Designation: F 1452 – 92

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 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 Sizes[2]

F 1161 Specification for Minimum Performance and Safety Requirements for Components and Systems of Anesthesia Gas Machines[2]

F 1343 Specification for Anesthetic Equipment-Scavenging Systems for Anesthetic Gases[2]

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 Code[5]

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.

Current edition approved December 15, 1992. Published June 1993.

[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 of zero or low concentration from the drift considered at one or several levels of concentration.

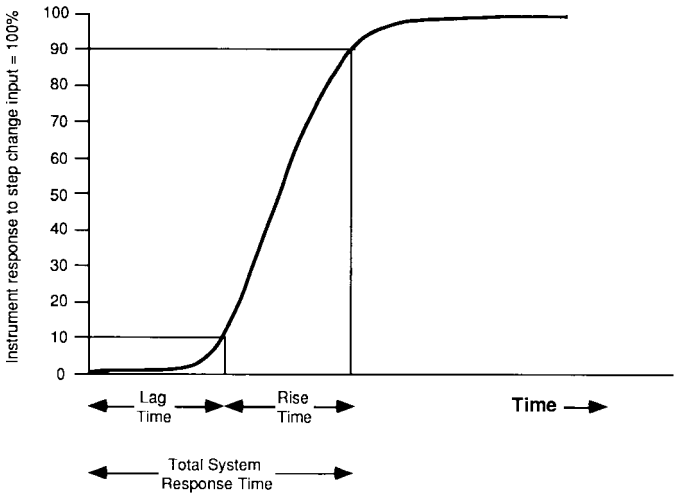

FIG. 1 Lag Time, Rise Time, and Total System Response (Delay Time is Synonymous with Lag Time and is the Preferred Term)

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

	(A)	(NA)	(AM/R)[A]
Section One—General			
1. Scope and object			X
2. Terminology and definitions			X
3. General requirements			X
4. General requirements for tests			X
5. Classification			X
6. Identification, marking, and 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			
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:

(*a*) The anesthetic gas measurement range and the accuracy and precision 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;
(*c*) The gas diversion flow, if gas diversion occurs;
(*d*) The stability of measurement accuracy;
(*e*) The RISE TIME;
(*f*) The anesthetic gas alarm range, its resolution, and delay time from detection to activation;
(*g*) The operating, nonoperating (standby), and storage temperature and humidity ranges, if applicable;
(*h*) Power requirements; and
(*i*) 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;

(*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;
(*b*) Interfering gases or vapors;
(*c*) Leaks or internal venting of sampled gas;
(*d*) Mechanical shock;
(*e*) Cyclic (ventilating) pressure in the breathing circuit;
(*f*) Barometric pressure;
(*g*) Fluctuation in ac mains or battery voltage;
(*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.

(*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:

(*a*) Checking and calibration before use;
(*b*) Routine inspection and testing;
(*c*) Recommended methods for cleaning and disinfection or sterilization;
(*d*) Recommended method for connecting an exhaust port of the ANESTHETIC GAS MONITOR to an ANESTHETIC GAS SCAVENGING SYSTEM, if applicable; and
(*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 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.

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.

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

SECTION FOUR—PROTECTION AGAINST MECHANICAL HAZARDS

21. *Mechanical Strength*—The requirements given in Clause 21 of the General Standard shall apply.

22. *Moving Parts*—The requirements given in Clause 22 of the General Standard shall apply.

23. *Surface, Corners and Edges*—The requirements given in Clause 23 of the General Standard shall apply.

24. *Stability in Normal Use*—The requirements given in Clause 24 of the General Standard shall apply.

25. *Expelled Parts*—The requirements given in Clause 25 of the General Standard shall apply.

26. *Vibration and Noise:*

26.1 If an ANESTHETIC GAS MONITOR is included as a part or integral to other equipment, the relevant specification for that equipment shall apply.

26.2 If, when tested, as described in 26.3, the A-weighted sound pressure level exceeds 60 dB, the circumstances under which it occurs shall be noted.

NOTE 4—If an accessory intended for a particular application reduces the A-weighted sound pressure level to 60 dB(A) or below, the manufacturer should state in which part or parts of the operating range this occurs.

