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Standard Specification for Humidifiers for Medical Use—Part 1: General Requirements for Active Humidification Systems[1]

This standard is issued under the fixed designation F 1690; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

Humidifiers are used to raise the water content of gases delivered to patients. Gases available for medical use do not contain sufficient moisture and may damage or irritate the respiratory tract of patients. Heat may be employed to increase the water output of the humidifier.

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

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

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

A rationale for the most important requirements is given in Appendix X1. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of this specification, but will expedite any subsequent revision.

This specification along with IEC (International Electrotechnical Committee) 601-1, henceforth known as the "General Standard," specify the minimum safety and performance requirements for humidification systems. This specification indicates which clauses of the General Standard apply and amends certain clauses with additions or modifications.

SECTION ONE—GENERAL

1. Scope

1.1 The requirements given in Clause 1 of the General Standard apply with the following additions and modifications:

1.1.1 Replace 1.1 with the following:

1.1.1.1 This specification includes requirements for the safety and performance of active vaporizing and nebulizing humidification systems, as defined in 3.63.1.6, suitable for inclusion in breathing systems (both intubated and non-intubated patients).

1.1.1.2 This specification also includes requirements for breathing tubes, including heated breathing tubes (heated-wire breathing circuits), and devices intended to control these heated breathing tubes, heated breathing tube controllers.

1.1.1.3 Heat and moisture exchangers (HMEs) are outside the scope of this specification. However, it is recognized that their safety and performance may affect that of humidification systems. Numerous studies have been published citing the benefits and risks of HMEs used in conjunction with humidification systems. It is advisable to review the instructions for

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use provided with the humidification systems and HMEs and the available literature for more details.

1.1.1.4 Devices commonly referred to as "room humidifiers," humidifiers used in heating, ventilation, and air-conditioning systems and humidifiers used to condition the environment within infant incubators are outside the scope of this specification.

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

1.1.1.6 Gas-powered nebulizers used for the delivery of drugs to patients through their respiratory system are outside the scope of this specification.

1.1.1.7 Appendices in this specification are not mandatory unless made so by an explicit statement in the main text.

1.2 The values stated in SI units are to be regarded as the standard.

2. Referenced Documents

2.1 The following standards contain provisions that, through reference in this text, constitute provisions of this specification. At the time of publication of this specification, the editions were current. All standards are subject to revision, and parties reading this specification are encouraged to investigate the possibility of applying the most recent editions of the following standards:

2.2 *ASTM Standards:* [2]

F 1054 Specification for Conical Fittings

F 1205 Specification for Anesthesia Breathing Tubes

F 1463 Specification for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care

2.3 *ANSI Standard:*

ANSI/CGA G7.1 Commodity Specification for Medical Grade Air[3]

2.4 *CGA Standard*

CGA Pamphlet G4.3 Commodity Specification for Medical Grade Oxygen[4]

2.5 *ISO Standards:*

ISO 3744 Acoustics—Determination of Sound Power Levels of Noise Sources—Engineering Methods for Free-Field Conditions Over a Reflecting Plane[3]

ISO 4135: 1979 Anesthesiology—Vocabulary[3]

ISO 8835-2: 1993(E) Inhalation Anesthesia Systems—Part 2: Anesthetic Circle Breathing Systems[3]

ISO 10651 Lung Ventilators for Medical Use—Part 3: Particular Requirements for Emergency and Transport Ventilators[3]

2.6 *IEC Standards*

IEC Publication 601-1—Safety of Medical Electrical Equipment—Part 1: 1988—General Safety Requirements[3]

IEC 601-2-19: 1990—Particular Requirements for the Safety of Baby Incubators[3]

IEC 601-1-2 Medical Electrical Equipment Part 1: General Requirements for Safety—Collateral Standard: Electromagnetic Compatibility[3]

IEC Publication 651: 1979 Sound Level Meters[3]

IEC Publication 801-2 Electromagnetic Compatibility for Industrial Process Measurement and Control Equipment—Part 2: 1990—Electrostatic Discharge Requirements[3]

3. Terminology

3.1 *Definitions*—The definitions given in Clause 2 of the General Standard apply with the following additions:

3.1.1 *accessible surface temperature*—the temperature of any surface that can be touched by a hand or finger during normal use, that includes filling and refilling of the humidifier (see ISO 4135).

3.1.2 *breathing tube*—a tube used to convey gases or vapors, or both, to the patient. The breathing tube can be heated.

3.1.3 *delivered gas temperature*—the temperature of the gas or aerosol, or both, measured at the patient connection port (see ISO 4135).

3.1.4 *heated breathing tube controller*—the device which controls the heating of a breathing tube. It can either stand alone or be part of the humidifier.

3.1.5 *humidification chamber*—that part of the humidifier that vaporizes or nebulizers water or water-based medicament (see ISO 4135).

3.1.6 *humidification system*—the breathing tube, heated breathing tube controller (if applicable), and humidifier that together meet the requirements of this specification and are intended to be used together.

3.1.7 *humidifier*—a device to add water or water-based medicament in the form of droplets or vapor, or both, to the inspired gas (see ISO 4135).

3.1.8 *Discussion*—This term includes both nebulizing and vaporizing humidifiers.

3.1.9 *humidifier outlet*—the outlet port of the humidifier that delivers the humidified gases (see ISO 4135).

3.1.10 *humidifier output*—the total mass of water (in the form of liquid and vapor) per unit volume of gas normalized to body temperature, atmospheric pressure, and saturated (BTPS, that is, at 37°C, 101.3 kPa (760 mm Hg), saturated with water vapor) at the patient connection port.

3.1.11 *liquid container*—the portion of the humidifier that holds the liquid or the humidification chamber (see ISO 4135).

3.1.11.1 *Discussion*—The liquid container may be detachable for filling.

3.1.12 *liquid reservoir*—a portion of the humidifier that replenishes the liquid container (see ISO 4135).

3.1.13 *maximum operating pressure*—the maximum pressure in the humidification chamber.

3.1.14 *measured gas temperature*—the temperature of the gas or aerosol, or both, that the humidification system is measuring and, if applicable, displaying (see ISO 4135).

3.1.15 *nebulizing humidifier*—a type of humidifier that produces vapor and droplet output (see ISO 4135).

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

[4] Available from Compressed Gas Association, 1235 Jefferson Davis Highway, Arlington, VA 22202.

3.1.16 *operating volume*—the usable volume of the liquid container when operated between the maximum and minimum levels, if so marked (see ISO 4135).

3.1.17 *patient connection port*—that opening at the patient end of a breathing system intended for connection to a tracheal or tracheostomy tube connector or adapter, a face mask or a face mask angle-piece, or a laryngeal mask (see ISO 4135).

3.1.18 *relative humidity*—the water vapor pressure at a particular temperature expressed as a percentage of the saturation vapor pressure (see ISO 4135).

3.1.19 *set temperature*—the temperature at which the humidifier system attempts to maintain delivered gas temperature (may be operator adjustable).

3.1.20 *thermal hazard*—a hazard resulting from fire, excessive surface temperature of excessive delivered gas temperature (see ISO 4135).

3.1.20.1 *Discussion*—Any toxic materials resulting from abnormal temperatures also constitute a thermal hazard.

3.1.21 *vaporizing humidifier*—a type of humidifier intended to produce output in the vapor phase (see ISO 4135).

4. Relationship of This Specification to the General Standard

4.1 A = applies, NA = not applicable, AM/R = applies with an amendment, addition, or revision to the requirements in the General Standard.

