Designation: F 1690 – 96 (Reapproved 2004)

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

[1] This specification is under the jurisdiction of ASTM Committee F29 on Anesthetic and Respiratory Equipment and is under the direct responsibility of Subcommittee F29.14 on Ventilators.

Current edition approved June 1, 2004. Published June 2004. Originally approved in 1996. Last previous edition approved in 1996 as F 1690 – 96.

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: