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Humidifiers for medical use — Safety requirements

Humidificateurs médicaux — Exigences de sécurité

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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 8185 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment.*

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

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Humidifiers for medical use — Safety requirements

0 Introduction

Humidifiers are used to raise the water content of gas delivered to the respiratory tract of patients, since the gases generally available for medical use lack sufficient moisture to be physiologically acceptable to the respiratory tract. Heat may be employed to increase the water output of the humidifier and thereby enhance patient comfort.

It has not been found possible to include guidance on the matter of droplet size in the case of nebulizing humidifiers.

A rationale for the most important requirements is given in annex O. 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. This annex does not form an integral part of the standard.

Section one — General

1 Scope and field of application

ISO 8185 is one of a series of International Standards based on IEC Publication 601-1; in IEC Publication 601-1 (the "General Standard"), this type of International Standard is referred to as a "Particular Standard". As stated in 1.3 of IEC Publication 601-1, the requirements of this International Standard take precedence over those of IEC Publication 601-1.

Humidifiers may be gas-powered, electrically powered or both. However, this International Standard has been prepared as a Particular Standard based on IEC Publication 601-1, 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 Publication 601-1 applies, it means that the clause applies only if the requirement is relevant to the humidifier under consideration.

The scope and object given in clause 1 of IEC Publication 601-1 applies except that 1.1 shall be replaced by the following:

> This International Standard specifies requirements for the safety of vaporizing and nebulizing humidifiers, including those suitable for inclusion in breathing systems, for use with both intubated and non-intubated patients.
>
> This International Standard also includes requirements for delivery tubes and accessory devices intended to control humidifier or delivery tube heaters.
>
> Devices commonly referred to as "room humidifiers" and humidifiers used in heating, ventilation and air conditioning systems are outside the scope of this International Standard.

Requirements for heat and moisture exchangers are given in ISO 9360 (in preparation).

2 References

ISO 2882, *Rubber, vulcanized — Antistatic and conductive products for hospital use — Electrical resistance limits.*

ISO 3744, *Acoustics — Determination of sound power levels of noise sources — Engineering methods for free-field conditions over a reflecting plane.*

ISO 5356, *Anaesthetic and respiratory equipment — Conical connectors —*

Part 1: Cones and sockets.

Part 2: Screw-threaded weight-bearing connectors.

ISO 5367, *Breathing tubes used with anaesthetic apparatus and ventilators.*

IEC Publication 79, *Electrical apparatus for explosive gas atmospheres —*

Part 3: Spark test apparatus for intrinsically-safe circuits.

Part 4: Method of test for ignition temperature.

IEC Publication 601, *Safety of medical electrical equipment —*

Part 1: General requirements. [1]

Part 2: Particular requirements for safety of baby incubators. [2]

IEC Publication 651, *Sound level meters.*

1) Cross-references to specific clauses, sub-clauses, etc. in IEC Publication 601-1 apply to the first edition published in 1977 and Amendment No. 1 to IEC Publication 601-1 published in 1984.

2) At present at the stage of draft [reference No. : 62D(C.O.)38].

3 Definitions

NOTE — Attention is drawn to the definitions given in ISO 4135, *Anaesthesiology — Vocabulary*.

For the purposes of this International Standard, the definitions given in clause 2 of IEC Publication 601-1 apply except that the definition given in 2.1.5 shall be replaced by the following:

applied part: The delivery tube outlet or, if a delivery tube is not normally fitted or used, the humidifier outlet.

For the purposes of this International Standard, the following additional definitions also apply:

3.1 absolute humidity: The mass of water vapour present in unit volume of moist gas, expressed in milligrams per litre or in grams per cubic metre.

3.2 accessible surface temperature: The temperature of any surface which can be touched by a hand or finger during normal use, including filling and refilling of the humidifier.

3.3 delivered gas temperature: The temperature of the gas, or aerosol, or both, that is being delivered to the patient, measured at the patient end of the breathing system.

3.4 delivery tube: The tube conveying humidified gas from the humidifier outlet.

3.5 delivery tube heater: A device to add heat to gas in the delivery tube.

3.6 delivery tube outlet: The termination of the delivery tube to which the patient connection may be made.

3.7 heat and moisture exchanger: A device which preserves a portion of the expired humidity and heat energy and returns it during inspiration.

3.8 humidification chamber: That part of the humidifier from which water or water-based medicament, referred to in this International Standard as "liquid", is immediately derived for the humidification of inspired gas.

3.9 humidifier: A device to add water to the inspired gas, in addition to that already in the breathing system.

NOTE — This term includes both nebulizing and vaporizing humidifiers.

3.10 humidifier heater: A system designed to provide heat to humidifier fluids.

3.11 humidifier outlet: The port of the humidifier from which gas flows.

3.12 humidifier outlet temperature: The temperature of the humidified gas, measured at the humidifier outlet.

3.13 liquid container: The container incorporated in the humidifier which is the direct source of liquid for the humidification chamber.

NOTE — The liquid container may be detachable for filling.

3.14 liquid output: The total mass of liquid present in the inspired gas, expressed in milligrams per litre or in grams per cubic metre.

3.15 liquid reservoir: A reservoir from which the liquid container may be replenished or which, in the absence of a liquid container, supplies liquid directly to the humidification chamber.

3.16 operating volume: The volume of liquid intended to be contained by the liquid container during normal use.

3.17 maximum operating pressure: The maximum pressure in the humidification chamber during normal use.

3.18 nebulizing humidifier: A humidifier from which the liquid output is predominantly in the droplet phase.

NOTE — Because the droplets themselves evaporate, there is also some liquid in the vapour phase.

3.19 operator control: A control, usually a knob, push-button or lever, provided to enable the user to cause the humidifier to perform its intended function without the need for tools.

3.20 operator indicator: A means provided to indicate a mode, state or condition of operation to the operator.

3.21 relative humidity: The water vapour pressure at a particular temperature expressed as a percentage of the saturation vapour pressure over a plane water surface at the same temperature.

3.22 saturation vapour pressure: The partial pressure of water vapour at a given temperature at a liquid-gas interface when free evaporation ceases.

