a) for warning statements, instructive statements, safety signs and drawings on the outside of the PASSIVE HUMIDIFIER: from the intended position of the person performing the related function; and

b) for the PASSIVE HUMIDIFIER: in NORMAL USE.

Check compliance for clear legibility by the following test:

The PASSIVE HUMIDIFIER or its part is positioned so that the viewpoint is the intended position of the USER. If the intended position of the USER is not specified and the position is not obvious, the viewpoint is at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m. The ambient illumination is the least favourable level in the range of 100 lx to 1 500 lx.

The observer has a visual acuity, corrected if necessary, of:

— *0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20); and*

— *is able to read N6 of the Jaeger test card;*

in normal room lighting conditions (approximately 500 lx).

The observer correctly reads the marking from the viewpoint.

6.1.2 Durability

The markings required by 6.2 shall be removable only with a TOOL or by appreciable force and shall be sufficiently durable to remain CLEARLY LEGIBLE during the EXPECTED SERVICE LIFE of the PASSIVE HUMIDIFIER. In considering the durability of the markings, the effect of NORMAL USE shall be taken into account.

Check compliance by the following tests:

a) *Markings are rubbed by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ethanol 96 % and then for 15 s with a cloth rag soaked with isopropyl alcohol.*

b) *After all the tests 6.1.2 a) and the rest of the tests of this document have been performed:*

   — *test markings to the requirements of 6.1.1; and*

   — *confirm that adhesive labels have not worked loose or become curled at the edges.*

6.2 Markings on the outside of the PASSIVE HUMIDIFIER or its parts

6.2.1 Identification

a) A PASSIVE HUMIDIFIER shall be marked with:

   1) the name or trademark and address of

      i) the MANUFACTURER; and

ii) where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale,

to which the RESPONSIBLE ORGANIZATION can refer;

2) a MODEL OR TYPE REFERENCE or symbols 5.1.6 from ISO 15223-1:2016 (Table B.1, symbol 4);

3) with an identification reference to the batch or serial number or symbols 5.1.5 or 5.1.7 from ISO 15223-1:2016 (Table B.1, symbol 3 or symbol 5); and

4) the date of manufacture or use-by date or symbols 5.1.3 or 5.14 from ISO 15223-1:2016 (Table B.1, symbol 1 or symbol 2), if applicable.

b) The serial number, lot or batch identifier, and the date of manufacture may be provided in a human readable code or through automatic identification technology such as barcodes or radio-frequency identification (RFID).

c) Detachable components of the PASSIVE HUMIDIFIER shall be marked with:

1) the name or trademark of the MANUFACTURER;

2) a MODEL OR TYPE REFERENCE; and

3) wherever reasonable and practicable, with an identification reference to the batch or serial number or symbols 5.1.5 or 5.1.7 from ISO 15223-1:2016 (Table B.1, symbol 3 or symbol 5);

unless misidentification does not result in an unacceptable RISK.

Check compliance by inspection.

6.2.2 Additional requirements

The marking of the PASSIVE HUMIDIFIER, parts or ACCESSORIES shall be CLEARLY LEGIBLE and shall include the following:

a) any special storage and handling and operating instructions;

b) any particular warnings and precautions relevant to the immediate operation of the PASSIVE HUMIDIFIER;

c) the RATED range of input flowrate;

d) the RATED maximum input pressure;

e) the RATED range of environmental operating conditions (temperature and altitude) of NORMAL USE; and

f) the maximum and minimum liquid levels.

If applicable, marking of USER-accessible parts or ACCESSORIES shall be CLEARLY LEGIBLE and shall include the following:

g) an arrow indicating the direction of the flow for FLOW-DIRECTION-SENSITIVE COMPONENTS that are USER-removable without the use of a TOOL; and

h) if a pressure-relief PROTECTION DEVICE is provided, the pressure at which it opens. This marking shall be on or near the pressure-relief PROTECTION DEVICE.

Check compliance by inspection.

6.2.3 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) Symbol 5.4.5 from ISO 15223-1:2016 (refer to Annex B, Table B.2, symbol 6) may be used.

d) The instructions for use shall disclose any natural rubber latex-containing components.

Check compliance by inspection.

6.2.4 Requirements for packaging

The marking on packages shall be CLEARLY LEGIBLE and shall include the following.

a) A description of the contents.

b) An identification reference to the batch, type or serial number or symbols 5.1.5, 5.1.6 or 5.1.7 from ISO 15223-1:2016 (Table B.1, symbol 3, symbol 4 or symbol 5).

c) For packages containing natural rubber latex, the word "LATEX", or symbol 5.4.5 from ISO 15223-1:2016 (Table B.1, symbol 6).

d) Any material, component, ACCESSORY or PASSIVE HUMIDIFIER that is intended for a single use or its packaging shall be marked "Single Use Only", "Do Not Reuse" or with symbol 5.4.2 from ISO 15223-1:2016 (Table B.1, symbol 8). For a specific MODEL OR TYPE REFERENCE, the indication of single use shall be consistent for the MODEL OR TYPE REFERENCE.

Check compliance by inspection.

6.2.5 Symbols

a) The meanings of the symbols used for marking shall be explained in the instructions for use.

b) Symbols required by this document shall conform to the requirements in the referenced IEC or ISO publication.

Check compliance by inspection.

6.3 Units of measurement

All gas volume, flow and leakage specifications in the ACCOMPANYING DOCUMENTATION

a) shall be expressed at STPD (STANDARD TEMPERATURE AND PRESSURE, DRY);

b) except those associated with the BREATHING SYSTEM that shall be expressed at BTPS (BODY TEMPERATURE AND PRESSURE, SATURATED).

Check compliance by inspection of the ACCOMPANYING DOCUMENTATION.

6.4 Instructions for use

6.4.1 Identification

a) The PASSIVE HUMIDIFIER shall be accompanied by documents containing the instructions for use.

b) The instructions for use shall be regarded as a part of the PASSIVE HUMIDIFIER.

c) The instructions for use shall identify the PASSIVE HUMIDIFIER by including, as applicable, the following:

1) the name or trade name of the MANUFACTURER;

2) an address or contact information to which the RESPONSIBLE ORGANIZATION can refer; and

3) the MODEL OR TYPE REFERENCE.

d) The instructions for use may be provided electronically, e.g. electronic file format on CDROM.

e) If the instructions for use are provided electronically, the USABILITY ENGINEERING PROCESS shall include consideration of which information also needs to be provided:

1) as hard copy; or

2) as markings on the PASSIVE HUMIDIFIER.

NOTE Instructions for use provided electronically might not be acceptable in all jurisdictions.

f) The instructions for use shall:

1) specify any special skills, training and knowledge required of the intended USER or the RESPONSIBLE ORGANIZATION; and

2) any restrictions on locations or environments in which the PASSIVE HUMIDIFIER can be used.

g) The instructions for use shall be written at a level consistent with the education, training and any special needs of the person(s) for whom they are intended.

Check compliance by inspection of the instructions for use, and, when provided electronically, by inspection of the USABILITY ENGINEERING FILE.

