Designation: F 1456 – 01

Standard Specification for Minimum Performance and Safety Requirements for Capnometers[1]

This standard is issued under the fixed designation F 1456; 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 carbon dioxide in a gaseous mixture has become a common practice in many areas of clinical medicine, such as anesthesia, pediatrics, respiratory care, and intensive care. This specification establishes minimum safety and performance requirements for capnometers based on parameters that are achievable within the limits of existing technology.

Appendix X1 contains a 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 into this specification.

This specification uses IEC 601-1:1988 including Amendment 1 and 2 (hereafter called the General Standard) for many of the general requirements for safety. Additional requirements specific to capnometers 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 capnometers for use with adults, children, and neonates.

1.1.2 It does not apply to qualitative devices or devices solely intended for use as cutaneous monitors.

1.1.3 It does not apply to devices intended for use in laboratory research applications or nonhuman applications.

1.1.4 This specification does not apply to capnometers intended for use with flammable anesthetic mixtures.

1.1.5 This specification does not apply to devices that are intended for use in single-breath, spot-check, or noncontinuous monitoring applications.

2. Referenced Documents

2.1 The following standards contain provisions, which through reference in this specification constitute provisions of this specification. At the time of publication of this 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 as follows.

2.2 *ASTM Standards:*

F 1054 Specification for Conical Fittings of 15-mm and 22-mm Sizes[2]

F 1463 Specification for Alarm Signals in Medical Equipment Used in Anethesia and Respiratory Care[2]

2.3 *IEC Standards:*

IEC 60079-4:1975 Electrical Apparatus for Explosive Gas Atmospheres—Part 4: Method of Test for Ignition Temperature[3]

IEC 60601-1:1988 Safety of Medical Electrical Equipment—Part I: General Safety Requirements Including Amendment 1 and Amendment 2[3]

IEC 60601-1-2:1992 Medical Electrical Equipment: Collateral Requirements Electromagnetic Compatibility[3]

2.4 *ISO Standards:*

ISO 4135:1995 Anaesthesiology—Vocabulary[3]

ISO 7000-1989 Graphical Symbols for Use on Equipment-Index and Synopsis[3]

ISO 7504:1984 Gas Analysis—Vocabulary[3]

2.5 *Other Standards:*

[1] This specification is under the jurisdiction of ASTM Committee F29 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, 25 W. 43rd St., 4th Floor, New York, NY 10036.

AAMI ES-1:1993 Safe Current Limits for Electromedical Apparatus[4]

AAMI HE-48:1993 Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices[4]

CGA C-9-1982 Standard Color Markings of Compressed Gas Cylinders Intended for Medical Use[5]

NFPA 53M Fire Hazards in Oxygen-Enriched Atmospheres—1990 Edition[6]

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) which 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 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 the equipment that may develop into a safety hazard which requires operator awareness or action.

3.1.5 *alarm system*—a system that is intended to make the operator(s) aware of an alarm condition in the patient or equipment, by means of its alarm signal or signals.

3.1.6 *capnometer*—a device for the measurement of carbon dioxide concentration or partial pressure in a gas mixture.

3.1.6.1 *Discussion*—The capnometer consists of all equipment including accessories, sensor, and sampling tubing (if a diverting capnometer) specified by the manufacturer for the intended use of the capnometer.

3.1.7 *carbon dioxide level*—the concentration of carbon dioxide in gaseous mixture.

3.1.7.1 *Discussion*—This may be expressed in any suitable unit such as volume percent, or partial pressure in kilopascals or millimetres of mercury.

3.1.8 *carbon dioxide reading*—the measured carbon dioxide level as indicated by the capnometer display.

3.1.9 *default parameter (default setting)*—those operating parameters within the device, which are preset by the manufacturer, the user, or the operator, and which the device itself sets, without further intervention, when it is turned on.

3.1.10 *delay time (lag time)*—the time from a step function change in CO_2 concentration at the sampling site to the achievement of 10 % of the final CO_2 value in the capnometer (see Fig. 1).

3.1.11 *display*—the visual representative of output data.

