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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 4.6 h), 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

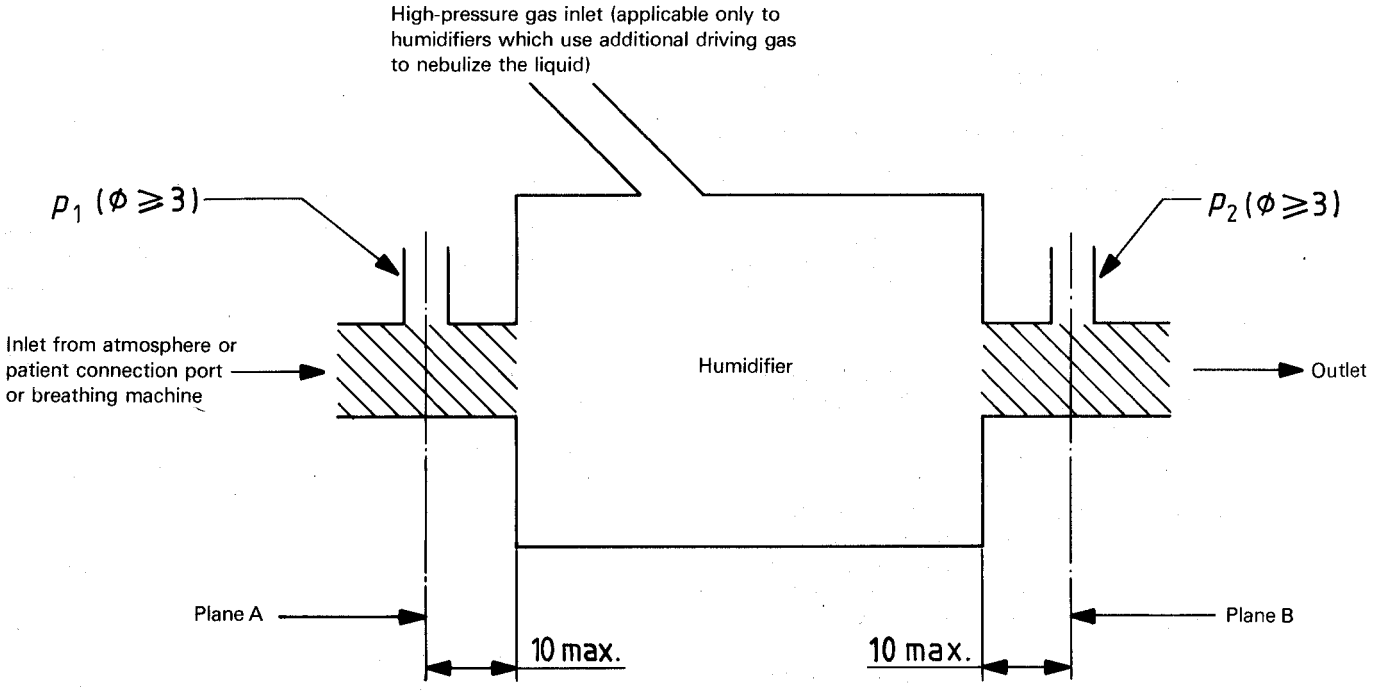

Figure — Test apparatus for flow resistance in a humidifier through which a patient may breathe spontaneously (see 6.8.4.1)

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.