6.4.2 General requirements

The instructions for use shall document:

a) a summary of the USE SPECIFICATION as specified in IEC 62366-1:2015, 5.1;

b) any special storage, handling and operating instructions;

c) the PRIMARY OPERATING FUNCTIONS;

d) any known contraindication(s) to the use of the PASSIVE HUMIDIFIER;

e) those parts of the PASSIVE HUMIDIFIER that cannot be serviced or maintained while in use with a PATIENT;

f) if the PASSIVE HUMIDIFIER, 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 PASSIVE HUMIDIFIER, its parts or ACCESSORIES were reused;

g) if the PASSIVE HUMIDIFIER, its parts or ACCESSORIES are intended for single use, information regarding the intended duration of use; and

h) a statement on the quality and purity of the water to be used in the PASSIVE HUMIDIFIER, and that adding other substances can have adverse effects.

Where the PATIENT is an intended USER, the instructions for use shall indicate:

i) that the PATIENT is an intended USER;

j) a warning against servicing and maintenance while the PASSIVE HUMIDIFIER is in use; and

k) which functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use, and which maintenance the PATIENT can perform (e.g. refilling the LIQUID CONTAINER or LIQUID RESERVOIR).

Check compliance by inspection of the instructions for use.

6.4.3 * Requirements for warnings and safety notices

The instructions for use shall include the following.

a) A warning statement to the effect that "WARNING: Do not add any attachments or accessories to the humidifier that are not listed in the instructions for use or the humidifier might not function correctly, affecting the quality of the therapy or injuring the patient."

b) A warning statement to the effect that "WARNING: Covering breathing tubes with a blanket or heating them in an incubator or with an overhead heater can affect the quality of the therapy or injure the patient."

c) A warning statement to the effect that "WARNING: Do not use the humidifier at an altitude above (insert maximum RATED altitude) or outside a temperature of (insert RATED temperature range). Using the humidifier outside of this temperature range or above this altitude can affect the quality of the therapy or injure the patient."

d) A warning statement to the effect that "WARNING: To prevent disconnection of the tubing or tubing system during use, especially during ambulatory use, only tubes in compliance with ISO 5367 or ISO 80601-2-74 should be used".

e) A warning statement to the effect that "WARNING: This humidifier is not suitable for patients whose upper airways have been bypassed by an endotracheal tube or tracheotomy. It provides insufficient humidification output to prevent irritation the respiratory tract or desiccation of secretions."

Check compliance by inspection of the instructions for use.

6.4.4 Requirements for installation

The instructions for use shall give recommended mounting methods and other relevant information for installation of the PASSIVE HUMIDIFIER.

Check compliance by inspection of the instructions for use.

6.4.5 Requirements for start-up PROCEDURE

NOTE For the purposes of this document, a start-up PROCEDURE is a pre-use test that is used to determine whether the PASSIVE HUMIDIFIER is ready for use.

The instructions for use shall contain the necessary information for the USER to bring the PASSIVE HUMIDIFIER into operation.

Check compliance by inspection of the instructions for use.

6.4.6 * Requirements for operating instructions

a) The instructions for use shall include:

1) the conditions under which the PASSIVE HUMIDIFIER maintains the accuracy of controlled variables as disclosed in the instructions for use;

EXAMPLE 1 Acceptable range of water level to maintain the HUMIDIFICATION OUTPUT.

2) the HUMIDIFICATION OUTPUT as determined in Clause 7;

3) the maximum volume of water, expressed in ml, available for vaporization contained in the LIQUID CONTAINER and, if provided, in the LIQUID RESERVOIR;

4) an indication of the expected duration of operation between refills, under specified operating conditions;

5) the MAXIMUM LIMITED PRESSURE of the PASSIVE HUMIDIFIER and ACCESSORIES;

6) the MAXIMUM OPERATING PRESSURE;

7) the RATED range of environmental operating conditions (temperature and altitude) of NORMAL USE;

8) the gas leakage of the PASSIVE HUMIDIFIER or individual components, as appropriate, at the maximum RATED pressure. The gas leakage should be determined in accordance with ISO 5367 or an equivalent method;

9) * unless the PASSIVE HUMIDIFIER is integrated into other equipment, the RATED range of the following characteristics of the assembled USER-detachable parts, over which the accuracies of set and monitored humidification are maintained:

   i) flowrate;

   ii) GAS PATHWAY resistance; and

   iii) GAS PATHWAY compliance.

   iv) These specifications may be presented in ranges.

   v) The accuracies of set and monitored values may be presented as a function of these characteristics.

   vi) Since these values can be affected by the depletion of the liquid, the minimum and maximum values shall be disclosed.

   NOTE 1 Compliance and resistance can be nonlinear. These characteristics might need to be specified over a range (e.g. at 15 l/min, 30 l/min, 60 l/min, maximum flowrate and the maximum RATED pressure).

   NOTE 2 The resistance and compliance can be determined in accordance with ISO 5367 or an equivalent method.

10) * Unless the PASSIVE HUMIDIFIER is integrated into other equipment, the pressure drop, as a function of flowrate, across the PASSIVE HUMIDIFIER and ACCESSORIES or individual components, as appropriate.

   NOTE 3 The pressure drop should be determined in accordance with ISO 5367 or an equivalent method.

b) If applicable, the instructions for use shall disclose:

1) the essential technical characteristics of each recommended BREATHING SYSTEM FILTER; and

   EXAMPLES Deadspace and resistance.

2) * for a PASSIVE HUMIDIFIER that entrains air for the purpose of diluting oxygen:

   i) a statement to the effect that the oxygen concentration can be affected by a partial obstruction downstream of the PASSIVE HUMIDIFIER, e.g. when using ACCESSORY equipment; and

   ii) a recommendation that the oxygen concentration be measured at the point of delivery to the PATIENT.

Check compliance by inspection of the instructions for use.

6.4.7 Requirements for CLEANING, DISINFECTION, and STERILIZATION

a) For PASSIVE HUMIDIFIER parts or ACCESSORIES that can become contaminated through contact with the PATIENT or with body fluids or expired gases during both NORMAL USE and SINGLE FAULT CONDITION, the instructions for use shall contain:

   1) details about CLEANING and DISINFECTION or CLEANING and STERILIZATION methods that may be used; and

   2) a list of the applicable parameters such as temperature, pressure, humidity, time limits and number of cycles that such PASSIVE HUMIDIFIER parts or ACCESSORIES can tolerate. Alternatively, another method to determine reduced performance and the end of useful life may be provided.

b) See also Clause 10.

c) This requirement does not apply to any material, component, ACCESSORY or PASSIVE HUMIDIFIER that is marked as intended for single use unless the MANUFACTURER specifies that the material, component, ACCESSORY or PASSIVE HUMIDIFIER needs CLEANING, DISINFECTION or STERILIZATION before use.

d) The instructions for use shall identify the portions of the GAS PATHWAYS through the PASSIVE HUMIDIFIER that can become contaminated with body fluids or expired gases during both NORMAL CONDITION and SINGLE FAULT CONDITION.