3.23 thermal hazard: A hazard resulting from fire, excessive surface temperature, excessive delivered gas temperature, or all three.

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

3.24 usable capacity of the liquid container: The difference, in millilitres, between the maximum and minimum operating volumes.

3.25 vaporizing humidifier: A humidifier from which the liquid output is predominantly in the vapour phase.

NOTE — Condensation of vapour results in some of the liquid output not being in the vapour phase.

4 General requirements and general requirements for tests

The requirements given in clauses 3 and 4 of IEC Publication 601-1 apply except for the following additions and modifications:

— amend 4.5 as follows:

The ambient temperature for the duration of tests shall be between 17 °C and 25 °C.

— in 4.6, add the following items:

e) The test gas shall be either air or oxygen at a known concentration. The humidity of the test gas shall not exceed 0,12 mg/l (0,12 g/m³), equivalent to a dew point of − 40 °C (see table below).

Table — Vapour pressures and quantities of water vapour above ice as a function of the temperature

Temperature °C	Pressure Torr[1)]	Humidity mg/l (g/m³)
0	4,579	4,8
− 5	3,008	3,24
− 10	1,95	2,17
− 15	1,24	1,38
− 20	0,77	0,88
− 25	0,47	0,55
− 30	0,28	0,33
− 35	0,17	0,206
− 40	0,093	0,115
− 45	0,052	0,066
− 50	0,029	0,038

1) 1 Torr = 1 mmHg = 133,322 Pa

f) The liquid container, if provided, shall be filled initially to the maximum operating volume with distilled or deionized water at the ambient test temperature. The liquid reservoir, if provided, shall be filled with distilled or deionized water in accordance with the manufacturer's instructions.

g) The datum plane for measurements shall be a transverse plane within 10 mm of the inlet of a test chamber having a wall thickness of between 2 mm and 3 mm and being in the form of a tube of polycarbonate or acrylic resin with a smooth interior surface and 55 ± 5 mm in length. The internal diameter of the chamber shall be approximately that of the internal diameter of the delivery tube outlet (or humidifier outlet, if appropriate).

h) Tests shall be performed for all the possible combinations of the following:

1) for the inlet flow: minimum, mean and maximum values of the recommended usable flow;

2) for operator control settings: the minimum, mean and maximum values for all operating controls;

3) in the heated and unheated modes, if the humidifier is designed to operate in both modes; if the humidifier is heated, the temperature measured at the datum plane of the test shall be recorded continuously for the duration of the tests.

i) The following measuring equipment shall be used:

1) gas-flow-measuring equipment calibrated to an accuracy of ± 5 % of the reading in the range 1 l/min to 200 l/min, corrected for the test temperature;

2) an oxygen analyser with an accuracy of ± 1 % (V/V) of oxygen or better.

5 Classification

The classification given in clause 5 of IEC Publication 601-1 applies except that the following addition shall be made to 5.2:

In general, conduction paths will exist and an electrically powered humidifier shall not be type BF or type CF equipment unless there are instructions against any connection which may provide an electrical path to earth.

6 Identification, marking and documents

The requirements given in clause 6 of IEC Publication 601-1 apply except for the following additions and modifications:

— The following additional general requirement also applies:

All markings pertaining to the operation of the humidifier (e.g. filling lines of the liquid container, venturi adjustments, etc.) shall be legible to an operator having visual acuity, corrected if necessary, of at least 1 seated or standing 1 m from the humidifier at an illuminance of 215 lx.

NOTES

1 Marking should not be obscured by the hand normally used to operate the associated controls.

2 All markings should have a luminance contrast of at least 50 % when compared with the surrounding background materials.

— In 6.1 e), add the following:

The humidifier shall be marked with its country of origin.

— In 6.1, add the following additional item:

y) 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. [1)]

1) See also annex O (in this International Standard).

3) If a pressure-relief mechanism is provided, the range of pressures, in kilopascals or conventional centimetres of water, at which it opens. This marking shall be on or near the relief device. [1)]

4) If the humidifier is driven by compressed gas, the ranges of the supply flows or pressures that are required.

5) If the humidifier is capable of producing a water content greater than 44 mg/l (44 g/m^3), the warning:

"CAUTION — EXCESSIVE QUANTITIES OF WATER CAN BE DELIVERED"

— In 6.3, add the following additional item:

f) The effect of movement of all controls shall be indicated by either the position of the control or a coupled indicator.

NOTE — The direction of control movement necessary to cause the controlled function to increase should be clearly marked on or next to the control.

— Replace 6.7 by the following [1)]:

If visual indicators used on the humidifier are not identified by marking, with the exception of alphanumeric displays, their colouring shall conform to the following requirements:

1) Continuous red shall be used to indicate to the operator that the humidifier or a portion of it has failed.

2) Flashing red shall be used to denote an emergency condition requiring an immediate response by the operator, e.g. in the case of a potential thermal hazard. Flashing red indicators shall be regularly intermittent.

3) Yellow shall be used to denote a condition in which there is need for caution or re-check, or in which an unexpected delay is experienced, e.g. when the liquid reservoir requires filling.

4) Green shall be used to indicate that the humidifier is ready for use or in use.

5) Blue shall be used only as an advisory indicator.

Compliance shall be checked by functional test and inspection.

— In 6.8.2, replace item d) by the following:

If the humidifier, its delivery tube or its breathing system components, if provided, are re-usable, the instructions for use shall contain details of suitable cleaning, disinfection and sterilization techniques.

— In 6.8.3a), add the following:

The technical description shall also include the following information:

1) The intended use of the humidifier (e.g. in anaesthesia, in respiratory care, at home or in hospital): whether or not the humidifier is suitable for use with intubated patients or for inclusion in ventilator or other positive pressure breathing systems. [1)]

2) The usable capacity, in millilitres, of the liquid container of the humidifier and that of the liquid reservoir, if provided.

3) The statement "THE CONTAINERS AND RESERVOIRS OF HUMIDIFIERS INTENDED FOR USE IN HOSPITAL SHOULD BE FILLED WITH STERILE LIQUID".