26.3 The A-weighted sound pressure level shall be measured as follows:

26.3.1 *Measuring Instruments*—A precision sound level meter of Type 1, as specified in IEC 651, shall be used. Measurements shall be made with the A-weighted network in use and the "slow" meter characteristics selected. The sound level meter shall be calibrated in accordance with the manufacturer's instructions.

26.3.2 *Test Environment*—Measurement shall be made in a free field over a reflecting plane, such as that specified in ISO 3744.

NOTE 5—The necessary conditions may be achieved economically on a hard, flat surface outdoors, in a large room, or in a smaller room with sufficient sound absorptive materials on its walls and ceiling.

26.3.3 *Ambient Conditions*—At the microphone positions, the A-weighted sound pressure levels of the background noise shall be at least 10 dB below the sound pressure level to be measured.

NOTE 6—If barometric pressure, temperature, or relative humidity deviate from those of 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 is intended 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 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*—The ANESTHETIC GAS MONITOR shall continue to function and meet the requirements 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 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 from the colors specified for medical gases.

46.3 Compliance with the requirements in 46.1 and 46.2 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 50.4.

50.4 *Test Method:*

50.4.1 *Principle*—ANESTHETIC GAS READINGS are determined at a number of anesthetic gas levels spanning the ANESTHETIC GAS MONITOR measurement range.

50.4.2 Test gases of an accuracy equal to or better than 0.03 % of the 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 accuracy may be substituted for the gravimetric method if the alternative method can be shown to be equivalent or better than the gravimetric method.

50.4.3 *Dry Gas Testing*—The anesthetic gas monitor shall be set up in accordance with the accompanying 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 given in Table 2 (with a dry gas accuracy of 0.03 volumes percent as in Clause 50.4.2) fully saturated at 37 ± 2°C.

TABLE 2 Dry Gas Test Mixtures

NOTE 1—5 % CO_2 is used for all gas mixtures containing halogenated gases except for the mixtures containing 0.5 % halothane, 1.0 % isoflurane, and 5.0 % enflurane, all of which contain no appreciable amounts of CO_2.

O_2, %	CO_2,%[A]	N_2O, %	Halothane, %	Isoflurane,%	Enflurane, %
100					
bal		65	0.5		
bal	5	65	1.0		
bal	5	65	4.0		
bal	5	65		0.5	
bal		65		1.0	
bal	5	65		5.0	
bal	5	65			0.5
bal	5	65			1.0
bal		65			5.0
bal	5	50			
		100			

[A] CO_2 may be excluded from the test gas mixture if the anesthetic gas monitor is not intended for use in gas mixtures containing CO_2.

[6] 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.

50.5 *Drift of Measurement Accuracy:*

(*1*) The anesthetic gas monitor shall meet the requirements specified in 50.3 for no less than 6 h when used in accordance with the accompanying documents.

(*2*) Compliance shall be checked by the test given in 50.6.

50.6 *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 the anesthetic gas monitor as specified in 50.4.4, sampling the gas test mixtures in Table 2 every 2 h for a minimum of 6 h.

50.6.2 *Test Method (Dry Gas):*

(*1*) If the ANESTHETIC GAS MONITOR is tested by the method in Clause 50.6.1, this clause does not apply.

(*2*) The ANESTHETIC GAS MONITOR shall be set up in accordance with the accompanying documents under the ambient conditions described in Clause 50.4.3. Connect the ANESTHETIC GAS MONITOR to a simulated common gas outlet supplying dry air at 23 ± 2°C into a simulated breathing system, with 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 and 3.5 ± 0.5 kPa (35 ± 5 cm H_2O) above ambient.

(*3*) Operate the monitor for a minimum of 1 h, and after that time perform an accuracy test using the dry gas method as described in Subclause 50.4.3, with the test gas mixtures given in Table 2.

(*4*) Continue to operate the ANESTHETIC GAS MONITOR for a minimum of 6 h, repeating the accuracy test every 2 h.

50.7 *Displays:*

(*1*) ANESTHETIC GAS LEVEL displays shall be marked continuously or on operator demand with kPa or V/V % (volume percent) anesthetic gas.

(*2*) Displays should not be obscured by the hand normally adjusting the control(s) associated with the display.