Check compliance by inspection of the instructions for use.

6.4.8 Requirements for maintenance

The instructions for use shall disclose a description of periodic visual safety inspections that should be performed by the USER.

Check compliance by inspection of the instructions for use.

6.4.9 Requirements for ACCESSORIES, supplementary equipment and used material

The instructions for use of a PASSIVE HUMIDIFIER shall identify

a) at least one set of ACCESSORIES and, if applicable, the equipment necessary for the PASSIVE HUMIDIFIER'S INTENDED USE.

If applicable, the instructions for use shall disclose

b) any restrictions on the positioning of components within the BREATHING SYSTEM;

   EXAMPLE Where such components are FLOW-DIRECTION-SENSITIVE COMPONENTS.

c) any adverse effect of any recommended ACCESSORY on the ESSENTIAL PERFORMANCE or BASIC SAFETY of the equipment to which the PASSIVE HUMIDIFIER is connected.

Check compliance by inspection of the instructions for use and inspection of the RISK MANAGEMENT FILE for any adverse effect of any recommended ACCESSORY.

6.4.10 Unique version identifier

The instructions for use of a PASSIVE HUMIDIFIER shall contain a unique version identifier such as its date of issue.

Check compliance by inspection of the instructions for use.

6.5 Technical description

The technical description shall disclose:

a) a pneumatic diagram of the PASSIVE HUMIDIFIER, including a diagram for USER-detachable parts of the BREATHING SYSTEM either supplied or recommended in the instructions for use;

b) a statement to the effect that the responsible organization should ensure the compatibility of the humidifier and other equipment as well as all of the parts and accessories used to connect to the patient before use.

Check compliance by inspection of the technical description.

7 * HUMIDIFICATION OUTPUT

a) Over the range of flowrates, settings, ambient temperature and gas inlet temperature of NORMAL USE, a PASSIVE HUMIDIFIER shall be capable of producing at the PATIENT-CONNECTION PORT a HUMIDIFICATION OUTPUT (in mg/l) over the RATED range of environmental conditions, gas flowrates and settings as disclosed in the instructions for use.

NOTE 1 PASSIVE HUMIDIFIERS are considered category 3 humidifiers, as the HUMIDIFICATION OUTPUT is less than that of active humidifiers, which add heat to the HUMIDIFICATION CHAMBER or BREATHING TUBE.

NOTE 2 The HUMIDIFICATION OUTPUT of category 1 and category 2 humidifiers is described in ISO 80601-2-74.

b) The HUMIDIFICATION OUTPUT shall either be:

1) determined for each BREATHING SYSTEM configuration indicated in the instructions for use; or

2) determined for the worst-case BREATHING SYSTEM configurations indicated in the instructions for use.

NOTE The worst-case BREATHING SYSTEM configuration can be different for different flowrates and HUMIDIFICATION OUTPUTS.

c) If worst-case BREATHING SYSTEM configurations are used, the rationale for their selection shall be documented in the RISK MANAGEMENT FILE.

Check compliance by inspection of the instructions for use and RISK MANAGEMENT FILE for the rationale, if applicable, and with the tests of Annex C.

8 Systems requirements

a) PASSIVE HUMIDIFIERS are frequently used in combination with other respiratory MEDICAL DEVICES. The addition of a PASSIVE HUMIDIFIER shall not affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the other respiratory MEDICAL DEVICE.

b) Where a PASSIVE HUMIDIFIER is intended to be used in combination with the other respiratory MEDICAL DEVICES as indicated in its instructions for use, it shall be evaluated in combination with the other respiratory MEDICAL DEVICES when applying the requirements of this document.

c) As appropriate, the requirements of the product standards of the other respiratory MEDICAL DEVICES indicated in the instructions for use shall also apply to the PASSIVE HUMIDIFIER.

9 Specific SINGLE FAULT CONDITIONS

A PASSIVE HUMIDIFIER shall be so constructed that the following SINGLE FAULT CONDITIONS shall not cause an unacceptable RISK:

a) operation of the PASSIVE HUMIDIFIER without any liquid; and

b) operation of PASSIVE HUMIDIFIER with overpressure as described in 5.1.5.

10 * CLEANING and DISINFECTION

10.1 General

a) GAS PATHWAYS through the PASSIVE HUMIDIFIER and its ACCESSORIES that can become contaminated with body fluids or expired gases during NORMAL CONDITION or SINGLE FAULT CONDITION shall be designed to allow for CLEANING and DISINFECTION or CLEANING and STERILIZATION. Dismantling may be used.

b) PASSIVE HUMIDIFIER 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.

c) Instructions for PROCESSING the PASSIVE HUMIDIFIER and its ACCESSORIES shall comply with ISO 17664:2017 and ISO 14937:2009 and shall be disclosed in the instructions for use.

NOTE ISO 14159[12] provides guidance for the design of enclosures.

Check compliance by inspection of the RISK MANAGEMENT FILE. When compliance with this document could be affected by the CLEANING or the DISINFECTION of the PASSIVE HUMIDIFIER or its parts or ACCESSORIES, clean and disinfect them 10 times in accordance with the methods indicated in the instructions for use, including any cooling or drying period. After these PROCEDURES, ensure that BASIC SAFETY is maintained. Confirm that the MANUFACTURER has evaluated the effects of multiple PROCESSING cycles and the effectiveness of those cycles.

10.2 Home healthcare environment

a) Any CLEANING or CLEANING and DISINFECTION PROCESSES intended to be performed in the HOME HEALTHCARE ENVIRONMENT by a LAY USER shall be capable of being performed by a LAY USER in the HOME HEALTHCARE ENVIRONMENT.

b) The USABILITY of each such PROCESS as it pertains to a LAY USER shall be evaluated using the USABILITY ENGINEERING PROCESS of IEC 62366-1:2015.

Check compliance by inspection of the USABILITY ENGINEERING FILE.

11 * BREATHING SYSTEM connectors and ports

11.1 General

a) If a PASSIVE HUMIDIFIER is intended to be placed in a BREATHING SYSTEM, any conical connector shall:

1) comply with ISO 5356-1:2015;

2) not engage with connectors complying with ISO 5356-1:2015; or

3) comply with connectors complying with ISO 80369-1:2010.

b) A non-conical connector shall:

1) not engage with a conical connector complying with ISO 5356-1:2015 unless they

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

Check compliance by functional testing and by inspection.

11.2 Outlet connector

11.2.1 Directly connected to the supply source

If the PASSIVE HUMIDIFIER is mounted to the oxygen source by using the inlet connector, the outlet connector shall be:

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

b) a coaxial 15 mm/22 mm conical connector complying with ISO 5356-1:2015; or

c) a nipple complying with EN 13544-2:2002+AMD1:2009, Figure 1, with a maximum internal bore diameter of 2,95 mm.

Check compliance by inspection.

11.2.2 Indirectly connected to the supply source

If the PASSIVE HUMIDIFIER is not mounted to the oxygen source by using the inlet connector, the outlet connector shall be:

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

b) a coaxial 15 mm/22 mm conical connector complying with ISO 5356-1:2015; or

c) a nipple complying with EN 13544-2:2002+AMD1:2009, Figure 1, with a maximum internal bore diameter of 2,95 mm.

d) a respiratory small-bore connector complying with ISO 80369-1.

