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Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems

Humidificateurs respiratoires médicaux — Exigences spécifiques des systèmes d'humidification respiratoires

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 8185 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This third edition cancels and replaces the second edition (ISO 8185:1997), which has been technically revised. It also incorporates the Technical Corrigendum, ISO 8185:1997/Cor. 1:2001.

In this corrected version the macro expansion error on page 30 has been replaced with the correct equation for the calculation of average specific enthalpy.

Introduction

This International Standard is a Particular Standard based on IEC 60601-1:1988, including Amendments 1 (1991) and 2 (1995), hereafter referred to as the General Standard. The General Standard is the basic standard for the safety of all **medical electrical equipment** used by, or under the supervision of, qualified personnel in the general medical and **patient** environment; it also contains certain requirements for reliable operation to ensure safety.

The General Standard has associated Collateral Standards and Particular Standards. The Collateral Standards include requirements for specific technologies and/or hazards and apply to all applicable **equipment**, such as medical systems, EMC, radiation protection in diagnostic X-ray **equipment**, software, etc. The Particular Standards apply to specific **equipment** types, such as medical electron accelerators, high frequency surgical **equipment**, hospital beds, etc.

NOTE Definitions of Collateral Standard and Particular Standard are found in IEC 60601-1:1988, 1.5 and A.2, respectively.

To facilitate the use of this International Standard, the following drafting conventions have been applied.

This International Standard uses the same main Clause titles and numbering as the General Standard, to facilitate cross-referencing of the requirements. The changes to the text of the General Standard are specified by the use of the following words.

— "Replacement" means that the indicated Clause or Subclause of the General Standard is replaced completely by the text of this International Standard.

— "Addition" means that the relevant text of this International Standard is supplementary to the requirements of the General Standard.

— "Amendment" means that existing text of the General Standard is modified as indicated by the text of this International Standard.

To avoid confusion with any amendments to the General Standard itself, a particular numbering has been employed for elements added by this International Standard: subclauses, tables and figures are numbered starting from 101; additional list items are lettered aa), bb), etc. and additional annexes are lettered AA, BB, etc.

In this International Standard, the following print types are used:

— requirements, compliance with which can be verified, and definitions: roman type;

— notes and examples: smaller roman type;

— description of type of document change and test methods: *italic type*;

— terms defined in the General Standard IEC 60601-1:1988, Clause 2 or in this International Standard: **bold type**.

Throughout this International Standard, text for which a rationale is provided in Annex AA is indicated by an asterisk (*).

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. Reduction of the **relative humidity** at the **patient connection port** can cause desiccation of tracheo-bronchial secretions in the tracheal or tracheostomy tube, and consequently may cause narrowing or even obstruction of the airway [19]. Heat can be employed to increase the water output of the **humidifier**.

In addition, many **humidifiers** utilise heated **breathing tubes** in order to increase operating efficiency and reduce water and heat loss. Ventilator and anaesthesia **breathing tubes** in common use might not withstand the heat generated by **humidifiers** and heated **breathing tube** mechanisms.

Many **humidifier** manufacturers use off-the-shelf electrical connectors for their electrically-heated **breathing tubes**. However, since different manufacturers have used the same electrical connector for different power outputs, electrically-heated **breathing tubes** can be physically, but not electrically, interchangeable. Use of improper electrically-heated **breathing tubes** has caused overheating, circuit melting, **patient** and **operator** burns, and fires. It was not found practical to specify the interface requirements for electrical connectors to ensure compatibility between **humidifiers** and **breathing tubes** produced by different manufacturers.

Since the safe use of a **humidifier** depends on the interaction of the **humidifier** with its many **accessories**, this International Standard sets total-system performance requirements, applicable to **accessories** such as **breathing tubes** (both heated and non-heated), temperature sensors, and devices intended to control the environment within these **breathing tubes**.

Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems

1 Scope

IEC 60601-1:1988, Clause 1, applies, except as follows:

Amendment (add at the end of 1.1):

This International Standard includes requirements for the basic safety and essential performance of **humidification systems**, as defined in 3.6. This International Standard also includes requirements for individual devices specified for use in **humidification systems** such as heated **breathing tubes** (heated-wire **breathing tubes**) and devices intended to control these heated **breathing tubes** (**heated breathing tube controllers**). ISO 5367 specifies other safety and performance requirements for **breathing tubes**.

