Designation: F 1452 – ~~92~~01

An American National Standard

Standard Specification for Minimum Performance and Safety Requirements for ~~Components and Systems of~~ Anesthetic Gas Monitors[1]

This standard is issued under the fixed designation F 1452; 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

The measurement of the concentration of ~~inhalation~~ inhaled anesthetic gases is becoming common practice. This specification establishes minimum safety and performance requirements for anesthetic gas monitors that are achievable within the limits of existing technology.

The appendix ~~that follows~~ contains rationale for some of the ~~most~~ important requirements. It is included to provide additional insight for the reasoning that led to the requirements and recommendations that have been incorporated in this specification.

~~SECTION~~

This specification uses IEC 60601-1:1988 including Amendment 1 and 2 (hereafter called the General Standard) for many of the general requirements for safety. Additional requirements specific to anesthetic gas monitors begin at Clause 60.

SECTION ONE—GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1. Scope

1.1 This clause of the General Standard applies except as follows:

1.1.1 This specification applies to ~~ANESTHETIC GAS MONITORS~~ anesthetic gas monitors used with adults, children, and neonates.

1.1.2 It does not apply to devices intended for use in laboratory research applications, non-human applications, or for calibration of anesthetic agent vaporizers.

1.1.3 This specification does not apply to anesthetic gas monitors intended for use with flammable anesthetic mixtures.

2. Referenced Documents

2.1 The following standards contain provisions, which~~,~~ through reference in this specification~~,~~ constitute provisions of this specification. At ~~a~~ the time of publication of this ~~document,~~ specification, the editions indicated were current. All standards are subject to revision, and parties using this specification are encouraged to investigate the possibility of applying the most recent editions of the standards listed ~~below.~~ as follows.

2.2 *ASTM Standards:*

---

[1] This specification is under the jurisdiction of ASTM Committee F~~-~~29 on Anesthetic and Respiratory Equipment and is the direct responsibility of Subcommittee ~~F29.01.06 on Anesthetic Agent Analyzers.~~ F29.11 on Gas Monitors.

Current edition approved ~~December 15, 1992.~~ April 10, 2001. Published ~~June 1993.~~ December 2001. Originally published as F 1452 – 92. Last previous edition F 1452 – 92.

F 1054 Specification for Conical Fittings of 15-mm and 22-mm Sizes[2]
F 1461 Specification for Alarm Signals in Medical Equipment Used in Anesthesia
F 1343 Specification for Anesthetic Equipment-Scavenging Systems for Anesthetic Gases and Respiratory Care[2]

2.3 *IEC Standards:*[3]

IEC 60079-4:1975 Electrical Apparatus for Explosive Gas Atmospheres—Part 4: Method of Test for Ignition Temperature
IEC 60601-1:1988 Medical Electrical Equipment—Part 1: General Requirements for Safety. Including Amendment 1 and
IEC 60601-1-2:1992 Medical Electrical Equipment: Collateral Requirements Electromagnetic Compatibility

2.4 *ISO Standards:*[3]

ISO 4135: 1995 Anaesthesiology—Vocabulary
ISO 7000-1989 Graphical Symbols for Use on Equipment—Index and Synopsis
ISO 7504:1984 Gas Analysis—Vocabulary

2.5 *Other Documents:*

NFPA 53M Fire Hazards in Oxygen-Enriched Atmospheres—1990 Edition[4]
AAMI HE-48:1993 Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices[5]
AAMI ES-1:1993 Safe Current Limits for Electromedical Apparatus[5]
CGA C-9-1982 Standard Color Markings of Compressed Gas Cylinders Intended for Medical Use

3. Terminology

3.1 Clause 2 of the General Standard applies together with ISO 4135 and the following additions:

3.1.1 *accuracy*—the quality that characterizes the ability of a device to give indications approximating to the true value of the quantity measured.

3.1.2 *alarm condition*—a condition that occurs when a variable that is being monitored by an alarm system equals or falls outside the set alarm limits.

3.1.2.1 *Discussion*—The monitored variable may be displayed or internal.

3.1.3 *alarm limit(s)*—value(s) that are set by the manufacturer, the device, the user, or operator which define the threshold range of the alarm condition.

3.1.3.1 *Discussion*—Terms such as "alarm limits" set points" or "alarm threshold" are frequently used to describe the same function.

3.1.4 *alarm signal*—a signal, the purpose of which is to alert the operator of an abnormal condition in the patient or equipment that may develop into a safety hazard which requires operator awareness or action.

[2] *Annual Book of ASTM Standards*, Vol 13.01.
[3] Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.
[4] Available from National Fire Protection Association (NFPA), 470 Atlantic Ave., Boston, MA 02210.
[5] Association for the Advancement of Medical Instrumentation, 1110 N. Globe Rd., Suite 220, Arlington, VA 22201-4795.

3.1.5 ~~*anesthetic gas level*~~*alarm system*~~—the volume percent~~—a system that is intended to make the operator(s) aware of ~~anesthetic gas~~ an alarm condition in ~~a gaseous mixture.~~ the patient or equipment, by means of its alarm signal or signals.

3.1.6 *anesthetic gas level*—the concentration (volume percent) of anesthetic gas in a gaseous mixture.

3.1.7 *anesthetic gas monitor*—a device for the measurement of the concentration ~~or partial pressure~~ (volume percent) of anesthetic gas(es) in ~~ventilatory gases.~~

~~3.1.6.1~~ a gaseous mixture.

3.1.7.1 *Discussion*—The anesthetic gas monitor consists of all equipment, including accessories, sensor, and sampling tube (if a diverting type), specified by the manufacturer for the intended use of the anesthetic gas monitor.

~~3.1.7 *anesthetic gas reading*—the measured anesthetic gas level as indicated by the analyzer display.~~

3.1.8 *anesthetic gas* ~~*scavenging systems*~~ *reading*~~—systems that collect and remove the excess~~—the measured anesthetic ~~gases and vapors released from equipment used in administering anesthetics under normal operating conditions, or exhaled~~ gas level as indicated by the ~~patient. Scavenging is intended to reduce ambient concentrations of anesthetic agents~~ monitor display.

3.1.8.1 *Discussion*—This may be expressed in an~~e~~y suitable unit such as volume percent, or parti~~z~~al pressure in~~g~~ kilopascals or millime~~a~~tres of mercury.

3.1.9 *anesthetic gas* ~~*transducer*~~ *scavenging systems*—complete systems that collect and remov~~i~~e excess gases and vapors released from equipment used in administering anesthesia, or exhaled by the patient for ~~converting~~ the ~~partial pressure or volume percent~~ purpose of conveying these gases and vapors to an ~~anesthetic gas or vapor into a signal for monitoring or recording.~~ appropriate place of discharge.

3.1.10 ~~*common gas outlet*—that port through which the dispensed mixture from the anesthetic apparatus is delivered to the breathing system.~~

~~3.1.11~~ *default parameter (default setting)*—those operating parameters within the ~~machine,~~ device, which are ~~pre-set at~~ preset by the manufact~~o~~ur~~y~~er, the user, or ~~by~~ the operator, and which the ~~machine~~ device itself sets, without further intervention, when it is turned on.

3.1.1~~2~~1 *delay time (lag time)*—the time from a step function change in anesthetic gas concentration ~~or partial pressure~~ (volume percent) at the sampling site to the achievement of 10 % of the ~~step change in~~ final anesthetic gas value in the ~~analyzer~~ monitor (see Fig. 1).

3.1.1~~3~~2 *display*—the visual representation of output data.

3.1.1~~4~~3 *diverting (sidestream) anesthetic gas monitor*—a monitor that transports a portion of ventilatory gases from the sampling site through a sampling tube to the sensor, which is remote from the sampling site.

3.1.1~~5~~4 *drift*—(from ISO 7504:1984) change of the anesthetic gas level display of ~~an analyzer~~ a monitor for a given level of concentration over a stated period of time~~,~~ under reference conditions that remain constant.

~~3.1.15.1 *Discussion*—It is necessary to distinguish the zero drift that concerns the operation of the instrument with samples of zero or low concentration from the drift considered at one or several levels of concentration.~~

~~3.1.16 *high priority alarm*—a combination of audible and visual alarms indicating that immediate action on the part of the operator is required.~~

---

[7] Available from ~~Good Manufacturing Practices for Medical Devices, Food and Drug Administration, 5600 Fishers Lane (HF2-220), Rockville, MD 20857, or call 800-638-2041.~~ Compressed Gas Association, 1235 Jefferson Davis Highway, Arlington, VA 22202.

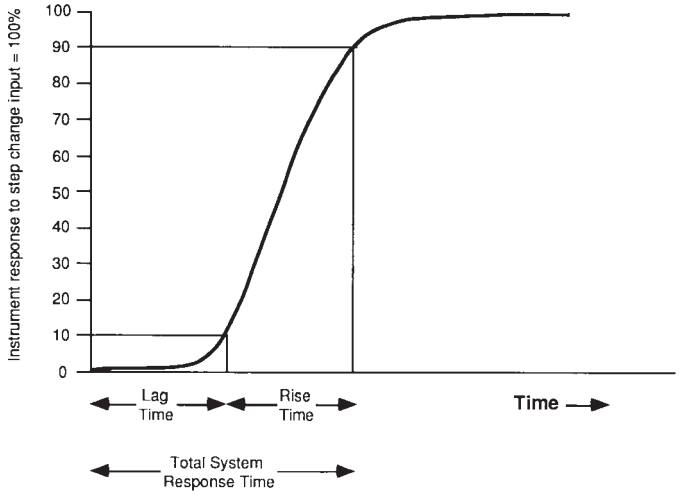


FIG. 1 Delay Time (Lag Time), Rise Time, and Total System Response ~~(Delay Time is Synonymous with Lag Time and is the Preferred Term)~~

3.1.17

3.1.15 *interference with measurement accuracy*— the difference between the anesthetic gas readings in the presence and absence of an interfering gas(es).

3.1.18 *low priority alarm*—an indication of a condition that requires awareness, but not necessarily action, on the part of the operator.

3.1.19 *medium priority alarm*—a combination of audible and visual alarms indicating that prompt action on the part of the operator is required.

3.1.20 *non-diverting*

3.1.16 *nondiverting anesthetic gas monitor*—an anesthetic gas monitor that uses a sensor at the sampling site.

3.1.217 *partial pressure*—thepressure that each gas in a gas mixture w could exert if it alone occupied the volume of the mixture at the same temperature.

3.1.2218 *operator*—(from IEC 60601-1) person handling equipment.

3.1.19 *rise time*—the time required to display achieve a rise from 10 to 90 % of the change in the final anesthetic gas value by in the anesthetic gas monitor when a step function change in anesthetic gas volume percent occurs at the sampling site (see Fig. 1).

3.1.230 *sampling site*—the location at which respiratory ventilatory gases are diverted from for measurement to a remote sensor in a diverting anesthetic gas monitor or the location of the sensor area in a non-diverting anesthetic gas monitor.

3.1.241 *sampling tube*—the conduit for transfer of respiratory ventilatory gases from the sampling site to the sensor in a diverting anesthetic gas monitor.

3.1.252 *sensor*—the part of the anesthetic gas monitor that is sensitive to the presence of the anesthetic gas.

3.1.263 *total system response time*—the sum of the delay time and rise time (see Fig. 1).

3.1.274 *user*—(from IEC 60601-1) authority responsible for the use and maintenance of equipment.

3.1.25 *volume percent (V/V%) of a gas or vapor*—the volume of an anesthetic a gas (or other gas or vapor) in a mixture, expressed as a percent of the total volume.