(*3*) Compliance shall be determined 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 as battery condition or signal operation, should return automatically from the check, test, or override position within a period not exceeding 1 min of no operator interaction.

NOTE 8—All other controls should also include means to prevent inadvertent change from the intended position and should have clearly distinguishable positions.

51.2 *Movement of Controls:*

(*1*) For controls that consist of a movable part and a non-movable part, movement upwards, to the right, or in a clockwise direction shall increase the control function. Movement downwards, to the left, or in an anti-clockwise direction shall decrease the control function.

(*2*) Rotary gas flow controls are exempt from this requirement.

NOTE 9—Controls and their associated markings should be visible or legible, or both, to an operator having a visual acuity (corrected, if necessary) of at least 1.0 when the operator is located at least 1 m in front of the ANESTHETIC GAS MONITOR and the illuminance level is 215 lx. Controls should be identified clearly with their associated markings.

51.3 *ALARMS:*

51.3.1 *Alarm Prioritization*—The alarm characteristics of monitors specified in this specification shall be grouped in three categories: HIGH PRIORITY, MEDIUM PRIORITY, and LOW PRIORITY (see Tables 3-5).

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

TABLE 3 Alarms[A]

Priority	Operator Response	Audible Indicators	Indicator Color and Flashing Frequency
High	immediate	not medium or low priority	red/1.4 to 2.8 Hz
Medium	prompt	not high or low priority	yellow/0.4 to 0.8 Hz
Low	awareness	not high or medium priority	yellow/constant (on)

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

TABLE 4 Test Concentrations of Interfering Gases or Vapors, %

Nitrogen	78 (use medical air)
Nitrous oxide	80
Helium	50
Halothane	5
Enflurane	5
Isoflurane	5
Ethanol	specified by manufacturer
Acetone	specified by manufacturer
(Chlorodifluoromethane)	5

TABLE 5 Test Gases for Pressure Effects

O_2, %fx	CO_2,%[A]	N_2O, %	Halothane, %	Isoflurane,%	Enflurane, %
bal	5	65	4.0		
bal	5	65		0.5	
bal	5	65			1.0

[A] CO_2 may be excluded from the test gas mixture if the anesthetic gas monitor is not intended for use in gas mixtures containing CO_2.

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) 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 by inspection.

51.4.8 The difference between the ALARM SET POINT and the ANESTHETIC GAS READING when the alarm 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 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

(*1*) Clauses 52 and 53 of the General Standard apply.

SECTION TEN—CONSTRUCTIONAL REQUIREMENTS

(*1*) Clauses 54 and 55 of the General Standard apply.

56. *Components and General Assembly:*

(*1*) This clause 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):*

60.1 The manufacturer shall disclose, in the accompanying documents, known effect on ANESTHETIC GAS READINGS (if any) caused by the gases given at the nominal concentrations listed in Table 6. The manufacturer shall make available

TABLE 6 Test Gas Mixtures (Dry) for Water Saturated Testing

O_2, %	CO_2,%[A]	N_2O, %	Halothane, %	Isoflurane,%	Enflurane, %
100					
bal	5	65	4.0		
bal	5	65		0.5	
bal	5	65			1.0

[A] CO_2 may be excluded from the test gas mixture if the anesthetic gas monitor is not intended for use in gas mixtures containing CO_2.

upon request the test methods used to make such determination.

61. *Pressure Effects:*

61.1 ANESTHETIC GAS MONITORS shall either:

(a) Meet the requirements given in 50.3 following exposure of the sampling site to a nominal positive pressure of 10 kPa (100 cm H_2O) and a nominal negative pressure of 1.5 kPa (15 cm H_2O) for 5 s each for 20 cycles; or

(b) be marked with 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 the test given in 61.2.

61.2 Compliance shall be tested as follows:

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

61.2.2 *Procedure*—Cycle the pressure at the SAMPLING SITE between a positive pressure with respect to ambient of 10 ± 1 kPa (100 ± 10 cm H_2O) and a negative pressure with respect to ambient of 1.5 ± 0.2 kPa (15 ± 2 cm H_2O) for not less than 5 s each. Repeat this procedure 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:*

62.1 For DIVERTING 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.

63. *Breathing System Connections*—If an ANESTHETIC GAS MONITOR is intended to be connected to the breathing system through a T-piece, the breathing system connection ports of the T-piece shall be a 15 or 22 mm, or both, conical connector in accordance with Specification F 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:*

64.1 The DIVERTING 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.

64.2 *Test Method*—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.