3.1.12 *diverting (sidestream) capnometer*—a capnometer that transports a portion of respiratory gases from the sampling site through a sampling tube to the sensor, which is remote from the patient.

3.1.13 *drift*—(from ISO 7504:1984) change of the carbon dioxide level display of a capnometer for a given level of concentration over a stated period of time, under reference conditions that remain constant.

3.1.14 *interference with measurement accuracy*—the difference between the carbon dioxide reading in the presence and absence of an interfering gas(es).

3.1.15 *nondiverting (mainstream) capnometer*—a capnometer that uses a sensor at the sampling site.

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

3.1.17 *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.

3.1.18 *rise time*—the time required to achieve a rise from 10 to 90 % of the final CO_2 value in the capnometer when a step function change in CO_2 concentration occurs at the sampling site (see Fig. 1).

3.1.19 *sampling site*—the location at which ventilatory gases are diverted for measurement to a remote sensor in a diverting capnometer or the location of the sensor area in a nondiverting capnometer.

3.1.20 *sampling tubing*—the conduit for transfer of ventilatory gases from the sampling site to the sensor in a diverting capnometer.

3.1.21 *sensor*—the part of the capnometer that is sensitive to the presence of carbon dioxide.

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

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

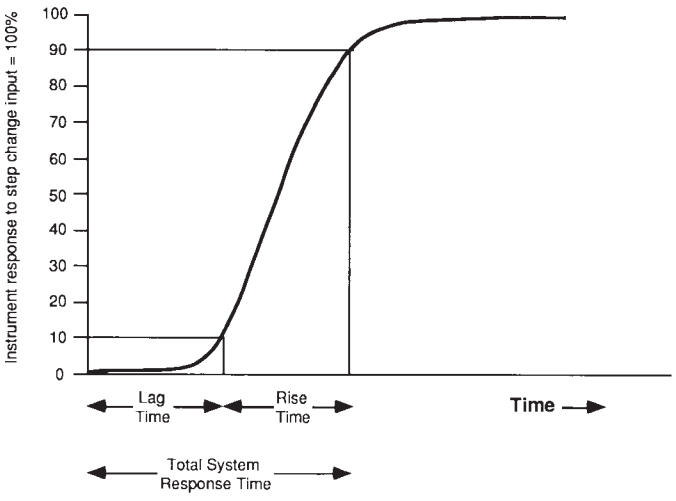


FIG. 1 Delay Time(Lag Time), Rise Time Total System Response Time

[4] Association for the Advancement of Medical Instrumentation, 1110 N. Globe Rd., Suite 220, Arlington, VA 22201-4795.

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

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

3.1.24 *volume percent (V/V %) of a gas*—the volume of a gas in a mixture, expressed as a percent of the total volume.

4. General Requirements and General Requirements for Tests

4.1 Clauses 3 and 4 of the General Standard apply, except as follows:

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

6. *Identification, Marking, and Document*—Clause 6 of the General Standard applies, except as follows:

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 ambient illuminance level of 215 lx, when viewing the information, markings, and so forth, perpendicular to, and including 15° above, below, left, and right.

NOTE 1—Care should be taken to avoid directing the light source so as to avoid glare.

6.1 d) If the size of the capnometer does not permit the complete marking as specified throughout this clause, at least the following shall be marked on the capnometer:

The name of the manufacturer,

A serial or lot or batch identifying number, and

Symbol 14 in Table D1 of the General Standard.

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

6.1 bb) The words "Not for use in breathing systems," if applicable.

6.1 cc) If applicable, the words "Not for use with flammable anesthetics" or a symbol.

6.1 dd) If applicable, the words "Not for use with inhalation anesthetic agents."

6.1 ee) The manufacturer shall mark the device with a warning to refer the user or operator to the accompanying documents or Symbol 14 in Table D1 of the General Standard for the expected adverse effects on the performance of the capnometer.

NOTE 2—It is recommended that illustrated service information be provided to include the following: instructions for preventive maintenance and service calibration, and those adjustments that are necessary to maintain the capnometer in the correct operating condition, as well as a description of those adjustments and replacements that can be performed by the user.