4. Relationship of This Specification to the General Standard

	Section One—General		
	(A)	(NA)	(AM/R)[A]
1. Scope and object			X
1. ScopeGeneral Requirements and object			X
2. Terminology and definitions			X
3. General requirements			X
4. General requirements for tests			X
4. General requirements General Requirements for tests			X
5. Classification			X
6. Identification, marking, and document			X
7. Power input	X		
	Section Two—Environmental Conditions		
8. Not used[B]		X	
9. Not used		X	
10. Environmental conditions	X		
11. Not used		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. Patient auxiliary currents			X
20. Dielectric strength	X		
	Section Four—Protection Against Mechanical Hazard		
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	
28. Suspended masses	X Tests	

Section Five—Protection Against Hazards from Unwanted or Excessive Radiation

29. X-radiation	X	
30. Alpha, beta, gamma, neutron radiation and other particle radiation	X	
30. Alpha, beta, gamma, neutron radiation	X	
4.1 Clauses 3 and other particle radiation		
31. Microwave radiation	X	
32. Light radiation (including visual radiation and lasers)	X	
33. Infra-red radiation	X	
34. Ultra-violet radiation	X	
35. Acoustical energy (including ultrasonics)	X	
36. Electromagnetic compatibility		X

Section Six—Protection Against Hazards of Ignition of Flammable Anesthetic Mixtures
Section Six—Protection Against Hazards 4 of Ignition of Flammable Anesthetic Mixtures

37. Locations and basic requirements	X	
38. Marking and accompanying documents	X	
39. Common requirements for Category AP and Category APG equipment	X	
40. Requirements and tests for Category AP equipment, parts or components thereof	X	
41. Requirements and tests for Category APG equipment, parts or components thereof	X	

Section Seven—Protection Against Excessive Temperatures and Other Safety Hazards

	(A)	(NA)	(AM/R)[A]
42. Excessive temperatures	X		
43. Fire prevention			X
44. Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, and disinfection			X
44. Overflow, spillage, leakage, humidity, ingress the General Standard apply, except as follows:			X
4.12 Test methods other than those specified in this specification, but of liquids, cleaning, sterilization, and disinfection			
45. Pressure vessels and parts subject to pressure			X
45. Pressure vessels and parts subject equal or greater accuracy, may be used to pressure			X
46. Human errors			X
47. Electrostatic charges			X
48. Materials in applied parts in contact with the body of the patient	X		
48. Materials in applied parts in contact verify compliance with the requirements of this specification. However, in the patient	X		
49. Interruption of the power supply	X		
49. Interruption event of dispute, the power supply	X		

Section Eight—Accuracy of Operating Data and Protection Against Hazardous Output
Section Eight—Accuracy of Operating Data methods specified in this specification shall be used as the reference methods.
6. *Identification, Marking, and Protection Against Hazardous Output*

50. Accuracy of operating data		X
50. Accuracy Document—Clause 6 of operating data		X
51. Protection against incorrect output		X

Section Nine—Abnormal Operation and Fault Conditions; Environmental Tests			
Section Nine—Abnormal Operation the General Standard apply, except as follows:			
Under "clearly legible," the first sentence shall be modified to read as follows:			
Warning statements, instructional messages, or drawings, affixed permanently and Fault Conditions; Environmental Tests			
52. Abnormal operation and fault conditions	X		
53. Environmental tests	X		
Section Ten—Constructional 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	X		
59. Construction and layout	X		
Additional Clauses			
60. Interfering gas and vapor effects (other than water vapor)	X		
61. Pressure effects	X		
62. Sample gas exhaust port	X		
63. Breathing system connections	X		
64. Obstruction of sampling tube	X		
64. Obstruction legible to an operator with a visual acuity of sampling tube	X		
65. Contamination of breathing systems	X		
65. Contamination 1.0 (corrected if necessary) from a distance of breathing systems	X		

[A] A = applies, NA = not applicable, and AM/R = applies with 1 m at an amendment, addition, or revision to the requirement in the General Standard.

[B] "Not used" means that material in this (these) section(s) ambient illuminance level of IEC 601-1:1977 has been deleted from 215 lx, when viewing the 1988 edition, but the section number is reserved for future use.

5. Clauses Containing Amendments, Additions, or Replacements to the Text in IEC 601-1:1988 information, markings, and so forth, perpendicular to, and including 15° above, below, left, and right.

NOTE 1—The clause numbers used refer 1—Care should be taken to avoid directing the specific section in light source so as to avoid glare.

6.1 d) If the General Standard.

4. *General Requirements and General Requirements for Tests*—The requirements given in Clauses 3 and 4 size of the General Standard apply, together with anesthetic gas monitor does not permit the following addition:

4.12 Test methods other than those complete marking as specified in throughout this draft specification, but of equal or greater accuracy, may clause, at least the following shall be used to verify compliance with marked on the requirements anesthetic gas monitor:

The name of this draft specification. However, in the manufacturevr,

A serial or lot or batch identifying number, and

Symbol 14 in Table D 1 of dispute, the methods specified in this draft specification General Standard.

6.1 aa) A serial number or other lot or batch identifier.

6.1 bb) The manufacturer shall be used as mark the reference methods.

5. *Classification*—The requirements given device with a warning to refer the user or operator to the accompanying documents or Symbol 14 in Clause 5 Table D1 of the General Standard apply, with for the following additions: expected adverse effects on the performance of the anesthetic gas monitor.

NOTE 2—An ANESTHETIC GAS MONITOR may have APPLIED PART(S) of different types (as classified in Clause 14.6 of the General Standard).

Clauses 5.4 and 5.6 are deleted and the following 2—It is added:

5.9 The method(s) of sterilization or disinfection recommended by the manufacturer shall that illustrated service information be included in provided to include the labeling following: instructions for preventive maintenance and may be included in the marking.

6. *Identification, Marking, service calibration, and Documents*—The requirements given those adjustments that are necessary to maintain the anesthetic gas monitor in Clause 6 of the General Standard apply, together with the following modifications:

Under" clearly legible," the first sentence shall be modified to read:

Warning statements, instructional messages, or drawings: affixed permanently and legible to an operator with a visual acuity of 1.0 (corrected if necessary) from a distance of 1 m at an illuminance level of 215 lx.

Warning statements, instructional messages, or drawings: affixed permanently and legible to an operator with correct operating condition, as well as a description of 1.0 (corrected if necessary) from a distance of 1 m at an illuminance level of 215 lx.

6.1 aa) All those adjustments and replacements that can be performed by the user.

6.1 cc) All operator interchangeable components of an ANESTHETIC GAS MONITOR anesthetic gas monitor that are flow-direction sensitive shall be marked clearly and durably marked with an arrow showing the direction of gas flow.

6.1 bb) If

6.1 dd) If a sampled gas inlet and outlet are provided, their presence shall be durably marked clearly either with text, or with the respective symbol for inlet and durably.

6.1 ee) Packages outlet from ISO 7000.

6.1 ee) Packages for single-use components shall be durably marked clearly with the following words:" SINGLE USE" words: "single-use" or "SINGLE PATIENT USE." "single-patient use" or the symbol. No 1051 given in ISO 7000, or both.

6.1 ff) All controls which increase or decrease a function shall be marked with a legible indication to inform the operator which action(s) is(are) required to increase/decrease the controlled function.

NOTE 3—Additionally, Symbol No. 1051 given in ISO 7000 may 3—Controls and their associated markings should be used.

6.5 Color visible or legible, or both, to an operator having a visual acuity (corrected, if necessary) of at least 1.0 when the operator insu located at least 1 m in front of the anesthetic gas monitor and the ambient illuminance level is 215 lx, when viewing the information, markings, and so forth, perpendicular to, and including 15° above, below, left, and right.

NOTE 4—Controls should be according to NFPA 70.

6.6 a) Replace Clause 6.6 a) identified with their associated markings.

6.1 gg) If applicable, the following:

Identification of the content of gas cylinders used in medical practice as a part of electrical equipment shall be in accordance with CGA C-9-1982. Colors of calibration gas cylinders not already specified in relevant national standards such as CGA C-9-1982 shall be color- coded differently from the colors specified for medical gases (see also Subclause 56.3a).

Identification words "Not for use with flammable anesthetics" or a symbol.

6.6 *Identification of Medical Gas Cylinders and Connections:*

on of the content of gas cylinders used in medical practice as a part of electrical equipment shall be in
A C-9-1982. Colors of calibration gas cylinders not already specified in relevant national standards such as
CGA C-9-1982 shall be color coded differently from the colors specified for medical gases (see also Sub

6.6 b) Replace Clause 6.6 b) with the following:

The point of connection of gas cylinders shall be so identified on equipment that errors are unlikely when a connection is made. If a sampled gas inlet and outlet are provided, the port shall be marked clearly.

The point 56.3a of the port shall be marked clearly.

6.6 c) If General Standard).

6.6 c) If color coding of labels for halogenated anesthetic agents is used, they shall be in accordance with Table 1.

6.7 Clause 6.7

6.8.2 *Instructions for Use:*

6.8.2 aa) A description of the General Standard shall apply.

6.8 Clause 6.8 purpose and intended use of the General Standard anesthetic gas monitor.

6.8.2 bb) A description of the principles of operation of the anesthetic gas monitor.

6.8.2 cc) The instructions for use shall apply, with include the following additions: following:

(A) The instructions for use shall additionally include the following information:

TABLE 1 Colors for Color Coding of Anesthetic Agents

Anesthetics Agent	Color	Federal Standard 595a	Pantone Color	Munsell Color
Halothane	red	11105	200 C	5R4/14
Enflurane	orange	22510	144	2.5YR6/16
Enflurane	orange	22510	151 C	2,5YR6/16
Halothane	red	11105	200	5R4/14
Isoflurane	purple	N/A[A]	245 C	7,5P4/12
Isoflurane	purple		none	252/253
Sevoflurane	yellow	N/A	108 C	6,25Y8,5/12
	7.blue	N/A	3015P C	10B4/12
Desflurane	blue	N/A	3015 C	10B4/10

[A] N/A = Not available.

(1) A description of the purpose and intended use of the ANESTHETIC GAS MONITOR;

() 2) A description of the principles of operation of the ANESTHETIC GAS MONITOR, including the relationship between gas concentration and its PARTIAL PRESSURE, and the effects of humidity.

A detailed specification including the following:

Performance Specifications:

(a) The anesthetic gas measurement range and the accuracy and precision of measurement;

(a) The) The anesthetic gas reading range and the accuracy of measurement;

(b) If the ANESTHETIC GAS MONITOR is capable of identifying the halogenated anesthetic gas(es) without user intervention, the manufacturer shall make the test methods and results supporting the claim available upon request;

(b) If the ANESTHETIC GAS MONITOR is capable of identifying the halogenated) In a diverting anesthetic gas monitor, the gas diversion flow and its tolerance;

(c) The gas diversion flow, if gas diversion occurs;

(c) The gas diversion flow, if gas diversion occurs;) The minimum sample flow at which the device will meet specifications;

(d) The stability of measurement accuracy;

(d) The) The stability of measurement accuracy;

(e) The RISE TIME;

(e) The RISE TIME;) The rise time and the total system response time;

(f) The anesthetic gas alarm range, its resolution, and delay time from detection to activation;

(f) The) The anesthetic gas reading alarm limit range, its resolution, default setting(s), and time from detection to activation;

(g) The operating, nonoperating (standby), and storage temperature and humidity ranges, if applicable;

(g) The operating, nonoperating (standby),) The ranges of temperature, atmospheric pressure, and humidity for operation and for storage;

(h) Power requirements; and

(h) Power requirements; and) The time from switching "ON" to obtaining specified operating performance;

(i) Time from switching on to obtaining specifiedow rate.