65. *Contamination 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 *Rationale for Modification of Clause 6.7*—Dot matrix and alphanumeric displays, as well as computer generated graphics, are not considered, for purposes of this specification, to be indicator lights, so that they do not need to meet the IEC requirements of having specific colors according 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.

X1.2 *Rationale for Clause 6.7 Relating to Instructions for Use (Numbers 1 to 8)* —The need to know the basic workings of the anesthetic gas monitor, its principles of operation, and many of its detailed specifications should be self-evident. It is necessary that the user have any or all of this information available, and that he know well any possible adverse effect on the claimed function of the analyzer due to any of a number of different conditions, for example, condensation from excess humidity, interfering gases, sensitivity to mechanical shocks, fluctuations in barometric pressure or supply voltage, etc. It should be equally self-evident that the user must be provided with instructions for proper operation of the anesthetic gas monitor as listed in Numbers 6 and 7 of that clause.

X1.3 *Rationale for 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 stated.

X1.4 *Rationale for Clause 8: Basic Safety Requirements* —The phase "not used" means that the original requirements in Clause 8 of the 1977 edition of IEC 601-1 are not used in the current (1988) edition of IEC 601-1.

X1.5 *Rationale for Clause 26.2*—It is important that the anesthetic gas monitor not generate so much noise in normal operation that it masks conversation or the sound of other alarms within the operating room.

X1.6 *Rationale for Clause 36.1*—Anesthetic Gas Monitors are not life-support devices, but a "vigilance adjunct." Therefore, it is acceptable if this device fails without creating a

safety hazard (that is, without affecting patient safety directly) or presenting erroneous data. The test voltages of 8 kV for air discharges and 3 kV for contact discharges using the IEC 801-2 (1991) network and procedure are adequate to ensure good performance under the conditions in which anesthetic gas monitors are used. It is necessary to limit the application of discharges to accessible parts, since to allow the application of charges to the interior of the device would require the device to have internal barriers that would make service of the device more difficult and costly. It is reasonable to require any person opening a device for maintenance to exercise both common sense and accepted work practices, which include ESD precautions.

X1.7 *Rationale R43.5*—Historical perspective is that the 10 VA requirement was intended to provide a general criteria of good practice for the design of power dissipating elements which may be required to operate in an Oxygen-enriched atmosphere. The implication is that these specific design limitations prevent ignition-producing elements from being designed.

NOTE X1.1—Curiously enough, the criteria stated does little in a real sense to provide practical direction in design for a lower possibility of ignition, and that is why the requirement, "The product of the RMS value of the no-load voltage and the RMS value of the short circuit current shall not exceed 10 VA," was removed.(*1*) All electrical circuits dissipate power (there is no such thing as a 100 % efficient circuit). Dissipation of power naturally raises surface temperatures of components in the circuit. Therefore, the clause applies to *all* electrical circuits.

(*2*) The maximum surface temperature of the power-dissipating element is the primary parameter of interest with respect to ignition in an oxygen-rich environment. Every flammable compound has a unique and intrinsic surface temperature above which ignition occurs spontaneously if oxygen is present. Therefore, the specification should be written in such a manner that emphasis is placed on controlling surface temperatures below the intrinsic ignition point for all flammable elements.

(*3*) The requirement for 10 VA as the maximum product of RMS no-load voltage and RMS short-circuit current implies a maximum power dissipation and therefore implies "good practice" with respect to maintaining surface temperatures below the ignition temperature. In fact, it does not, as it does not limit power or temperature.

(*4*) The reason that it does not limit power is that it is not a measure of the power being dissipated under any" normal" circumstance. Under no load (zero current conditions), the power dissipated by the circuit element is zero. (Power = V × I, and RMS no-load voltage multiplied by zero current is zero.) Under short-circuit current, the power is undefined. This is because modern circuits, and especially power supplies, usually have provisions to actively reduce the drive voltage when abnormally low circuit resistance is detected ("foldback" under short-circuit conditions).