	A	NA	AM/R
Section One—General:			
1. Scope and object,			X
2. Terminology and definitions,			X
3. General requirements,			X
4. General requirements for tests,			X
5. Classification,	X		
6. Identification, marking, and documents, and			X
7. Power input.	X		
Section Two—Environmental Condition:			
8. Basic safety categories,	X		
9. Removable protective means,	X		
10. Environmental conditions,	X		
11. Not used, and	X		
12. Not used.	X		
Section Three—Protection Against Electric Shock Hazards:			
13. General,	X		
14. Requirements related to classification,	X		
15. Limitation of voltage or energy, or both,	X		
16. Enclosures and protective covers,	X		
17. Separation,	X		
18. Protective earthing, functional earthing, and potential equalization,	X		
19. Continuous leakage currents and patient auxiliary currents, and			X
20. Dielectric strength.	X		
Section Four—Protection Against Mechanical Hazards:			
21. Mechanical strength,			X
22. Moving parts,	X		
23. Surfaces, corners, and edges,	X		
24. Stability in normal use,	X		
25. Expelled parts,	X		
26. Vibration and noise,	X		
27. Pneumatic and hydraulic power,	X		
28. Suspended masses,	X		
29. X-radiation,	X		
30. Alpha, beta, gamma, neutron radiation and other particle radiation,	X		
31. Microwave radiation,	X		
32. Light radiation (including lasers),	X		
33. Infrared radiation,	X		
34. Ultraviolet radiation,	X		
35. Acoustical energy (including ultrasonics), and	X		
36. Electromagnetic compatibility.			X
Section Six—Protective Against Hazards of Ignition of Flammable Anesthetic Mixtures:			
37. Locations and basic requirements,			X
38. Marking, accompanying documents,	X		
39. Common requirements for category AP and category APG equipment,	X		
	A	NA	AM/R
40. Requirements and tests for category AP equipment, parts and components thereof,	X		
41. Requirements and tests for category APG equipment, parts and components thereof,	X		
42. Excessive temperatures,			X
43. Fire prevention,			X
44. Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection,	X		
45. Pressure vessels and parts subject to pressure,	X		
46. Human errors,	X		
47. Electrostatic charges,	X		
48. Materials in applied parts in contact with the body of the patient, and	X		
49. Interruption of the power supply.	X		
Section Eight—Accuracy of Operating Data and Protection Against Hazardous Output:			
50. Accuracy of operating data, and			X
51. Protection against incorrect output.			X
Section Nine—Abnormal Operation and Fault Conditions; Environmental Test:			
52. Abnormal operation and fault conditions, and	X		
53. Environmental tests.	X		
Section Ten—Construction Requirements:			
54. General,	X		
55. Enclosures and covers,	X		
56. Components and general assembly,			X
57. Main parts, components, and layout,	X		
58. Protective earthing; terminals and connections, and	X		
59. Construction and layouts.	X		

5. Clauses Containing Amendments, Additions, or Replacements to the Text in IEC 601-1:1988, and Additional Clauses 60 Through 65

NOTE 1—The clause numbers used reference the specific section in the General Standard.

5.1 (3) *General Requirements*—The requirements given in Clause 3 of the General Standard apply with the following additions:

5.1.1 (k) Operation of the humidifier without any liquid.

5.1.2 (l) If the humidifier includes a temperature sensor; any single fault condition with the temperature sensor. For example:

5.1.2.1 Temperature sensor single open-circuit,

5.1.2.2 Temperature sensor single short-circuit, and

5.1.2.3 Temperature sensor disconnected from the temperature control system.

5.1.3 (m) A safety hazard (for example, thermal injury to the patient) resulting from software error.

5.2 (4) *General Requirements for Tests*—The requirements given in Clause 4 of the General Standard apply with the following additions and modifications:

5.2.1 (4.5) *Ambient Temperature, Humidity, Atmospheric Pressure*—Modify Clause 4.5(a) of the General Standard with the following:

5.2.1.1 (a) Unless otherwise specified, all tests shall be carried out at ambient condition "b": 23 ± 2°C, RH = 50 ± 5 % and an atmospheric pressure from 860 to 1060 hPa.

5.2.2 (4.6) *Other Conditions*—Amend Clause 4.6 of the General Standard with the follows:

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

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

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

5.3 (5) *Classification*—The requirements given in Clause 5 of the General Standard apply.

5.4 (6) *Identification, Marking, and Documents*—The requirements given in Clause 6 of the General Standard apply with the following additions and modifications:

5.4.1 *Marking on the Outside of Equipment or Equipment Parts*—Amend Clause 6.1 as follows: (aa) The marking on the outside shall also include the following:

5.4.1.1 (1) The maximum and minimum liquid levels, if these are necessary for the correct operation of the humidifier.

5.4.1.2 (2) The direction of flow, in the case of flow-direction-sensitive humidifiers or humidification systems.

5.4.1.3 (3) If a pressure-relief mechanism is provided, the range of pressures over which it opens. This marking shall be on or near the relief device.

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

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

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

5.4.2 (6.7) *Indicator Lights and Push Buttons*—The requirements of Clause 6.7 of the General Standard apply with the following modifications:

5.4.3 (6.7a) *Color of Indicator Lights*—Replace Clause 6.7(a) with the following:

5.4.3.1 Humidifiers and humidification systems for medical use shall meet the requirements of Specification 1463.

5.5 (6.8) *Accompanying Documents*—Amend Clause 6.8.2(a) as follows: The instructions for use shall also include the following information:

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

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

5.5.3 (2) If the humidifier includes an integral venturi mechanism that entrains air for the purpose of diluting oxygen, the following shall be provided:

5.5.3.1 (a) A statement to the effect that the oxygen concentration may be affected by a partial obstruction downstream of the humidifier, for example, the use of accessory equipment.

5.5.3.2 (b) A recommendation that the oxygen concentration should be measured at the point of delivery to the patient.

5.5.4 (3) The intended use of the humidifier system:

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

5.5.4.2 (5) The operating volume and, if provided, the usable volume of the liquid reservoir.

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

5.5.4.4 (7) The maximum operating pressure of the humidifier.

5.5.4.5 (8) The pressure drop, as a function of flow, across the humidifier shall be stated, when tested in accordance with the test methods given in ISO 8835-2:1993(E).

5.5.4.6 (9) The gas leakage of the humidifier at the maximum operating pressure.

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

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

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

5.5.4.10 (13) The time required (warm-up time) for the delivered gas temperature to reach set temperature from a starting temperature of 23 ± 2°C when operated according to the manufactures instruction.

5.5.4.11 (14) The circumstances under which the A-weighted sound pressure level exceeds 50 db measured 1 m from the device (see Clause 63.2).

5.5.4.12 (15) The maximum delivered gas temperature if the humidification system is not provided with a means of continuously indicating the measured gas temperature (see Clause 56.1).

5.5.4.13 (16) Identification of all accessories, if the normal use of the humidifier requires specific accessory (for example, heated breathing tubes) in order to meet the requirements of this specification.

5.5.4.14 (17) The range of the measured gas temperature which will generate an alarm (accuracy alarm, see Clause 50.2.4.2).

5.5.4.15 (18) Appropriate warning about operation of the breathing tubes if they may be affected by normal clinical operation, for example, covering the tubes with a blanket.

5.5.4.16 (19) The temperature that, when exceeded by the delivered gas temperature, causes the humidification system to generate a medium priority alarm. This temperature shall not exceed 41°C (maximum temperature alarm, see Clause 51.6).

5.6 (6.8.2d) *Cleaning, Disinfection, and Sterilization of Parts in Contact With the Patient*—Modify the beginning of Clause 6.8.2(d) as follows:

5.6.1 For reusable equipment parts which come into contact... .

5.7 (6.8.3) *Technical Description*—The requirements of Clause 6.8.3 of the General Standard apply with the following amendments:

5.7.1 Maximum operating potential:

5.7.2 The heated breathing tube controller shall state the maximum operating potential in terms of its mode of operation (for example, maximum steady-state voltage and current for electrically heated breathing tubes).

5.8 (7) *Power Input*—The requirements given in Clause 7 of the General Standard apply.

SECTION TWO—ENVIRONMENTAL CONDITIONS

6. (8) Basic Safety Requirements:

6.1 The requirements given in Clause 8 of the General Standard apply.

7. (9) Removable Protective Means:

7.1 The requirements given in Clause 8 of the General Standard apply.

8. (10) Environmental Conditions:

8.1 The requirements given in Clause 10 of the General Standard apply.

8.2 The requirements given in Clause 11 of the General Standard apply.

8.3 The requirements given in Clause 12 of the General Standard apply.

SECTION THREE—PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

9. (13) General

9.1 The requirements given in Clause 13 of the General Standard apply.

10. (14) Requirements Related to Classification

10.1 The requirements given in Clause 14 of the General Standard apply.

11. (15) Limitation of Voltage or Energy, or Both

11.1 The requirements given in Clause 15 of the General Standard apply.

12. (16) Enclosures and Protective Covers

12.1 The requirements given in Clause 16 of the General Standard apply.

13. (17) Separation (Previous Title: Insulation and Protective Impedances)

13.1 The requirements given in Clause 17 of the General Standard apply.

14. (18) Protective Earthing, Functional Earthing, and Potential Equalization

14.1 The requirements given in Clause 18 of the General Standard apply.

15. (19) Continuous Leakage Currents and Patient Auxiliary Currents

15.1 The requirements given in Clause 19 of IEC 601-1:1988 apply with the following amendment: Amend 19.3 such that the enclosure leakage current for single-fault conditions is limited to 300 μA.