(i) Time from switching) The interval (expressed in hours) between user/operator interventions of the water handling system based on a sample gas temperature of 37°C, a room temperature of 23°C, and 100 % water-saturated sample. This shall be stated for both the manufacturers' specified minimum and maximum sample flow rate.

(j) A statement whether the device is equiperatin;

(j) A statement whether the device is equipped with automatic barometric pressure compensation;

(k) The detection threshold for a sing pere; and

(k) The detection threshold for a single halogenated anesthetic agent in a gas mixture; and

(l) The detection threshold(s) for mance.

(l) The detection threshold(s) for multiple halogenated anesthetic agents in a gas mixture (see also Clause 51.8.13).

(4) Details of any known adverse effects2) *Known Adverse Effects on stated function (for example, measurement accuracy and precision, integrity Stated Performance as a Result of electrical isolation, and the integrity of pneumatic components) due to the following;*

Following:

(a) Humidity or condensate, including, for example, any adverse effects if an accessory is provided to improve the function of the sensor in the presence of condensation or particulate water;

(a) Humidity or condensate, including, for example, any adverse) Quantitative effects of humidity or condensate;

(b) Interfering gases or vapors;

(b) Interfering) Quantitative effects of interfering gases and vapors (see also Clause 60.1);

(c) Leaks or internal venting of sampled gas;

(c) Leaks) Leaks or internal venting of sampled gas;

(d) Mechanical shock;

(e) Cyclic (ventilating) pressure in the breathing circuit;

(e) Cyclic (ventilating)) Cyclic pressure up to 10 kPa (100 cm H_2O);

(f) Barometric pressure;

(f) Barometric) Quantitative effects of barometric pressure;

(g) Fluctuation in ac mains or battery voltage;

(g) Fluctuation) Quantitative details of fluctuation in ac mains or battery voltage, or both; and

(*h*) If automatic compensation for barometric pressure is not provided, then the accompanying documents shall contain an explanation that the readings in concentrations units are correct only under the pressure at which the anesthetic gas monitor is calibrated; and

(*i*) Other sources of interference, if any.

(*j*) Other) Other sources of interference, if any.

(5) An illustration of the features of the anesthetic gas monitor, indicating the function3) *Operation and location of all operating controls, adjustments, and system components necessary for correct operation.*

(*6*) Instructions for operation of the anesthetic gas monitor, including the following:

Maintenance:

(*a*) Checking and calibration before use;

(*a*) Checking and calibration) Calibration or verification or both before use and during use;

(*b*) Routine inspection and testing;

(*b*) Routine) Routine inspection and testing;

(*c*) Recommended methods for cleaning an d disinfection or sterilization;

(*c*) Recommended methods for cleaning, disinfecting, or sterilizing, or combination thereof, and, if applicable, any limitations on the number of these cycles;

(*d*) Recommended method for connecting an exhaust port of the ANESTHETIC GAS MONITOR to an ANESTHETIC GAS SCAVENGING SYSTEM, if applicable; and

(*d*) Recommended) If applicable, the recommended method for connecting the exhaust port of the anesthetic gas monitor to an anesthetic gas scavenging system;

(*e*) Recommended method of verifying alarm functions.

(*7*) A description of any recommended in-use calibration or verification, or both, procedure employing recommended test gas(es).

(*8*) A description of) If applicable, the correct installation of the ANESTHETIC GAS MONITOR and a detailed description of sampling arrangements and any connecting tubing.

(*9*) Upon request by the user, disclosure of the electromagnetic compatibility standard or test recommended method to which for returning the anesthetic sampled gas monitor was tested.

(*10*) The instructions for use shall include information concerning any precautions to be taken if a specific unusual risk is associated with the disposal of a device, after its useful life.

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

8. *Basic Safety Requirements*—Not used.

anesthesia breathing system;

SECTION TWO—ENVIRONMENTAL CONDITIONS

9. *Removable Protective Means*—Not used. Replaced by Subclause 6.1.z.

10. *Environmental Conditions*—The requirements given in Clause 10 of the General Standard apply.

11. Not used.

12. Not used; transferred to Subclause 3.6.

SECTION THREE—PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

13. *General Comments: Protection Against Electric Shock Hazards*—The requirements given in Clause 13 of the General Standard apply.

14. *Requirements Related to Classification*—The requirements given in Clause 14 of the General Standard apply.

15. *Limitation of Voltage and/or Energy*—The requirements given in Clause 15 of the General Standard apply.

16. *Enclosures and Protective Covers*—The requirements given in Clause 16 of the General Standard apply.

17. *Separation (Formerly Insulation and Protective Impedances)*—The requirements given in Clause 17 of the General Standard apply.

18. *Protective Earthing, Functional Earthing and Potential Equalization*—The requirements given in Clause 18 of the General Standard apply.

19. *Continuous Leakage Currents and Patient Auxiliary Currents*—The requirements given in Clause 19 of the General Standard apply with the following exception:

(*1*) When national standards mandate more restrictive limits, these more restrictive limits shall apply.

(*2*) In item 19.1 e), add the following:

(*a*) For non-diverting anesthetic gas monitors at the sensor;

(*b*) For diverting anesthetic gas monitors, at the junction of the sampling tubing and the body of the anesthetic gas monitor.

(*b*) For diverting anesthetic gas monitors, at the junctionf) Recommended method(s) of ~~the sampling tubing and the body of the anesthetic gas monitor.~~

~~20. *Dielectric Strength*—The requirements given in Clause 20 of the General Standard apply.~~

~~**SECTION FOUR—PROTECTION AGAINST MECHANICAL HAZARDS**~~

verifying all operator-adjustable alarm system functions.

~~21. *Mechanical Strength*—The requirements given in Clause 21~~

6.8.2 dd) An illustration of the features of the anesthetic gas monitor, indicating the function and location of all operating controls, adjustments, and system components necessary for correct operation.

6.8.2 ee) A description of the correct installation of the anesthetic gas monitor and a description of sampling arrangements and any connecting tubing, if applicable.

6.8.2 ff) Information concerning the disposal of the device.

6.8.2 gg) If applicable, the location of any latex-based components.

SECTION TWO—ENVIRONMENTAL CONDITIONS

All clauses and subclauses of this section of the General Standard ~~shall apply.~~

~~22. *Moving Parts*—The requirements given in Clause 22~~ apply.

SECTION THREE—PROTECTION AGAINST ELECTRICAL SHOCK HAZARDS

All clauses and subclauses of this section of the General Standard ~~shall apply.~~

~~23. *Surface, Corners* apply, except as follows:~~

19. *Continuous Leakage Currents and ~~Edges~~*—~~The~~ Patient Auxiliary Currents— The requirements ~~given in~~ of Clause ~~23~~ 19 of the General Standard apply, with the following addition and amendment:

19.1 e) For the purposes of this specification, the applied part for a non-diverting anesthetic gas monitor is the sensor, and for the diverting anesthetic gas monitor, the sample gas inlet at the device.

19.3 The leakage current limits of AAMI ES-1 apply.

~~24. *Stability in Normal Use*—The requirements given in Clause 24~~

SECTION FOUR—PROTECTION AGAINST MECHANICAL HAZARDS

All clauses and subclauses of this section of the General Standard ~~shall apply.~~

~~25. *Expelled Parts*—The~~ apply.

SECTION FIVE—PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

All clauses and subclauses of this section of the General Standard apply, except as follows:

36. *Electromagnetic Compatibility*—The requirements ~~given in~~ of Clause ~~25~~ 36 of the General Standard ~~shall~~ apply, with the following addition:

36.1 The requirements of IEC 601-1-2 apply.

~~26. *Vibration*~~

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

All clauses and ~~Noise:~~ subclauses of this section of the General Standard do not apply.

~~26.1 If an ANESTHETIC GAS MONITOR is included~~

SECTION SEVEN—PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

All clauses and subclauses of this section of the General Standard apply, except as ~~a part or integral~~ follows:

43. *Fire Prevention*—The requirements of Clause 43 of the General Standard apply, with the following addition:

43.1 To reduce the risk to patients, other ~~equipment,~~ persons, or the ~~relevant specification for that equipment shall apply.~~

~~26.2 If, when tested,~~ surroundings as a result of fire, ignitable material, under normal and single-fault c~~r~~ondition, shall not at the same time be subjected to conditions in ~~26.3,~~ which:

The temperature of the ~~A-weighted sound pressure level exceeds 60 dB,~~ material is raised to its minimum ignition temperature, and

An oxidant is present.

The minimum ignition temperature is determined in accordance with IEC 60079-4 using the ~~circumstances~~ oxidizing conditions present under ~~wh~~ normal and single-fault condition.

Compliance is checked by determining the temperature the material is raised to under normal and single-fault condition.

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

Compliance is checked by observing if ignition occurs under the most unfavorable combination of normal condition(s) with a single fault.

46. *Human Errors*—Clause 46 of the General Standard applies with the following addition:

NOTE 4—If an accessory intended for a particular application reduces 5—To minimize operator errors and consider human factors in the A-weighted sound pressure level to 60 dB(A) or below, design of anesthetic gas monitor, controls that merit the manufacturer operator's close attention should state in which part or parts be arranged close to the operator's line of sight when observing the operating range this occurs.

26.3 The A-weighted sound pressure level shall patient. It is also recommended that the contents of AAMI HE-48 be reviewed. While general guidance may be obtained from AAMI HE-48, the involvement of individuals with human factors expertise is strongly recommended.

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

All clauses and subclauses of this section of the General Standard apply, except as follows:

26.3.1 *Measuring Instruments*— *follows:* A precision sound level meter

51. *Protection Against Hazardous Output*— The requirements of Type 1, as specified in IEC 651, shall be used. Measurements shall be made Clause 51 of the General Standard apply with the A- followeing additions:

51.5 *Measurement Accuracy:*

51.5.1 The accuracy of the anesthetic gas readings is detwermined after exposurke of the sampling site to cyclic pressure changes (see Clause 51.5.4)

51.5.2 For halogenated anesthetic gases, the difference between the mean anesthetic gas reading and the "slow" meter characteristics selected. The sound anesthetic gas level meter shall be within ±(0.2 volume percent +15 % of alnesthetibc gas level) over the full measurement range specified in accordance with the manufacturer's instructions.

26.3.2 *Test Environment*— Measurement accompanying documents. In addition, six standard deviations (±3.0 σ) of the anesthetic gas reading (for a given gas level) shall be made in a free field over a reflecting plane, such as that specified in ISO 3744. less than or equal to 0.6 volume percent for all halogenated anesthetic gases except desflurane which shall be less than or equal to 1.0 volume percent.

NOTE 5—The necessary conditions may be achieved economically on a hard, flat surface outdoors, in a large room, 6—Six standard deviations is equivalent to ±3.0 σ. This means that 99.73 % (about 399⁄400) of all readings occur within ±3.0 σ (=0.6 volume percent or in a smaller room with sufficient sound absorptive materials on its walls 1.0 volume percent) volume percent from the mean reading. See rationale for details.

51.5.3 For nitrous oxide, the difference between the mean nitrous oxide gas reading and ceiling.

26.3.3 *Ambient Conditions*—At the microphone positions, nitrous oxide gas level shall be within ±(5.0 volume percent +5 % of the A-weighted sound pressure levels nitrous oxide gas level) over the full measurement range specified in the accompanying documents. In addition, six standard deviations (±3.0 σ) of the background noise nitrous oxide gas reading (for a given gas level) shall be at least 10 dB below the sound pressure level less than or equal to be measured. 10.0 volume percent.