6.1 ff) All operator interchangeable components of a capnometer that are flow-direction sensitive shall be durably marked with an arrow showing the direction of gas flow.

6.1 gg) If a sampled gas inlet and outlet are provided, their presence shall be durably marked either with text, or with the respective symbols for inlet and outlet from ISO 7000.

6.1 hh) Packages for single-use components shall be marked with the following words: "single-use" or "single-patient use" or the Symbol No. 1051 given in ISO 7000, or both.

6.1 jj) 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—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 capnometer 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 identified with their associated markings.

6.6 *Identification of Medical Gas Cylinders and Connections:*

6.6 a) 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 of the General Standard).

6.8.2 *Instructions for Use:*

6.8.2 aa) A description of the purpose and intended use of the capnometer.

6.8.2 bb) A description of the principles of operation of the capnometer.

6.8.2 cc) The instructions for use shall include the following:

(*1*) *Performance Specifications:*

(*a*) The carbon dioxide reading range and the accuracy of measurement;
(*b*) In a diverting capnometer, the gas diversion flow and its tolerance;
(*c*) The minimum sample flow at which the device will meet specifications;
(*d*) The stability of measurement accuracy;
(*e*) The rise time, and the total system response time;
(*f*) The carbon dioxide reading alarm limit range, its resolution, default setting(s), and time from detection to activation;
(*g*) The ranges of temperature, atmospheric pressure, and humidity for operation and for storage;
(*h*) The time from switching "ON" to obtaining specified operating performance;
(*i*) 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 manufacturer's specified minimum and maximum sample flow rate; and
(*j*) A statement whether the device is equipped with automatic barometric pressure compensation.

(*2*) *Known Adverse Effects on Stated Performance asa Result of the Following:*

(*a*) Quantitative effects of humidity or condensate;
(*b*) Quantitative effects of interfering gases and vapors; (see also Clause 60.1);
(*c*) Leaks or internal venting of sampled gas;
(*d*) Mechanical shock;
(*e*) Cyclic pressure up to 10 kPa (100 cmH_2O);
(*f*) Quantitative effects of barometric pressure;
(*g*) Quantitative details of fluctuation in ac mains or battery voltage, or both;
(*h*) Other sources of interference, if any.

(*3*) *Operation and Maintenance:*

(*a*) Calibration or verification, or both, before use and during use;
(*b*) Routine inspection and testing;

(*c*) Recommended methods for cleaning, disinfecting, or sterilizing, or combination thereof, and, if applicable, any limitations on the number of these cycles;
(*d*) If applicable, the recommended method for connecting the exhaust port of the capnometer to a gas scavenging system;
(*e*) If applicable, the recommended method for returning the sampled gas to the anesthesia breathing system; and
(*f*) Recommended method(s) of verifying all operator-adjustable alarm system functions.

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

6.8.2 ee) A description of an in-service test using a recommended test gas as the calibration gas.

6.8.2 ff) A description of the correct installation of the capnometer and a description of sampling arrangements and any connecting tubing, if applicable.

6.8.2 gg) Information concerning the disposal of the device.

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

SECTION TWO—ENVIRONMENTAL CONDITIONS

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

SECTION THREE—PROTECTION AGAINST ELECTRICAL SHOCK HAZARDS

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

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

Clause 19.1 e), add the following:

For the purposes of this specification, the applied part for a nondiverting capnometer is the sensor, and for diverting capnometers, the sample gas inlet at the device.

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

SECTION FOUR—PROTECTION AGAINST MECHANICAL HAZARDS

All clauses and subclauses of this section of the General Standard 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 in Clause 36 of the General Standard apply, with the following addition:

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

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

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

SECTION SEVEN—PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

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

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

43.1 To reduce the risk to patients, other persons, or the surroundings as a result of fire, ignitable material, under normal and single-fault condition, shall not at the same time be subjected to conditions in which:

The temperature of the 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 oxidizing conditions present under 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 5—To minimize operator errors and consider human factors in the design of capnometer, controls that merit the operator's close attention should be arranged close to the operator's line of sight when observing the 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:

51. *Protection Against Hazardous Output*—The requirements of Clause 51 of the General Standard apply with the following additions:

51.5 *Measurement Accuracy:*

51.5.1 The accuracy of the capnometer readings is determined after exposure of the sampling site to cyclic pressure changes (see Clause 51.5.4).

