SLOVENSKI STANDARD
oSIST prEN ISO 20789:2019

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Anestezijska in dihalna oprema - Pasivni vlažilniki (ISO 20789:2018)

Anaesthetic and respiratory equipment - Passive humidifiers (ISO 20789:2018)

Anästhesie- und Beatmungsgeräte - Passive Anfeuchter (ISO 20789:2018)

Matériel d'anesthésie et de réanimation respiratoire - Humidificateurs passifs (ISO 20789:2018)

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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.

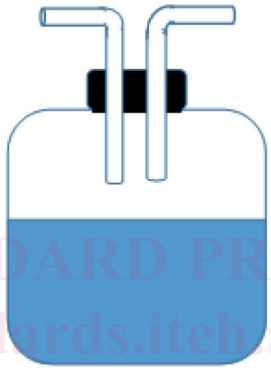

Figure 1 — Cold pass-over PASSIVE HUMIDIFIER

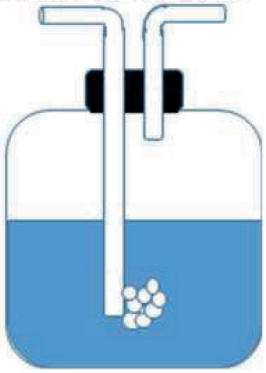

Figure 2 — Cold bubble-through PASSIVE HUMIDIFIER

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.