Designation: F 1456 – 9201

An American National Standard

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, ~~respiratory therapy,~~ pediatrics, respiratory care, and intensive care. This ~~draft~~ 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 ~~draft~~ specification.

This ~~draft~~ specification ~~references~~ uses IEC 601-1:1988 including Amendment 1 and 2 (hereafter ~~referred to as~~ called the General Standard) for many of the general requirements for safety. ~~R~~ 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 The scope given in Clause 1~~

1.1 This clause of the General Standard applies except ~~that 1.1 shall be replaced by the following:~~ as follows:

1.1.1 This specification ~~specifies requirements for the safety and performance of capnometers as defined in Subclause 3.5. It~~ applies to capnometers for use~~d~~ 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 Capnometers~~

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 ~~outside the scope of this specification.~~ 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 ~~text,~~ specification constitute provisions of this specification. At the time of publication of this specification, the editions indicated were ~~valid.~~ current. All standards are subject to revision, and parties ~~to agreements based on~~ using this specification are encouraged to investigate the possibility of applying the most recent editions of the standards listed ~~below.~~ as follows.

2.2 *ASTM Standards:*

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[1] This specification is under the jurisdiction of ASTM Committee F~~-~~29 on Anesthetic and Respiratory Equipment and is the direct responsibility of Subcommittee ~~F29.03 on Division Three on Ventilators and Ancillary Devices.~~ F29.11 on Gas Monitors.

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F 1054 Specification for Conical Fittings of 15-mm and 22-mm s Sizes[2]
F 1463 Specification for Alarm Signals in Medical Equipment Used in Anethesia and Respiratory Care[2]
2.3 *ISO Standards:*[3]
ISO 32:1977 Gas CylindersIEC Standards:
IEC 60079-4:1975 Electrical Apparatus for Medical Use—Marking Explosive Gas Atmospheres—Part 4: Method of Test for Identification Ignition Temperature[3]
IEC 60601-1:1988 Safety of Contents
ISO 5356/1:1987 Anaesthetic and Respiratory Equipment—Connectors, Part Medical Electrical Equipment—Part I: Cones General Safety Requirements Including Amendment 1 and Sockets
ISO 5356/2:1987 Anaesthetic and Respiratory Equipment—Connectors, Part II: Screw-Threaded-Weight-Bearing Connectors
ISO 7249 Controls—Terms, Suitability, Design Requirements
ISO 7250 Basic List of Anthropomorphic Measurements Amendment 2[3]
IEC 60601-1-2:1992 Medical Electrical Equipment: Collateral Requirements Electromagnetic Compatibility[3]
2.4 *IECSO Standards:*
ISO 4135:1995 Anaesthesiology—Vocabulary[3]
IEC 65:1985 Safety Requirements
ISO 7000-1989 Graphical Symbols for Mains Operated Electronic Use on Equipment-Index and Related Apparatus Synopsis[3]
ISO 7504:1984 Gas Analysis—Vocabulary[3]
2.5 *Other Standards:*
AAMI ES-1:1993 Safe Current Limits for Household and Similar Use
IEC 79-3:1972 Electrical Electromedical Apparatus[4]
AAMI HE-48:1993 Human Factors Engineering Guidelines and Preferred Practices for Explosive Atmospheres—Part III: Spark Test Apparatus for Intrinsically Safe Units
IEC 79-4:1975 Electrical Apparatus for Explosive Gas Atmospheres—Part IV: Method the Design of Test for Ignition Temperature
IEC 601-1:1988 Safety of Medical Electrical Equipment—Part I: General Safety Requirements
IEC 801-2:1991 Electromagnetic Compatibility Devices[4]
CGA C-9-1982 Standard Color Markings of Compressed Gas Cylinders Intended for Industrial-Process Measurement and Control Equipment—Part 2: Electrostatic Discharge Requirements Medical Use[5]
NFPA 53M Fire Hazards in Oxygen-Enriched Atmospheres—1990 Edition[6]

3. Terminology

3.1 *Definitions*—For the purposes of this specification, the definitions given in ClauseClause 2 of the General Standard apply, along applies together with ISO 4135 and the following definitions: 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 w 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 set point limit(s)*—the setting of the adjustment control, or display value,—value(s) which indicates are set by the carbon dioxide reading, at manufacturer, the device, the user, or beyond operator which define the threshold range of the alarm is intended to be activated. condition.

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

3.1.4 *alarm system signal*—those parts—a signal, the purpose of which is to alert the capnometer which: (*1*) establish the alarm set point(s); and (*2*) activate operator of an alarm when abnormal condition in the carbon dioxide reading is less than patient or equal to the low-alarm set point, if provided, equipment that may develop into a safety hazard which requires operator awareness or is equal to or greater than the high-alarm set point. 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 ventilatory gases.
3.1.5.1 a gas mixture.

[2] *Annual Book of ASTM Standards*, Vol 13.01.
[3] Available from American National Standards Institute, 1430 Broadway, 25 W. 43rd St., 4th Floor, New York, NY 10018. 10036.
[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.

3.1.6.1 *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.

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

3.1.67.1 *Discussion*—This may be expressed in any suitable unit such as ~~percent by~~ volume percent, or partial pressure in ~~kPa (or mm Hg).~~

~~3.1.7~~ kilopascals or millimetres of mercury.