NOTE It is expected that the male RESP-6000 (R2) connector of ISO 80369-2[13] will meet this criterion.

Check compliance by inspection.

11.3 FLOW-DIRECTION-SENSITIVE COMPONENTS

Any USER-detachable FLOW-DIRECTION-SENSITIVE COMPONENT shall be designed to prevent incorrect assembly.

Check compliance by inspection of USER-detachable FLOW-DIRECTION-SENSITIVE COMPONENTS and inspection of the RISK MANAGEMENT FILE.

11.4 * Accessory port

If provided, each ACCESSORY port of the PASSIVE HUMIDIFIER, BREATHING SYSTEM, its parts and ACCESSORIES shall:

a) comply with ISO 80369-1:2010;

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

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

NOTE 1 It is expected that the RESP-125 (R1) connector of ISO 80369-2[13] will meet this criterion.

NOTE 2 This port is generally used for measuring pressure, sampling of gases or for introduction of therapeutic aerosols.

Check compliance by inspection.

11.5 Monitoring probe port

If a port is provided for introduction of a monitoring probe, it:

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

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

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

Check compliance by functional testing and inspection.

11.6 Oxygen inlet port

11.6.1 Directly connected to the supply source

If the PASSIVE HUMIDIFIER is mounted to the source by using the oxygen connector, the inlet oxygen connector shall be a female 9/16-18 UNF-2A-RH threaded nut.

Check compliance by functional testing and by inspection.

11.6.2 Indirectly connected to the supply source

If the PASSIVE HUMIDIFIER is not mounted to the source by using the connector, the inlet connector shall comply with ISO 80369-1.

NOTE 1 It is expected that the RESP-125 (R1) connector of ISO 80369-2[13] will meet this criterion.

Check compliance by functional testing and by inspection.

11.7 Air inlet port

11.7.1 Directly connected to the supply source

If the PASSIVE HUMIDIFIER is mounted to the source by using the air connector, the inlet air connector shall be a female 3/4-16 UNF-2A-RH threaded nut.

Check compliance by functional testing and by inspection.

11.7.2 Indirectly connected to the supply source

If the PASSIVE HUMIDIFIER is not mounted to the source by using the connector, the inlet connector shall comply with ISO 80369-1.

NOTE 1 It is expected that the RESP-125 (R1) connector of ISO 80369-2[13] will meet this criterion.

Check compliance by functional testing and by inspection.

11.8 Filling port

Any filling port shall not accept any of:

a) the connectors specified in ISO 5356-1:2015; or

b) the connectors specified in ISO 80369 series.

Check compliance by functional testing and by inspection.

12 * Requirements for the BREATHING SYSTEM and ACCESSORIES

12.1 General

As safe use depends on the interaction of the PASSIVE HUMIDIFIER with ACCESSORIES, this document sets total-system performance requirements referenced to the PATIENT-CONNECTION PORT. Therefore, total system performance requirements are applicable to both the PASSIVE HUMIDIFIER and BREATHING TUBES intended for use with a PASSIVE HUMIDIFIER.

The PASSIVE HUMIDIFIER with ACCESSORIES should have a means of reducing condensate in the BREATHING TUBES.

EXAMPLE The placement of water traps.

All BREATHING SYSTEMS, their parts and ACCESSORIES shall comply with the requirements of this document, whether they are produced by the MANUFACTURER of the PASSIVE HUMIDIFIER or by another entity ("third-party manufacturer" or healthcare provider).

Check compliance by the tests of this document.

12.2 Accompanying documentation

a) The MODEL OR TYPE REFERENCE of at least one compatible PASSIVE HUMIDIFIER shall be disclosed in the ACCOMPANYING DOCUMENTATION provided with each BREATHING SYSTEM or ACCESSORY, compliant with 10.1.

b) Statements shall be included in the ACCOMPANYING DOCUMENTATION of each BREATHING SYSTEM, part or ACCESSORY to the effect that:

   1) breathing systems, their parts and accessories are validated for use with specific humidifiers;

   2) incompatible parts can result in degraded performance which can affect safety; and

   3) the responsible organization is accountable for the compatibility of the humidifier and all of the parts and accessories used to connect to the patient before use.

Check compliance by inspection of the ACCOMPANYING DOCUMENTATION.

12.3 BREATHING TUBES

BREATHING TUBES intended for use in the BREATHING SYSTEM shall comply with ISO 5367:2014 at the maximum HUMIDIFICATION OUTPUT of the PASSIVE HUMIDIFIER.

Check compliance by application of the tests of ISO 5367:2014 while connected to the specified PASSIVE HUMIDIFIER operated at its maximum RATED output.

12.4 Liquid container level

Means shall be provided to permit the USER, without dismantling the PASSIVE HUMIDIFIER, to determine:

a) the liquid level in the LIQUID CONTAINER; and

b) if provided, the LIQUID RESERVOIR.

Check compliance by inspection.

12.5 Filling cap

Reusable filling caps, if provided, shall be tethered to part of the PASSIVE HUMIDIFIER.

Check compliance by inspection.

13 Compatibility with substances

a) A PASSIVE HUMIDIFIER and its parts or ACCESSORIES shall be designed and manufactured to minimize health RISKS due to substances leached from the PASSIVE HUMIDIFIER or its components during operation, including routine inspection and adjustments by the USER, in accordance with the instructions for use.

b) Particular attention should be paid to the toxicity of materials and their compatibility with substances and gases with which they come into contact during use, including routine inspection and adjustments by the USER, in accordance with the instructions for use.

Check compliance by inspection of the relevant validation reports.

14 * BIOCOMPATIBILITY

a) A PASSIVE HUMIDIFIER and its parts or ACCESSORIES intended to come into direct or indirect contact with biological tissues, cells or body fluids shall be assessed and documented according to the guidance and principles given in the ISO 10993-1:2009.

b) The MANUFACTURER of a PASSIVE HUMIDIFIER, BREATHING SYSTEM, its parts and ACCESSORIES shall address in the RISK MANAGEMENT PROCESS the RISKS associated with the leaching or leaking of substances into the GAS PATHWAY.

c) The GAS PATHWAYS of a PASSIVE HUMIDIFIER and its parts or ACCESSORIES shall be assessed and documented according to the guidance and principles given in the ISO 18562-1:2017.

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

e) The accessible parts and GAS PATHWAYS of a PASSIVE HUMIDIFIER, BREATHING SYSTEM, its parts or 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 on the device itself or on the packaging that it contains phthalates.

f) The symbols of EN 15986:2011[38] (Table B.1, symbol 7) may be used.

g) If the INTENDED USE of a PASSIVE HUMIDIFIER, BREATHING SYSTEM, its parts or ACCESSORIES includes treatment of children or treatment of pregnant or nursing women, a specific justification for the use of these phthalates or such substances shall be included in the RISK MANAGEMENT FILE.

h) The instructions for use of a PASSIVE HUMIDIFIER, BREATHING SYSTEM, its parts or ACCESSORIES that contain such phthalates or such substances shall contain:

   1) information on RESIDUAL RISKS for these PATIENT groups; and

   2) if applicable, on appropriate precautionary measures.

