INTERNATIONAL STANDARD

ISO 8185

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Humidifiers for medical use — General requirements for humidification systems

Humidificateurs médicaux — Exigences générales relatives aux systèmes d'humidification

Reference number
ISO 8185:1997(E)

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 nongovernmental, 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.

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.

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

This second edition cancels and replaces the first edition (ISO 8185:1988), which has been technically revised.

Annexes M, N, P, Q and R form an integral part of this International Standard. Annexes O, S and T are for information only.

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Introduction

Humidifiers are used to raise the water content of gases delivered to patients. Gases available for medical use do not contain sufficient moisture and may damage or irritate the respiratory tract or dessicate secretions of patients whose supraglottic airways have been by-passed. Heat may be employed to increase the water output of the humidifier.

In addition, many humidifiers utilize heated delivery tubes in order to increase operating efficiency and reduce excessive water and heat loss. Ventilator and anaesthesia delivery tubes in common use may not withstand the heat generated by humidifiers and heated delivery tubes mechanisms.

Many humidifier manufacturers use off-the-shelf electrical connectors for their electrically heated delivery tubes. However, since different manufacturers have used the same electrical connector for different power outputs, electrically heated delivery tubes may be physically, but not electrically, interchangeable. Improper electrically heated delivery tubes use has caused overheating, circuit melting, patient and care-giver burns, and fires. Reduction of the relative humidity at the patient connection port may cause dessication of tracheo-bronchial secretions (see reference [20], annex T). It was not found practical to specify the interface requirements for electrical connectors to ensure compatibility between humidifiers and delivery tubes produced by different manufacturers.

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

A rationale for the most important requirements is given in annex S. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of this International Standard, but will expedite any subsequent revision.

Humidifiers for medical use — General requirements for humidification systems

Section 1: General

1.1 Scope

Clause 1 of IEC 60601-1:1988 applies with the following amendment:

ISO 8185 is one of a series of International Standards based on IEC 60601-1; in IEC 60601-1 (the "General Standard"), this type of International Standard is referred to as a "Particular Standard". As stated in 1.3 of IEC 60601-1:1988, the requirements of this International Standard take precedence over those of IEC 60601-1.

Humidifiers may 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 humidifier system under consideration.

This International Standard includes requirements for the safety and performance of humidifiers, as defined in 1.3.107, suitable for inclusion in breathing systems.

This International Standard also includes some requirements for delivery tubes, including heated delivery tubes (heated-wire delivery tubes), and devices intended to control these heated delivery tubes, heated delivery tube controllers.

This International Standard is not applicable to heat and moisture exchangers (HMEs).

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

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

1.2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

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 5356-1:1996, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.*

ISO 9703-1:1992, *Anaesthesia and respiratory care alarm signals — Part 1: Visual alarm signals.*

ISO 9703-2:1994, *Anaesthesia and respiratory care alarm signals — Part 2: Auditory alarm signals.*

ISO 10524:1995, *Pressure regulators and pressure regulators with flow-metering devices for medical gas systems.*

ISO 10651-1:—[1)], *Lung ventilators for medical use — Part 1: Particular requirements for critical care ventilators.*

IEC 60079-3:1990, *Electrical apparatus for explosive gas atmospheres — Part 3: Spark-test apparatus for intrinsically-safe circuits.*

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.*

IEC 60601-1-2:1993, *Medical electrical equipment — Part 1: General requirements for safety. 2. Collateral standard: Electromagnetic compatibility — Requirements and tests.*

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

IEC 60801-2:1991, *Electromagnetic compatibility for industrial-process measurement and control equipment — Part 2: Electrostatic discharge requirements.*

1.3 Definitions

NOTE — Attention is drawn to the definitions given in ISO 4135.

The definitions given in clause 2 of IEC 60601-1:1988 and the following definitions apply.

1.3.101 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.

1.3.102 delivery tube: Tube conveying humidified gas from a humidifier outlet.

NOTE — The delivery tube may be heated.

1.3.103 delivered gas temperature: Temperature of the gas, or aerosol, or both, measured at the patient connection port.

1.3.104 heated delivery tube controller: Device which controls the heating of a delivery tube.

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

1.3.105 humidification chamber: That part of the humidifier which vaporizes or nebulizes water or water-based medicament.

1.3.106 humidification system: Delivery tube, heated delivery tube controller (if applicable), humidifier and any other accessories which when used together are intended to meet the requirements of this International Standard.

1) To be published. (Revision of ISO 10651-1:1993)

1.3.107 humidifier : Device to add water in the form of droplets or vapour, or both, to the inspired gas.

NOTE — This term includes vaporizing, bubble-through and ultrasonic humidifiers.

1.3.108 humidifier outlet: Outlet port of the humidifier which delivers the humidified gases.

1.3.109 humidifier 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.

1.3.110 liquid container: That portion of the humidifier which holds the liquid.