4) The warning **"THE TEMPERATURE OF LIQUID INTRODUCED INTO THE LIQUID CONTAINER OR RESERVOIR DURING FILLING SHALL NOT EXCEED 37 °C"**.

5) If the humidifier includes an integral mechanism which entrains air for the purpose of diluting oxygen, or if it can be supplied with supplementary oxygen, a recommendation that the oxygen concentration should be measured at the point of delivery to the patient.

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

7) The maximum operating pressure.

8) If the humidifier is intended to deliver a mean gas flow in excess of 30 l/min, the recommended minimum and maximum gas flows. [1)]

9) If the humidifier is intended for use with a spontaneously breathing patient, the pressure drop, in kilopascals or conventional centimetres of water, as a function of flow, at the minimum and maximum flows recommended by the manufacturer and at one intermediate flow.

10) The gas leakage, in millilitres per minute, of the humidifier at the maximum operating pressure.

11) If the tidal volume of the patient can be influenced by the inclusion of the humidifier in a breathing system, the internal compliance (subtracting gas leakage) of the humidifier and, if provided, its delivery tube. If the internal compliance can be affected by a change in the volume of liquid in the liquid container, the compliance at the maximum and minimum operating volumes shall be stated in millilitres per conventional centimetre of water or millilitres per kilopascal. [1)]

1) See also annex O (in this International Standard).

12) The liquid output of the humidifier, in milligrams per litre or in grams per cubic metre, within the operating range of gas flows and temperatures.

NOTE — This may be expressed conveniently in the form of a graph comprising at least three points and including approximations of the maximum, mean and minimum flows.

If relative humidity is used as an index of liquid output, the temperature and the point of measurement shall be stated.

13) If the humidifier can deliver a liquid output greater than 44 mg/l (44 g/m^3), the conditions under which this occurs.

14) If the use of delivery tubes other than those supplied or recommended by the manufacturer will impair the safety or effectiveness of the humidifier, the statement "THE USE OF DELIVERY TUBES NOT RECOMMENDED FOR USE WITH THIS PRODUCT MAY IMPAIR ITS PERFORMANCE AND SAFETY".

15) For a heated humidifier, the warm-up time required for it to reach operating temperature from a starting temperature of 21 ± 2 °C.

16) For a heated humidifier, the range of delivery tube outlet temperatures at a stated ambient temperature (± 2 °C) between 17 °C and 25 °C, and advice that the user should monitor the delivered gas temperature. The manufacturer shall draw the attention of the user to any circumstances during the performance of the tests given in 42.3.3, 42.3.4, 42.3.5 and 50.5 (in this International Standard) in which the temperature exceeds 41 °C. He shall advise the user to monitor the gas temperature continuously at the delivery tube outlet (or, if the humidifier is intended for use without a delivery tube, at the humidifier outlet) using a device, which may be free-standing, giving auditory and visible high-temperature alarms when the temperature exceeds 41 °C.

17) If the manufacturer supplies a delivery tube heater, which delivery tube(s) to use and whether or not degradation of anaesthetic agents is liable to take place.

18) If, when tested under the conditions given in 4.6h), the temperatures of any of the accessible surfaces of the humidifier exceeded 55 °C, if metal, or 75 °C, if non-metal.

19) If, when tested as described in 6.8.4.5, the A-weighted sound pressure level exceeds 60 dB, the circumstances under which this occurs. [1)]

NOTE — If an attachment intended for a particular therapeutic application reduces the A-weighted sound pressure level to 60 dB or below, the manufacturer should state in which part of parts of the operating range this occurs.

20) Instructions for the operating and maintenance of the humidifier (including calibration if this is to be carried out by the user).

21) A statement as to whether or not the humidifier is intended for single use.

22) Filling instructions and the need for sterility.

23) If particular agents, such as anaesthetic gases and vapours, impair the performance of the humidifier outside the requirements of this International Standard, a statement to that effect.

If the humidifier is intended for use with a delivery tube, the manufacturer shall either identify at least one accessory delivery tube which does not impair the performance of the humidifier or shall state the performance of the humidifier with a designated delivery tube.

NOTE — The manufacturer or supplier should provide examples of the different functions of the humidifier under typical operating conditions.

24) Unless it can be demonstrated that the humidifier is not susceptible to electromagnetic interference, the instructions for use shall include the statement "FUNCTION OF THIS HUMIDIFIER MAY BE ADVERSELY AFFECTED BY THE OPERATION OF HIGH-FREQUENCY SURGICAL APPARATUS OR SHORT-WAVE OR MICROWAVE EQUIPMENT IN THE VICINITY".

25) Details of all materials used in the construction of the humidifier which may come into contact with respirable gases delivered to the patient.

NOTE — In some countries there are national regulations concerning the biocompatibility of materials used in anaesthetic equipment.

26) A statement as to whether or not the humidifier is suitable for use with anaesthetic agents.

— In 6.8.4, add the following:

The additional information required to be given in the technical description as specified in 6.8.3a) items 9), 10), 11), 15) and 18) (in this International Standard), shall be obtained by carrying out the tests described in 6.8.4.1 to 6.8.4.5.

6.8.4.1 Flow resistance

Measure the pressure drop between plane A and plane B as shown in the figure. If the humidifier is intended for use with a delivery tube, fit a delivery tube recommended by the manufacturer for the duration of the test. Plane A shall be a maximum of 10 mm from the humidifier inlet and plane B shall be a maximum of 10 mm from the humidifier outlet or, if the humidifier is intended for use with a delivery tube, from the delivery tube outlet.

The internal diameters of any adaptors used in the test shall be not less than the internal diameters of the humidifier inlet and outlet ports.

1) See also annex O (in this International Standard).