Check compliance by inspection of the relevant validation reports, by inspection of the packaging or the PASSIVE HUMIDIFIER, by inspection of the instructions for use and inspection of the RISK MANAGEMENT FILE for identification of the presence of substances that are carcinogenic, mutagenic or toxic to reproduction and justification for their use.

15 * Requirements for fire prevention

a) A PASSIVE HUMIDIFIER and its parts or ACCESSORIES equipped with an oxygen inlet connector shall include a means to prevent the propagation of fire back through the PATIENT connector.

b) This means shall not be detachable by the USER without the use of a TOOL.

c) This means also may stop the flow of gas.

Check compliance by inspection and the following test.

d) *Connect the oxygen inlet to an oxygen source capable of delivering the maximum RATED flowrate of NORMAL USE for the oxygen inlet with ACCESSORY connection tubing of approximately 2 m length connected to the outlet connector.*

e) *Wait for steady-state conditions to be achieved.*

f) *Ignite the ACCESSORY connection tubing or cannula at the end opposite to the outlet connector.*

g) *Observe the fire propagating along the connecting tubing towards the PASSIVE HUMIDIFIER.*

h) *Confirm that the fire is not propagating back through the outlet connector into the PASSIVE HUMIDIFIER or ACCESSORY and that the fire extinguishes at this point.*

16 USABILITY

a) A PASSIVE HUMIDIFIER shall provide adequate USABILITY such that the RISKS resulting from NORMAL USE and USE ERROR are acceptable.

b) A USABILITY ENGINEERING PROCESS complying with IEC 62366-1:2015 shall be performed except:

1) the planning for and execution of production and POST-PRODUCTION monitoring in the context of applying the USABILITY ENGINEERING PROCESS within the framework of ISO 14971, and

2) maintenance of the USABILITY ENGINEERING PROCESS.

While applying the USABILITY ENGINEERING PROCESS, the following shall be considered PRIMARY OPERATING FUNCTIONS:

c) filling the LIQUID CONTAINER and, if provided, the LIQUID RESERVOIR;

d) observing the water level in the LIQUID CONTAINER and, if provided, in the LIQUID RESERVOIR;

e) configuring the ACCESSORIES including connection of the detachable parts to the HUMIDIFIER;

EXAMPLE 1 Connection to a MOBILE pole.

f) connecting the PATIENT-interface to the PASSIVE HUMIDIFIER;

g) disconnecting the PATIENT-interface from the PASSIVE HUMIDIFIER;

h) PROCESSING the PASSIVE HUMIDIFIER; and

i) performing a basic pre-use functional check of the PASSIVE HUMIDIFIER;

The following actions associated with humidification 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 PASSIVE HUMIDIFIER'S USER INTERFACE.

j) for a TRANSIT-OPERABLE PASSIVE HUMIDIFIER, positioning the PATIENT and the equipment on a wheelchair.

Check compliance by inspection of the USABILITY ENGINEERING FILE. Evidence of compliance with this clause and all requirements of this document referring to inspection of the USABILITY ENGINEERING FILE are satisfied if the MANUFACTURER has:

— *established a USABILITY ENGINEERING PROCESS;*

— *established acceptance criteria for USABILITY; and*

— *demonstrated that the acceptance criteria for USABILITY have been met.*

Annex A
(informative)

Rationale and guidance

A.1 General guidance

This annex provides a 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.

A.2 Rationale for particular clauses and subclauses

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

Clause 1 Scope

The HUMIDIFICATION OUTPUT of a so called "cold bubble-through" or "cold pass-over" PASSIVE HUMIDIFIER is less than active humidifiers and hence does not generally meet the clinical requirements when invasive ventilation (in which the upper airway is bypassed) is used.

Subclause 4.3 Gas flowrate and leakage specifications

Quantities of gas are frequently expressed as the volume that the gas occupies at standardized conditions. Generally one atmosphere (101,325 kPa) is used as standard pressure. However, several standard temperatures are used. Whereas 0 °C is used as standard temperature in physics, either 20 °C or 21,1 °C (70 °F) is often used in engineering. In ventilation, the gas in the lungs has a temperature identical to body temperature (approximately 37 °C) irrespective of the temperature of the gas delivered to the PATIENT. The volume of a given amount of gas increases by about 13,6 % from 0 °C to 37 °C or by 5,8 % from 20 °C to 37 °C.

Gas delivery systems supplying pressurized gas to medical equipment, including PASSIVE HUMIDIFIERS, follow engineering conventions and specify gas quantities and flow rates at STPD conditions. This practice is followed in this document for all requirements concerning gas input.

However, PASSIVE HUMIDIFIERS complying with this document are likely to be used with ventilators that inflate the PATIENT'S lungs relative to a local atmospheric pressure between 70 kPa and 110 kPa. In addition, the gas in the lungs is always saturated with water vapour regardless of the humidity of the gas delivered to the PATIENT'S airway. With a standard temperature of 0 °C, 1 l of gas referenced to STPD can expand the lungs by 1,8 l at a pressure of 70 kPa. In order to have the values comparable among different PASSIVE HUMIDIFIERS, it is essential that the information for any PASSIVE HUMIDIFIER be referenced to the same standard conditions. Because it is the volume of gas and not the number of molecules that expands the lungs, BTPS is the appropriate set of reference conditions to use.

Subclause 4.4 PASSIVE HUMIDIFIER testing errors

When testing PASSIVE HUMIDIFIER 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 third-party testers to recognize 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 accepts 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 5.1.2 Requirements for instability from unwanted lateral movement

TRANSIT-OPERABLE PASSIVE HUMIDIFIERS need to be capable of being attached to wheelchairs and particularly automobiles when the PATIENT is using the PASSIVE HUMIDIFIER while traveling. A sudden stop in an automobile can cause the PASSIVE HUMIDIFIER to become a hazardous flying object. This means of attachment should not involve the use of a TOOL as the PASSIVE HUMIDIFIER needs to be easily attached and detached.

Subclause 5.1.3 Requirements for audible acoustic energy

Noise is ubiquitous in our environment. High intensities of noise have been associated with numerous health effects in adults, including noise-induced hearing loss and high blood pressure. The potential health effects of noise on the newborn include cochlear damage and disruption of the normal growth and development of premature infants. A noise level with peak intensity of 50 dB is considered an acceptable level of background noise[14].

Subclause 5.1.4 Overflow

PASSIVE HUMIDIFIERS often are mounted on poles in NORMAL USE but are often not mounted exactly horizontally. The committee felt that a 20° tilt (beyond that of NORMAL USE) could be construed as reasonably foreseeable, and therefore required that the PASSIVE HUMIDIFIER should operate normally, which includes not spilling any liquid, when operated under NORMAL CONDITIONS at this position.