NOTE 6—If barometric pressure, temperature, or relative humidity deviate from those of 7—Six standard conditions, appropriate corrections may be used.

26.3.4 *Anesthetic Gas Monitor Installation*— The ANESTHETIC GAS MONITOR shall be mounted as recommended by the instructions for use and in a manner typical of its intended use. If it deviations is intended equivalent to be table-mounted, the table top shall be a hard, acoustically reflecting surface, unless a resilient pad is recommended in the installation instructions. If it is wall-mounted, the wall shall be of hard, acoustically reflecting material.

26.3.5 *Procedure*—Operate the ANESTHETIC GAS MONITOR over its normal working range. Place the microphone at the position of maximum sound pressure level in the horizontal plane passing through the geometric center of the ANESTHETIC GAS MONITOR and at a radius of 1 m. At each setting, if the ANESTHETIC GAS MONITOR is intended for use with a sampling tube, make a second measurement using the recommended sampling tubing. Place the sampling tubing inlet so as to lie on the specified horizontal plane, with the axis of the sampling tubing vertical and 150 mm from the microphone on the axis between the ANESTHETIC GAS MONITOR and the microphone. If the length of the sampling tubing does not allow this disposition, move the microphone toward the ANESTHETIC GAS MONITOR until the distance between it and the sampling tubing is 150 mm. If the manufacturer recommends or supplies accessories for particular diagnostic applications and states ±3.0 σ. This means that these reduce the A-weighted sound pressure level to 60 dB or less, repeat the measurements with the accessories fitted. If any such accessory incorporates a port intended for connection to a tracheal or tracheostomy tube, connect the tube of an internal diameter equal to or greater than that of the port and at a length such that its other end will be sufficiently distant from the sound level meter not to interfere with the noise measurements.

27. *Pneumatic and Hydraulic Power*—The requirements given in Clause 27 of the General Standard shall apply.

28. *Suspended Masses*—The requirements given in Clause 28 of the General Standard shall apply.

SECTION FIVE—PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

(*1*) The requirements given in Clauses 29 through 35 of this section of the General Standard shall apply.

(2) The manufacturer shall mark the device with a warning to refer to the accompanying documents for the expected adverse effects on the performance of the anesthetic gas monitor when exposed to electrocautery, electrosurgery, defibrillation, X-ray (gamma radiation), infrared radiation, conducted transients, magnetic fields including magnetic resonance imaging (MRI), and radiofrequency interference that are known at the time of preparation of the accompanying documents.

36. *Electromagnetic Compatibility*—The requirements in Clause 36 of the General Standard apply, with the following addition (the test method in 36.1 is derived from IEC 801-2:1991:

36.1 *Protection from Electrostatic Discharge*— *99.73 % (about* The ANESTHETIC GAS MONITOR shall continue to function and meet the requirements 399/400) of this draft specification or shall fail without causing a safety hazard when tested in accordance with IEC 801-2. The discharges shall have a potential of 3 kV ± 5 % dc for a contact discharge and 8 kV± 5 % dc for an air discharge. Discharges shall be applied only to accessible parts and coupling planes (as defined in IEC 801-2). If an anomaly occurs, such as display interrupt, alarm activation, etc., it should be possible to restore normal operation within 30 s after the electrostatic discharge has been applied. (Silencing of an activated alarm shall not be considered a failure.)

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

37. *Locations and Basic Requirements*—The requirements given in Clause 37 of the General Standard shall apply.

38. *Marking, Accompanying Documents*—The requirements given in Clause 38 of the General Standard shall apply.

39. *Common Requirements for CATEGORY AP and CATEGORY APG EQUIPMENT*—The requirements given in Clause 39 of the General Standard apply.

40. *Requirements and Tests for CATEGORY AP EQUIPMENT, Parts and Components Thereof* —The requirements given in Clause 40 of the General Standard shall apply.

41. *Requirements and Tests for CATEGORY APG EQUIPMENT, Parts and Components Thereof*—The requirements given in Clause 41 of the General Standard shall apply.

SECTION SEVEN—PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

42. *Excessive Temperatures* —The requirements given in Clause 42 of the General Standard shall apply.

43. *Fire Prevention*—The requirements given in Clause 43 of the General Standard apply, together with the following additional requirements:

43.1 In order to eliminate the risk of fires caused by electrical components which may be a source of ignition in oxygen or nitrous oxide enriched atmospheres (or mixtures of gases containing anesthetic gases referred to in Clause 37), at least one of the following requirements shall be met:

(a) Electrical components shall be separated from compartments in which accumulations of such gases can occur by a barrier complying with the requirements given in 43.2.

(b) Compartments containing electrical components shall be ventilated according to the requirements given in 43.3 of this draft specification.

(c) Electrical components, which in normal use and single fault condition can be a source of ignition, shall comply with the requirements given in Clause 43.5 of this draft specification.

43.2 Any barrier required under the provisions of 43.1(*a*) shall be sealed at all joints and at any holes for cables, shafts, or other purposes.

(1) Compliance shall be checked by the following methods, as appropriate:

(*a*)	Inspection;
(*b*)	By compliance test for enclosures with restricted breathing, given in 40.5 of the General Standard;
(*c*)	If, under normal conditions, a pressure difference exists between the spaces separated by the barrier, the test method given in 43.4.

43.3 The ventilation required in 43.1(*b*) shall be such that, when tested by the method described in 43.5, the oxygen level in the enclosed compartment containing electrical components shall not exceed 4 % above the ambient oxygen level; if this requirement is met by forced ventilation, an alarm shall be provided to warn of failure of the ventilation.

43.4 Oxygen levels in enclosed compartments shall be tested as follows:

43.4.1 *Principle*— The oxygen level in the enclosed compartment is measured after the ANESTHETIC GAS MONITOR has been operated for 18 h under single fault conditions.

43.4.2 *Procedure*—Place the ANESTHETIC GAS MONITOR in a room in which the air exchange is between 3 and 10 room readings occur within ±3.0 σ (=10.0 volume percent) volumes per hour. Flow 100 % O_2 through the ANESTHETIC GAS MONITOR at the maximum diverting flow. Switch off the mains supply and measure the oxygen level in the enclosed compartment. Operate the ANESTHETIC GAS MONITOR under single fault conditions, with the least favorable control setting selected and with the mains voltage deviating by ±10 %, if applicable. After 18 h, switch off the supply mains and measure the oxygen level in the enclosed compartment.

43.4.3 *Expression of Results*—Record the oxygen levels measured at the beginning and end of the 18 h period.

43.5 Electrical circuits, which can produce sparks or generate increased surface temperatures and which can be a source of ignition, shall be so designed that no ignition occurs. The following requirement shall be satisfied in normal condition and single fault condition:

(*1*) The surface temperature of components shall not exceed 300°C, unless it can be shown that no ignition occurs when the component(s) is(are) exposed to 100 % O_2 at temperatures above 300°C.

(*2*) Short- and open-circuiting of resistors, capacitors, and inductances complying with the requirements given in Clause 14 of IEC 65:1985 are not considered to be single fault conditions.

43.6 Compliance shall be checked by measuring the surface temperatures of the components under normal and single fault conditions. If the surface temperature of the component(s) exceeds 300°C, inspect for ignition when the component(s) is(are) exposed to 100 % O_2 at the measured temperature.

44. *Overflow, Spillage, Leakage, Humidity, Ingress of Liquids, Cleaning, Sterilization and Disinfection*—The requirements given in Clause 44 of the General Standard apply, as well as those given in "Good Manufacturing Practices" issued by the Food and Drug Administration.[6]

45. *Pressure Vessels and Parts Subject to Pressure*—The requirements given in Clause 45 of the General Standard apply, except for 45.7(*b*), and with the following addition:

45.7(*c*) It shall be so installed that it is accessible for inspection, maintenance, and repair according to the accompanying documents.

46. *Human Errors*—The requirements given in Clause 46 of the General Standard apply, together with the following additional clauses:

46.1 Connections for calibration gases for which Diameter Index Safety System (DISS) or Pin Index Safety System (PISS) are not specified shall not be interchangeable with diameter or pin index systems.

46.2 Colors of calibration gas cylinders not already specified in relevant national standards, such as CGA C-9-1982, shall be color-coded differently percent from the colors specified mean reading. See rationale for medical gases.

46.3 Compliance with the requirements in 46.1 and 46.2 details.

Compliance shall be determined by inspection of the accompanying documents and the ANESTHETIC GAS MONITOR.

47. *Electrostatic Discharges*—The requirements given in Clause 47 shall apply.

48. *Materials in Applied Parts in Contact with the Body of the Patient*—The requirements given in Clause 48 of the General Standard apply.

49. *Interruption of the Power Supply*—The requirements given in Clause 49 of the General Standard apply.

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

50. *Accuracy of Operating Data*—The requirements given in Clause 50 of the General Standard apply, with the following additional clauses:

50.3 *Measurement Accuracy:*

(*1*) For halogenated anesthetic gases, the difference between the mean ANESTHETIC GAS READING and the ANESTHETIC GAS LEVEL shall be within ± (0.15 volume percent + 15 % of ANESTHETIC GAS LEVEL) over the full measurement range specified in the accompanying documents. In addition, six standard deviations of the ANESTHETIC GAS READINGS (for a given ANESTHETIC GAS LEVEL) shall be less than or equal to 0.6 volume percent.

(*2*) For nitrous oxide, the difference between the mean ANESTHETIC GAS READING and the ANESTHETIC GAS LEVEL shall be within ± (2.0 volume percent + 8 % of the ANESTHETIC GAS LEVEL) over the full measurement range specified in the accompanying documents. In addition, six standard deviations of the ANESTHETIC GAS READINGS (for a given nitrous oxide level) shall be less than or equal to 10.0 volume percent.

(*3*) Compliances shall be checked by the test given in 50101.5.4.

50101.5.4 *Test Method:*

50101.5.4.1 *Principle*—ANESTHETIC GAS READINGSAfter exposing the sampling site ten times to a cyclic pressure in accordance with Fig. 2, anesthetic gas readings are determined at a number of anesthetic gas levels spanning the ANESTHETIC GAS MONITOR anesthetic gas monitor measurement range.

50101.5.4.2 *Test Gases*—Test gases of an accuracy shall be equal to or better greater than 0.03 % of five times more accurate (⅕ the error) than the required test unit accuracy. This is calculated as ⅕ (0.2) times the error tolerance of the essential requirement stated in clause 50.3 as determined by gravimetric methods shall be used for these tests. Alternative methods of certifying gas composition Clauses 51.5.2 and 51.5.3.

NOTE 8—Test gases with the aforementioned accuracy may be substituted for the gravimetric method if the alternative method can be shown to be equivalent obtained from test gas manufacturers or better than by in-house production of the required test gas mixtures with accuracy verimfied by otherie methods (for example, mass spectrometry or refractometry).