15.2 Amend 19.4 h) 9) as follows:

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

15.2.2 See Fig. 25 of the General Standard.

16. (20) Dielectric Strength

16.1 The requirements given in Clause 20 of the General Standard apply.

SECTION FOUR—PROTECTION AGAINST MECHANICAL HAZARDS

17. (21) Mechanical Strength

17.1 The requirements given in Clause 21 of the General Standard apply.

18. (22) Moving Parts

18.1 The requirements given in Clause 22 of the General Standard apply.

19. (23) Surface, Corners, and Edges

19.1 The requirements given in Clause 23 of the General Standard apply.

20. (24) Stability in Normal Use

20.1 The requirements given in Clause 24 of the General Standard apply with the following addition:

20.1.1 (24.7) When the humidifier is tilted through 20° in any direction from its normal operating position, there shall be no spillage of water from the liquid container or liquid reservoir into the breathing system.

20.1.2 Compliance shall be checked by inspection.

21. (25) Expelled Parts

21.1 The requirements given in Clause 25 of the General Standard apply.

22. (26) Vibration and Noise

22.1 The requirements given in Clause 26 of the General Standard apply.

23. (27) Pneumatic and Hydraulic Power

23.1 The requirements given in Clause 27 of the General Standard apply.

24. (28) Suspended Masses

24.1 The requirements given in Clause 28 of the General Standard apply.

NOTE 2—The requirements given in Clauses 29 through 35 of the General Standard apply.

SECTION FIVE—PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

25. (36) Electromagnetic Compatibility

25.1 The requirements given in Clause 36 of the General Standard apply with the following additions:

25.1.1 (36.1) Protection from electromagnetic disturbance.

25.1.1.1 The humidifier system shall continue to function and meet the requirements of this specification or shall fail without causing a safety hazard when tested in accordance with IEC 601-1-2:1993. If an anomally occurs, such as alarm activation, as loss of function without the integrity of the associated protective system being compromised, this shall not be considered a safety hazard, provided it is possible to restore normal operation within 30 s after cessation of the electromagnetic disturbance.

NOTE 3—Compliance should be checked by using a worst case system configuration, for example, temperature sensor having longest leads and electrically heated breathing tube of greatest length.

25.1.2 Discharges shall be applied only to accessible parts and coupling planes (as defined in 601-1-2 Clause 36.202.1). If an anomaly occurs, such as display interrupt or alarm activation, it should be possible to restore normal operation within 30 s after the electrostatic discharges have been applied.

NOTE 4—Silencing of an activated alarm shall not be considered a failure.

SECTION SIX—PROTECTION AGAINST THE HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES

26. (37) Locations and Basic Requirements

26.1 The requirements given in Clause 37 of the General Standard apply.

27. (38) Marking, Accompanying Documents

27.1 The requirements given in Clause 38 of the General Standard apply.

28. (39) Common Requirements for Category AP and Category APG Equipment

28.1 The requirements given in Clause 39 of the General Standard apply.

29. (40) Requirements and Tests for Category AP Equipment, Parts, and Components Thereof

29.1 The requirements given in Clause 40 of the General Standard apply.

30. (41) Requirements and Tests for Category APG Equipment, Parts, and Components Thereof

30.1 The requirements given in Clause 41 of the General Standard apply.

SECTION SEVEN—PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

31. (42) Excessive Temperatures

31.1 The requirements given in Clause 42 of the General Standard apply with the following additions:

31.1.1 (42.8) The accessible surface temperature within 25 cm of the patient connection port shall not exceed 44°C.

32. (43) Fire Prevention

32.1 The requirements given in Clause 43 of the General Standard apply, with the following additions:

32.1.1 In order to reduce the risk to patients, other persons or the surroundings due to fire or ignitable material, under normal and single-fault conditions, shall not, at the same time, be subjected to conditions in which:

32.1.2 The temperature of the material is raised to its minimum ignition temperature, and

32.1.3 An oxidant is present.

32.1.4 The minimum ignition temperature is determined in accordance with IEC 79-4 using the oxidizing conditions present under the normal and single-fault condition.

32.1.5 Compliance is checked by determining the temperature the material is raised to under the normal and singlefault condition.

32.1.6 If sparking can occur under normal or single-fault conditions, the material subjected to the energy dissipation of the spark shall not ignite under the oxidizing conditions present.

32.1.7 Compliance is checked by observing if ignition occurs under the most unfavorable combination of normal conditions with a single fault.

33. (44) Overflow, Spillage, Leakage, Humidity, Ingress of Liquids, Cleaning, Sterilization, and Disinfection

33.1 The requirements given in Clause 44 of the General Standard apply.

34. (45) Pressure Vessels and Parts Subject to Pressure

34.1 The requirements given in Clause 45 the General Standard apply.

35. (46) Human Error

35.1 The requirements given in Clause 46 the General Standard apply.

36. (47) Electrostatic Charges

36.1 The requirements given of Clause 47 of the General Standard apply.

37. (48) Materials in Applied Parts in Contact with the Body of the Patient

37.1 The requirements given in Clause 48 of the General Standard apply.

38. (49) Interruption of the Power Supply

38.1 The requirements given in Clause 49 of the General Standard apply.

SECTION EIGHT—ACCURACY OF OPERATING DATA AND PROTECTING AGAINST HAZARDOUS OUTPUT

39. (50) Accuracy of Operating Data

39.1 The requirements given in Clause 50 of the General Standard apply with the following additions:

39.1.1 (50.1) *Marking of Controls and Instruments*—If the humidifier system includes a means of continuously indicating the measured gas temperature, then the displayed measured gas temperature shall have a temperature display range of at least 25 to 45°C.

39.1.2 (50.2) *Accuracy of Controls and Instruments:*

39.1.2.1 (50.2.1) All calibrated operator controls and graduated or digital indicators shall be accurate to ± 5 % of their full-scale value except temperature displays and controls.

39.1.2.2 (50.2.2) The displayed measured gas temperature shall be accurate to ±2°C.

39.1.2.3 Compliance shall be checked by the test given in Annex A1.

39.1.2.4 (50.2.3) If the humidifier includes an integral venturi mechanism that entrains air for the purpose of diluting oxygen or other gas mixtures the nominal oxygen concentration value shall not differ by more than ±10 % of the control setting.

39.1.2.5 (50.2.4) The following requirements do not apply during the period the system is in transition to a new state of thermal equilibrium following a change in gas flow or change in set temperature, or both; however, no thermal hazard shall exist during this period.

39.1.2.6 (50.2.4.1) Under normal conditions, the measured gas temperature averaged during any period of 5 min shall not differ by more than ±2°C from the set temperature.

39.1.2.7 (50.2.4.2) If the measured gas temperature differs from the set gas temperature by more than the range that is specified by the manufacturer in the instructions for use (see Clause 6.8.2a), a medium priority (caution) alarm shall be generated.

40. (51) Protection Against Hazardous Output

40.1 The requirements given in Clause 51 of the General Standard apply with the following additions:

40.1.1 (51.5) Under normal conditions and single fault conditions, the volume of liquid-exiting the humidifier outlet shall not exceed 1 mL/min nor 20 mL/h for humidifiers intended for use with neonates or 5 mL/min nor 20 mL/h for all other humidifiers.

40.1.1.1 (51.6.1) If the delivered gas temperature is capable of exceeding 41°C under normal conditions or singlefault conditions, then the humidification system shall include a means of continuously indicating the measured gas temperature.

40.1.1.2 (51.6.2) The humidification system shall generate a medium priority alarm whenever the measured gas temperature exceeds a temperature specified by the manufacturer, which shall not exceed 41°C (see Clause 6.8.2 a) 19). If the operator is able to silence the auditory alarm, the duration of the cancellation shall not exceed 120 s.

40.1.2 (51.7) Under normal conditions and single-fault conditions, the humidification system shall interrupt heating when the measured gas temperature exceeds 41°C.

40.1.3 (51.8) Under normal conditions and single-fault conditions, a thermal overshoot at the patient connection port shall not exceed an energy equivalent to 43°C and 100 % relative humidity (a specific enthalpy not to exceed 194-kJ/kg dry gas) when averaged over any 30 s.

NOTE 5—Permissible combinations of temperature and relative humidity are for example:

Temperature	Relative Humidity, %
43	100
44	95
45	90
48	76
50	68

40.1.4 Compliance shall be checked by inspection and measurement of energy as specified in Annex A2 during normal use and under the following conditions:

40.1.4.1 Turn humidification system on, wait 30 min, and then run the minimum and maximum continuous flow as recommended by the manufacturer.