Permanently mounted PASSIVE HUMIDIFIERS are unlikely to be subject to such tilting, nor would PASSIVE HUMIDIFIERS that are intended to be operated while placed on a table or floor, and so 10° was regarded as a sufficient test angle for these.

A 15 % overfill is also reasonably foreseeable and the PASSIVE HUMIDIFIER should operate normally, which includes not spilling any liquid, when operated under NORMAL CONDITIONS with this amount of overfill.

Subclause 5.1.5 Overpressure requirement

A PASSIVE HUMIDIFIER designed to be connected to a pressurized gas supply is required to continue to operate reliably throughout its RATED range of supply pressures. These pressures can only be maintained if the PASSIVE HUMIDIFIER in NORMAL CONDITION does not attempt to draw more flow from the gas source than the gas source is designed to supply. It is also expected that these PASSIVE HUMIDIFIERS should be designed to prevent an unacceptable RISK under possible SINGLE FAULT CONDITIONS of the pressurized gas supply.

Pressurized medical gas supplies, including MEDICAL GAS PIPELINE SYSTEMS and cylinder pressure regulators conforming to current relevant standards, supply gas-specific terminal outlets at a pressure that is within an internationally agreed pressure range of 280 kPa to 600 kPa under NORMAL CONDITION. It is expected that PASSIVE HUMIDIFIERS should operate to their declared specification at any supply pressure within this range.

In the case of a pressure regulator failure the gas supply pressure could rise to the pressure regulator's supply pressure – which can be cylinder (tank) pressure. To safeguard against this or similar

eventualities, gas-specific medical gas supply systems are required to be provided with a means to limit their output pressure to not more than 1 000 kPa. All gas-powered equipment should be designed so as not to present an unacceptable RISK if its supply pressure rises up to this value.

PASSIVE HUMIDIFIERS with maximum RATED input pressures exceeding 600 kPa are required to fulfil these conditions at up to twice their maximum RATED input pressure.

To ensure that the minimum pressure of 280 kPa can be maintained in practice, MEDICAL GAS PIPELINE SYSTEMS supplying compressed medical gases through gas-specific terminal outlets are designed so that they can maintain this pressure at the input of gas-powered devices while supplying steady-state flows up to 60 l/min at a single outlet connected directly to the pipeline; account is taken of the pressure drop in the pipeline supplying the outlet and the pressure drop, at 60 l/min, across the terminal unit and the hose assembly connecting the device to the pipeline.

The MEDICAL GAS PIPELINE SYSTEM is also required to be capable of supplying sufficient gas that this flow can be drawn from a predetermined number of adjacent terminal units simultaneously. The actual number will have been determined during the design and installation of the MEDICAL GAS PIPELINE SYSTEM by the application of a "diversity factor"; a factor agreed between the supplier and RESPONSIBLE ORGANIZATION to be appropriate for each section of the installation according to the designated purpose of each area supplied. Recommended diversity factors are formulated to ensure that the MEDICAL GAS PIPELINE SYSTEM is capable of supplying an average flow of 60 l/min to the required proportion of terminal outlets. However, if the flow demand from many adjacent equipment exceeds 60 l/min there is an increased possibility that the PASSIVE HUMIDIFIER input pressure could fall below 280 kPa, mainly because of the increased pressure drop across the terminal unit and input hose assembly (also because of the flow-drop characteristic in the case of pressure regulators supplying a single terminal outlet).

In addition to steady-state flows of 60 l/min, the switching of the internal pneumatic system and the operation of a PATIENT demand system can result in equipment requiring transient input flows far in excess of 60 l/min. Because of the compressibility of gas at pipeline pressures and the diameter of piping that is employed in order to minimize the pressure drop, such transient demands can generally be accommodated from the gas within the pipes of the MEDICAL GAS PIPELINE SYSTEM. There can be temporary pressure drops of the input pressure at the inlet of the MEDICAL DEVICES, to below 280 kPa, due to transient flows in excess of 200 l/min (over 3 s) but most of these drops will be within the supply hose assemblies specified by the MANUFACTURER. MANUFACTURERS need to evaluate their own designs to establish whether any consequent transient pressure drop affects the performance of their MEDICAL DEVICE when used with recommended supply hose configurations and when connected to alternative gas-specific terminal outlets such as those fitted to cylinder pressure regulators conforming to ISO 10524-1[15].

MEDICAL DEVICES that can draw greater average or transient flows during INTENDED USE are permitted, but their ACCOMPANYING DOCUMENTATION are required to disclose those flows and warn of the need for a different diversity factor.

The average flow of 60 l/min is greater than the test flow used during the commissioning of MEDICAL GAS PIPELINE SYSTEMS. In itself, this should be of no concern because the specific conditions specified for the test do not allow a direct comparison between the two values. The committee responsible for pipeline standards, ISO/TC 121/SC 6, in consultation with ISO/TC 121/SC 1 and ISO/TC 121/SC 3, agreed to the 60 l/min average flow value, and also the 200 l/min for up to 3 s transient flows, during preparation of the current standard for MEDICAL GAS PIPELINE SYSTEMS and were aware of the need to satisfy that specification when finalizing the MEDICAL GAS PIPELINE SYSTEM test requirements.

MANUFACTURERS should be aware that other medical gas supply system standards permit the fitting of gas-specific terminal outlets to supply systems such as pendant supply units. Such subsystems restrict the flow that can be drawn from their terminal outlets.

Subclause 6.4.3 Requirements for warnings and safety notices

The USER should be aware that only the parts or ACCESSORIES listed in the instruction for use have been validated by the MANUFACTURER. The use of non-validated parts can represent an unacceptable RISK.

For example, the connection of parts to the BREATHING SYSTEM that are not listed in the instruction for use can increase the inspiratory or expiratory pathway resistance of the BREATHING SYSTEM or can increase the unintentional leakage of the BREATHING SYSTEM to a level that affects the BASIC SAFETY or clinical performance.

Subclause 6.4.6 Requirements for operating instructions

a) 9)

Resistance to flow anywhere in the GAS PATHWAY can increase the work of breathing. It can also interfere with the effectiveness of intermittent mandatory ventilation (IMV) or triggering mechanisms in lung ventilators.

a) 10)

The internal compliance of the BREATHING SYSTEM, which includes the PASSIVE HUMIDIFIER, needs to be known in order to accurately determine the tidal volume settings of volume-controlled ventilators.

b) 2)

The amount of air entrained by a PASSIVE HUMIDIFIER (e.g. by a Venturi mechanism) is a function of gas velocity. Changes in gas velocity (e.g. because of a partial obstruction of the ventilation circuit) directly affects the oxygen concentration.

Clause 7 HUMIDIFICATION OUTPUT

During normal breathing inspired air is warmed and humidified in the upper airways to 31 °C and 30,8 mg/l BTPS, by the time it reaches the pharynx, and 37 °C and 44 mg/l at the carina. By heating and humidifying the gas flow to the same level which occurs naturally, the effects of drying can be prevented, increasing PATIENT comfort and tolerance to therapy[16][17][18].