51.5.2 The carbon dioxide reading shall be within ±12 % of the test gas value or ±4 mm Hg whichever is greater, over the full measurement range of the capnometer, corrected to one atmosphere (760 mm Hg).

Compliance shall be checked by the test given in 51.5.4.

51.5.3 For capnometers with waveform display capabilities, noise shall be limited as follows:

Six standard deviations of the carbon dioxide readings (over the range from 0 to 5 %) shall be less than or equal to 0.6 volume percent.

NOTE 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) from the mean reading. See rationale for details.

The manufacturer shall provide test methods and results upon request.

51.5.4 *Test Method:*

51.5.4.1 *Principle*—Carbon dioxide gas readings are determined at a number of carbon dioxide gas levels spanning the carbon dioxide monitor measurement range after exposing the sampling site ten times to a cyclic pressure in accordance with Fig. 2.

51.5.4.2 *Test Gases*—Test gases shall be equal to or greater than 5 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 51.5.2.

NOTE 7—Test gases with the aforementioned accuracy may be obtained from test gas manufacturers or by in-house production of the required test gas mixtures with accuracy verified by other methods (for example, mass spectrometry or refractometry).

51.5.4.3 *Gas Testing*—The capnometer shall be set up and calibrated in accordance with the accompanying documents and tested using the test gases given in Table 1, at an ambient temperature of 23 ± 2°C. For each numerically displayed carbon dioxide level, verify that the accuracy requirements of 51.5.2 are met.

51.5.5 *Drift of Measurement Accuracy:*

51.5.5.1 The capnometer shall meet the requirements specified in 51.5.2 for no less than 24 h when used in accordance with the accompanying documents. Compliance shall be checked by the test given in 51.5.6.

51.5.6 *Test Method:*

51.5.6.1 With the capnometer set up, calibrated, and operated in accordance with the accompanying documents, use the test gases in Table 1, at an ambient temperature of 23 ± 2°C, and sample all of the test gas mixtures at 6 h and again at 24 h. Between the test periods allow the device to sample ambient air.

TABLE 1 Gas Testing

Nitrogen	Carbon Dioxide, % (V/V)
Balance	0.0
Balance	2.5
Balance	5.0
Balance	10.0

51.5.7 *Rise Time Testing:*

51.5.7.1 The manufacturer shall disclose in 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 *Test Method:*

51.5.8.1 The capnometer shall be set up in accordance with the accompanying documents and attached to the appropriate test apparatus (see Figs. 3 and 4).

Connect the capnometer to a suitable recording device.

With the 5 % carbon dioxide gas mixture from Table 1, cycle the valve(s) and record the rise time. Repeat the procedure, for this gas mixture 20 times and determine the average rise time.

51.5.9 *Combined Gas Accuracy Testing:*

51.5.9.1 The capnometer shall be set up and calibrated in accordance with the accompanying documents and tested using the test gases given in Table 2, at an ambient temperature of 23 ± 2°C. For each numerically displayed anesthetic gas, verify that the accuracy requirements of 51.5.2 are met.

51.6 *Displays*—Carbon dioxide displays shall be marked continuously or on operator demand with kilopascals, percent, or millimetres of mercury. If the units of measure can be changed by the operator from the user-selected default units of measure, the units of measure shall be displayed continuously.

NOTE 8—User-selected default units of measure may be the same as the manufacturers' default units of measure.