40.1.4.2 Operate humidification system, interrupt gas flow for 3 min, and then reinstate gas flow at minimum, maximum, and average continuous flow.

40.1.4.3 Operate the humidification system from a continuous minimum to maximum flow and from a continuous maximum to minimum flow.

NOTE 6—For the purpose of this test, the conditions above apply only under normal conditions.

SECTION NINE—ABNORMAL OPERATION AND FAULT CONDITIONS

41. (52) Abnormal Operation and Fault Conditions

41.1 The requirements given in Clause 52 of the General Standard apply.

42. (53) Environmental Tests

42.1 The requirements given in Clause 53 of the General Standard apply.

SECTION TEN—ABNORMAL OPERATION AND FAULT CONDITIONS

43. (54) General

43.1 The requirements given in Clause 54 of the General Standard apply.

44. (55) Enclosure and Covers

44.1 The requirements given in Clause 55 of the General Standard apply.

45. (56) Components and General Assembly

45.1 The requirements given in Clause 56 of the General Standard apply with the following additions and modifications:

45.1.1 (56.3) *Connector—General:*

45.1.1.1 If a humidifier is intended to be placed in a breathing system fitted with conical breathing system connectors, the conical connectors shall be in accordance with Specification F 1205. If intended for adult use, they shall be of 22-mm size; if intended for pediatric use or with neonates, the connectors shall be of 15-mm size.

45.1.1.2 If the humidifier is fitted with any other type of connector, these connectors shall mate with breathing tubes complying with Specification F 1205 and shall not accept or permit connection to the 15-mm or 22-mm conical connectors complying with Specification F 1205.

45.1.1.3 If the humidifier incorporates an independent filling or accessory orifice (for example, an air entrainment or a heater orifice), that orifice shall not accept any of the connectors specified in conical fitting of 18 122-mm sizes.

45.1.2 Compliance shall be checked by inspection and manipulation.

45.2 (56.12) *Breathing Tubes:*

45.2.1 (56.12.1.1) Breathing tubes intended for use in humidification systems shall meet the requirements of ISO 5367.

45.2.2 (56.12.1.2) The machine end of breathing tubes intended for use in humidification systems shall either:

45.2.2.1 Meet the requirements of ISO 5367, or

45.2.2.2 Be a proprietary fitting that shall not permit connection to breathing tubes complying with ISO 5367 or any of the conical connectors complying with ISO 5356-1.

45.2.2.3 Compliance is checked by inspection.

45.2.3 (56.12.2) Breathing tubes and associated connectors capable of being attached to humidifiers shall not kink, occlude, leak, or otherwise cause a safety hazard.

45.2.3.1 Compliance is checked by inspection and testing according to Clause 53.12.3 of ISO 10651.

45.2.4 (56.12.3) Breathing tubes that are capable of being attached to humidifiers shall not kink, occlude, leak or otherwise cause a safety hazard when the breathing tubes are subject to the constant maximum output potential of the heated breathing tube controller (see Clause 6.8.3.e).

45.2.4.1 Compliance is checked by inspection and testing according to Clause 56.12.3 of ISO 10651 while applying the constant maximum output potential of the heated breathing tube controller.

46. (57) Main Parts, Components, and Layout

46.1 The requirements given in Clause 57 of the General Standard apply.

47. (58) Protective Earthing—Terminals and Connections

47.1 The requirements given in Clause 58 of the General Standard apply.

48. (59) Construction and Layout

48.1 The requirements given in Clause 59 of the General Standard apply.

SECTION ELEVEN—ADDITIONAL REQUIREMENTS SPECIFICALLY RELATED TO HUMIDIFIERS

49. (60) Humidifier Output

49.1 All humidification systems shall be capable of producing a humidifier output of at least 10 mg H_2O/L; humidification systems intended for use with patients whose supraglottic airways have been bypassed shall also be capable of producing a humidifier output of at least 33 mg H_2O/L.

49.2 Compliance shall be checked by the test in Annex A3.

50. (61) Maximum Pressure Drop

50.1 The maximum pressure drop across the humidifier shall not exceed 2 kPa throughout the operating range of flows. Exclusive of nebulizing-type humidifiers, humidifiers intended for use with patients who's breathing is spontaneous or assisted, the pressure drop across the humidifier shall not exceed 0.2 kPa at a flow of 60 L/min.

50.2 Compliance shall be checked by functional test.

51. (62) Liquid Container

51.1 (62.1) *Filling*—Filling the liquid container, or liquid reservoir if provided, to the marked maximum liquid level if so marked, shall not allow more than 1 mL of liquid to enter any part of the breathing system if the humidifier is intended for use with neonates and nor more than 5 mL for all other humidifiers.

51.2 (62.2) *Liquid Level*—It shall be possible to determine the liquid level in the liquid container, and if fitted the liquid reservoir, without dismantling the humidifier.

51.3 (62.3) *Filling Cap*—If intended to be reused, the cap shall be attached to the humidifier.

52. (63) Noise Measurement

52.1 (63.1) If humidifiers within a humidification system are intended to be used in association with incubators, the humidifiers shall not cause the noise level requirements in IEC 601-2-19 to be exceeded.

52.2 (63.2) The steady state noise generated by the humidifier shall not exceed 50 dBA at any point 1 m from the humidifier.

52.3 Compliance is checked by testing in accordance with ISO 3744.

53. (64) Temperature Sensors and Temperature Sensor Ports

53.1 Temperature sensors and mating ports shall meet the following requirements:

53.1.1 (64.1) Temperature sensors shall meet the dimensional requirements in Annex A4, or shall meet the requirements in 53.1.3 (64.3).

53.1.2 (64.2) When the temperature sensors and mating ports are engaged according to the manufacturers recommendations, the following requirements shall be met:

53.1.2.1 (64.2.1) When tested as described in Annex A4, the engaged connection shall not become disconnected.

53.1.2.2 (64.2.2) When leak tested as described in Annex A4, the leakage from the engaged connector shall not exceed 5 mL/min.

53.1.3 (64.3) Temperature sensors that do not comply with the dimensional requirements of Annex A4 shall be sufficiently different that they cannot be interchanged with those that do.

54. (65) Humidifier Leakage

54.1 (65.1) The gas leakage from the humidifier shall not exceed 10 mL/min when tested in 54.2 (65.2).

54.2 (65.2) Seal off all parts but the humidifier inlet. Apply static pressure of 8.0 ± 0.5 kPa to the inlet port. Measure or calculate the leakage to atmosphere.

55. Annexes and Appendixes

55.1 Appendixes A to L of the General Standard and Annex A1-Annex A4, and Annex A5 apply.

ANNEXES

(Mandatory Information)

A1. TEMPERATURE DISPLAY ACCURACY

A1.1 Temperature display accuracy shall be confirmed by introducing two standard temperature sensors, as defined in Annex A5, into the humidifier system configured according to operating instructions and detailed in Fig. A1.1.

NOTE A1.1—If necessary add extension tubing so that no sensors are unduly influenced by ambient drafts and temperatures. The tubing shall be of equal diameter as the breathing tubes and long enough so that all sensors are at least located a distance from ambient equal to ten times the breathing tube diameter.

A1.2 The distances from the normal location of the humidification system's temperature sensor to the location of the standard temperature sensors ("dd" in Fig. A1.1) shall be equidistant, and shall be from 20 to 30 mm.

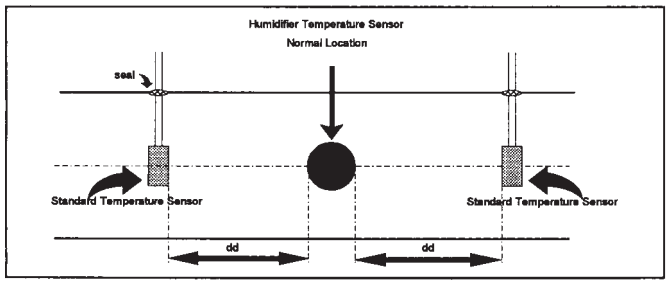


FIG. A1.1 Temperature Display Accuracy

A1.3 Temperatures shall be sampled at least every 2 s.

A1.4 Operate the humidification system over the manufacturer's recommended flow range.

A1.5 Set the minimum set temperature and confirm that the measured gas temperature equals the arithmetic mean ±2°C of the two standard temperature sensors in a steady state condition.

A1.6 Quickly changing the set temperature from the minimum to maximum setting.

NOTE A1.2—This change should simulate a step function from minimum to maximum to the extent that it is practical.