Physiological humidity levels prevent depletion of moisture from the mucociliary transport system and maintain normal mucus clearance. When the airway is exposed to low levels of humidity the aqueous layer decreases, the mucus layer thickens and cilia beat more slowly[19]. This reduces the airway defence mechanism and increases the RISK of respiratory infection[20].

Cold bubble-through or cold pass-over devices are types of PASSIVE HUMIDIFIERS. PASSIVE HUMIDIFIERS that do not add energy to the system (either the HUMIDIFICATION CHAMBER or BREATHING TUBES) are considered category 3 humidifiers, as the HUMIDIFICATION OUTPUT is less than active humidifiers (category 1 and category 2[3]), which add heat to the HUMIDIFICATION CHAMBER or BREATHING TUBES.

PASSIVE HUMIDIFIERS do not achieve the improvement in respiratory water loss, nasal resistance or the increase in PATIENT compliance that can be achieved using heated humidification[16][20][21][22][23][24][25][26][27][28][29][30][31][32].

PASSIVE HUMIDIFIERS (category 3) can achieve absolute humidification levels of 7 mg/l to 16 mg/l, depending on the flow rate, ambient temperature, and ambient RELATIVE HUMIDITY. PASSIVE HUMIDIFIERS have been shown to increase the level of ambient humidity by 2 mg/l to 7 mg/l[21][23][26]. HUMIDIFICATION OUTPUT may decrease during use as the gas flow cools the water. Hence, it is important that category 3 PASSIVE HUMIDIFIERS state the HUMIDIFICATION OUTPUT produced at the PATIENT-CONNECTION PORT over these conditions[3].

ISO 80601-2-74 provides the rationale for the levels of HUMIDIFICATION OUTPUT for category 1 and category 2 humidifiers.

— Category 1 humidifiers are intended for PATIENTS with bypassed airways (invasive ventilation). Category 1 humidifiers need to be capable of producing a HUMIDIFICATION OUTPUT of at least 33 mg/l at the PATIENT-CONNECTION PORT.

— Category 2 humidifiers are intended for PATIENTS whose upper airways have not been bypassed (non-invasive ventilation, nasal high flow therapy, sleep apnoea or continuous positive airway pressure (CPAP) treatment). Category 2 humidifiers need to be capable of producing a HUMIDIFICATION OUTPUT of at least 12 mg/l at the PATIENT-CONNECTION PORT.

All of the above discussion assumes a PATIENT at standard body temperature of 37 °C. For cases of intentional hypothermia or hyperthermia, the limits should be adjusted accordingly.

Clause 10 CLEANING and DISINFECTION

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 PASSIVE HUMIDIFIERS, their ACCESSORIES and parts cannot be used if there is a potential RISK of the PATIENT, USER or other person being infected as a result of contact with the PASSIVE HUMIDIFIER, ACCESSORY or part.

Therefore non-single use PASSIVE HUMIDIFIERS, their ACCESSORIES and parts require an appropriate level of DISINFECTION, depending on their use, but rarely need to be sterile.

Recommendations for hygienic PROCESSING of PASSIVE HUMIDIFIERS, their 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 PASSIVE HUMIDIFIER aware of how to implement these tasks in a responsible manner through appropriate delegation; and

— help all parties involved in the PROCESSING of PASSIVE HUMIDIFIERS, their ACCESSORIES and parts to comply 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 PASSIVE HUMIDIFIERS, as all other MEDICAL DEVICES that have been contaminated with human pathogenic microorganisms, are a potential source of infection for humans. Any PASSIVE HUMIDIFIER 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 PASSIVE HUMIDIFIERS, their re-usable ACCESSORIES and parts that have been used are required to undergo a PROCESSING PROCESS, 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 a PASSIVE HUMIDIFIER, its ACCESSORIES or parts:

— protecting the PATIENT, the USER and the RESPONSIBLE ORGANIZATION (including personnel involved in performing the PROCESSING PROCESS);

— the limits of the PROCEDURES used for PROCESSING (such as the number of PROCESSING cycles); and

— the need to guarantee that the PROCEDURES result in a consistently high and verifiable quality, based on an established quality management system.

The recommended PROCESSING PROCESS should be determined by:

— the potential degree and type of contamination of the PASSIVE HUMIDIFIER, ACCESSORIES or parts; and

— the RISK of infecting another PATIENT resulting from their reuse and the type of application of the PASSIVE HUMIDIFIER.

Special consideration of the possible RISK associated with the contamination of gas-conducting components due to the PATIENT'S rebreathing 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:

— the documented PROCESSING PROCEDURE'S effectiveness has been VERIFIED through appropriate scientific methods by the MANUFACTURER; and

— 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 PASSIVE HUMIDIFIER, ACCESSORIES or parts;

— the RISK for the pathogenic microorganisms to be transmitted to the PATIENT, USER or other persons; and

— the microorganism's resistance to the recommended PROCESSING PROCEDURES.

The RISKS posed by a reprocessed PASSIVE HUMIDIFIER, ACCESSORIES or parts are determined by the following factors:

a) undesired effects, which can result from:
   - the previous use;
   - the previous PROCESSING PROCESSES; and
   - 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 PROCESSES (such as CLEANING agents, disinfectants and other substances, including their reaction products);
   - changes of physical, chemical or functional properties of the device; and
   - 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 PROCESS and the feasibility of the PROCESSING PROCESS for the PASSIVE HUMIDIFIER, ACCESSORIES or parts, the MANUFACTURER should consider the following points:

— the RISKS involved in the PROCESSING PROCESS;

— the cost effectiveness of the PROCESSING PROCESS;

— the practicability of the PROCESSING PROCESS;

— the availability of the CLEANING equipment and the CLEANING agents specified in the PROCESSING PROCESS;

— the efficiency of the PROCESSING PROCESS;

— the reproducibility of the PROCESSING PROCESS;

— quality management requirements of the PROCESSING PROCESS; and

— the environmental impact of the PROCESSING PROCESS and the disposal of the PASSIVE HUMIDIFIER, ACCESSORIES or parts.

The MANUFACTURER should VERIFY all CLEANING agents and PROCESSING PROCEDURES used with regard to their suitability and repeatability with the PASSIVE HUMIDIFIER, ACCESSORIES or parts, depending on the type of use.

The RESPONSIBLE ORGANIZATION should VERIFY that manual CLEANING and DISINFECTION of the PASSIVE HUMIDIFIER, ACCESSORIES or parts are always carried out in accordance with the PROCEDURES specified in the ACCOMPANYING DOCUMENTATION.

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 PASSIVE HUMIDIFIER, 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, USER 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 PASSIVE HUMIDIFIER 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 PASSIVE HUMIDIFIER.

The extent and type of the tests depends on the PASSIVE HUMIDIFIER, ACCESSORY or part and these need to be defined in the ACCOMPANYING DOCUMENTATION.

Clause 11 BREATHING SYSTEM connectors and ports

Non-standard BREATHING SYSTEM connectors can represent an unacceptable RISK as attempts are made to fit a standard BREATHING SYSTEM to a ventilator or PASSIVE HUMIDIFIER. Non-standard BREATHING SYSTEM connectors can cause leaks if used with similar but not compatible connectors.

