



Designation: F 1452 – 92

Standard Specification for Minimum Performance and Safety Requirements for Components and Systems of Anesthetic Gas Monitors¹

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INTRODUCTION

The measurement of the concentration of inhalation 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 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 ONE—GENERAL

1. Scope

1.1 This specification applies to ANESTHETIC GAS MONITORS used with adults, children, and neonates. It does not apply to devices intended for use in laboratory research applications, non-human applications, or for calibration of anesthetic agent vaporizers.

2. Referenced Documents

2.1 The following standards contain provisions which, through reference in this specification, constitute provisions of this specification. At a time of publication of this document, 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.

2.2 ASTM Standards:

F 1054 Specification for Conical Fittings of 15 mm and 22 mm Sizes²

F 1161 Specification for Minimum Performance and Safety Requirements for Components and Systems of Anesthesia Gas Machines²

F 1343 Specification for Anesthetic Equipment-Scavenging Systems for Anesthetic Gases²

2.3 IEC Standards:³

IEC 601-1:1988 Medical Electrical Equipment—Part 1: General Requirements for Safety. (This particular IEC

standard is referred to as the General Standard throughout this document; the section and clause numbering as well as the titles used here follow those used in IEC 601-1.)

IEC 651:1979 Sound Level Meters

IEC 801-2:1993 Electromagnetic Compatibility for Industrial-Process Measurement and Control Equipment—Part 2: Electrostatic Discharge Requirements

2.4 ISO Standards:³

ISO 3744:1981 Acoustics—Determination of Sound Power Levels of Noise Sources: Engineering Methods for Free-Field Conditions over a Reflecting Plane

ISO 4135:1979 Anesthesiology—Vocabulary

ISO 5356-1:1986 Anesthetic and Respiratory Equipment—Conical Connectors—Part 1: Conical Connectors for the Breathing System

ISO 5356-2:1987 Anesthetic and Respiratory Equipment—Conical Connectors—Part 2: Screw-Threaded Weight-Bearing Connectors

ISO 7000-1984 Graphical Symbols For Use on Equipment—Index and Synopsis

ISO 7504:1984 Gas Analysis—Vocabulary

ISO 7767:1988 Oxygen Analyzers for Monitoring Patient Breathing Mixtures—Safety Requirements

2.5 Other Documents:⁴

CGA C-9-1982 Standard Color Markings of Compressed Gas Cylinders Intended for Medical Use in the United States

NFPA 70-1993 National Electric Code⁵

3. Terminology

3.1 *Definitions*—The definitions given in Clause 2 of the

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

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² *Annual Book of ASTM Standards*, Vol 13.01.

³ Available from American National Standards Institute, 1430 Broadway, New York, NY 10018.

⁴ Available from Compressed Gas Association, 1235 Jefferson Davis Highway, Arlington, Va 22202.

⁵ Available from National Fire Protection Association (NFPA), 470 Atlantic Ave., Boston, MA 02210.

General Standard apply, with 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*—an indication that some undesirable condition exists.

3.1.3 *alarm set point*—the setting of the adjustment control, or display value, that indicates the anesthetic gas reading, at or beyond which the alarm is intended to be activated.

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

3.1.4 *alarm system*—those parts of the anesthetic gas monitor which: (1) establish the alarm set point(s); (2) activate an alarm when the anesthetic gas reading is less than or equal to the low alarm set point, if provided, or is equal to or greater than the high alarm set point.

3.1.5 *anesthetic gas level*—the volume percent of anesthetic gas in a gaseous mixture.

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

3.1.6.1 *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*—systems that collect and remove the excess anesthetic gases and vapors released from equipment used in administering anesthetics under normal operating conditions, or exhaled by the patient. Scavenging is intended to reduce ambient concentrations of anesthetic agents in anesthetizing areas.

3.1.9 *anesthetic gas transducer*—a device for converting the partial pressure or volume percent of an anesthetic gas or vapor into a signal for monitoring or recording.

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, which are pre-set at the factory, or by the operator, and which the machine itself sets, without further intervention, when it is turned on.

3.1.12 *delay time*—the time from a step function change in anesthetic gas concentration or partial pressure at the sampling site to the achievement of 10 % of the step change in anesthetic gas value in the analyzer (see Fig. 1).

3.1.13 *display*—the visual representation of output data.

3.1.14 *diverting 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.