Dimensions in millimetres

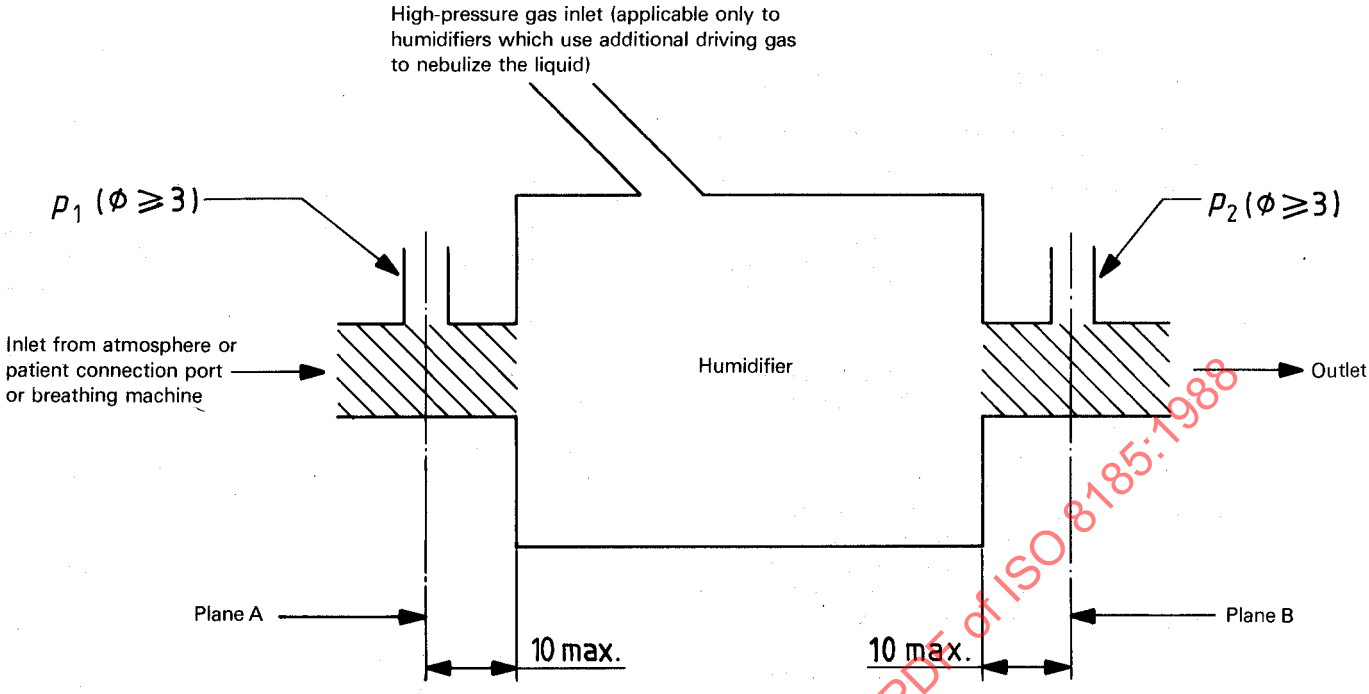

Figure — Test apparatus for flow resistance in a humidifier through which a patient may breathe spontaneously (see 6.8.4.1)

6.8.4.2 Gas leakage

Occlude all ports of the humidifier except one. Apply the maximum operating pressure, as stated by the manufacturer, plus 10 % (i.e. 1,1 times maximum operating pressure) to the open port by injection of air from a graduated syringe. The pressure shall be confirmed by a gauge accurate to at least ± 1 % of the reading. Determine the gas leakage, in millilitres per minute, from the change in volume (corrected for the compliance of the humidifier and necessary test attachments) when the pressure has fallen to 50 % of the initial value.

6.8.4.3 Internal compliance

Occlude all orifices except one and eliminate all leaks. Pressurize the humidifier by injecting air through the open port from a graduated syringe or similar volumetric device to a pressure of 2,5 kPa (25 cmH_2O). Record the volume change when a steady state has been attained. Calculate the compliance (the change in volume per unit change in pressure), correcting for the compliance of the test apparatus. Carry out the test at both the minimum and maximum operating volumes, if applicable, and express the results in millilitres per conventional centimetre of water or millilitres per kilopascal. Repeat the test at pressures of 5 kPa, 7,5 kPa and 10 kPa (50 cmH_2O, 75 cmH_2O and 100 cmH_2O).

6.8.4.4 Warm-up time

The warm-up time of a humidifier which is heated or supplied with a delivery tube heater shall be determined during warm-up from a stabilized starting temperature of 21 ± 2 °C to the maximum stable delivery tube outlet gas temperature (or humidifier gas outlet temperature, if appropriate) recommended by the manufacturer. Elapsed time from switch-on to attainment of the set temperature shall be measured. The measurement shall be made in the datum plane of the test chamber.

6.8.4.5 Noise

6.8.4.5.1 Measuring instruments

A precision sound level meter complying with the requirements for a type 1 instrument specified in IEC Publication 651 shall be used. Measurements shall be taken using the frequency-weighting characteristic A and the time-weighting characteristic S of the sound level meter. The sound level meter shall have been calibrated in accordance with the manufacturer's instructions.

6.8.4.5.2 Test environment

Measurements shall be taken in a free field over a reflecting plane as specified in ISO 3744.

NOTE — The necessary conditions may be achieved economically on a hard, flat surface outdoors, in a large room or in a smaller room with sufficient sound absorptive materials on its walls and ceiling.

6.8.4.5.3 Ambient conditions

At the microphone positions, the A-weighted sound pressure levels of the background noise shall be at least 10 dB below the sound pressure level to be measured.

NOTE — If barometric pressure, temperature or relative humidity deviate excessively from those of standard conditions, appropriate corrections may be required.

6.8.4.5.4 Humidifier installation

The humidifier shall be mounted as recommended in the instructions for use or in a manner typical for its intended use. If it is intended to be table-mounted, the table top shall be a hard, acoustically reflecting surface, unless a resilient pad is recommended in the installation instructions. If it is wall-mounted, the wall shall be of a hard, acoustically reflecting material.

6.8.4.5.5 Measurements

Operate the humidifier over its normal working range, in addition to the settings specified in 4.6h) (in this International Standard). Place the microphone at the position of maximum sound pressure level in the horizontal plane passing through the geometric centre of the humidifier and at a radius of 1 m.