50101.5.4.3 *DryGas Testing*—The anesthetic gas monitor shall be set up and calibrated in accordance with the accompanying

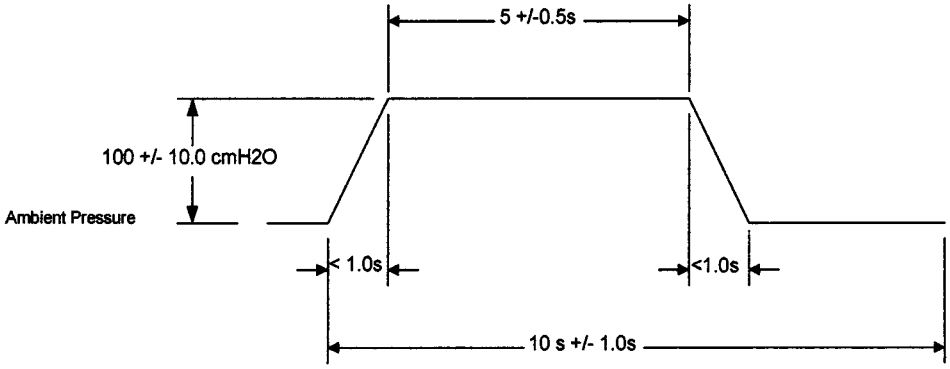


FIG. 2 Cyclic Pressure

documents and tested using ~~dry test gas mixtures, given in Table 1, at an ambient temperature of 23 ± 2°C. For each numerically displayed anesthetic gas, verify that~~ the ~~accuracy requirements of 50.3 are met.~~

~~50.4.4 *Water Saturated Gas Testing:*~~

~~(1) Connect the ANESTHETIC GAS MONITOR to a simulated breathing system containing air fully saturated with water at 37 ± 2°C, with the system being cycled at a frequency of 10 breaths/min between a pressure of ambient and 35 cm H_2O (3.5 kPa).~~

~~(2) Following the accompanying documents, with the sampling site connected to the breathing system, operate the monitor with condensate visible at the sampling site for a minimum of 1 h.~~

~~(3) At this point, perform an accuracy~~ test ~~using the gas mixtures~~ gases given in Table 2 ~~(with a dry gas accuracy of 0.03 volumes percent as in Clause 50.4.2) fully saturated,~~ at ~~37~~ an ambient temperature of 23 ± 2°C. For each numerically displayed anesthetic gas, verify that the accuracy requirements of 51.5.2 and 51.5.3. are met.

TABLE 2 ~~Dry Gas Test~~Mixtures~~Note 1—5 % CO_2 is used for all gas mixtures A~~containing halogenated gases except for the ~~mixtures containing 0.5 % halothane~~cy, ~~1.0 % D~~risofluranet, and ~~5.0 % enflurane, all of wh~~ Rich ~~contain no apprs~~see Tiabl~~me~~ Meamos~~urements of CO_2.~~

~~O_2,~~ %Nitrogen	~~C~~Nitrous O2~~xide~~[A],%	Halo-thane[A]	~~N_2~~Enflur-ane[A] ~~O_2, %~~	~~Hal~~Isoth~~flur~~-ane, %[A]	~~Is~~Sevoflur-ane,%[A]	~~En~~Desflur-ane, %[A]
~~100~~						
Balance	30					
~~bal~~		~~65~~				
Balance	65[B,C]					
Balance		0.5				
~~bal~~	~~5~~	~~65~~				
Balance		1.0[B]				
Balance		4.0[C,D]				
Balance			0.5			
~~Balance~~			~~1.0~~			
Balance			1.0[B]			
~~bal~~	~~5~~	~~65~~	~~4.0~~			
Balance			5.0[C,D]			
~~bal~~	~~5~~	~~65~~		~~0.5~~		
Balance				0.5		
~~bal~~		~~65~~		~~1.0~~		
Balance				1.0[B]		
~~bal~~	~~5~~	~~65~~		~~5.0~~		
Balance				5.0[C,D]		
~~bal~~	~~5~~	~~65~~			~~0.5~~	
Balance					0.5	
~~bal~~	~~5~~	~~65~~			~~1.0~~[B]	
Balance					1.0[B]	
~~bal~~		~~65~~			~~5.0~~[C,D]	
Balance					5.0[C,D]	
~~bal~~						~~5~~
Balance						5
	~~50~~					~~10~~[B]
Balance						10[B]
		~~100~~				~~15~~[C,D]
Balance						15[C,D]

[A] ~~CO_2~~Included if the anesthetic gas monitor is intended for use with this gas.

[B] This ~~may~~ixture to be ~~excl u~~dsed ~~from~~r the Drift ~~Mest gas mixture if th~~me ~~anesthet~~i Ac~~gcur~~acy Tes~~monitor~~ (~~is not intended~~for use in g as ~~mp~~lixtures~~con-tainingb~~le).

[C] ~~CO_2~~This mixture to be used for the Rise Time Testing (if applicable).

[D] Or full-scale reading, if lower than specified value.

5θ1.5.5 *Drift of Measurement ~~Accuracy:~~*

~~(1) The~~ Accuracy— The anesthetic gas monitor shall meet the requirements specified in 5θ1.5.2 and 51.5.3. for no less than 6 h when used in accordance with the accompanying documents.~~(2)~~ Compliance shall be checked by the test given in 5θ1.5.6.

5θ1.5.6 *~~Test Methods:~~*

~~50.6.1 Test Method (Water Saturated):~~

~~(1) This requirement does not apply to ANESTHETIC GAS MONITORS intended solely for use in dry fresh gas mixtures.~~

~~(2) Continue to operate~~ Method—With the anesthetic gas monitor ~~as specified~~ set up, calibrated, and operated in ~~50.4.4, sampling~~ accordance with the ~~gas~~ accompanying documents, use the test ~~m~~ gases i~~x~~dentified for drift measurement accuracy testing in Table 2, at an ambient temperature of 23 ± 2°C, and sample all of the identified test gas mixtures every ~~2~~ 3 h for a minimum of 6 ~~h.~~

~~50.6.2 Test Method (Dry Gas):~~

~~(1) If~~ h. Between the ~~ANESTHETIC GAS MONITOR is tested by~~ test periods allow the device to sample ambient air.

51.5.7 *Rise Time Testing*—Th~~o~~e manufacturer shall disclose in ~~Clause 50.6.1, this clause does not apply.~~

~~(2) The ANESTHETIC GAS MONITOR~~ the accompanying documents the rise time for a 10 to 90 % step function change in concentration, when tested as described in 51.5.8.

For diverting-type monitors, the manufacturer shall disclose the gas diversion flow rate at which the device meets the disclosed rise time.

For nondiverting-type monitors, the manufacturer shall disclose the rise time at 2 L/min.

51.5.8 *Rise Time Test Method*—The anesthetic gas monitor shall be set up in accordance with the accompanying documents ~~under~~ and attached to the ~~ambient conditions described~~ appropriate test apparatus arranged as in ~~Clause 50.4.3. Connect~~ Figs. 3 and 4.

Connect the ~~ANESTHETIC GAS MONITOR~~ anesthetic gas monitor to a ~~simulated common~~ suitable recording device.

With the respective gas ~~outlet supplying dry air at 23 ± 2°C into a simulated breathing system, with~~ mixture from Table 2 (see Table 2, Footnote D), using the ~~system cycling at a frequency of 10 ± 1 breaths/min at an I:E ratio of 1:2 ± 20 %, between a pressure of ambient~~ test apparatus, cycle the valve(s) and ~~3.5 ± 0.5 kPa (35 ± 5 cm H_2O) above ambient.~~

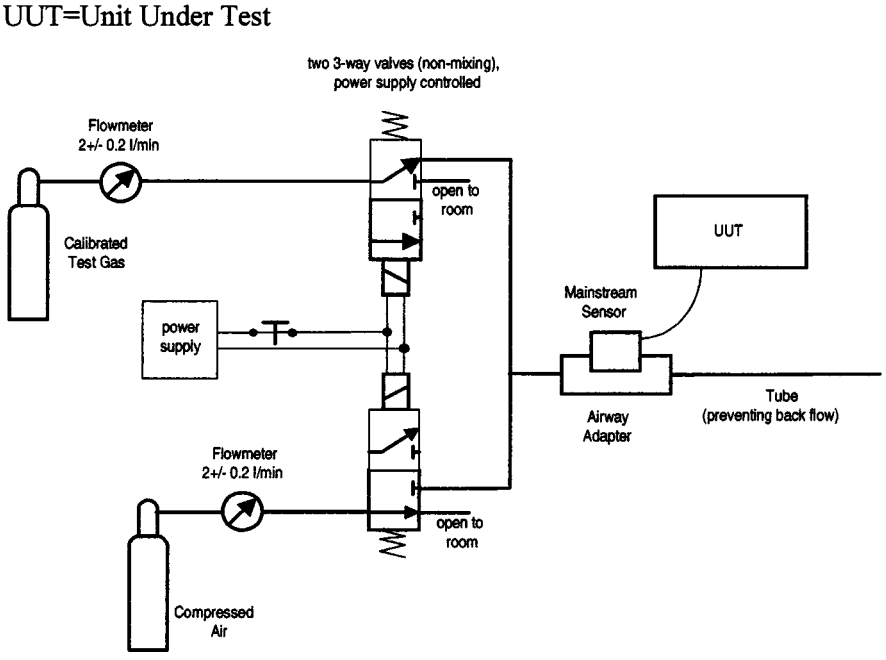
~~(3) Operate~~ record the ~~monitor~~ rise time. Repeat the procedure for ~~a minimum of 1 h,~~ this single gas mixture 20 times and ~~after that time perform an accuracy test using~~ determine the average rise time.

51.5.9 *Combined Gas Accuracy Testing*—The anesthetic gas ~~method as described~~ monitor shall be set up and calibrated in ~~Subclause 50.4.3,~~ accordance with the accompanying documents and tested using the test ~~gas mixtures~~ gases given in Table ~~2.~~

~~(4) Continue to operate the ANESTHETIC GAS MONITOR for a minimum~~ 3, at an ambient temperature of ~~6 h, repeating~~ 23 ± 2°C. For each numerically displayed anesthetic gas, verify that the accuracy ~~test every 2 h.~~

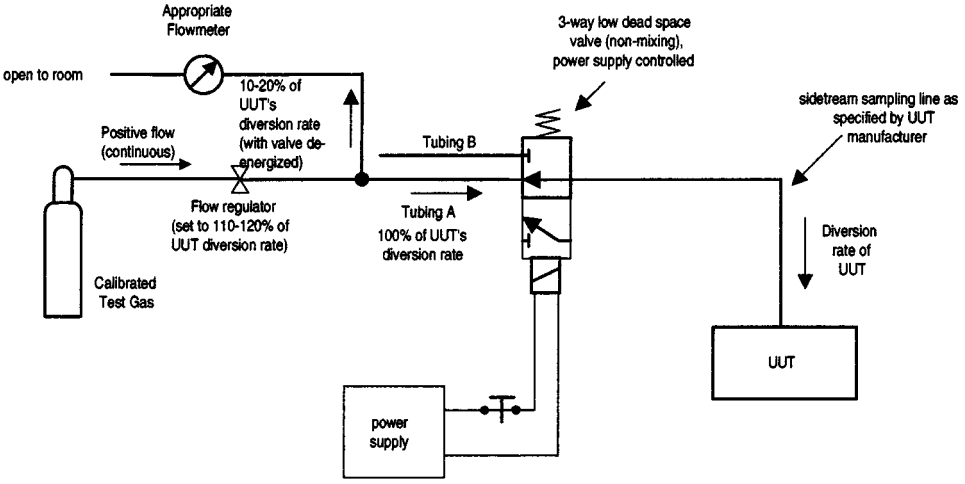
~~50.7 Displays:~~

~~(1) ANESTHETIC GAS LEVEL~~ requirements of 51.5.2 and 51.5.3. are met.



