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Standard Specification for Humidifiers for Medical Use—Part 1: General Requirements for Active Humidification Systems¹

This standard is issued under the fixed designation F1690; 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 [3.1.7](#), 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 use provided with the humidification systems and HMEs and the available literature for more details.

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.

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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

F1054 [Specification for Conical Fittings](#) (Withdrawn 2005)³

F1205 [Specification for Anesthesia Breathing Tubes](#) (Withdrawn 2008)³

F1463 [Specification for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care](#) (Withdrawn 2005)³

2.3 ANSI Standard:

ANSI/CGA G7.1 [Commodity Specification for Medical Grade Air](#)⁴

2.4 CGA Standard

CGA Pamphlet G4.3 [Commodity Specification for Medical Grade Oxygen](#)⁵

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](#)⁴

ISO 4135: 1979 [Anesthesiology—Vocabulary](#)⁴

ISO 8835-2: 1993(E) [Inhalation Anesthesia Systems—Part 2: Anesthetic Circle Breathing Systems](#)⁴

ISO 10651 [Lung Ventilators for Medical Use—Part 3: Particular Requirements for Emergency and Transport Ventilators](#)⁴

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 The last approved version of this historical standard is referenced on www.astm.org.

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

⁵ Available from Compressed Gas Association, 1235 Jefferson Davis Highway, Arlington, VA 22202.

2.6 IEC Standards

IEC Publication 601-1—[Safety of Medical Electrical Equipment—Part 1: 1988—General Safety Requirements](#)⁴

IEC 601-2-19: 1990—[Particular Requirements for the Safety of Baby Incubators](#)⁴

IEC 601-1-2 [Medical Electrical Equipment Part 1: General Requirements for Safety—Collateral Standard: Electromagnetic Compatibility](#)⁴

IEC Publication 651: 1979 [Sound Level Meters](#)⁴

IEC Publication 801-2 [Electromagnetic Compatibility for Industrial Process Measurement and Control Equipment—Part 2: 1990—Electrostatic Discharge Requirements](#)⁴

3. Terminology

3.1 Definitions:

3.1.1 The definitions given in Clause 2 of the General Standard apply with the following additions:

3.1.2 *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).

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

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

3.1.5 *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.

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

3.1.7 *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.

3.1.8 *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).

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

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

3.1.11 *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.

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

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

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

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

3.1.15 *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).

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

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

3.1.18 *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).

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

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

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

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

3.1.22 *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.

Section One—General:			
	A	NA	AM/R
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.

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”: $23 \pm 2^\circ\text{C}$, $\text{RH} = 50 \pm 5\%$ 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.

starting temperature of $23 \pm 2^{\circ}\text{C}$ when operated according to the manufacturer's 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 anomaly 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.