NOTE — The liquid container may be detachable for filling.

1.3.111 liquid reservoir: A portion of the humidifier which replenishes the liquid container.

1.3.112 maximum operating pressure: Maximum pressure in the humidifcation chamber.

1.3.113 measured gas temperature: Temperature of the gas, or aerosol, or both, that the humidification system is measuring and, if applicable, displaying.

1.3.114 operating volume: Volume accessible to the breathing gas of the liquid container when operated between the maximum and minimum levels, if so marked.

1.3.115 patient connection port: That opening at the patient end of a breathing system intended for connection to a tracheal or tracheostomy tube connector or adapter, a face mask or a face mask angle-piece, or a laryngeal mask.

NOTE — For the purposes of this International Standard, for delivery tubes that do not connect directly to a patient (e.g. tracheal tubes, face masks), the patient end of a delivery tube will be considered the patient connection port.

1.3.116 relative humidity: Water vapour pressure at a particular temperature, expressed as a percentage of the saturation vapour pressure.

1.3.117 set temperature: Temperature at which the humidifier system attempts to maintain delivered gas temperature.

NOTE — This temperature may be operator-adjustable.

1.3.118 thermal hazard: Hazard resulting from fire, excessive surface temperature or excessive delivered gas temperature.

NOTE — Any toxic materials resulting from abnormal temperatures also constitute a thermal hazard. See also annex N.

1.4 General requirements

The requirements given in clause 3 of IEC 60601-1:1988 apply, with the following additions:

3.6 k) Operation of the humidifier without any liquid

3.6 l) 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 temperature control system

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

1.5 General requirements for tests

The requirements given in clause 4 of IEC 60601-1:1988 apply with the following additions and modifications:
4.5 a) Modify existing IEC 60601-1:1988 text with the following:

Unless otherwise specified, all tests shall be carried out at ambient conditions according to "b" (see Table 1) of 23 °C ± 2 °C, RH = 50 % ± 5 % and an atmospheric pressure from 860 hPa to 1060 hPa.

Amend clause **4.6** of IEC 60601-1:1988 as follows:

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

g) Unless otherwise specified, the liquid container shall be filled at the beginning of a test to the maximum operating volume with distilled water at the ambient test temperature. The liquid reservoir, if provided, shall also be filled with distilled water in accordance with the manufacturer's instructions.

h) For the purpose of checking compliance, the measured gas temperature shall be sensed no more than 50 mm from the patient connector port (see also annex N).

1.6 Classification

The requirements given in clause 5 of IEC 60601-1:1988 apply.

1.7 Identification, marking and documents

The requirements given in clause 6 of IEC 60601-1:1988 apply with the following additions and modifications:

6.1 Marking on the outside of equipment or equipment parts

Amend existing IEC 60601-1:1988 text as follows:

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, in the case of flow-direction sensitive humidifiers or humidification systems;

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

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

5) if the humidifier is intended for use only with patients whose supraglottic airways have not been bypassed, a warning to indicate that the humidifier is not for use with patients whose supraglottic airways have been bypassed;

6) if the manufacturer knows of adverse effects on the performance of the humidifier when exposed to, for example, electrocautery, electrosurgery, defibrillation, X-ray (gamma radiation), infrared radiation, conducted transients, magnetic fields including magnetic resonance imaging (MRI), and radiofrequency interference, a warning to, e.g. "See the accompanying documents" for information related to exposure of this device to, for example, electromagnetic fields.

6.7 a) Colour of indicator lights

Replace existing IEC 60601-1:1988 text with the following:

Humidifiers and humidification systems for medical use shall met the requirements of ISO 9703-1 and ISO 9703-2.

6.8 Accompanying documents

Amend 6.8.2 a) as follows:

The Instructions for use shall also include the following information:

1) For humidifiers, at least one delivery tube and other necessary accessories that, when used together with the humidifier, meet the requirements of this International Standard. In addition, a warning to the effect that it is potentially unsafe to configure this humidifier with any delivery tube or accessory that is not specified for use with this humidifier.

For delivery tubes or accessories, at least one humidifier that, when used with the delivery tube or accessories, will meet the requirements of this International Standard. In addition, a warning to the effect that it is potentially unsafe to configure this delivery tube or accessory with any humidifier that is not specified for use with this delivery tube or accessory.

2) If the humidifier includes an integral Venturi mechanism which entrains air for the purpose of diluting oxygen, the following shall be provided:

a) a statement to the effect that the oxygen concentration may be affected by a partial obstruction downstream of the humidifier, e.g. the use of accessory equipment;

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

3) The intended use of the humidifier system.

4) If the humidifier is intended for use with patients whose supraglottic airways are bypassed, the maximum flow and delivered gas temperature that permits a humidifier output of at least 33 mg/l, at a range of operator control settings.

5) The ranges of operator control settings that result in the gas at a patient connection port having a relative humidity equal to 100 %.