A1.7 Confirm that the measured gas temperature equals the arithmetic mean ±4°C of the two standard temperature sensors during the transition period from minimum to maximum set temperature.

A1.8 Confirm that the measured gas temperature equals the arithmetic mean ±2°C of the two standard temperature sensors in a steady state condition for the maximum set temperature.

A2. SPECIFIC ENTHALPY CALCULATIONS

A2.1 Calculate specific enthalpy using the following formulas (see Refs **(1-3)**.[5] Measurements of the temperature at the humidifier outlet and the delivered gas temperature can be made with the standard temperature sensor, as defined in Annex A5, and should be sampled at least every 2 s.

t_d = delivered gas temperature, °C,
t_h = lower of delivered gas temperature and humidifier outlet temperature, °C

NOTE A2.1—$t_h = t_d$ when the humidifier outlet is the patient connection port.

A2.1.1 For each measurement calculate the p_v, g, and h as follows:

[5] The boldface numbers given in parentheses refer to a list of references at the end of the text.

A2.1.2 *Absolute Temperature*:

$$Th = 273.16 + t_h \ [K] \quad \text{(A2.1)}$$

$$Td = 273.16 + t_d \ [K] \quad \text{(A2.2)}$$

A2.1.3 *Vapor Pressure*:

$$P_v = 10^{30.59051 - 8.2\log(Th) + 2.4804 \times 10^{-3} \times Th} - \frac{3142.31}{T_h} \text{[kPa]} \quad \text{(A2.3)}$$

A2.1.4 *Moisture Content*:

$$g = 0.625 \times \frac{P_v}{101.325 - 1.005p_v} \text{[kg/kg]} \quad \text{(A2.4)}$$

A2.1.5 *Specific Enthalpy*:

$$h = 1.0067 \times t_d + gx(2501.82 + 1.8 \times t_d) \ \text{[kJ/kg]} \quad \text{(A2.5)}$$

Then for any 30-s period, calculate the average specific enthalpy:

$$\bar{h} = \frac{1}{N\Delta t} \sum_{i=t'}^{i=t'+N\Delta t} h(t)\Delta \quad \text{(A2.6)}$$

where:

$h(t)$ = specific enthalpy h at time, t, $\Delta t \leq 2$ s,
$N\Delta t$ = 30 s, and
t' = any time after specified warm-up period.

A3. HUMIDIFIER OUTPUT CALCULATIONS

A3.1 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.

A3.2 The following procedure should be performed at the specified test settings and with measurement equipment such that a total measurement accuracy of ±1 mg/L is achieved:

A3.2.1 Configure the humidification system according to the operating instructions.

A3.2.2 The entire test setup should be mounted on a set of scales so that mass measurements can be made simply and accurately.

A3.2.3 If necessary, add extension tubing such that no sensors are unduly influenced by ambient drafts and temperatures. The tubing should be of equal diameter to the breathing tube and of length such that all sensors shall be displaced at least ten times the breathing tube diameter from ambient.

A3.2.4 Arrange relative elevations of the humidifier, breathing tube, and humidification chamber as applicable such that:

A3.2.4.1 Condensation that does not represent humidification reaching the patient does not leave the system and is included in m_1 (defined below).

A3.2.4.2 Condensation that represents humidification reaching the patient leaves the system and is not included in m_1(defined below).

A3.2.5 The humidifier output shall be expressed in milligrams per litre moist gas (normalized to 37°C).

A3.2.5.1 Install a temperature sensor as defined in Annex A5 in the air stream at a site representing the delivered gas temperature. Call this temperature T_2 (°C).

A3.2.5.2 Connect the humidifier to a medical-grade dry gas source. The temperature of this dry gas entering the humidification chamber should be ±m1°C of the ambient temperature. Call this temperature T_1 (°C).

A3.2.5.3 If the humidifier or its breathing tube is heated and the test is being carried out in the heated mode, allow the temperature to stabilize for the recommended warm-up time.

A3.2.5.4 Turn off the humidifier, disconnect all accessories, including the air supply, electrical connections, and any extension tubing to remove any extraneous influences on the weight measurement. Weigh only the humidifier, its contents and the recommended breathing tube; record this mass as m_0. This is the initial mass of the system.

A3.2.5.5 Reconnect all accessories. Turn the humidifier back on to begin the test (record time as t_0) and maintain operator control settings throughout the test. Monitor the dry gas flow rate and temperature to ensure compatibility with the objective of total measurement accuracy of 1 mg/L.

A3.3 The test may be stopped when the measurement error of the following quantities maintains a total measurement accuracy of ±1 mg/L.

A3.3.1 The humidifier has used a sufficient quantity of the usable capacity of the liquid container; and

A3.3.2 The time of the test is of sufficient duration.

A3.3.2.1 Record the time as t_1, and record the duration of the test, $t_1 - t_0$.

NOTE A3.1—Special attention is drawn to the objective of a total measurement error of less than ±1 mg/L. Measurement of time, temperature, especially flow rate and mass-used should be sufficiently accurate relative to the value of the quantity to maintain that objective. In practice the mass and estimated output of the humidifier will give a guide as to the minimum duration of the test to maintain overall accuracy. An error analysis of the measurement equipment and estimated results is strongly recommended as a guide.

A3.3.2.2 Make a weight measurement as for A3.2.5.4; record this mass as m_1. The difference $m_0 - m_1$ represents the total moisture reaching the patient over the test duration.

A3.4 The humidifier output, expressed in milligrams per litre moist gas normalized to 37°C (that is, BTPS, body temperature, standard pressure, saturated) is given by the following formula:

$$\frac{1000\,m}{1.0658\,V(1 + 0.0034(37 - T_1))} \quad \text{(A3.1)}$$

where:

m = ($m_0 - m_1$) is the mass, g, of water used,
m_0 = mass, g, at time t_0,
m_1 = mass, g, at time t_1,

V = volume of dry gas at ambient temperature (that is, the product of flow times the duration of test), and

T_1 = temperature of dry gas, °C.

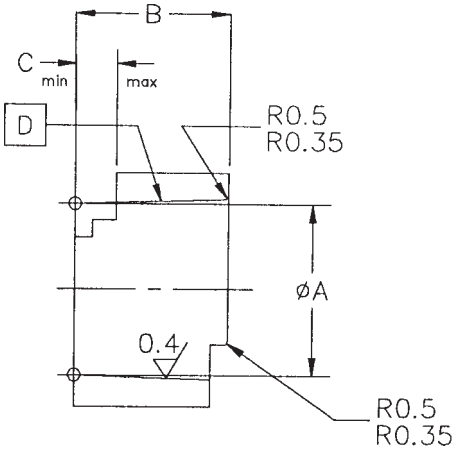
A4. TEMPERATURE SENSORS AND MATING PORTS

A4.1 *Dimensional Requirements for Temperature Sensors:*

A4.1.1 The axial length of the taper of temperature sensors shall be at least 10.5 mm. See Fig. A4.1.

A4.1.2 When the temperature sensor is engaged with the ring gage shown below, by applying an axial force of 35.0 ± 3.5 *N* and while maintaining the same force rotating the sensor up to 20°, its leading edge shall be within the minimum and maximum steps of the gage. The temperature sensor and gage shall be maintained at ambient temperature.

A4.1.3 Dimensions in millimetres and surface roughness values in micrometres:



A = 7.550 ± 0.005
B = 9.000 ± 0.005
C = 2.50 ± 0.005
D = 1:40

FIG. A4.1 Temperature Sensor Engaged with Ring Gauge

A4.2 *Test Method for Security of Engagement of the Temperature Sensors to Mating Ports*:

A4.2.1 Condition temperature sensors and mating ports at 41 ± 2°C and 95 ± 5 % RH for at least 1 h.

A4.2.2 Engage the temperature sensor with the mating port in accordance with the manufacturer's instructions for use.

A4.2.3 Condition the engaged components, without activation of any disengagement mechanism, for at least 1 h at the conditions specified in A4.2.1A4.2.1.

A4.2.4 Apply an axial separation force of 25 ± 2.5 *N* for 10 s at a rate not exceeding 20 Ns^{-1}.

A4.3 *Test Method for Leakage from Temperature Sensors Engaged in Mating Ports*:

A4.3.1 Apply a static pressure of 8.0 ± 0.5 kPa to the temperature sensor and mating port assembly.

A4.3.2 Measure or calculate the leakage to atmosphere from the sensor and mating port assembly.