3.1.15 *drift*—(from ISO 7504:1984) change of the anesthetic gas level display of an analyzer 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

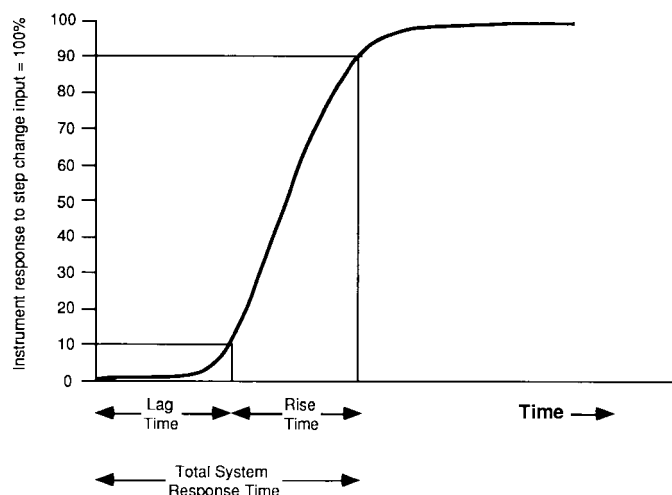


FIG. 1 Lag Time, Rise Time, and Total System Response (Delay Time is Synonymous with Lag Time and is the Preferred Term)

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.

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

3.1.21 *partial pressure*—the pressure that each gas in a gas mixture would exert if it alone occupied the volume of the mixture at the same temperature.

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

3.1.23 *sampling site*—the location at which respiratory gases are diverted from 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.

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

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

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

3.1.27 *volume percent (V/V) of a gas or vapor*—the volume of an anesthetic 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
2. Terminology and definitions			X
3. General requirements			X
4. 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		
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		
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			
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
45. Pressure vessels and parts subject to pressure			X
46. Human errors			X
47. Electrostatic charges			X
48. Materials in applied parts in contact with the body of the patient	X		
49. Interruption of the power supply	X		

Section Eight—Accuracy of Operating Data and Protection Against Hazardous Output

50. Accuracy of operating data			X
51. Protection against incorrect output			X

Section Nine—Abnormal Operation 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		
65. Contamination of breathing systems	X		

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

^B "Not used" means that material in this (these) section(s) of IEC 601-1:1977 has been deleted from 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

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

4. *General Requirements and General Requirements for Tests*—The requirements given in Clauses 3 and 4 of the General Standard apply, together with the following addition:

4.12 Test methods other than those specified in this draft specification, but of equal or greater accuracy, may be used to verify compliance with the requirements of this draft specification. However, in the event of dispute, the methods specified in this draft specification shall be used as the reference methods.

5. *Classification*—The requirements given in Clause 5 of the General Standard apply, with the following additions:



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 is added:

5.9 The method(s) of sterilization or disinfection recommended by the manufacturer shall be included in the labeling and may be included in the marking.

6. *Identification, Marking, and Documents*—The requirements given 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.

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

6.1 bb) If a sampled gas inlet and outlet are provided, their presence shall be marked clearly and durably.

6.1 cc) Packages for single use components shall be marked clearly with the following words: “SINGLE USE” or “SINGLE PATIENT USE.”

NOTE 3—Additionally, Symbol No. 1051 given in ISO 7000 may be used.

6.5 Color of the insulation of conductors shall be according to NFPA 70.

6.6 a) Replace Clause 6.6 a) with 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).

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.

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

TABLE 1 Colors for Color Coding of Anesthetic Agents

Anesthetics	Color	Federal	Pantone	Munsell
Enflurane	orange	22510	144	2.5YR 6/16
Halothane	red	11105	200	5R4/14
Isoflurane	purple	none	252/253	7.5P 4/12

6.7 Clause 6.7 of the General Standard shall apply.

6.8 Clause 6.8 of the General Standard shall apply, with the following additions:

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

(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:

- The anesthetic gas measurement range and the accuracy and precision of measurement;
- 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;
- The gas diversion flow, if gas diversion occurs;
- The stability of measurement accuracy;
- The RISE TIME;
- The anesthetic gas alarm range, its resolution, and delay time from detection to activation;
- The operating, nonoperating (standby), and storage temperature and humidity ranges, if applicable;
- Power requirements; and
- Time from switching on to obtaining specified operating performance.

(4) Details of any known adverse effects on stated function (for example, measurement accuracy and precision, integrity of electrical isolation, and the integrity of pneumatic components) due to the following:

- 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;
- Interfering gases or vapors;
- Leaks or internal venting of sampled gas;
- Mechanical shock;
- Cyclic (ventilating) pressure in the breathing circuit;
- Barometric pressure;
- Fluctuation in ac mains or battery voltage;
- 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
- Other sources of interference, if any.

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

- Checking and calibration before use;
- Routine inspection and testing;
- Recommended methods for cleaning and disinfection or sterilization;
- Recommended method for connecting an exhaust port of the ANESTHETIC GAS MONITOR to an ANESTHETIC GAS SCAVENGING SYSTEM, if applicable; and
- 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 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 method to which the anesthetic 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.