At each setting, if the humidifier is intended for use with a delivery tube, take a second measurement using the recommended delivery tube. The delivery tube outlet shall be placed so as to lie on the specified horizontal plane, with the axis of the delivery tube vertical and 150 mm from the microphone on the axis between the humidifier and the microphone. If the length of the delivery tube does not allow this set-up, move the microphone towards the humidifier until the distance between it and the delivery tube outlet is 150 mm.

If the manufacturer recommends or supplies attachments for particular therapeutic applications and states that these reduce the A-weighted sound pressure level to 60 dB or less, repeat the measurements with the attachments fitted. If any such attachment incorporates a port intended for connection to a tracheal or tracheostomy tube, connect a tube of an internal diameter equal to or greater than that of the port and a length such that its other end will be sufficiently distant from the sound level meter not to interfere with the noise measurements.

7 Power input

The requirements given in clause 7 of IEC Publication 601-1 apply.

Section two — Safety requirements

8 Basic safety categories

The requirements given in clause 8 of IEC Publication 601-1 do not apply as they are not relevant to humidifiers.

9 Removable protective means

The requirements given in clause 9 of IEC Publication 601-1 apply.

10 Special environmental conditions

The requirements given in clause 10 of IEC Publication 601-1 apply.

11 Special measures with respect to safety

The requirements given in clause 11 of IEC Publication 601-1 apply.

12 Single fault condition

The requirements given in clause 12 of IEC Publication 601-1 apply.

Section three — Protection against electric shock hazards

13 General

The requirements given in clause 13 of IEC Publication 601-1 apply.

14 Requirements related to classification

The requirements given in clause 14 of IEC Publication 601-1 apply.

15 Limitation of voltage and/or current

The requirements given in clause 15 of IEC Publication 601-1 apply.

16 Enclosures and protective covers

The requirements given in clause 16 of IEC Publication 601-1 apply.

17 Insulation and protective impedances

The requirements given in clause 17 of IEC Publication 601-1 apply.

18 Earthing and potential equalization

The requirements given in clause 18 of IEC Publication 601-1 apply.

19 Continuous leakage currents and patient auxiliary currents

The requirements given in clause 19 of IEC Publication 601-1 apply except that the following addition shall be made to 19.4 h) :

> The patient leakage current shall be measured from the humidifier outlet port and from any parts of the humidifier that, in normal use, are fitted between the humidifier outlet port and the patient. All these parts, including the outlet port, shall be connected together electrically, with the exception of parts connected electrically to the protective earth terminal.
>
> Parts not connected together electrically shall be tested separately.

20 Dielectric strength

The requirements given in clause 20 of IEC Publication 601-1 apply.

Section four — Protection against mechanical hazards

21 Mechanical strength

The requirements given in clause 21 of IEC Publication 601-1 apply except that 21.2, 21.3 and 21.4 shall be deleted and the following addition shall be made to 21.6:

The humidifier shall be filled with water to its maximum operating volume prior to carrying out each drop test.

22 Moving parts

The requirements given in clause 22 of IEC Publication 601-1 apply.

23 Surfaces, corners and edges

The requirements given in clause 23 of IEC Publication 601-1 apply.

24 Stability and transportability

The requirements given in clause 24 of IEC Publication 601-1 apply except for the following additions and modifications:

— Replace 24.3 by the following [1]:

When the humidifier is tilted through 20° in any direction from its normal operating position, there shall be no spillage from the liquid container or liquid reservoir into the breathing system. If the manufacturer states that the humidifier is intended for use during the transport of patients (e.g. movement by ambulance from one location to another), the humidifier shall be capable of withstanding a tilt of 30° in any direction from the normal operating position without allowing liquid from the liquid container or liquid reservoir to enter any part of the breathing system.

— In 24.4, add the following additional item:

f) Fill the liquid container and liquid reservoir to their maximum recommended levels. Connect the humidifier to a breathing system and tilt the humidifier through 20°, or through 30° if the humidifier is intended for use during transport of patients, and check that no liquid from the liquid container or liquid reservoir enters the breathing system.

25 Expelled parts

The requirements given in clause 25 of IEC Publication 601-1 apply.

26 Vibration and noise

The requirements given in clause 26 of IEC Publication 601-1 shall be replaced by the following requirement:

If humidifiers are intended to be used in association with incubators complying with the requirements of the particular standard for the safety of baby incubators (IEC Publication 601-2-?), attention is drawn to the noise level requirements given in that standard.

27 Pneumatic and hydraulic power

The requirements given in clause 27 of IEC Publication 601-1 apply.

28 Suspended masses

The requirements given in clause 28 of IEC Publication 601-1 apply.

1) See also annex O (in this International Standard).

Section five — Protection against hazards from unwanted or excessive radiation

29 X-radiation

The requirements given in clause 29 of IEC Publication 601-1 apply.

30 Alpha, beta, gamma, neutron radiation and other particle radiation

The requirements given in clause 30 of IEC Publication 601-1 apply.

31 Microwave radiation

The requirements given in clause 31 of IEC Publication 601-1 apply.

32 Light radiation (including visual radiation and lasers)

The requirements given in clause 32 of IEC Publication 601-1 apply.

33 Infra-red radiation

The requirements given in clause 33 of IEC Publication 601-1 apply.

34 Ultraviolet radiation

The requirements given in clause 34 of IEC Publication 601-1 apply.

35 Acoustical energy (including ultrasonics)

The requirements given in clause 35 of IEC Publication 601-1 apply.

36 Electromagnetic compatibility

The requirements given in clause 36 of IEC Publication 601-1 apply.

Section six — Protection against the hazards of explosions in medically used rooms

37 General

The requirements given in clause 37 of IEC Publication 601-1 together with the following additional sub-clauses apply:

37.5 Humidifiers which are suitable for use with anaesthetic agents but which are not intended for use with flammable anaesthetic agents shall be restricted to use with those agents which are not ignited in the flammability tests given in annex N (in this International Standard).