A5. STANDARD TEMPERATURE SENSOR

A5.1 The standard temperature sensor can be constructed as indicated as follows:

A5.1.1 The standard temperature sensor shall have the following characteristics:

A5.1.1.1 Time constant ≥0.5 and ≤1.0 for a step change of 22 to 37°C in water at 1-m/s flow.

A5.1.1.2 Influence from changes in ambient temperature ≤0.01/1°C.

A5.1.2 An example for construction of such a sensor is indicated as follows:

A5.1.2.1 A sheath with thermal conductivity ≥386 W/(m°C) with the dimensions given in Fig. A5.1; for example, a piece of solid ⅛-in. copper rod with appropriate drilled spaces.

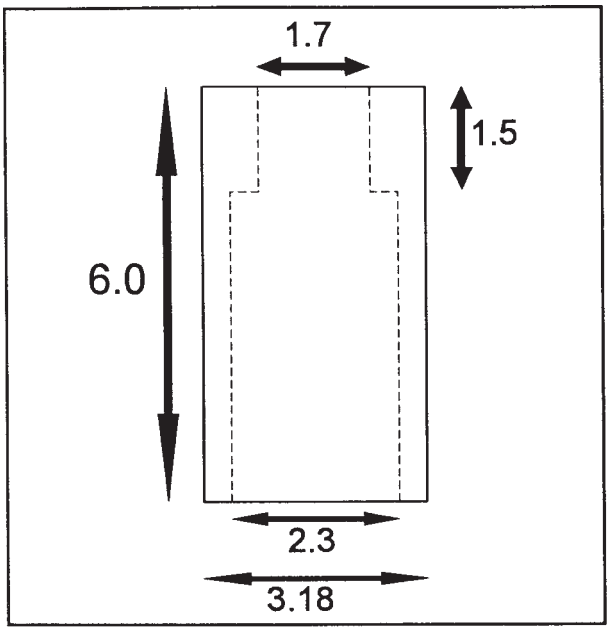
A5.1.2.2 A thermistor with an accuracy of ± 0.1°C from 25 to 45°C in isothermal stirred air or water.[6]

A5.1.2.3 The thermistor shall be epoxied into the copper sheath, as in Fig. A5.2. The epoxy shall have a thermal conductivity ≥0.183 W/(m°C).[7]

A5.1.3 Measure or calculate the leakage to atmosphere from the sensor and matting port assembly.

[6] The YSI Series 400 bead, Fenwal 192-222 LET-DO1, available from Yellow Springs Instruments, Inc., PO Box 279, Yellow Springs, OH 45387 has been found suitable for this purpose.

[7] For example, Creative Materials Inc. (CMI) 108-50 thermally conductive, low-stress epoxy, has been found suitable for this purpose.



NOTE 1—All dimensions in millimetres.

FIG. A5.1 Temperature Sensor Construction

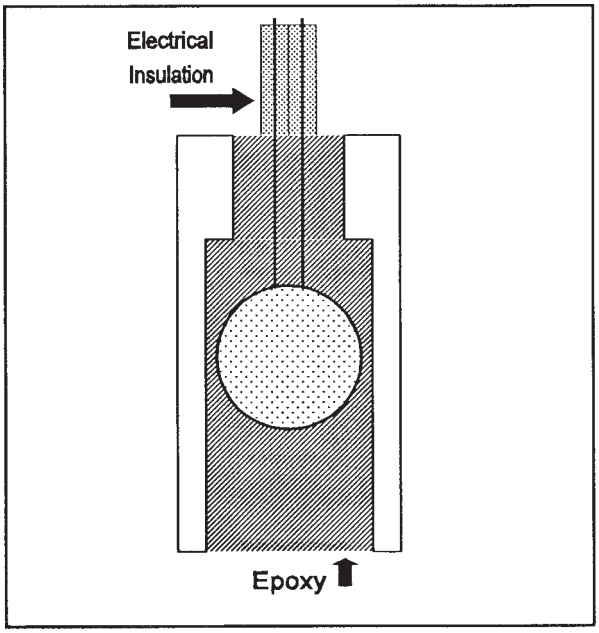


FIG. A5.2 Thermistor Epoxied Into the Copper Sheath

APPENDIX

(Nonmandatory Information)

X1. RATIONALE STATEMENT

X1.1 This appendix provides a rationale for certain requirements of this specification and is intended for those who are familiar with the design and use of humidifiers but who have not participated in its development. An understanding of the reasons for these requirements is provided to aid in the application of this specification. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate a revision of this specification.

X1.1.1 The appropriate clause numbers are indicated.

X1.1.1.1 (6.1,aa),4 Gas supply pressures used in different parts of the world vary considerable, and it is important that the safe range of supply pressures are marked on the humidifier. Moreover, humidifiers of similar appearance may have different supply requirements. Fig. X1.1

X1.1.1.2 (6.8.2a) 1 The safe use of a humidifier is dependent on the interaction of the humidifier with its many accessories, such as breathing tubes (both heated and non heated), temperature sensors and heated breathing tube controllers. To that end, the committee felt that the best way to address the problems created by the proliferation of components which were physically, but not functionally, interchangeable was to consider the whole system in which all of the components operate, that is, the humidification system, and set total system performance requirements.

X1.1.1.3 The committee recognizes that there are many more breathing tube manufacturers than humidifier manufactures. It is the committee's intent for accessory manufactures, such as breathing tube manufactures, to test their accessories with a host of humidifiers so that users can configure the humidification system that is most appropriate.

X1.1.1.4 In addition, the user is warned that a humidification system that has not been tested together to meet the requirements of this specification may not be safe.

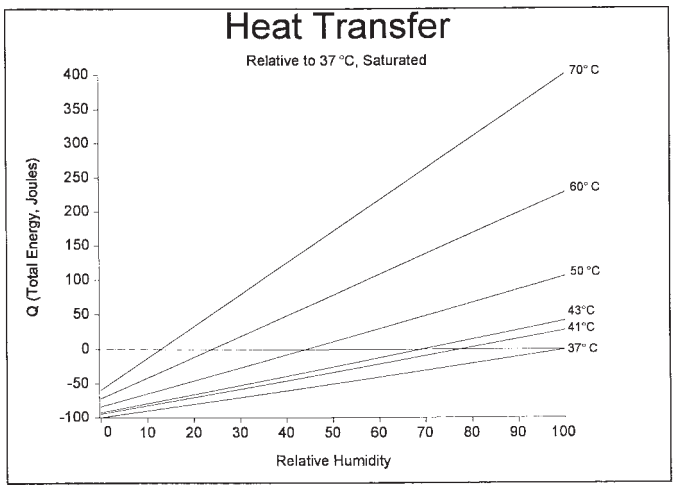


FIG. X1.1 Heat Transfer Calculations

X1.1.1.5 (6.8.2a) 2 The amount of air entrained by a venturi for the dilution of oxygen is a function of gas velocity. Changes in gas velocity, for example, as a result of a partial obstruction of the ventilation circuit, will directly effect the oxygen concentration.

X1.1.1.6 (6.8.2a) 8 Resistance to flow may increase the work of breathing. It may also interfere with the effectiveness of intermittent mandatory ventilation (IMV) or triggering mechanisms in lung ventilators.

X1.1.1.7 (6.8.2a) 10 The internal compliance of the ventilator breathing system, that includes the humidifier, must be known in order to accurately determine the tidal volume settings of constant volume ventilators.

X1.1.1.8 (6.8.2a) 15 The noise levels generated by humidifiers may contribute significantly to ambient noise levels in hospitals. Humidifiers are often positioned close to the patient. In special environments, such as adjacent to infant incubators, the effect is more pronounced and may lead to permanent injury.

X1.1.1.9 (6.8.3e) So that manufactures of breathing tubes are able to completely test their components in order to meet the requirements of Clause 6.8.2 a) 1 and 56.12.3, the breathing tube controller manufacturer must disclose the maximum amount of energy that the breathing tube could ever experience. Since many of the breathing tube manufactures "reverse-engineer" the breathing tube, the worst-case, maximum energy output of the controller is not always known.

X1.1.1.10 (24.7) Humidifiers are often mounted on poles. However, these humidifiers are often not mounted perfectly horizontal. The committee felt that 20° tilt could be construed as mounted correctly, and therefore felt that the humidifier had to be able to operate normally, including not spilling any liquid, when operated at this position.

X1.1.1.11 (42.6) The objective of this clause is to protect the patient from skin burns due to contact with the external surface of the breathing tube. See reference section for rationale for selecting 44°C.

X1.1.1.12 (43) Reports of fire caused by medical devices are unusual. However, when such fires occur in the hospital environment they can have tragic consequences.