Subclause 11.4 ACCESSORY port

The use of Luer taper or Luer-lock connectors complying with ISO 594-1[33], ISO 594-2[34] or ISO 80369-7:2016[35] are not permitted for use in a BREATHING SYSTEM, as there are several case reports of accidental connection with intravenous fluids and parenteral and enteral feeding solutions causing serious morbidity and mortality due to aspiration of these foreign substances into the lungs.

Clause 12 Requirements for the BREATHING SYSTEM and ACCESSORIES

It is the responsibility of the MANUFACTURER of a BREATHING SYSTEM, its parts or ACCESSORIES to VERIFY that their product complies with the requirements of this document.

BREATHING TUBES up to the PATIENT-CONNECTION PORT form part of the total-system performance requirements. MANUFACTURERS of BREATHING TUBES need to ensure that total-system performance requirements are met by testing the BREATHING TUBES with the recommended PASSIVE HUMIDIFIER.

Clause 14 BIOCOMPATIBILITY

Since much of the BREATHING SYSTEM is likely to be draped over or around the PATIENT, it is 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 BREATHING SYSTEM and the PASSIVE HUMIDIFIER need to be investigated regarding BIOCOMPATIBILITY and compatibility with substances that might pass into the PATIENT via the GAS PATHWAYS.

Clause 15 Requirements for fire prevention

Based on the data provided by the NFPA Fire Analysis and Research Division it is clear that the use of a firebreak in a HOME HEALTHCARE ENVIRONMENT should enhance the safety of PATIENTS, their families and their homes. The RISK of ignition is increased because use is not supervised by a healthcare worker and there is a likelihood a PATIENT will smoke while using the device. In the USA, there were an average of 222 home structure fires per year involving oxygen administration apparatus between 2006 and 2010. It is estimated that these fires led to 75 deaths and 113 injuries per year.

A PASSIVE HUMIDIFIER and its parts or ACCESSORIES should be equipped with a means to prevent the propagation of fire. For example, through validation the LIQUID RESERVOIR can be sufficient in itself to prevent fire reaching the flow source. This is the same requirement as was added to ISO 80601-2-69[4]. It is not a flow-stop requirement, but a fire-stop requirement.

Annex B
(informative)

Symbols on marking

Symbols are frequently used on MEDICAL DEVICES in preference to words with the intention of obviating language differences and permitting easier comprehension of a marking or indication, sometimes in a restricted space. Consistent use of these symbols and safety signs in all fields of use (e.g. medical, consumer products, and general transportation) will help USERS to become familiar with their meaning. Conversely, any inconsistent use will lead to confusion and mistakes and jeopardize safety.

IEC 60878-1[36] provides a useful compendium of graphical symbols and safety sign used on MEDICAL DEVICES that were complied from relevant ISO and IEC standards. In Table B.1, the symbol graphic and title are provided for information.

Table B.1 — Symbols on marking

No.	Symbol	Reference	Title and description
1		ISO 7000-2497 Symbol 5.1.3 ISO 15223-1:2016	Date of manufacture Indicates the date when the MEDICAL DEVICE was manufactured. NOTE 1 On MEDICAL DEVICES, the date shall be expressed as in ISO 8601 as four digits for the year and, where appropriate, two digits for the month and two digits for the day. NOTE 2 If this symbol is filled, the date of manufacture as well as the name and address of the MANUFACTURER can be combined in one symbol. See ISO 15223-1:2016, Annex A and ISO 7000-3082.
2		ISO 7000-2607 Symbol 5.1.4 ISO 15223-1:2016	Use-by date The date shall be expressed as in ISO 8601 as four digits for the year and, where appropriate, two digits for the month and two digits for the day. For some MEDICAL DEVICES (e.g. IVDs), this date is only valid when the MEDICAL DEVICE is unopened.
3		ISO 7000-2492 Symbol 5.1.5 ISO 15223-1:2016	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.
4		ISO 7000-2493 Symbol 5.1.6 ISO 15223-1:2016	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.

Table B.1 *(continued)*

No.	Symbol	Reference	Title and description
5		ISO 7000-2498 Symbol 5.1.7 ISO 15223-1:2016	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.
6		ISO 7000-2725 Symbol 5.4.5 ISO 15223-1:2016	Contains or presence of [natural rubber latex] On MEDICAL DEVICES: to indicate that the equipment contains the identified product or substance. NOTE Replace "XXX" with the symbol or other identification of the substance that is contained or present, where LATEX is used for natural rubber latex.
7		ISO 7000-2725 EN 15986:2011[38]	Contains or presence of xxx Where PHT is used for phthalate On MEDICAL DEVICES: to indicate that the equipment contains the identified product or substance. NOTE Replace "XXX" with the symbol or other identification of the substance that is contained or present, where PHT is used for phthalate.
8		ISO 7000-1051 Symbol 5.4.2 ISO 15223-1:2016	Do not reuse Indicates a MEDICAL DEVICE that is intended for one use or for use on a single PATIENT during a single PROCEDURE. NOTE Synonyms for "do not re-use" are "single use", "use only once".

Annex C
(normative)

Determination of HUMIDIFICATION OUTPUT

C.1 General

The HUMIDIFICATION OUTPUT is defined as the mass of water vapour per unit volume of gas (mg/l) at BTPS reference conditions, which is physiologically more appropriate than other reference conditions.

Commercially available hygrometers do not have the necessary speed of response to provide consistent and correct results when operated in the non-isothermal environment of the BREATHING SYSTEM. Therefore, the use of such instruments should be restricted to constant-flow humidity measurements. However, the use of such instruments is suitable to VERIFY the maintenance of clinical performance during all of the tests of this document except the determination of the HUMIDIFICATION OUTPUT required in Clause 7.

The use of a dew point hygrometer requires a conversion from the specified units of mg/l (reference BTPS) to equivalent values for dew point. See Table C.1.

Table C.1 — Equivalent dew point for HUMIDIFICATION OUTPUT

Humidifier classification[a]	Absolute humidity under BTPS conditions mg/l	Equivalent dew point °C
Category 1	33	32,2
Category 2	12	15,9
Category 3	6 (typical)	13
[a] Category 1 and Category 2 humidifiers are classified in ISO 80601-2-74.		

C.2 Principle

The HUMIDIFICATION OUTPUT is measured using the gravimetric method, which is a simple technique.

This test method specifies dry input gas, so that any moisture in the output gas has been added by the PASSIVE HUMIDIFIER. The volume of output air is normalized to the volume it would occupy under BTPS conditions (37 °C, ambient pressure, saturated with water vapour).

C.3 Test conditions

There are several practical considerations required to perform this test method in order to calculate the HUMIDIFICATION OUTPUT. As several different definitions of "standard conditions" exist, it is important to know the reference conditions for the flowmeter calibration.

Table C.2 provides the most commonly encountered reference conditions and a corresponding correction factor to scale the volumetric flow reading referenced to standard conditions to a volumetric flow referenced to BTPS conditions as required to perform the gravimetric calculation.