NOTE Heated **breathing tubes** are **medical electrical equipment** and are subject to the requirements of IEC 60601-1.

***** This International Standard also includes requirements for **active HME** (heat and moisture exchanger) devices, which actively add heat and moisture to increase the humidity level of the gas delivered from the HME to the **patient**. This International Standard is not applicable to passive HMEs, which return a portion of the **patient's** expired moisture and heat to the respiratory tract during inspiration without adding heat and moisture. ISO 9360-1 and ISO 9360-2 specify safety and performance requirements for passive HMEs and describe methods for testing performance.

Respiratory tract **humidifiers** can be gas-powered, electrically-powered, or both. However, this International Standard has been prepared as a Particular Standard based on IEC 60601-1, which gives general requirements for all aspects of safety, not only electrical safety, and many of the requirements are therefore applicable to **humidifiers** not powered by electricity. Where this International Standard specifies that a Clause of IEC 60601-1 applies, it means that the Clause applies only if the requirement is relevant to the **humidification system** under consideration.

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

This International Standard is not applicable to nebulizers used for the delivery of drugs to **patients**.

In the planning and design of products within the scope of this International Standard, it is advisable to give due consideration to the environmental impact from the product during its life cycle. Environmental aspects are addressed in Annex GG.

NOTE Additional aspects of environmental impact are addressed in ISO 14971.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3744:1994, *Acoustics — Determination of sound power levels of noise sources using sound pressure — Engineering method in an essentially free field over a reflecting plane*

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

ISO 5356-1:2004, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5367:2000, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

ISO 7396-1:2002, *Medical gas pipeline systems — Part 1: Pipelines for compressed medical gases and vacuum*

ISO 9360-1:2000, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml*

ISO 9360-2:2001, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml*

ISO 10524-1:2006, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

IEC 60079-4:1975, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety, and its Amendment 1:1991 and Amendment 2:1995*

IEC 60601-1-2:2001, *Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-6:2004, *Medical electrical equipment — Part 1-6: General requirements for safety — Collateral standard: Usability*

IEC 60601-1-8:2003, *Medical electrical equipment — Part 1-8: General requirements for safety — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 60601-2-19:1990, *Medical electrical equipment — Part 2: Particular requirements for safety of baby incubators*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in Clause 2 of IEC 60601-1:1988, IEC 60601-1-8:2003, ISO 4135:2001, and the following apply.

NOTE For convenience, the sources of all defined terms used in this International Standard are given in Annex II.

3.1
accessible surface temperature
temperature of any surface which can be touched by a hand or finger during **normal use**, which includes filling and refilling of the **humidifier**

3.2
active HME
device where water, water vapour or heat is actively added to the heat and moisture exchanger (HME) to increase the humidity level of the gas delivered from the HME to the **patient**

3.3
delivered gas temperature
temperature of the gas, or aerosol, or both, at the **patient connection port**

3.4
heated breathing tube controller
device which controls the temperature or the heating of a **breathing tube**

NOTE The controller can be either stand-alone or part of the **humidifier**.

3.5
humidification chamber
part of the **humidifier** in which vaporization or nebulization takes place

3.6
humidification system
complete system that comprises a **humidifier** and **accessories**

NOTE **Accessories** can include a **breathing tube** (heated or unheated), **breathing tube** heater, **heated breathing tube controller,** and temperature sensor.

3.7
humidification system output
total mass of water (in the form of liquid and vapour) per unit volume of gas normalized to body temperature, atmospheric pressure and saturated (BTPS), i.e. at 37 °C, 101,3 kPa (760 mmHg) and saturated with water vapour at the **patient connection port**

3.8
humidifier
device that adds water in the form of droplets or vapour, or both, to the inspired gas

NOTE This term includes vaporizing, bubble-through and ultrasonic **humidifiers** and **active heat and moisture exchangers (HMEs)**.