37.6 Electrical circuits which may be a source of ignition in the gas conducting system of a humidifier not classified "AP" or "APG" shall meet the requirements given in 43.7 (in this International Standard).

38 Classification, marking and accompanying documents of anaesthetic-proof equipment

The requirements given in clause 38 of IEC Publication 601-1 apply.

39 Common requirements for "AP" and "APG" equipment

The requirements given in clause 39 of IEC Publication 601-1 apply except that the following additional item shall be added to 39.3:

k) A humidifier classified and marked "APG" or "AP" shall be provided with an electrostatic charge leakage path between the breathing system input and outlet ports and from each of these ports to the protective earth, if provided. The resistance shall not exceed $10^6\ \Omega$. The requirements given in ISO 2882 shall also apply.

Compliance shall be checked by measurement of the resistance.

40 Requirements and tests for anaesthetic-proof equipment, equipment parts or components (AP)

The requirements given in clause 40 of IEC Publication 601-1 apply.

41 Requirements and tests for anaesthetic-proof category G equipment, equipment parts or components

The requirements given in clause 41 of IEC Publication 601-1 apply.

Section seven — Protection against excessive temperatures, fire and other hazards, such as human errors

42 Excessive temperatures

The requirements given in clause 42 of IEC Publication 601-1 apply except for the following modifications:

— Amend 42.1 (last entry in table X a) as follows[1]:

The requirement for equipment parts which may in normal use have unintended contact with a patient does not apply to heated humidifiers; for these humidifiers, the maximum enclosure temperature shall be 55 °C, if metal, or 75 °C, if non-metal.

Heated surfaces necessary to the proper functioning of the humidifier and exposed only during assembly in preparation for use, dismantling after use or during filling procedures are excluded from the requirements in 42.1.

— Replace 42.3 by the following:

42.3.1[1] In the case of heated humidifiers, either the gas temperature at the delivery tube outlet (or, if intended for use without a delivery tube, at the humidifier outlet) shall not exceed 41 °C in normal steady-state use or single fault conditions or the gas temperature at the delivery tube outlet (or, if intended for use without a delivery tube, at the humidifier outlet) shall be indicated continuously and the temperature-measuring device shall activate auditory and visual alarms when the temperature exceeds 41 °C. If a delayed auditory alarm is used, the delay shall not exceed 1 min. If a failure of the temperature-control system can constitute a thermal hazard, an additional non-self-resetting thermal cut-off shall be provided. The thermal cut-off shall also activate a visual indicator. The alarms shall continue until the fault condition responsible for their activation has been corrected.

NOTE — The auditory alarm may be free-standing.

42.3.2[1] The accessible surface temperature of the delivery tube shall not exceed 41 °C within 50 mm of the delivery tube outlet.

Compliance shall be checked by the tests given in 42.3.3 to 42.3.5.

42.3.3 At the minimum and maximum temperature control settings and the minimum and maximum flows recommended by the manufacturer, measure the gas temperature in the datum plane of the test chamber under the following conditions:

1) normal use;

2) starting without liquid (i.e. with no liquid in or immediately available to the humidification chamber or liquid container);

3) after exhaustion of the water supply (i.e. when the liquid container and liquid reservoir, if a reservoir is provided, become exhausted during normal use, so that no liquid is available to the humidification chamber).

42.3.4 If temperature control is derived from a temperature sensor fitted at the delivery tube outlet (or, if intended for use without a delivery tube, at the humidifier outlet), carry out the test described in 42.3.3 under the following conditions:

1) both open-circuit and short-circuit;

2) with the temperature sensor removed from its normal site, if it is detachable or easily dislocated;

3) with the temperature sensor disconnected from the temperature-control system.

42.3.5 The accessible surface temperature of the delivery tube shall be measured with an instrument capable of indicating temperature to an accuracy of ± 1 °C. Operate the humidifier throughout the range of flows and settings recommended by the manufacturer over the ambient temperature range given in 4.5 (in this International Standard) and measure the highest accessible surface temperature of the delivery tube that is obtained.

43 Fire prevention

The requirements given in clause 43 of IEC Publications 601-1 together with the following additional sub-clauses apply:

43.3 In order to minimize the risk of fire in normal use or in single fault conditions at least one of the following requirements shall be satisfied:

a) electrical components shall be separated from compartments in which accumulations of oxygen or mixtures of oxygen with anaesthetic agents can occur by a barrier complying with the requirements given in 43.4;

b) compartments containing electrical components shall be ventilated according to the requirements given in 43.5;

c) electrical components which, in normal use or single fault conditions, can be a source of ignition, shall comply with the requirements given in 43.7.

43.4 Any barrier required under the provision of 43.3a) shall be sealed at all joints and holes for cables, shafts or other purposes.

Compliance shall be checked by inspection and, if applicable, by the compliance test described in 43.6.

1) See also annex O (in this International Standard).

43.5 The ventilation required under the provision of 43.3b) shall be such that the oxygen concentration in the compartment containing electrical components shall not exceed 4 % (*V*/*V*) above the ambient level. If this requirement is met by forced ventilation, a failure alarm shall be provided.

Compliance shall be checked by the test given in 43.6.

43.6 Arrange the humidifier in a test room in which the air exchange is between 3 and 10 changes per hour. Measure the oxygen concentration under the following conditions:

a) single fault conditions;

b) selection of the least favourable control settings;

c) supply mains voltage variation of ± 10 %.

The oxygen concentration shall be measured for such a period that the highest concentration of oxygen occurs.

Repeat the measurements after 18 h during which time the power supply shall have been switched off and the gas supply shall have continued to flow.

43.7 [1] Electrical circuits which can produce sparks or generate increased surface temperatures and which might otherwise be a source of ignition shall be designed so that in normal use and single fault conditions no ignition occurs and no other thermal hazard is introduced. At least the following requirements shall be satisfied:

a) the product of the effective open-circuit voltage and effective short-circuit current shall not exceed 10 V·A — compliance shall be checked by measuring or calculating the voltages and currents;

b) when measured in normal use and in single fault conditions, the surface temperature of components shall not exceed 300 °C — compliance shall be checked by measuring the surface temperatures of components.