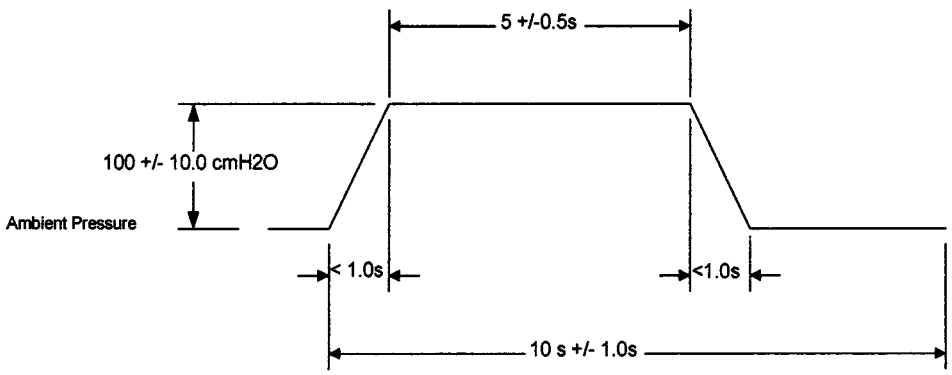


FIG. 2 Cyclic Pressure

UUT=Unit Under Test

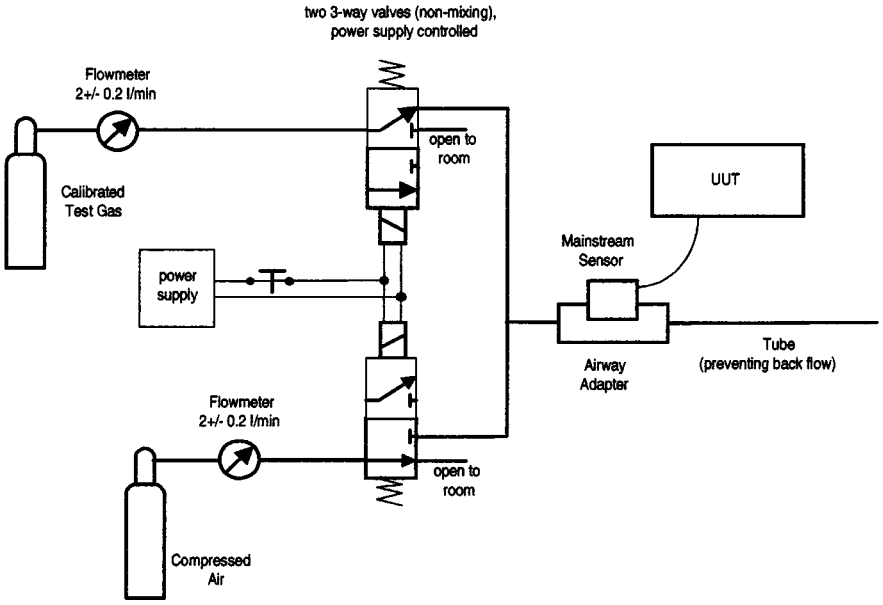
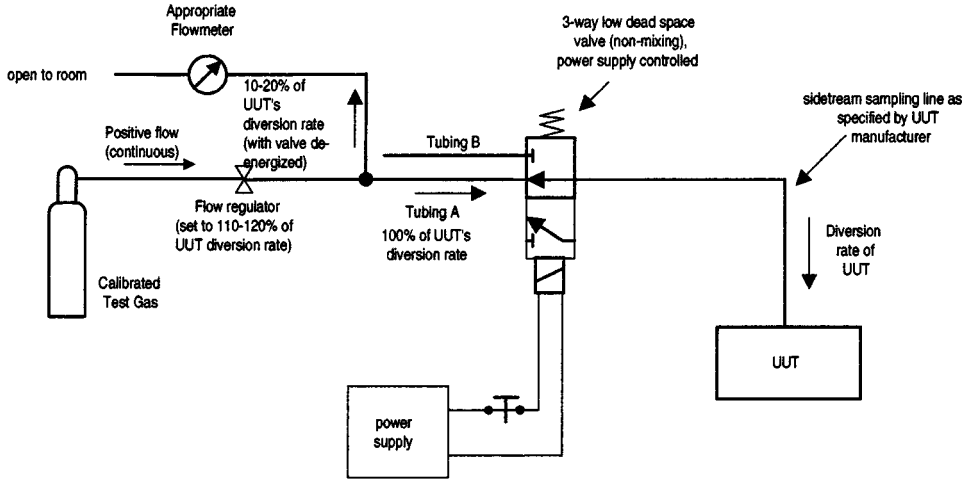


FIG. 3 Nondiverting Monitor—Rise Time Test Apparatus



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 2 Mixtures for Combined Gas Accuracy Testing

Carbon Dioxide	Nitrous Oxide[A]	Oxygen
5.0	balance	30
5.0	balance	60

[A] If not for use with nitrous oxide, use nitrogen.