X1.1.1.13 The risk of a fire is fundamentally determined by the three elements that are necessary in order to start a fire: ignitable material (fuel), a temperature equal to or above the minimum ignition temperature of the material, or sparks with energy dissipation equal to or above the minimum ignition energy of the materials, and an oxidant.

X1.1.1.14 Therefore, following the basic safety concepts of the General Standard, the objective in the design of the equipment must be to ensure that under both normal and single-fault conditions the temperature of any material is not raised to its minimum ignition temperature or the spark energy

does not exceed the material ignition energy level. Alternatively, contained ignition may occur provided it is self-limiting so that no hazard is created, for example, a fuse or a resistor within a sealed compartment.

X1.1.1.15 Minimum ignition temperatures for a large number of specific materials are well established and published in the literature, although normally only for ambient air and pure oxygen environments. The minimum ignition temperature may be critically dependent upon the concentration of oxidant present. If ignition temperatures for other materials or oxygen concentrations are required these may be determined using the methods and apparatus described in IEC 79-4.

X1.1.1.16 In considering the ignitable materials particular attention should be paid to materials which may accumulate during prolonged use, for example, airborne particles of paper or cotton.

X1.1.1.17 The risk of fire directly caused by sparking of electrical circuits is generally considered insignificant in medical equipment as temperature rise resulting from the power dissipation caused by a spark will not normally reach the ignition temperature of the solid materials generally used when following good design practice.

X1.1.1.18 However, if materials with a low ignition temperature and a very low thermal capacity, for example, cotton wool, paper or organic fibre accumulations, are present, then it may not be possible to determine the surface temperatures attained during exposure to spark energy and specific tests, for example, ignition tests, may be necessary to ensure safety under these conditions.

X1.1.1.19 In certain standards currently in use the requirements to minimize fire are based on a limitation on temperature and electrical energy and oxidant concentration to absolute values:

X1.1.1.20 The temperature value is based on the minimum hotplate ignition temperature for fire-retardant cotton in 100 % oxygen that is given in the American NFPA publication 53M as 310°C. The assumption was therefore made that 300°C was an acceptable temperature limit in medical equipment with oxygen-enriched atmospheres.

X1.1.1.21 The origin of the electrical energy values that have been used is less clear and it would seem that, in the absence of specific controlled tests, figures have been adopted from other published standards. However, simple tests and detailed analysis of the known factors involved in causing an oxygen fire show that these figures can be either over restrictive or potentially hazardous depending, in particular, on the manner in which the power may be dissipated and the proximity and type of any “fuel” present.

X1.1.1.22 It is now generally accepted that there are no single or universally applicable ranges of temperatures, energy, and concentration of oxidant which can ensure safety under all circumstances. Ultimately electrical energy is only significant in its ability to raise the temperature of ignitable materials, and this in turn depends upon the particular configuration and the proximity of any ignitable materials.

X1.1.1.23 Under single-fault conditions in a typical electrical circuit the possible number of failure modes is very high. In this case full ensurance of safety may only be possible by using appropriate hazard and safety analysis procedures taking into consideration the three basic elements, that is, material, temperature, and oxidant.

X1.1.1.24 An appropriate design might limit the electrical energy in the circuit to ensure that temperatures remain below the minimum air ignition temperature under normal conditions and seal compartments or add forced ventilation to ensure that the oxygen content does not exceed that of ambient air under a single-fault condition.

X1.1.1.25 Alternatively, it may be appropriate to limit the electric energy to ensure temperatures below the minimum ignition temperature for a pure oxygen environment, even under single-fault conditions.

X1.1.1.26 The particular combination of material, oxidant, and temperature determines whether a fire will occur, not a single value of any one of these variables.

X1.1.1.27 (50.1) For humidification systems that display the measured gas temperature, the committee concluded that a range from 25 to 45°C was the minimum that an operator needed to operate the humidification system. It should be very clear to the operator if the displayed measured gas temperature is higher than 45°C or lower than 25°C.

X1.1.1.28 (50.2.1) The committee concluded that ±5 % of full scale was an acceptable level for accuracy for this device.

X1.1.1.29 (50.2.2) In order to ensure patient safety, it is important that an operator is present with accurate information. The displayed measured gas temperature must be an accurate representation of the temperature sensors indicating actual delivered gas temperatures. An accuracy of ±2°C was believed by the committee to represent a practical and achievable level.

X1.1.1.30 (50.2.4) It was not found practical or necessary to apply the requirements of Clause 50.2 to control systems during transitioning.

X1.1.1.31 (50.2.4.1) Humidifier control systems, by their nature, continuously adjust the system components that effect the delivered gas temperature. The delivered gas temperature will tend to cycle about the set temperature. A good indication clinically of the performance of the humidification system is the average delivered gas temperature.

X1.1.1.32 (50.2.4.2) Since control circuits of humidifiers continuously adjust the system that effects the delivered gas temperature, this medium priority (caution) alarm will notify the clinician that the delivered gas temperature has exceeded the set temperature by more that an acceptable amount. It was agreed that this “acceptable amount” could be left to the manufacturer of the system to decide. Operators of these devices should take into account this information when purchasing and operating these devices.

X1.1.1.33 (51.5) Excessive liquid output could cause patient injury and water to accumulate in the breathing tube.

X1.1.1.34 (51.6) Sustained delivered gas temperatures above 41°C represents a potential thermal hazard to the patient. It is therefore important that the operator have a continuous display of the measured gas temperature and be alerted when the temperature exceeds 41°C.

X1.1.1.35 (51.7 and 51.8) Although it is rarely needed for patient care, a sustained delivered gas temperature of 41°C at any level of saturation is not a thermal hazard to the patient.

Studies to measure the relative importance of exposure time and temperature in the causation of cutaneous burns determined that surface temperatures of at least 44°C and 6 h of exposure were required to cause irreversible damage to epidermal cells **(4)**. As the degree of perfusion to the tracheobronchial mucosa far exceeds that enjoyed by cutaneous tissue, it is permissible to use the results of these studies to establish a safe level of temperature exposure for the airway. This is confirmed by studies conducted by the U.S. Navy Medical Research and Development Command that concluded that fully saturated gas at 45°C can be inspired for up to 1 h without damaging the mucosa of the respiratory tract.

X1.1.1.36 Delivered gas temperatures above 41°C, depending on the combination of gas temperature, level of saturation, and the length of time the patient is exposed, may be hazardous. It is therefore important that the operator be provided with a continuous display of delivered gas temperature and that in the event that the gas temperature exceeds 41°C the humidifier automatically interrupt heating and an alarm be activated.

X1.1.1.37 Gas at body temperature and fully saturated (37°C and 100 % relative humidity (RH)) will not transfer thermal energy to or from the patient. Dry gas at body temperature (37°C and 0 % RH) will draw heat away through evaporation. Gas at 41°C and fully saturated has the capacity to deliver less than 130 kJ per kg of dry gas breathed by the patient.

X1.1.1.38 To protect the patient from thermal injury, heating of the humidification system is interrupted if the delivered gas temperature exceeds 41°C. A thermal overshoot not to exceed an energy equal to 43°C and 100 % RH averaged over 30 s (194 kJ per kg of dry gas) is inconsequential to the patient and is permitted to simplify construction of the humidifier.

X1.1.1.39 (56.12) Delivery tubes have been reported to kink, occlude, and perforate due to the heat generated by humidifiers and supplemental electrical heating. It is believed that a delivery tube that is tested to meet the requirements of this specification and that does not kink, occlude, and perforate during these tests, will not be a safety hazard in clinical use.

X1.1.1.40 (60.1) 10 mg H_2O/L is equivalent to approximately 60 % relative humidity at 22°C ambient conditions, that is the lowest recommended humidity level for non-intubated patients. Humidifiers may be used in patients whose supraglottic airway has been bypassed by a tracheostomy or tracheal tube. Normal nasal breathing delivers air just below the larynx with a water content of approximately 33 mg H_2O/L. Humidifiers should approximate performance of the nasal airway. (See Refs **5, 6**, and **7**.)

X1.1.1.41 (63) Excessive noise can hinder voice communications, mask audio signals, cause stress, and contribute to sociocusis (nearly loss caused by prolonged exposure to a noisy environment) in patients and attending clinical staff.

X1.1.2 (Annex A1)—It is difficult to measure temperature at the precisely the same location as the device temperature sensor without modifying the gas flow, hence thermal transfer characteristics from the gas to the sensor. The philosophy of the test is to measure temperature either side of the sensor and interpolate the temperature to the site under test. Temperature drop in the circuit may be non-linear hence the objective is to place the standard sensors as close as possible to the device under test, but with minimal disruption of gas flow patterns.