NOTE—UUT = unit under test.

FIG. 3 Nondiverting Monitor—Rise Time Test Apparatus



Note 1: Length and inner diameter of Tubing A must be identical to that of Tubing B
Note 2: Tubing B is open to room

FIG. 4 Diverting Monitor—Rise Time Test Apparatus

TABLE 6 3 Test GasMixtures (Dry) for Wat Combiner Sd Gats Accuratedcy Testing

O2, %Carbon Dioxide	CNitrous O2xide[A],%	Oxy-gen	Nitro-gen[A]	N2Halo-thane[B]O, %	HaEnflothur-ane, %[B]	Isoflur-ane,%[B]	ESevoflur-ane[B]	Desflur-ane, %[B]
100						bal		
5	30	40	balance	2.0				
5	65	4.0			bal			
5	30	40	balance		2.0			
5	65		0.5			2.0		
5	30	40	balance			2.0		
bal	30	40	balance				2.0	
5	30	40	balance				2.0	
5	65			1				.0
5	30	40	balance					8.0

[A] CO2For test gases prepared in-house, nitrous oxide can be increased to "balance" and nitrogen eliminated.

[B] may be exIncluded from the test gas m ixture if the anesthetic gas monitor is not intended for use with these gas mixtures containing CO_2.

51.6 *Displays*—Anesthetic gas level displays shall be marked continuously or on operator demand with kPa kilopascals or V/V % (volume percent) anesthetic gas.

(2) Displays should not volume percent. If the units of measure can be obscured changed by the hand normally adjusting operator from the control(s) associated with user-selected default units of measure, the display.

(3) Compliance units of measure shall be displayed conterinuously.

Compliance shall be checked by inspection of markings and instructions for use.

51. *Protection Against Hazardous Output*—The requirements given in Clause 51 of the General Standard are replaced by the following:

51.1 *Control Function and Position:*

(1) The measurement and test positions of controls shall be clearly distinguishable.

(2) When the display of a non-measurement mode is not obviously distinguishable from a normal monitoring display, the ANESTHETIC GAS MONITOR shall return automatically from such nonmeasurement mode to normal monitoring mode within a period not exceeding 1 min of no operator interaction.

(3) Calibration controls shall include a means to prevent inadvertent change from the intended position.

NOTE 7—User-operable function checks, other than "power on" for test controls such 9—User-selected default units of measure may be the same as battery condition or signal operation, should return automatically from the check, test, or override position within a period manufacturers' default units of measure.

51.7 If the intended test control function is not clexarly distinguishable when displayed on the anesthetic gas monitor, the corresponding 1 control(s) shall automatically return from such control function position(s). The positions of no operator interaction. measurement and test controls shall be clearly distinguishable.

NOTE 8—All 10—User-operable function checks, other than "power on" for test controls such as battery condition or signal operation, should also

include means to prevent inadvertent change return automatically from the intended check, test, or override position and should have clearly distinguishable positions.

51.2 *Movement within a period not exceeding 1 min of C no operator interaction.*

51.8 *Alarms:*

(*1*) For controls that consist of a movable part and a non-movable part, movement upwards, to the right, or

51.8.1 The requirements in a clockwise direction Specification F 1463 apply.

51.8.2 Temporary silencing of audible alarm signals, if provided, shall i not exceed 2 min. The visual signals shall remain until the control function. Movement downwards, to alarming condition no longer exists. If permanent silencing of the left, or in an anti-clockwise direction shall decrease audible portion is provided, the control function.

(*2*) Rotary gas flow controls are exempt from this requirement. shall require deliberate action on the part of the operator and shall incorporate a design feature to impede unintentional permanent alarm signal silencing.

NOTE 9—Controls and their associated markings 11—The audible components of alarm signals should be visible or legible, or both, designed to allow silencing until the anesthetic gas monitor is placerd in use (that is, cornnected to the pavtient) to reduce nuisance alarm signals.

51.8.3 There shall be a visual indication that an audible alarm signal has been silenced. The visual ity (ndication shall remain until the operator ree-enables the aud,ifble alarm signal.

51.8.4 Whenever the device is powered "ON," the user default alarm limits shall be applied and display)ed. If alarm limits are automatically hidden after power "ON," they shall be displayed for at least 1.0 when 15 s.

If the displayed alarm limits are changed by the operator i from the user defaulot alarm limits, the changed alarm limits shall be displayed for at least 15 s. If alarm limits can be hidden, the alarm limits shall be displayed on operator demand.

The operator shall not be able to change the user-selected default alarm limits.

NOTE 12—User-selected default alarm limits may be the same as the manufacturer's default alarm limits.

51.8.5 The audible indicators for all alarm signals shall reset automatically when the condition causing the alarm has cleared.

51.8.6 The anesthetic gas monitor shall have a high anesthetic gas alarm signal for halogenated anesthetic gas(es) and nitrous oxide. This alarm signal shall be at least medium priority.

NOTE 13—The anesthetic gas monitor may have a low anesthetic gas alarm signal.

51.8.7 Alarm limit(s) for both high and, if provided, low anesthetic gas reading shall be operator adjustable.

51.8.8 If the anesthetic gas monitor has an automatic change in front of the ANESTHETIC GAS MONITOR alarm signal priority setting, it shall change only to a higher alarm signal priority, and only after activation of the illuminance level lower priority alarm signal.

51.8.9 If operator-adjustable change in alarm signal priority is 215 lx. Controls should be identified clearly with their associated markings.

51.3 *ALARMS:*

51.3.1 *Alarm Prioritization*—The provided, it shall not allow a change to a lower priority than specified in this specification.

51.8.10 If alarm characteristics limit(s)s are adjustable by the operator, operator adjustment of alarm limit(s)s onr default parameters shall require a deliberate action on the part of the operator.

51.8.11 All alarm signals specified in this specification 51.8 shall be grouped provided with a default setting, and that default setting shall be disclosed in three categories: HIGH PRIORITY, MEDIUM PRIORITY, the accompanying documents (see Clause 6.8.2 cc)).

51.8.12 The difference between the alarm limit(s) and LOW PRIORITY (see Tables 3. the anesthetic gas reading when the alarm signal is activated shall not exceed 0.2 volume percent for halogenated anesthetic gas(es) and 2.0 volume percent for nitrous oxide.

51.8.12.1 Compliance is checked by generating at least four stable anesthetic gas readings that span the range of the alarm system in approximately equal steps by varying the anesthetic gas level delivered to the sensor, or by electrically simulating the sensor, or by adjusting the calibration control (if provided). For each anesthetic gas reading, adjust the alarm limit(s) so that the alarm signal is deactivated. Incrementally adjust the alarm limit(s) until the alarm signal is activated, and record the anesthetic gas reading at which the alarm signal is activated. The difference between the alarm limit(s) and the corresponding anesthetic gas reading shall not exceed 0.2 volume percent for halogenated gases and 2 volume percent for nitrous oxide.

51.8.13 The anesthetic gas monitor shall be capable of detecting when more than one halogenated anesthetic agent exists within a gas mixture. (See Clause 6.8.2 cc)).

When the gas mixture contains more than one halogenated anesthetic agent, it shall activate at least a low-priority alarm signal.

If the anesthetic gas monitor is capable of quantifying the individual halogenated agents, it shall activate at least a medium priority alarm signal whenever more than one halogenated agent has been detected and the total Minimum Alveolar Concentration (MAC) value of halogenated agents and nitrous oxide is equal to or greater than 3.

NOTE 14—For the purposes of this specification, MAC values are those listed in the drug package insert for each halogenated agent. At the time of publication of this specification, the values shown in Table 45).

51.3.1.1 The audible components of these alarms should be designed to allow silencing until the ANESTHETIC GAS

TABLE 3 4 Minimum Alveolarms *Concentration (MAC) Values*

PriHaloirigenatyed Agent	Operator Response	1 MAudible Indicators
High High not medium or low priority	immediate Halothane red/1.4 to 2.8Hz	0.77
Enflurane	1.7	
Medium Medium not high orlow priority	prompt Isoflurane yellow/ 0.4to 0.8 Hz	1.15
Desflurane	7.3 (25-year-old patient)	
Low Low not high or medium pri ority	awareness Sevoflurane yellow/ constant (on)	2.1
Nitrous oxide	105	

A A single color indicator per category is sufficient to satisfy the requirements in the table above.

MONITOR is placed in use (that is, connected to the patient) in order to reduce nuisance alarms.

51.3.1.2 There shall be a visual indication that an audible alarm has been silenced.

51.3.1.3 The set points of adjustable alarms shall be indicated continuously or on user demand.

51.3.2 HIGH PRIORITY ALARMS:

51.3.2.1 There shall be a visual indication of the HIGH PRIORITY ALARM. It shall be different and distinguishable from the visual signals specified in 51.3.3 and 51.3.4.

51.3.2.2 There shall be a simultaneous audible indication of the HIGH PRIORITY ALARM. This audible indication shall be different and distinguishable from the audible signals specified in 51.3.3 and 51.3.4.

51.3.2.3 The audible indicators shall reset automatically when the condition causing the alarm has cleared.

51.3.2.3.1 Alphanumeric or computer-generated graphic displays are exempt from color and flashing frequency requirements. However, if an alphanumeric or computer generated graphics display does not meet the visual requirements as given in Table 3, an alternative visual method that does meet those requirements shall be employed. The visual indicators of alarm categories in Table 3 shall conform to the requirements of ASTM F29.03.04, under consideration.

51.3.2.3.2 Compliance shall be checked by functional tests and inspections, to be furnished by the manufacturer in the operator's manual.

51.3.3 *MEDIUM PRIORITY ALARMS:*

51.3.3.1 There shall be a visual indication of the MEDIUM PRIORITY ALARM. It shall be different and distinguishable from the visual signals specified in 51.3.2 and 51.3.4.

51.3.3.2 There shall be a simultaneous audible indication of the MEDIUM PRIORITY ALARM. This audible indication shall be different and distinguishable from the audible signals specified in 51.3.2 and 51.3.4.

51.3.3.3 The audible indicator shall reset automatically when the condition causing the alarm has cleared.

51.3.4 *LOW PRIORITY ALARMS:*

51.3.4.1 There shall be a visual indication of the LOW PRIORITY ALARM. It shall be different and distinguishable from the visual signals specified in 51.3.2 and 51.3.3.

51.3.4.2 The audible indicator, if provided, shall reset automatically when the condition causing the alarm has cleared.

51.4 *Alarm Characteristics:*

51.4.1 The ANESTHETIC GAS MONITOR shall have high anesthetic gas reading alarm(s) published MAC values for halogenated ANESTHETIC GAS(ES).

51.4.2 The ANESTHETIC GAS MONITOR may have (a) low ANESTHETIC GAS READING.

51.4.3 Alarm set points for both high and, if provided, low ANESTHETIC GAS READING shall be operator-adjustable.

51.4.4 When the ANESTHETIC GAS MONITOR is switched on, the high ANESTHETIC GAS READING for halogenated anesthetic gas(es) shall be (a) medium priority signal(s).

51.4.5 If low ANESTHETIC GAS READING are provided, they shall be low priority signal(s).

51.4.6 If the ANESTHETIC GAS MONITOR has an operator-adjustable high ANESTHETIC GAS READING alarm priority control, it shall allow the operator to change the ALARM priority between MEDIUM and HIGH PRIORITY only after the ANESTHETIC GAS MONITOR is switched on.

51.4.7 If the ANESTHETIC GAS MONITOR has an automatic change in ALARM priority setting, it shall change only to a higher alarm priority, and only after activation of the MEDIUM PRIORITY ALARM.