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection

The requirements given in clause 44 of IEC Publication 601-1 apply except that the following addition shall be made to 44.7 [1]:

There shall be no facility for self-sterilization of the humidifier by heat.

45 Pressure vessels and parts subject to pressure

The requirements given in clause 45 of IEC Publication 601-1 together with the following additional sub-clauses apply:

45.11 [1] A means of pressure relief shall be provided if the humidifier can be damaged or its performance influenced adversely by excessive pressure, when it is used in accordance with the manufacturer's instructions. The means of pressure relief shall be self-resetting when the normal operating condition is restored.

Compliance shall be checked by the test given in 45.12.

45.12 For humidifiers without pressure-relief valves, occlude all orifices except one. Pressurize the humidifier through the open orifice to twice the stated maximum operating pressure and check that the humidifier maintains mechanical integrity.

For humidifiers with pressure-relief valves, occlude all orifices except the relief valve and one other orifice, then pressurize through the latter orifice. Check that the valve limits pressure to the stated pressure ± 10 % under the conditions of maximum flow recommended for normal use. Relieve the pressure and check that the normal operating condition is restored by confirming that the humidifier can be pressurized to the maximum indicated relief pressure less 10 %.

46 Human errors

The requirements given in clause 46 of IEC Publication 601-1 apply except that the following addition shall be made to 46.5:

Techniques such as locks, shielding, friction-loading and detents are recommended.

47 Electrostatic charges

The requirements given in clause 47 of IEC Publication 601-1 apply.

48 Materials in applied parts in contact with the body of the patient

The requirements given in clause 48 of IEC Publication 601-1 apply.

49 Interruption of the power supply

The requirements given in clause 49 of IEC Publication 601-1 apply.

1) See also annex O (in this International Standard).

Section eight — Accuracy of operating data and protection against incorrect output

50 Accuracy of operating data

The requirements given in clause 50 of IEC Publication 601-1 together with the following additional sub-clauses apply:

50.3 [1] All calibrated operator controls and graduated or digital indicators shall be accurate to within 10 % of their full scale value.

Compliance shall be checked using a method appropriate to the function concerned. The manufacturer shall specify the procedure to be used.

50.4 [1] If the humidifier includes a servo-controller for output temperature, the average gas temperature at the delivery tube outlet shall not differ by more than ± 2 °C from the set temperature during any period of 5 min after the manufacturer's stated warm-up period.

Compliance shall be checked by the test given in 50.5.

50.5 Temperature stability of ± 2 °C shall be confirmed at the minimum and maximum temperature control settings by determining the average of continuous readings during a period of 5 min after the set temperature has been reached. Temperatures shall be measured by means of a sensor with an accuracy of ± 0,2 °C. Temperature measurements shall be carried out at the minimum and maximum gas flows recommended by the manufacturer and, in addition, if the humidifier is suitable for inclusion in a breathing system, at constant gas flows of 2 l/min, 5 l/min and 15 l/min for neonatal, and paediatric and adult use, respectively.

50.6 [1] If the humidifier includes an integral mechanism that entrains air for the purpose of diluting oxygen or other gas mixtures and the nominal oxygen concentration value is marked on the control, the error shall not exceed ± 10 % of the indicated control setting.

Compliance shall be checked by the test given in 50.7.

50.7 If the humidifier being tested has an integral mechanism that entrains air for the purpose of diluting oxygen, the average oxygen concentration during a 5 min period shall be determined to an accuracy of ± 2,5 % (V/V) oxygen. When carrying out this determination the outlet of the test chamber shall not be subject to back pressure.

51 Protection against incorrect output

The requirements given in clause 51 of IEC Publication 601-1 apply except for the following additions and modifications:

— Replace 51.1 by the following [1]:

51.1 At high gas flows, the volume of liquid entering the breathing system shall not exceed 1 ml/min for humidifiers intended for use with neonates and no more than 5 ml/min for all other humidifiers.

Compliance shall be checked by the test given in 51.5.

— Add the following additional sub-clause:

51.5 Connect the humidifier to a gas supply as recommended by the manufacturer and carry out the test at the maximum gas flow and at twice the maximum gas flow recommended by the manufacturer or at the maximum attainable gas flow, whichever is the less, in bursts of 1 s at a frequency of 20 min^{-1}, and in the following conditions:

a) with the liquid container filled to the minimum operating volume, if appropriate, and any liquid reservoir filled, in accordance with the manufacturer's instructions;

b) as in a), but with the liquid container filled to the maximum operating volume.

In both cases, the duration of the test shall be 30 min and the liquid shall not be heated.

Measure the volume of liquid coming out of the humidifier outlet.

Section nine — Fault conditions causing overheating and/or mechanical damage; environmental tests

52 Fault conditions causing overheating and/or mechanical damage

The requirements given in clause 52 of IEC Publication 601-1 apply.

53 Environmental tests

The requirements given in clause 53 of IEC Publication 601-1 apply.

1) See also annex O (in this International Standard).

Section ten — Constructional requirements

54 General

The requirements given in clause 54 of IEC Publication 601-1 apply.

55 Enclosures and covers

The requirements given in clause 55 of IEC Publication 601-1 apply.

56 Components and general assembly

The requirements given in clause 56 of IEC Publication 601-1 apply except for the following additions and modifications:

— In 56.3, add the following additional items:

c) If a humidifier intended to be placed in a breathing system is fitted with conical breathing system connectors, they shall be in accordance with ISO 5356-1 or ISO 5356-2. If intended for adult use, the connectors shall be of 22 mm size; if intended for paediatric use or with neonates, the connectors shall be of 15 mm size. If the humidifier is fitted with connectors that are not conical, these connectors shall mate with breathing tubes complying with ISO 5367 and shall not accept or permit connection to the 15 mm or 22 mm conical connectors complying with ISO 5356-1.

d) If the humidifier incorporates an independent filling or accessory orifice (e.g. an air entrainment or a heater orifice), that orifice shall not accept any of the connectors specified in ISO 5356-1.

Compliance shall be checked by inspection and manipulation.