6) The operating volume and, if provided, the usable volume of the liquid reservoir.

7) If the humidifier is powered by pressurized gas, the recommended ranges of flows or supply pressures and method(s) of connection.

8) The maximum operating pressure of the humidifier.

9) The pressure drop, as a function of flow, across the humidifier shall be stated. Testing should be in accordance with ISO 8835-2, or an equivalent method.

10) The gas leakage of the humidifier at the maximum operating pressure.

11) The internal compliance of the humidifier, if the patient's tidal volume can be influenced by inclusion of the humidifier in the breathing system.

12) The internal compliance of the humidifier at the maximum and minimum operating volumes, if it can be affected by a change in the volume of liquid in the liquid container.

13) The humidifier output over the humidifier's recommended operating range of gas flows and temperatures.

14) The time required (warmup time) for the delivered gas temperature to reach set temperature from a starting temperature of (23 ± 2) °C when operated according to the manufacturer's instructions.

15) The circumstances under which the A-weighted sound pressure level exceeds 50 dB measured 1 m from the device (see 63.2).

16) The maximum delivered gas temperature, if the humidification system is not provided with a means of continuously indicating the measured gas temperature (see 51.6.1).

17) Identification of all accessories, if the normal use of the humidifier requires a specific accessory (e.g. heated delivery tubes) in order to meet the requirements of this International Standard.

18) The range of the measured gas temperature which will generate an alarm (see 50.2.4.2).

19) Appropriate warning about operation of the delivery tubes if they may be affected by normal clinical operation, e.g. covering the tubes with a blanket.

20) The temperature that, when exceeded by the delivered gas temperature, causes the humidification system to generate a medium-priority alarm. This temperature shall not exceed 41 °C (see 51.6.2).

6.8.2 d) Cleaning, disinfection and sterilization of parts in contact with the patient

Modify the beginning of 6.8.2 d) as follows:

For reusable equipment parts which come into contact . . .

6.8.3 Technical description

The requirements of clause 6.8.3 of IEC 60601-1:1988 apply with the following amendments:

6.8.3 e) Maximum operating potential

The heated delivery tube controller shall state the maximum operating potential in terms of its mode of operation (e.g. maximum steady-state voltage and current for electrically heated delivery tubes).

1.8 Power input

The requirements given in clause 7 of IEC 60601-1:1988 apply.

Section 2: Environmental conditions

2.1 Basic safety requirements

The requirements given in clause 8 of IEC 60601-1:1988 apply.

2.2 Removable protective means

The requirements given in clause 9 of IEC 60601-1:1988 apply.

2.3 Environmental conditions

The requirements given in clause 10 of IEC 60601-1:1988 apply with the following addition:

10.2.3 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) 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.

The requirements given in clause 11 of IEC 60601-1:1988 apply.

The requirements given in clause 12 of IEC 60601-1:1988 apply.

Section 3: Protection against electric shock hazards

3.1 General

The requirements given in clause 13 of IEC 60601-1:1988 apply.

3.2 Requirements related to classification

The requirements given in clause 14 of IEC 60601-1:1988 apply.

3.3 Limitation of voltage and/or energy

The requirements given in clause 15 of IEC 60601-1:1988 apply.

3.4 Enclosures and protective covers

The requirements given in clause 16 of IEC 60601-1:1988 apply.

3.5 Separation

The requirements given in clause 17 of IEC 60601-1:1988 apply.

3.6 Protective earthing, functional earthing and potential equalization

The requirements given in clause 18 of IEC 60601-1:1988 apply.

3.7 Continuous leakage currents and patient auxiliary currents

The requirements given in clause 19 of IEC 60601-1:1988 apply, with the following amendment:

19.4 h) Measurement of the patient leakage current

19.4 h) 9) The humidifier connected to the delivery tube and other necessary accessories shall be tested using metal foil as described under subclause 19.4 g) 5). The metal foil is wrapped around the patient connection port.

See Figure 25 of IEC 60601-1:1988.

3.8 Dielectric strength

The requirements given in clause 20 of IEC 60601-1:1988 apply.

Section 4: Protection against mechanical hazards

4.1 Mechanical strength

The requirements given in clause 21 of IEC 60601-1:1988 apply.

4.2 Moving parts

The requirements given in clause 22 of IEC 60601-1:1988 apply.

4.3 Surface, corners and edges

The requirements given in clause 23 of IEC 60601-1:1988 apply.

4.4 Stability in normal use

The requirements given in clause 24 of IEC 60601-1:1988 apply.

4.5 Expelled parts

The requirements given in clause 25 of IEC 60601-1:1988 apply.

4.6 Vibration and noise

The requirements given in clause 26 of IEC 60601-1:1988 apply.

4.7 Pneumatic and hydraulic power

The requirements given in clause 27 of IEC 60601-1:1988 apply.

4.8 Suspended masses

The requirements given in clause 28 of IEC 60601-1:1988 apply.