(*1*) Compliance shall be checked healthy 40-year-old adult male patient as listed by inspection.

51.4.8 The difference between the ALARM SET POINT U.S. Food and the ANESTHETIC GAS READING when the alarm Drug Administration.

Compliance is activated shall not exceed 0.2 volumes percent for halogenated anesthetic gas(es) and 2.0 volumes percent for nitrous oxide.

(*1*) Compliance shall be checked by the procedure given in 51.4.9.

51.4.9 Generate at least four stable ANESTHETIC GAS READINGS that span the range inspection of the alarm system in approximately equal steps by varying the ANESTHETIC GAS LEVEL delivered to the SENSOR, or by electrically stimulating the SENSOR, or by adjusting the calibration control (if provided).

(*1*) For each ANESTHETIC GAS READING, adjust the ALARM SET POINT so that the alarm is deactivated. Incrementally adjust the ALARM SET POINT until the alarm is activated, and record the ANESTHETIC GAS READING at which the alarm is activated. The difference between the ALARM SET POINT and the corresponding ANESTHETIC GAS READING shall not exceed 0.2 volumes percent for halogenated gases and 2 volumes percent for nitrous oxide.

51.5 *Announcement of Alarm Condition:*

51.5.1 If ALARM SET POINTS are adjustable by the operator, operator adjustment of ALARM SET POINTS or DEFAULT PARAMETERS shall require a deliberate sequence of actions on the part of the operator. Temporary silencing of audible alarms, if provided, shall not exceed 2 min. The visual signals shall remain until the alarming condition no longer exists. If permanent silencing of the audible portion is provided, the control shall require deliberate action on the part of the operator and shall incorporate a design feature to impede accidental alarm silencing. The visual indication shall remain until the operator re-enables the audible alarm.

51.5.2 All alarms shall be provided with a DEFAULT SETTING, and that DEFAULT SETTING shall be disclosed in the accompanying documents.

SECTION NINE—ABNORMAL OPERATION AND FAULT CONDITIONS
SECTION documents (see Clause 6.8.2 cc)).

SECTION NINE—ABNORMAL OPERATION AND FAULT CONDITIONS

(*1*) Clauses 52

The clauses and 53 subclauses of the General Standard apply.

SECTION TEN—CONSTRUCTIONAL REQUIREMENTS

(*1*) Clauses 54 and 55 this section of the General Standard apply. except as follows:

56. *Components and General Assembly:*

(*1*) This clause Assembly—Clause 56 of the General Standard applies, except as follows:

~~Components~~ of the ANESTHETIC GAS MONITOR should be made of materials that are compatible with the gases and agents with which those components are designed to come into contact, thus minimizing health risks due to substance

leached from the anesthetic agent monitor in use .

(*2*) Clauses 57, 58, and 59 of the General Standard apply.

6. Additional Requirements Specifically Related to Anesthetic Gas Monitors

60. *Interfering Gas and Vapor Effects (Other Than Water Vapor):*

rer shall disclose, in the accompanying documents, known effect on ANESTHETIC GAS READINGS (if es given at the nominal concentrations listed in Table 6. The manufacturer shall make available upon request the test methods used to make such determination.

61. *Pressure Effects:*

61.1 ANESTHETIC GAS MONITORS shall either:

ments given in 50.3 following exposure of the sampling site to a nominal positive pressure of 10 kPa (100 cm H_2 O)and a nominal negative pressure of 1.5 kPa (15 cm H_2O) for 5 s each for 20 cycles; or the warning "not for use in breathing systems," and a similar warning shall appear in the accompanying documents.

(*1*) Compliance with (*a*) shall be checked by thetestgiven in 61.2.

61.2 Compliance shall be tested as follows:

The accuracy of the ANESTHETIC GAS READINGS is determined after exposure of the SENSOR to pressure changes.

Cycle the pressure at the SAMPLING SITE between a positive pressure with respect to ambient of 10 ± $_2$O) and a negative pressure with respect to ambient of 1.5 ± 0.2 kPa (15 ± 2 cm H_2O) for not less than ocedure 20 times, and then conduct the test for measurement accuracy using the dry gas method as described in Subclause 50.4.3, using the gases listed in Table 3.

62. *Sample Gas Exhaust Port:*

NG ANESTHETIC GAS MONITORS, an exhaust port shall be provided to collect or route the diverting gas from the anesthetic gas monitor. (1) Compliance shall be checked by inspection.

m Connections—If an ANESTHETIC GAS MONITOR is intended to be connected to the breathing system breathing system connection ports of the T-pieceshall be a 15 or 22 mm, or both, conical connector in fication 1 1054 (or ISO 5356-1). The sampling gas and outlet ports of a DIVERTING ANESTHETIC GAS MONITOR shall not be interchangeable with the breathing system connection ports of a breathing system.

64. *Obstruction of the SAMPLING TUBE:*

NG ANESTHETIC GAS MONITOR shall have a means to indicate obstruction of the SAMPLING TUBE.

(*1*) Compliance shall be checked by the test given in 64.2.

With the ANESTHETIC GAS MONITOR operating according to the accompanying documents, obstruct the SAMPLING TUBE totally, and verify that the requirements of 64.1 are met.

of Breathing Systems—It shall not be possible to reverse the direction of flow through the SAMPLING TUBE in a DIVERTING ANESTHETIC GAS MONITOR.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1

cation of Clause 6.7—Dot matrix and alphanumeric displays, as well as computer generated graphics, are poses of this specification, to be indicator lights, so that they do not need to meet the IEC requirements of ccording to whether they indicate a high priority or a medium priority alarm. It was thought that the displays and graphics were sufficiently "attention getting" so that they did not require associated alarm lights.

Clause 6.7 Relating to Instructions for Use (Numbers 1 to 8) —The need to know the basic workings of tor, its principles of operation, and many of its detailed specifications should be self-evident. It is necessary r all of this information available, and that he know well any possible adverse effect on the claimed function ny of a number of different conditions, for example, condensation from excess humidity, interfering gases, al shocks, fluctuations in barometric pressure or supply voltage, etc. It should be equally self-evident that ded with instructions for proper operation of the anesthetic gas monitor as listed in Numbers 6 and 7 of that clause.

Clause 7: Power Input—This is a typical statement which says that this particular requirement of the parent document, IEC 601-1 (1988), applies without any exemptions from, or additions to, the requirements as sta

Clause 8: Basic Safety Requirements —The phase "not used" means that the original requirements in Clause

Components applies with the following amendment and addition:

56.1 g):

ts of the anesthetic gas monitor should be made of materials that are compatible with the gases with which those components are designed to come into contact, thus minimizing health risks as a result of substance leached from the anesthetic gas mo

sthetic gas monitor has additional modes, other than the standard operating mode, the current mode shall be indicated continuously. This indication shall be legible.

-48 *Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices* contains information concerning implementation of these alternative modes.

adjustable controls used for calibration shall include a means to prevent unintentional changes from the intended position.

5. Additional Requirements Specifically Related to Anesthetic Gas Monitors

as and Vapor Effects— The manufacturer shall disclose in the accompanying documents, known effects on gs (if any) caused by the gases given at the nominal (±20 %) concentrations listed in Table 5 (see Clause 6.8.2 L). The manufacturer shall make available upon request the test methods used to make such determinatio

Compliance is checked by inspection of the accompanying documents.

and Sampling Loss—The rate of leakage for a non-diverting anesthetic gas monitor in both the ready for use and "OFF" configuration shall not be greater than 10 mL/min at a pressure of 6 kPa (60 cm H_2 O).

be checked by using a pressure gage having an accuracy to within ±0.6 kPa (6 cm H_2O) and a flow metering uracy within ±2 mL/min. Tests shall be performed in both the ready-for-use and OFF configuration. Assemble onitor so that the sampling site is installed in a dimensionally suitable port of a test apparatus containing an n a test gas and airflow metering device are attached. Connect the pressure gage to a third port of a test just the flow to raise the pressure in the test apparatus to 6 kPa (60 cm H_2O). Determine the flow necessary to maintain this pressure. This leakage flow shall be less than 10 mL/min.

Exhaust Port—For all diverting anesthetic gas monitors, an exhaust port shall be provided to collect or route n the anesthetic gas monitor. This port shall be incompatible with the sample gas inlet port on the anesthetic gas monitor and shall not be a Luer type (see Clause 6.8.2 cc)).

Compliance shall be checked by inspection.

mpling Flow—A diverting anesthetic gas monitor shall have a means to indicate when the flow through the sampling tube has fallen below the manufacturer's specified minimum (see Clause 6.8.2 cc)).

ecked by gradual reduction of the sample flow. Verify that device indicates when the sample flow has fallen specified by the manufacturer and that this value is stated in the accompanying documents. This test is to be conducted with the anesthetic gas monitor operating in accordance with the accompanying documents.

on of Breathing Systems—It shall not be possible to reverse the direction of flow through the sampling tube in a diverting anesthetic gas monitor.

Compliance is checked by inspection.

5. Keywords

5.1 anesthetic gas monitors; performance requirements; safety requirements

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

use 1.1.2— Devices used in laboratory research applications are often experimental or intended primarily for position of the requirements of this specification on devices for research might unduly limit development of beneficial new techniques or devices.

use 6.8 Relating to Instructions for Use—The need to know the basic workings of the anesthetic gas monitor, ation, and many of its detailed specifications should be self-evident. It is necessary that the user have any or n available and that he know well any possible adverse effect on the claimed function of the monitor caused of different conditions, for example, condensation from excess humidity, interfering gases, sensitivity to fluctuations in barometric pressure or supply voltage, and so forth. It should be equally self-evident that the user must be provided with instructions for proper operation of the anesthetic gas monitor.

use 36—Anesthetic gas monitors are not life-support devices but are a "vigilance adjunct." Therefore, it is vice fails without creating a safety hazard (that is, without affecting patient safety directly) or presenting erroneous data.

use 43—Reports of fire caused by medical devices are unusual. However, when such fires occur in the healthcare environment they can have tragic consequences.

The risk of fire is fundamentally determined by the three elements which are necessary to start a fire:

Ignitable material (fuel),
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.

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, and under the oxidizing conditions to which the material may be exposed, 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.

Minimum ignition temperatures for a large number of specific materials are well established in published literature, although normally only in ambient air and 100 % oxygen environments. The minimum ignition temperature may be critically dependent upon the concentration of the 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.

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

The effect of sparks in environments containing oxidants is quite different from that in explosive gas mixtures. Spark energy is the most potent form of energy in igniting explosive gas mixtures, while in environments containing oxidants, thermal energy is more fundamental. It is possible that at higher power levels sufficient spark energy can be dissipated in the interface between sparking conductors or their surroundings so that sustained burning occurs but there is at present no documented evidence as to the power level at which this might occur for different materials and environments. Where the potential spark power dissipation deviates from the well-established safe practice, specific spark tests should be conducted simulating the most unfavorable environment which can be reasonably foreseen.

The accumulating materials previously mentioned are particularly susceptible to ignition by spark energy because of their low ignition temperatures and very low thermal capacity coupled with poor conductance.

In certain standards currently in use, the requirements to minimize fire risk are based on limitation of temperature and electrical energy and oxidant concentration to absolute values.

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

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 accepted working practices or from tests performed in other environments. 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.

It is, therefore, now generally accepted that there are no single or universally applicable ranges of temperature, energy, and concentration of oxidant that can ensure safety under all circumstances while not being unduly restrictive. Ultimately, electrical energy is only significant in respect of 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.