— In 56.8, add the following:

Humidifiers shall be provided with a "POWER ON" indicator.

— Replace 56.9 by the following[1]:

Controls, other than operator controls, shall either be inaccessible or require the use of a tool for their operation.

Compliance shall be checked by inspection.

— In 56.10, add the following additional item[1]:

d) Movement of controls

For controls that consist of a movable part used as a reference point and a non-movable part used as a scale, movement upwards, to the right or in a clockwise direction shall increase the control function.

NOTE — An example of such a control is a rotating knob with a fixed circular scale.

For controls that consist of a movable part used as a scale and a non-movable part used as a reference point, movement upwards, to the right or in a clockwise direction shall decrease the control function.

NOTE — An example of such a control is a thumb-wheel bearing numbers, only one of which is visible through an aperture.

Needle valves are exempt from these requirements.

57 Mains parts, components and layout

The requirements given in clause 57 of IEC Publication 601-1 apply except that 57.1 b) does not apply.

58 Protective earth terminals

The requirements given in clause 58 of IEC Publication 601-1 apply.

59 Construction and layout

The requirements given in clause 59 of IEC Publication 601-1 apply.

The following new clauses shall be added:

60 Liquid output[1]

60.1 A liquid output of at least 10 mg/l shall fall within the operating range of all humidifiers; humidifiers intended for intubated patients shall have a liquid output of at least 30 mg/l.

Compliance shall be checked by the test given in 60.2.

60.2 Measurements shall be carried out between the minimum and maximum gas flows recommended by the manufacturer. If the humidifier incorporates an integral mechanism for the entrainment of air for the purpose of diluting oxygen, all entrainment orifices shall be occluded during the test.

The following procedure shall be performed at the specified test settings in order to derive an accuracy of 1 %:

a) Weigh the humidifier and its contents (with the recommended delivery tube, if provided); record this mass as m_0.

b) Connect the delivery tube outlet or humidifier outlet, as appropriate, to the test chamber. Arrange the axis of the delivery tube and test chamber to be vertically

1) See also annex O (in this International Standard).

above the humidifier outlet. If the humidifier is intended for use without a delivery tube, arrange the axis of the test chamber to coincide with that of the humidifier outlet under recommended operating conditions.

c) Connect and introduce the oxygen- and temperature-measuring probes into the test chamber in the datum plane (where applicable). If the humidifier is fitted or supplied with a remote temperature sensor which is not integral with the delivery tube, position the sensor in the datum plane of the test chamber.

d) Connect the humidifier to a dry gas source as recommended by the manufacturer.

e) If the humidifier is electrically powered, connect to a suitable electrical power source. If the humidifier or its delivery tube is heated and the test is being carried out in the heated mode, allow the temperature to stabilize.

f) Begin the test (record time as t_0) and maintain operator control settings throughout the test. Stop the test (record time as t_1) when the humidifier has used (75 ± 5) % of the usable capacity of the liquid container or after 4 h, whichever occurs first. Record the duration of the test ($t_1 - t_0$) in seconds.

NOTE — Depending on the mass and output of the humidifier, the duration of the test may need to be extended beyond the period of 4 h in order to satisfy the requirements to derive liquid output to an accuracy of 1 %.

g) Disconnect the test chamber immediately.

h) Weigh the humidifier (with the delivery tube, if provided) and its contents; record this mass as m_1.

The liquid output, expressed in milligrams per litre or grams per cubic metre, is given by the following formula:

$$\frac{m \times 1\,000}{V\,[1 + 0{,}003\,7\,(37 - \theta)] + 1{,}408\,1\,m}$$

where

m ($= m_0 - m_1$) is the mass, in grams, of water used

where

m_0 is the mass, in grams, at time t_0,

m_1 is the mass, in grams, at time t_1;

V is the volume of dry gas (i.e. the product of flow times the duration of test);

θ is the temperature of moist gas, in degrees Celsius.

In all tests commence the measurements after 5 min of normal operation or, in the case of heated humidifiers and humidifiers with a delivery tube heater, after warm-up to the set operating temperature.

NOTE — This test determines the mass of water present in dry gas, whereas the definition of absolute humidity refers to the mass of water in moist gas. The test has been adopted because of its simplicity and the customary reporting of values referring to moist gas.

61 Maximum pressure drop

61.1 The maximum pressure drop across the humidifier shall not exceed 3 kPa throughout the operating range of flows.

Compliance shall be checked by the test given in 61.2.

61.2 Measure the pressure drop, in kilopascals or conventional centimetres of water, throughout the operating range of flows to an accuracy of 10 % between planes A and B as shown in the figure. If the humidifier is normally used with a delivery tube, fit a delivery tube recommended by the manufacturer for the duration of the test. Plane A shall be a maximum of 10 mm from the humidifier inlet and plane B shall be a maximum of 10 mm from the humidifier outlet or, if the humidifier is intended for use with a delivery tube, from the delivery tube outlet.

The internal diameters of any adaptors used in the test shall be not less than the internal diameters of the humidifier inlet and outlet ports.

62 Liquid container

62.1 Filling [1)]

62.1.1 If the liquid contained is intended to be replenished from an integral or remote external source, such as the liquid reservoir, the design of the humidifier shall be such that no more than 1 ml of liquid enters any part of the breathing system during the filling process if the humidifier is intended for use with neonates and no more than 5 ml for all other humidifiers.

NOTES

1 If the liquid container is detachable, filling beyond the maximum operating volume should not cause more than 1 ml of liquid to enter the breathing system from humidifiers intended for use with neonates and no more than 5 ml for all other humidifiers.

2 See also clause 56 in this International Standard.

Compliance shall be checked by the test given in 62.1.2.

62.1.2 Fill the liquid container in accordance with the manufacturer's instructions and measure the spillage into the breathing system, in millilitres.

For detachable liquid containers, detach the liquid container and fill completely. Re-attach the liquid container and operate the humidifier at the maximum flow recommended by the manufacturer for 1 min. Measure the spillage (including normal liquid output) in millilitres.

1) See also annex O (in this International Standard).