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British Standard

# Medical electrical equipment

Part 2. Particular requirements for safety

## Section 2.24 Specification for humidifiers

[ISO title: Humidifiers for medical use – Safety requirements]

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Appareils électromédicaux

Partie 2. Conditions particulières de sécurité

Section 2.24 Humidificateurs – Spécifications

Elektromedizinische Geräte

Teil 2. Besondere Sicherheitsanforderungen

Abschnitt 2.24 Befeuchter

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## National foreword

This British Standard has been prepared under the direction of the Health Care Standards Committee and is identical with ISO 8185 : 1988 'Humidifiers for medical use — Safety requirements', prepared by Technical Committee 121, Anaesthetic and respiratory equipment, of the International Organization for Standardization (ISO). It supersedes BS 4494 : 1970, which is withdrawn. Whereas the scope of BS 4494 was restricted to humidifiers for use with breathing machines, this British Standard covers all vaporizing and nebulizing humidifiers, including those suitable for inclusion in breathing systems, intended for use with both intubated and non-intubated patients.

The format used in this British Standard follows that used in other Sections of Part 2 of BS 5724, some of which themselves are identical to or based on parts of IEC 601.

**Terminology and conventions.** The text of the international standard has been approved as suitable for publication as a British Standard without deviation. Some terminology and certain conventions are not identical to those used in British Standards; attention is drawn especially to the following.

The comma has been used as a decimal marker. In British Standards it is current practice to use a full point on the baseline as the decimal marker.

The symbol 'l' has been used to denote litre (and in its submultiples). In British Standards it is current practice to use the symbol 'L'.

Wherever the words 'International Standard' appear, referring to this standard, they should be read as 'British Standard'.

## Cross-references

| International standard | Corresponding British Standard                                                                                                                                                                       |
|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ISO 2882 : 1979        | BS 2050 : 1978 Specification for electrical resistance of conducting and antistatic products made from flexible polymeric material<br>(Technically equivalent)                                       |
| ISO 3744 : 1981        | BS 4196 Sound power levels of noise sources<br>Part 4 : 1981 Engineering methods for determination of sound power levels for sources in free-field conditions over a reflecting plane<br>(Identical) |
| ISO 4135 : 1979        | BS 6015 : 1980 Glossary of terms used in anaesthesiology<br>(Identical)                                                                                                                              |
| ISO 5356-1 : 1987      | BS 3849 Conical connectors for anaesthetic and respiratory equipment<br>Part 1 : 1988 Specification for cones and sockets<br>(Identical)                                                             |
| ISO 5356-2 : 1987      | BS 3849 Conical connectors for anaesthetic and respiratory equipment<br>Part 2 : 1988 Specification for screw-threaded weight-bearing connectors<br>(Identical)                                      |
| IEC 601-1 : 1977       | BS 5724 Medical electrical equipment<br>Part 1 : 1979 Specification for general safety requirements<br>(Technically equivalent)                                                                      |
| IEC 651 : 1979         | BS 5969 : 1981 Specification for sound level meters<br>(Identical)                                                                                                                                   |

The Technical Committee has reviewed the provisions of ISO 5367 : 1985, IEC 79-3 : 1972, IEC 79-4 : 1975 and Amendment No. 1 to IEC 601-1, to which reference is made in the text, and has decided that they are acceptable for use in conjunction with this standard.

In clause 26 of this standard a reference that could be informative, rather than normative as implied by its identification as a requirement, is made to the requirements for noise levels given in the IEC 601 : Part 2 for safety of baby incubators, which is at the stage of draft. Until that standard is published, the necessary information may be obtained from the Secretary to Technical Committee HCC/46, at BSI, 2 Park Street, London W1A 2BS. When IEC 601 : Part 2 is published, it is intended to implement it as a revision of BS 5724 : Part 2 : Section 2.20 'Specification for nursing incubators'.

**NOTE. *Typographical error.*** The wording to the left of the figure, on page 7, should read as follows 'Inlet from atmosphere or patient connection port of breathing machine.'

**Compliance with a British Standard does not of itself confer immunity from legal obligations.**

British Standard

# Medical electrical equipment

Part 2. Particular requirements for safety  
Section 2.24 Specification for humidifiers

## 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.<sup>1)</sup>*

*Part 2: Particular requirements for safety of baby incubators.<sup>2)</sup>*

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/m<sup>3</sup>), 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<br>°C | Pressure<br>Torr <sup>1)</sup> | Humidity<br>mg/l (g/m <sup>3</sup> ) |
|-------------------|--------------------------------|--------------------------------------|
| 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  $55 \pm 5$  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  $\pm 5\%$  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  $\pm 1\%$  (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 6.1e), 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.<sup>1)</sup>

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.<sup>1)</sup>

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<sup>3</sup>), 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<sup>1)</sup>:

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.<sup>1)</sup>

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.<sup>1)</sup>

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.<sup>1)</sup>

<sup>1)</sup> 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<sup>3</sup>), 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  $21 \pm 2$  °C.

16) For a heated humidifier, the range of delivery tube outlet temperatures at a stated ambient temperature ( $\pm 2$  °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.<sup>1)</sup>

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).