3.9
liquid container
part of the **humidifier** which holds the liquid

NOTE 1 The **liquid container** can be accessible to the breathing gas.

NOTE 2 The **liquid container** can also be part of the **humidification chamber**.

NOTE 3 The **liquid container** can be detachable for filling.

3.10
liquid reservoir
part of the **humidifier** which replenishes the **liquid container**

3.11
maximum operating pressure
maximum **pressure** in the **humidification chamber**

3.12
measured gas temperature
temperature of the gas, or aerosol, or both, that the **humidification system** is measuring and, if applicable, displaying

3.13
relative humidity
water vapour **pressure**, expressed as a percentage of the saturation vapour **pressure,** at a particular temperature

3.14
set temperature
temperature at which the **humidification system** attempts to maintain **measured gas temperature**

NOTE The **set temperature** can be **operator**-adjustable.

4 General requirements and general requirements for tests

IEC 60601-1:1988, Clauses 3 and 4, apply, except as follows:

3.6

Addition:

aa) Operation of the **humidifier** without any liquid.

bb) If the **humidifier** includes a temperature sensor, any **single fault condition** with the temperature sensor. For example:

- temperature sensor single open-circuit;
- temperature sensor single short-circuit;
- temperature sensor disconnected from the **humidifier** control system; or
- temperature sensor disconnected from **breathing tube** or **humidifier**.

cc) A **safety hazard** (e.g. thermal injury to the **patient**) resulting from software error.

4.6 Other conditions

Addition:

aa) The test gas shall be medical-grade air, medical-grade oxygen, or a mixture of the two.

NOTE Reference test gas to BTPS (37 °C, RH = 100 %, 101 kPa)

bb) Unless otherwise specified, the **liquid container** and **liquid reservoir**, if provided, 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.

cc) For the purpose of checking compliance with requirements of this International Standard, the **delivered gas temperature** shall be sensed in the **breathing tube** no more than 50 mm from the **patient connection port** (see Annex BB).

5 Classification

IEC 60601-1:1988, Clause 5, applies.

6 Identification, marking and documents

IEC 60601-1:1988, Clause 6, applies, except as follows:

6.1 Markings on the outside of equipment or equipment parts

Amendment:

*g) * Connection to the supply*

NOTE A heated **breathing tube** connector to the **humidifier** or **heated breathing tube controller** is a connection to the supply that can need this marking.

Amendment (add at end of item):

p) Output

NOTE The **applied part** electrical connector of a **humidifier** for heated **breathing tubes** is an output that needs this marking.

Addition:

aa) The marking on the outside shall also include the following:

1) the maximum and minimum liquid levels, if these are necessary for the correct operation of the **humidifier**;

2) the direction of flow, for a **humidifier** or **humidification system** with **flow-direction-sensitive components**;

3) if a **pressure**-relief mechanism is provided, the **pressure** at which it opens. This marking shall be on or near the **pressure**-relief device;

4) *** if the **humidifier** is driven by compressed gas, the ranges of the supply flowrates and **pressures** that are required;

5) the **humidification system** and its parts shall be marked with regard to proper disposal, as appropriate.

6.8.2 Instruction for use

a) General Information

Amendment (add after the last bullet):

— The instructions for use shall also include the following information:

1) *** For a **humidifier,** identification of at least one set of **accessories** and, if applicable, a ventilator necessary for its intended use, and a warning to the effect that it is potentially unsafe to configure a **humidifier** with **breathing tubes** or **accessories** and a ventilator that are not specified for use with the **humidifier.**

2) For **breathing tubes** or other **accessories** intended to be used within **humidification systems**, identification of at least one **humidifier** that, when used with the **breathing tube** or **accessories**, will meet the requirements of this International Standard.

3) * A warning to the effect that it is potentially unsafe to configure **breathing tubes** or **accessories** with any **humidifier** and ventilator that are not specified for use with these **breathing tubes** or **accessories**.

4) * If the **humidifier** entrains air for the purpose of diluting oxygen, the following shall be provided:

   i) a statement to the effect that the oxygen concentration can be affected by a partial obstruction downstream of the **humidifier**, e.g. when using **accessory equipment**;

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

5) The intended use of the **humidification system**, and whether or not the **humidification system** is intended for use with a **patient** whose upper airways have been bypassed.