(*a*) Thus, the voltage and current used in the calculation specified occur under cases of either no power dissipation, or undefined (or abnormally low-by design) power dissipation, and do not indicate the maximum power dissipation of the circuit under worst-case load. Most high power circuits are designed to dissipate maximum power in some intervening condition of load between no load and short circuit.

(*5*) The maximum power dissipation of the circuit does not determine the surface temperature of the element. Circuit elements in common design are designed to dissipate 100 watts easily, ten times the implied power of the clause, without significant increase in surface temperatures. They simply have a large heat-sinking capability, designed to accommodate the high levels of power dissipated. Certainly, this is an example of "good practice" and should not be restricted by the specification.

(*a*) Because of these facts, it is very unlikely that any piece of equipment with significant electronics will meet the criteria stated in the clause for all elements of the design. Power supply designers, as a matter of practice, would not be able to meet the specification as presently stated; nor would they be likely to use the information to provide design direction, due to its simplistic view. Therefore, this clause is commonly disregarded, and other criteria are used to qualify the ignition-resistance of the equipment design.

(*b*) While this clause may have merit in providing guidance for relatively simple circuit designs, it is felt that it is not comprehensive enough to provide direction for the more complex modern designs and does not even speak to the issue of primary concern, assurance that ignition surface temperatures are not exceeded in normal or single fault conditions.

X1.8 *Rationale R50.3: Measurement Accuracy*—The required accuracies 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 table below with the statement of clinical requirements.

Actual Anesthetic Gas Concentration, %	Clinical Requirement for Accuracy	Resultant Performance Accuracy, %
	Halogenated Agents, %	
0.50	±0.20	±0.23
1.00	±0.30	±0.30
1.50	±0.30	±0.38
2.50	±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 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 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 example:

68.27 % of all the readings occur within ±1.0 sigma (standard deviation) from the mean.
95.45 % of all the readings occur within ±2.0 sigma from the mean.
99.73 % of all the readings occur within ±3.0 sigma from the mean.
99.9937 % of all the readings occur within ±4.0 sigma 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 (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, or 1 reading in 15 000 for ±4.0 sigma.)

(*3*) 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 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 volumes percent."

Six standard deviations is equivalent to ±3.0 sigma (and shall not exceed 0.6 volumes percent).

This means that 68.27 % (just over 2/3) of all the readings occur within± 0.1 volumes percent from the mean reading; that 95.45 % (just over 19/20) of all the readings occur within ±0.2 volumes percent from the mean reading; and that 99.73 % (about 399/400) of all the readings occur within ±0.3 volumes percent from the mean reading.

(*5*) 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 standard deviations is equivalent to± 3.0 sigma (and shall not exceed 10.0 volumes percent). This means that 68.27 % (just over 2/3) of all the readings occur within ±1.7 volumes percent from the mean reading; that 95.45 % (just over 19/20) of all the readings occur within ±3.3 volumes percent from the mean reading; and that 99.73 % (about 399/400) of all the readings occur within ±5.0 volumes percent from the mean reading.

X1.9 *Rationale for Clause 50.4.2*—After review of many possibilities, 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 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 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 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 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 is not unreasonable to use a gas monitor for that period of time without having to re-calibrate it.

X1.13 *Rationale R51.1: Control Function and Position, Note 7*—This note indicates a desirability to avoid a potential malfunction after the user tests some function, leaves the associated control 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. The committee also felt (Clause 51.3.4) that when the gas monitor was first turned on, the high concentration alarm should be a medium priority signal (that is, that operator response be prompt but need not be

urgent). The committee was concerned with two factors when arriving at this conclusion: (*1*) they wanted to avoid a proliferation of high priority alarms on the anesthesia machine and 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 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 is incrementally *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 that clarifying all 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 and assigned a name, and a corresponding graphic representation of these terms was generated. The ground rules were as follows:

(a) Define the alarm set point as the setting that relates to the intended displayed value at which alarm activation occurs. This definition speaks to the *intent* of the clinician, rather than 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 is now defined 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 at which the clinician intended the alarm to be activated (the new definition of alarm set point).

(*4*) This simplification could be reached when the monitor manufacturers realized that the practical implementation of digital monitoring systems caused very close correlation between the 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.