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

51.7 If the intended test control function is not clearly distinguishable when displayed on the capnometer, the corresponding control(s) shall automatically return from such control function position(s). The positions of measurement and test controls shall be clearly distinguishable.

NOTE 9—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.

51.8 *Alarms:*

51.8.1 The requirements in Specification F 1463 apply.

51.8.2 Temporary silencing of audible alarm signals, if provided, shall not exceed 2 min. The visual alarm 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 unintentional permanent alarm signal silencing.

NOTE 10—The audible components of alarm signals should be designed

to allow silencing until the capnometer is placed in use (that is, connected to the patient) to reduce nuisance alarm signals.

51.8.3 There shall be a visual indication that an audible alarm signal has been silenced. The visual indication shall remain until the operator re-enables the audible alarm signal.

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

If the displayed alarm limits are changed by the operator from the user-default 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 11—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 For inspired carbon dioxide, the capnometer shall have a high carbon dioxide alarm signal of at least medium priority.

51.8.7 For exhaled carbon dioxide, the capnometer shall have operator adjustable high and low carbon dioxide alarm signals of at least medium priority.

51.8.8 If the capnometer has an automatic change in alarm signal priority setting, it shall change only to a higher alarm signal priority, and only after activation of the lower priority alarm signal.

51.8.9 If operator-adjustable change in alarm signal priority is provided, it shall not allow a change to a lower priority than specified in this specification.

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

51.8.11 All alarm signals specified in 51.8 shall be provided with a default setting, and that default setting shall be disclosed in the accompanying documents (see 6.8.2 cc)1)e).

51.8.12 The difference between the alarm limit and the carbon dioxide reading when the alarm signal is activated shall not exceed 0.2 volume percent (1.4 mm Hg at 760 mm Hg barometric pressure, BTPS) carbon dioxide.

51.8.12.1 Compliance is checked by generating at least four stable carbon dioxide readings that span the range of the alarm system in approximately equal steps by varying the carbon dioxide level delivered to the sensor, or by electrically stimulating the sensor, or by adjusting the calibration control (if provided). For each carbon dioxide reading, adjust the alarm limit so that the alarm signal is deactivated. Incrementally adjust the alarm limit until the alarm signal is activated, and record the carbon dioxide reading at which the alarm signal is activated. The difference between the alarm limit and the corresponding carbon dioxide reading shall not exceed 0.2 volume percent (1.4 mm Hg at 760 mm Hg barometric pressure, BTPS).

SECTION NINE—ABNORMAL OPERATION AND FAULT CONDITIONS

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

56. *Components and General Assembly*—Clause 56 of the General Standard applies with the following amendment and additions:

56.1 g):

NOTE 12—Components of the capnometer 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 capnometer in use.

56.12.1 If the capnometer has additional modes, other than the standard operating mode, the current mode shall be indicated continuously. This indication shall be legible.

NOTE 13—AAMI HE-48 *Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices* contains information concerning implementation of these alternative modes.

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

5. Additional Requirements Specifically Related to Capnometers

60. *Interfering Gas and Vapor Effects*—The manufacturer shall disclose in the accompanying documents, known effects on carbon dioxide gas readings (if any) caused by the gases given at the nominal (±20 %) concentrations listed in Table 3 (see Clause 6.8.2). The manufacturer shall make available upon request the test methods used to make such determination.

Compliance is checked by inspection of the accompanying documents.

61. *Gas Leakage and Sampling Loss*—The rate of leakage for a nondiverting capnometer 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_2O).

Compliance shall be checked by using a pressure gage having an accuracy to within ±0.6 kPa (6 cm H_2O) and a flow metering device having an accuracy within ±2 mL/min.