6) * If the **humidifier** is intended for use with **patients** whose upper airways are bypassed, the operating range of gas flowrates and settings which provide a **humidification system output** of at least 33 mg/l.

7) The maximum volume of water, expressed in millilitres, available for vaporization contained in the **liquid container** and, if provided, in the **liquid reservoir**.

8) If the **humidifier** is powered by pressurized gas, the **rated** ranges of flowrates and supply **pressures** and method(s) of connection.

9) The **maximum operating pressure** of the **humidifier**.

10) * The inspiratory and expiratory **pressure** drop, as a function of flowrate, across the **humidification system** or individual components, as appropriate. The pressure drop should be determined in accordance with ISO 5367 or an equivalent method. The pressure drop for **active HMEs** should be determined in accordance with ISO 9360-1 and ISO 9360-2.

11) The gas leakage of the **humidification system** or individual components, as appropriate, at the **maximum operating pressure**. The gas leakage should be determined in accordance with ISO 5367 or an equivalent method. The gas leakage for **active HMEs** should be determined in accordance with ISO 9360-1 and ISO 9360-2.

12) * The internal compliance of the **humidification system** or individual components, as appropriate. If this internal compliance can be affected by the depletion of the liquid, the minimum and maximum compliance values shall be disclosed. The internal compliance should be determined in accordance with ISO 5367 or an equivalent method. The internal compliance for **active HMEs** should be determined in accordance with ISO 9360-1 and ISO 9360-2.

13) The **humidification system output** and **relative humidity** over the recommended operating range of gas flowrates and settings.

14) The time required (warm-up time) for the **measured gas temperature** to reach the **set temperature** from a starting temperature of (23 ± 2) °C when operated in accordance with the **accompanying documents**.

15) The maximum **delivered gas temperature**, if the **humidification system** is not provided with a means of continuously indicating the **measured gas temperature.**

16) Appropriate warning about operation of the **breathing tubes** if they can be affected by normal clinical procedures (e.g. tubes covered with a blanket or heated in an incubator or overhead heater for a neonate).

17) The operating ambient temperature range and the operating gas inlet temperature range.

18) A warning if humidity performance of the device can be compromised when used outside the specified ambient temperature range or humidity range.

19) Known adverse effects on the performance of the **humidification system** when exposed to, for example, electrocautery, electrosurgery, defibrillation, X-ray (gamma radiation), infrared radiation, conducted transient magnetic fields including magnetic resonance imaging (MRI), and radiofrequency interference.

20) Information concerning the disposal of the **humidification system** or components thereof.

21) * The location in the **humidification system** to which the displayed gas temperature is referenced.

Replacement:

d) For components specified for reuse, which come into contact with the **patient** or breathing gases during **normal use**, the instructions for use shall contain:

— any details about cleaning and disinfection or cleaning and sterilisation methods that can be used (see 44.7);

— the list of the applicable parameters such as temperature, pressure, humidity, time limits and number of cycles that such **humidification system**, parts or **accessories** can tolerate.

For non-**patient** contact parts, a list of cleaning solutions suitable for cleaning those parts.

7 Power input

IEC 60601-1:1988, Clause 7 applies.

8 Basic safety categories

IEC 60601-1:1988, Clause 8 applies.

9 Removable protective means

IEC 60601-1:1988, Clause 9 applies.

10 Environmental conditions

IEC 60601-1:1988, Clause 10 applies, except as follows:

10.2.1 Environment

Replacement:

a) An operating ambient temperature range as specified in the **accompanying documents**.

Addition:

10.2.101 Pneumatic power supply

If the **humidifier** is intended to be connected to a medical gas supply system (either a medical gas pipeline system complying with ISO 7396-1 or a pressure regulator complying with ISO 10524-1) it shall operate and meet the requirements of this International Standard for a pneumatic power supply range of 280 kPa to 600 kPa and shall not cause a **safety hazard** under the **single fault condition** when the medical gas supply inlet pressure is 1000 kPa.