X1.1.3 (Annex A2)—Energy content or specific enthalpy is not directly measurable, however it is determinable from the temperature and water vapor content of the gas. The gas exiting the humidifier is assumed to be 100 % RH to give a worst case energy content by means of the maximum water vapor content. However, if it can be demonstrated or measured otherwise this would be a more appropriate figure to use. At the time of issue of this specification, no commercially available humidity measuring devices with adequate response time or appropriate thermal characteristics were known to exist.

X1.2 Temperature al one does not determine whether a humidified gas presents a thermal hazard to a patient. The degree of saturation must also be known in order to determine the thermal energy of the humidified gas (see chart following):

$Q(total) = Q(air) + Q(water\ vapor) + Q(latent\ heat\ of\ vaporization)$
$Q(air) = Cp(air) \times mass(air) \times [T(air) - 37°C]$
$Q(water\ vapor) = Cp(wv) \times mass(wv) \times [T(wv) - 37°C]$
$Q(atent\ heat\ of\ vaporization) = 2257\ J/g \times mas(water\ vapor)$

X1.2.1 *Example*:

TV = 1 L
Temperature = 50°C
Absolute Humidity:

@37°C	= 44 mg H_2O/L
@50°C	= 83 mg H_2O/L
density (air)	= 1.293 g/L
Cp (dry air)	= 1.0067 J/g°C@37°C
Cp (water)	= 4.179 J/g°C@37°C
CP (wv)	= 1.884 J/g°C@37°C
Q(air)	= 1.0067 J/g°C × (1 L × 1.293 g/L) × (50-37)°C = 16.92
Q(water)	= 4.179 J/g°C × (1 L × (83-44) × 10^{-3} g/L) × (50-37)°C = 2.119 J
Q(wv)	= 1.884 J/g°C × (1 L × (83-44) × 10^{-3} g/L) × (50-37)°C = 1.08 J
Q(latht)	= 2257 J/g°C × (1 L × (83-44) × 10^{-3} g/L) = 88.02 J
Q(total)	= 16.92 + 2.119 + 1.08 + 88.02 = 108.1 J

X1.2.2 The thermal energy of the humidified gas can be expressed in terms of its thermodynamic properties. Applying the first law of thermodynamics for the transfer of thermal energy under an isobaric (constant pressure) condition yields the following:

$$dQ = dU + dW \quad \text{(X1.1)}$$

X1.2.3 Calculating work under an isobaric condition:

$$dW = PdV \quad \text{(X1.2)}$$

Therefore:

$$dQ = dU + PdV \quad \text{(X1.3)}$$

X1.2.4 From Ref **(8)** "We find that in this very restricted case (constant pressure), the heat transfer during the process is given in terms of the change in the quantity U + PV between initial and final states. Inasmuch as all of these quantities are thermodynamic properties, functions only of the state of the

system, their combination must also have these same characteristics. Therefore, we find it convenient to define a new extensive property called enthalpy (H): H = U + PV".

X1.2.5 *Extensive Property*—That which can not be directly measured but must be calculated (for example, enthalpy). In contrast to an intensive property is one which can be directly measured (for example, temperature).

Differentiating:

$$dH = dU + PdV + VdP \tag{X1.4}$$

Substituting:

$$dQ = dU + PdV \tag{X1.5}$$

Therefore:

$$dH = dQ - PdV + PdV + VdP \tag{X1.6}$$

$$dH = dQ + VdP \tag{X1.7}$$

Under isobaric conditions, $dP = 0$, therefore:

$$dH = dQ \tag{X1.8}$$

X1.2.6 The value of specific enthalpy of 194 kJ/jg (dry gas) represents a safe level delivered in any 30-s period. This specific enthalpy level is based on Refs **(4)** and **(9)**.

X1.2.7 (Annex A3) A gravimetric technique is selected as the simplest, most consistent method to give a measure of humidifier output. Hygrometers will not provide consistent and correct results when operated in the non-isothermal environment of the breathing circuit. Attention is drawn to the definition of humidifier output that is defined as milligram water vapor per unit moist gas at 37°C. This is physically and physiologically more appropriate than other definitions as, for example, milligram per litre of dry gas.

X1.2.7.1 *Derivation*— Humidifier output:

$$n = \frac{mass\ of\ water}{volume\ of\ dry\ air\ at\ 37°C + volume\ of\ water\ at\ 37°C\ (saturated)} \tag{X1.9}$$

$$n = \frac{m_w}{V_1(1 + y(37 - T_1)) + V_{water\ 37°C\ saturated}} \tag{X1.10}$$

where: y = expansion coefficient for dry air from 23 to 37°C.

X1.2.7.2 *Derivation of y*:

$$y = \frac{\frac{(specific\ volume\ dry\ air,\ 37°C)}{(specific\ volume\ dry\ air,\ 23°C)} - 1}{37–23°C}$$

$$= \frac{\frac{0.8784}{0.8387} - 1}{14}$$

$$= \frac{0.04734}{14}$$

$$= 0.00338 \tag{X1.11}$$

$$V_{water\ 37°C,sat} = volume\ dry\ air\ 37°C \times \frac{(specific\ volume\ water\ vapor,\ 37°C)}{(specific\ volume\ dry\ air,\ 37°C)} \tag{X1.12}$$

$$V_{water\ 37°C} = V_1(1 + y(37 - T_1)) \times \frac{0.9362 - 0.8784}{0.8784}$$

$$= 0.6580 \times V_1\,(1 + y(37 - T_1)) \tag{X1.13}$$

X1.2.7.3 *Derivation of Water Vapor Volume*—Substituting Eq X1.13 and the value from Eq A2.3 into Eq A2.2, rationalizing units and rearranging:

$$humidifier\ output = \frac{1000\ m}{1.0658\ V(1 + 0.0034(37 - T_1))} \tag{X1.14}$$

X1.2.8 (Annex A5) The standard temperature sensor includes an additional copper thermal mass to effect an averaging of temperature across the circuit, to minimize effects of condensation forming on the sensor, to reduce effects of precise positioning of the sensor, to increase thermal transfer to the sensor, and to ensure a stable temperature measurement.

NOTE X1.1—The copper sleeve is most easily manufactured from standard copper tube, diameter 3.18 mm or ⅛ in. The temperature bead may be a YSI Series 400 bead or equivalent.[7] Dimensions are not critical within reason. The simplest dimension check on the copper sleeve is by weight. The sleeve is 0.23 g nominal; a tolerance of ± 0.05 mm on all dimensions equates to ± 0.03 g.

REFERENCES

(**1**) Goff, J. A., and Gratch, S., "Thermodynamic Properties of Mist Air," *Trans ASHVE*, Vol 51, 1945, pp. 125–164.

(**2**) Goff, J. A., and Gratch, S.," Thermodynamic Properties of Water From − 160 to 212°F," *Trans ASHVE*, Vol 52, 1946, pp. 92–122.

(**3**) Goff, J. A., "Standardization of Thermodynamic Properties of Moist Air," *Trans ASHVE*, Vol 55, 1949, pp. 459–484.

(**4**) Moritz, A. R., MD and Henriques, F. C., Jr, MD, "Studies of Thermal Injury II The Relative Importance of Time and Surface Temperature in the Causation of Cutaneous Burns," *The American Journal of Pathology*, Vol 23, 1947, pp. 695–720.

(**5**) Fonkalsrud, E., Sanchez, M., et al, "A Comparative Study of the Effects of Dry Versus Humidified Ventilation on Canine Lungs," *Surgery*, Vol 78, No. 3, September 1975, pp. 373–380.

(**6**) Dery, R., Pelletier, J., et al, "Humidity in Anesthesiology, III Heat and Moisture Patterns in the Respiratory Tract During Anesthesia with the Semi-Closed System," *Can Anes Soc J*, Vol 14, No. 4, July 1967.

(**7**) Dery, R., "The Evolution of Heat and Moisture in the Respiratory Tract During Anesthesia with a Non-Rebreathing System," *Can Anes Soc J*, Vol 20, No. 3, May 1973.

(**8**) Wylan, and Sonntag, *Fundamentals of Classical Thermodynamics*, John Wiley and Sons, 1985.

(**9**) Stoll, Alice M., and Greene, Leon C., "Relationship Between Pain and Tissue Damage Due to Thermal Radiation," *Journal of Applied Physiology*, Vol 14, 1959, pp. 373–382.