Tests shall be performed in both the ready-for-use and OFF configuration. Assemble the capnometer so that the sampling site is installed in a dimensionally suitable port of a test apparatus containing an inlet fitting to which a test gas and airflow metering device are attached. Connect the pressure

TABLE 3 Test Concentrations of Interfering Gases or Vapors, % (V/V)

Gas or Vapor	Level, % (V/V)
Halothane	4
Enflurane	5
Isoflurane	5
Sevoflurane	5
Desflurane	5
Ethanol	specified by the manufacturer
Acetone	specified by the manufacturer
Methane	specified by the manufacturer
Helium	50
Tetrafluoroethane[A] (Freon 134a)	1
Dichlorofluromethane[A] (Freon 21)	1

[A] These are known propellants used with metered dose inhalers.

gage to a third port of a test apparatus. Slowly adjust 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.

62. *Sample Gas Exhaust Port*—For all diverting capnometers, an exhaust port shall be provided to collect or route the diverted gas from the capnometer. This port shall be incompatible with the sample gas inlet port on the capnometer and shall not be a Luer type (see Clause 6.8.2 cc).

Compliance shall be checked by inspection.

63. *Minimum Sampling Flow*—A diverting capnometer 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).

Compliance is checked by gradual reduction of the sample flow. Verify that device indicates when the sample flow has fallen below the minimum specified by the manufacturer and that this value is stated in the accompanying documents . This test is to be conducted with the capnometer operating in accordance with the accompanying documents.

64. *Contamination of Breathing Systems*—It shall not be possible to reverse the direction of flow through the sampling tube in a diverting capnometer.

Compliance is checked by inspection.

5. Keywords

5.1 capnometers; performance requirements; safety requirements

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

Rationale for Clause 1.1.3—Devices used in laboratory research applications are often experimental or intended primarily for nonmedical uses. Imposition of the requirements of this specification on devices for research might unduly limit development of beneficial new techniques or devices.

Rationale for Clause 6.8 Relating to Instructions for Use—The need to know the basic workings of the capnometer, 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 monitor 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, and so forth. It should be equally self-evident that the user must be provided with instructions for proper operation of the capnometer.

Rationale for Clause 36—Capnometers are not life-support devices but are 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.

Rationale for Clause 43—Reports of fire caused by medical devices are unusual. However, when such fires occur in the hospital 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 which 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.

Rationale for Clause 51.5—Accurate knowledge of inspired and exhaled carbon dioxide concentration provides the clinician with information regarding the patient's cardiopulmonary status, function of the airway, and integrity of the breathing circuit. Adjustments to pulmonary ventilation, blood volume, and systemic circulation are often based on values of exhaled carbon dioxide. Recognition of unintended esophageal intubation, partial and complete airway obstruction, and rebreathing of exhaled carbon dioxide from the breathing system are often first recognized by changes in the respired carbon dioxide concentrations. For clinicians to use capnometers routinely for enhancement of patient safety and management, there must be confidence in the reliability and accuracy of the displayed data from the capnometer. The accuracy requirements detailed in Clause 51 are sufficient to meet these safety concerns.

There was concern among manufacturers that one random reading beyond the accuracy specified would be viewed as a failure to perform 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.

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, for example:

68.27	% of all the readings occur within $\pm 1.0\ \sigma$ (standard deviation) from the mean
95.45	% of all the readings occur within $\pm 2.0\ \sigma$ from the mean
99.73	% of all the readings occur within $\pm 3.0\ \sigma$ from the mean
99.9937	% of all the readings occur within $\pm 4.0\ \sigma$ from the mean

There is a general consensus that the limit of practical consideration for the values of a Gaussian set is bounded by $\pm 3.0\ \sigma$ (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 $\pm 2.0\ \sigma$, or 1 reading in 15 000 for $\pm 4.0\ \sigma$.)

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. The randomness specification for capnometers states: "in addition, six standard deviations of the carbon dioxide readings (over the range from 0 to 5 %) shall be less than or equal to 0.6 vol %."

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