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

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 single-fault condition.

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

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

Amended Rationale for Clause 51.5: Measurement Accuracy— The section immediately following is a reprint of the rationale from Specification F1452:1992, when halothane, enflurane, and isoflurane were the only halogenated agents clinically available. Currently, there are two additional halogenated agents available, sevoflurane and desflurane. The committee addressed establishing the measurement accuracy for these new agents in the same way that was applied by the original committee. Testing for accuracy is spread over the entire range of measurement capabilities of the anesthetic gas monitors, and verified using halogenated agent concentrations on the low-medium and high end of the clinically used concentrations.

Rationale Measurement Accuracy—From Specification F1452:1992— The required accuracy for halogenated anesthetic gases and nitrous oxide were probably the single most extensively discussed subject during committee deliberations. The committee furthermore had before it the results of extensive deliberations at the international level on the same subject. The final figures were arrived at after clinicians both nationally and internationally stated their “clinical requirements” for deviation from actual values

at different concentrations of halogenated anesthetics and nitrous oxide (that is, clinically permissible inaccuracy of the readout). The resultant values, when the device is operating within these specifications, are compared in the following table with the statement of clinical requirements.

Actual Anesthetic Gas Concentration, %	Clinical Requirement for Accuracy	Resultant Performance Accuracy, %
~~Halogenated Agents, %~~		
~~0.50~~	±0.20	
0.50		
	Halogenated Agent, %	
0.50	±0.20	±0.23
1.00	±0.30	±0.30
1.50	±0.30	±0.38
~~2.50~~	~~±0.50~~	~~±0.53~~
2.30	±0.50	±0.53
4.00	±1.00	±0.75
	Nitrous Oxide, %	
40	±5.0	±5.2
50	±5.0	±6.0
60	±6.0	±6.8
80	±8.0	±8.4

~~(1) There~~

There was concern among manufacturers that one random reading beyond the accuracy specified would be viewed as a failure to perform ~~to~~ the specification, and clinicians were concerned that the relatively simple accuracy specifications proposed would allow periodic cycling within the accuracy limits to be accepted.

To resolve both of these concerns, and provide a specification supported by classical statistical methods, two refinements were added. Specifically, the term "mean" was added to the accuracy specification, indicating that the monitor was to be tested in such a manner that deviation of the recorded value for the displayed gas reading from the true mean was to be statistically insignificant. The method by which this is to be accomplished is left to the discretion of the testing party, but methods are well known, and the confidence tests of methodology are well founded in the mathematics of statistics.

~~(2) The~~

The randomness of the data displayed (often referred to as "noise") is critical not only to the test methodology, but to the user as well. It is important not only to develop figures of merit for this parameter, but also to establish the method by which this parameter will be measured. In general, randomness is found to occur in a Gaussian (normal) distribution. The mathematics of such distributions are well-known and allow relatively simple calculations to be performed to establish the practical range of ~~readings. As an~~ readings, for example:

~~68.27~~	~~% of all the readings occur within ±1.0 sigma (standard deviation) from the mean.~~
68.27	% of all the readings occur within ±1.0 σ (standard deviation) from the mean,
~~95.45~~	~~% of all the readings occur within ±2.0 sigma from the mean.~~
95.45	% of all the readings occur within ±2.0 σ from the mean,
~~99.73~~	~~% of all the readings occur within ±3.0 sigma from the mean.~~
99.73	% of all the readings occur within ±3.0 σ from the mean, and
~~99.9937~~	~~% of all the readings occur within ±4.0 sigma from the mean.~~
99.9937	% of all the readings occur within ±4.0 σ from the mean.

There is a general consensus that the limit of practical consideration for the values of a Gaussian set is bounded by ±3.0 ~~sigma~~ σ (99.73 %). While it is still possible for a reading to occur beyond this limit, it only occurs 0.27 % of the time. (Approximately 1 reading in 400 will be beyond this limit, versus 1 reading in 20 ~~for ± 2.0 sigma,~~ for ±2.0 σ, or 1 reading in 15 000 for ±4.0 ~~sigma.)~~

~~(3) The~~ σ.)

The fact that the deviations of readings are easily quantifiable (by calculation of the standard deviation) then allows for simple methods to be used to establish limits of clinical ~~acceptability.~~

~~(4) The~~ acceptability. The randomness specification for halogenated agents states: "in addition, six standard deviations of the anesthetic gas readings (for a given anesthetic gas level) shall be less than or equal to 0.6 volume~~s~~ percent."

Six standard deviations is equivalent to ±3.0 ~~sigma~~ σ (and shall not exceed 0.6 volume~~s~~ percent). This means that 68.27 % (just over ~~2/3)~~ ⅔) of all the readings occur within ±0.1 volume~~s~~ percent from the mean reading; that 95.45 % (just over ~~19/20)~~ 19⁄20) of all the readings occur within ±0.2 volume~~s~~ percent from the mean reading; and that 99.73 % (about ~~399/400)~~ 399⁄400) of all the readings occur within ±0.3 volume~~s~~ percent from the mean reading.

~~(5) The~~

The randomness specification for nitrous oxide states: "in addition, six standard deviations of the anesthetic gas readings (for a given nitrous oxide level) shall be less than or equal to 10.0 ~~volumes percent."~~

~~(6) Six~~ volume percent."

Six standard deviations is equivalent ~~to ± 3.0 sigma~~ to ±3.0 σ (and shall not exceed 10.0 volume~~s~~ percent). This means that

68.27 % (just over 2/3) ⅔) of all the readings occur within ±1.7 volumes percent from the mean reading; that 95.45 % (just over 19/20) 19⁄20) of all the readings occur within ±3.3 volumes percent from the mean reading; and that 99.73 % (about 399/400) 399⁄400) of all the readings occur within ±5.0 volumes percent from the mean reading.

X1.9 *Rationale reading.*

Rationale for Clause 50.4.2—After review of many possibilities, the 60.2—Mixed Halogenated Agents Alarm Signal— The committee felt that it was reasonable, especially from the point of view of clinical requirements and economics, that test gases, in order to provide the required operating accuracies as stated in R50.3 just above, needed to be equal to or better than 1/5 of the required accuracies. That is to say, that test gases for halogenated anesthetic agents had to have added a concentration known within± 0.04 volumes percent of the stated concentration; similarly, for nitrous oxide, the test gas would have to be certified to be within ±1 volume percent of the claimed concentration.

X1.10 *Rationale for Table 2, Which is Part of the Description of the Procedure to Confirm Accuracy of the Anesthetic*—The menu of test gases outlined in Table 1 was constructed in order to cover the complete spectrum of possible concentrations of background gases (that is, oxygen or carbon dioxide, or both) and halogenated anesthetics. It will be noted requirement that the concentrations recommended may provide for testing of several gases at the same time. (For example, the third mixture listed in the table can be used to calibrate an anesthetic agent analyzer at 5 % carbon dioxide test point, a 65 % nitrous oxide test point, and a 1 % halothane concentration test point, with the background gas being oxygen.) Five percent carbon dioxide was chosen because it is monitor alarm when the usual concentration of exhaled carbon dioxide. The values of 0.5, 1, and 4 % halogenated agent are used merely to span the usual range of concentrations of these anesthetics clinically available.

X1.11 *Rationale R50.4.4: Water Saturated Gas Testing*—This test is run after 1 h of simulated breathing system conditions so that the device has detected more than one anesthetic agent analyzer is exposed to fully saturated gas and the varying pressures typically seen in an anesthetic breathing circuit. The test is designed to demonstrate that the anesthetic agent monitor will function well under these two potentially interfering conditions.

X1.12 *Rationale R50.5: Drift of Measurement Accuracy*—The test period of 6 h, during which the anesthetic gas monitor should have a limited drift in its measuring accuracy, was chosen because many anesthetic cases last that long and it mixture. The committee feels this alarm signal is not unreasonable needed to use a gas monitor for that period of time without having to re-calibrate it.

X1.13 *Rationale R51.1: Control Function help identify cross-filled vaporizers and Position, Note 7*—This note indicates a desirability to avoid detect a potential malfunction after the user tests some function, leaves the associated control failure in the test position, and then attempts to use the monitor clinically.

X1.14 *Rationale for Clause 51.3: Alarms*—This entire section has been constructed carefully to provide the following: a mandatory high concentration alarm, an optional low concentration alarm, and operator-adjustable alarm set points for both high and low concentration alarms. vaporizer "lockout" systems. The committee also felt (Clause 51.3.4) that when the gas monitor was first turned on, the high concentration alarm signal requirements were established in two parts. A low-priority alarm should be a medium priority signal (that is, that operator response be prompt but need not be urgent). The committee was concerned allowed for devices with two factors when arriving at this conclusion: (*1*) they wanted to avoid a proliferation automatic identification of high priority alarms on the anesthesia machine and individual halogenated agents in the operating room; and (*2*) a higher-than-expected-concentration of anesthetic agent required only a prompt operator response because, in most instances, this was not an immediate life threatening situation.

X1.15 *Rationale R51.4*—A great deal of effort has been expended in the discussion of alarm methodology for anesthetic gas monitors. A great deal of progress has been made to resolve the underlying conflict in existing equipment design philosophy between two "competing" alarm strategies.

(*1*) Most digital-based monitor alarm systems now allow the operator to set the high mixture containing more than one halogenated agent, and low (if provided) alarming point by means of a digital display that reflects precisely the display value which will either:

(a) Cause the alarm to be activated when the anesthetic gas displayed concentration equals the *alarm* setting; or

(b) Causes the alarm to be activated when the anesthetic gas displayed concentration *exceeds* the alarm setting (further complicated by low alarms, as the alarm activation occurs when the display value total MAC is incrementally *less less than* the alarm setting).

(*2*) It was decided to clarify (with terminology and a graphic representation) the full aspects of alarms. It was felt 3. For devices that clarifying all are not capable of the aspects of the alarm systems was required to bring resolution of this complex issue (see Fig. 2).

(*3*) Thus, a number of general terms were defined automatically quantifying individual halogenated agents and assigned a name, and a corresponding graphic representation of these terms was generated. The ground rules were as follows:

(a) Define when the alarm set point as the setting that relates combined MAC is equal to the intended displayed value at which alarm activation occurs. This definition speaks to the *intent* of the clinician, rather or greater than 3, the specific design strategy of the monitor.

(b) Alarm limit was removed as a defined term, and the specification (Clause 51.4.8) re-written to speak to alarm accuracy as simply the difference between the alarm set point and the displayed reading at which the alarm activation occurs. (Basically, this means that the alarm set point signal is now defined required to be the *intended*alarm limit.)

(c) Accommodate the two alarm strategies within the tolerance of accuracy specified for the alarms. This, in effect, clarifies that the most important aspect to specify is the maximum acceptable difference between the displayed reading at alarm activation and the displayed reading least at which the clinician intended the alarm medium priority. These requirements were created to be activated (the new definition of alarm set point).

(*4*) This simplification could be reached when provide the monitor manufacturers realized that the practical implementation capability of digital monitoring systems caused very close correlation changing between halogenated agents without creating nuisance alarm set point display and the displayed reading, thereby allow alarm activation to Strategy B to occur one display digit past the alarm setting and still be well within the alarm accuracy tolerance under consideration. This, then, met the original intent of allowing both alarm strategies to occur within the same specification.

(*5*) To restate the present situation, Clause 51.4.8 specifies the maximum difference between the alarm set points and the displayed readings at which alarm activation occurs, with a maximum allowable difference that accommodates either alarm strategy. signals.