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

~~3.1.8 *cutaneous oxygen and carbon dioxide partial pressure monitoring equipment*—equipment or associated transducers, or both, for the monitoring or recording, or both, of partial pressures of oxygen and carbon dioxide at the skin surface.~~

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 ~~or partial pressure~~ at the sampling site to the achievement of 10 % of the final CO_2 value in the capnometer (see Fig. 1).

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

~~3.1.11 *diverting capnometer*—a capnometer that transports a portion of respired gases from the sampling site through a sampling tube to the sensor, which is remote from the patient.~~

3.1.12 ~~*high-priority alarm*~~*diverting (sidestream) capnometer*~~—an indication of danger and meaning~~—a capnometer that ~~immediate action on the part~~ transports a portion of respiratory gases from the ~~o~~ sampling site through a sampling tube to the sensor, which is ~~required.~~ remote from the patient.

3.1.13 ~~*interference with measurement accuracy*~~*drift*~~— the difference between the carbon dioxide reading in the presence~~—(from ISO 7504:1984) change of ~~an interfering gas mixture and~~ the carbon dioxide ~~reading in~~ level display of a ~~corresponding mixture in which the interfering gas or vapor fraction has been replaced by nitrogen.~~ capnometer for a given level of concentration over a stated period of time, under reference conditions that remain constant.

3.1.14 ~~*low-priority alarm*~~*interference with measurement accuracy*~~—an indication of a condition that requires awareness on~~—the difference between the ~~part of~~ carbon dioxide reading in the ~~operator, but not necessarily action.~~ presence and absence of an interfering gas(es).

~~3.1.15 *medium-priority alarm*—an indication meaning that prompt action on the part of the operator is required.~~

~~3.1.16 *non-diverting*~~*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 ~~*oxygen level*—the concentration of oxygen in a gaseous mixture.~~

~~3.1.17.1 *Discussion*—This may be expressed in any suitable unit such as percent by volume or partial pressure in kPa (or mm Hg).~~

~~3.1.18~~ *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.

~~3.1.19 *percent (%) v/v carbon dioxide (or other gases)*—the level of carbon dioxide (or other gas) in a mixture, expressed as a percent volume fraction.~~

~~3.1.20~~

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 ~~or partial pressure~~ occurs at the sampling site (see Fig. 1).

3.1.219 *sampling site*—the location at which ~~respiratory~~ ventilatory gases are diverted for measurement to a remote sensor in

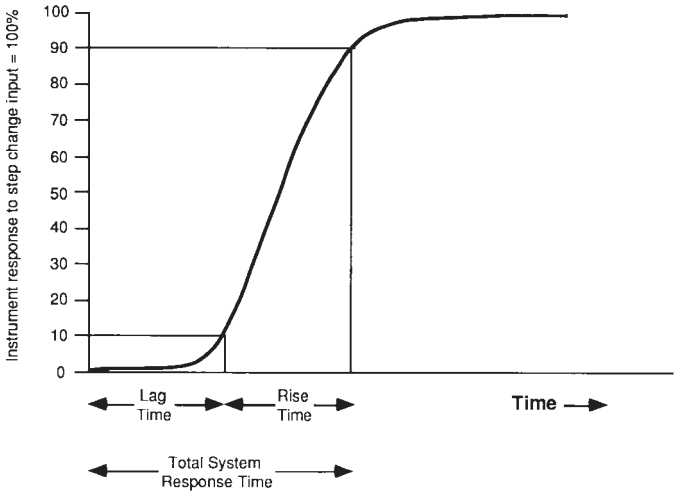


FIG. 1 Delay Time(Lag Time), Rise Time Total System Response Time

a diverting capnometer or the location of the sensor area in a non-diverting capnometer.

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

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

~~3.1.24 *sensor area*—the part of the sensor at which carbon dioxide is detected.~~

~~3.1.25~~

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

~~3.1.26 *transducer*~~

3.1.23 *user*~~—a device~~—(from IEC 60601-1) authority responsible for ~~converting~~ the ~~partial pressure or concentration~~ use and maintenance of equipment.

3.1.24 *volume percent (V/V %) of a gas ~~into~~*—the volume of a ~~signal for monitoring or recording.~~ gas in a mixture, expressed as a percent of the total volume.

4. ~~Relationship~~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 ~~S~~ 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:

~~(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 documents~~			~~X~~
~~7. Power input~~	~~X~~		
~~Section Two—Environmental Conditions~~			
~~8. Basic safety requirements (not used)~~			
~~9. Removable protective means (not used)~~			
~~10. Environmental conditions~~	~~X~~		
~~11. Special measures with respect to safety (not used)~~			
~~12. SINGLE FAULT CONDITION (not used)~~			
~~Section Three—Protection Against Electric Shock Hazards~~			
~~13. General~~	~~X~~		
~~14. Requirements related to classification~~	~~X~~		
~~15. Limitation of voltage and/or energy~~	~~X~~		
~~16. Enclosures and PROTECTIVE COVERS~~	~~X~~		
~~17. Separation~~	~~X~~		
~~18. Protective earthing, functional earthing, and potential equalization~~	~~X~~		
~~19. Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS~~			~~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 (not used)~~			
~~27. Pneumatic and hydraulic power~~	~~X~~		
~~28. Suspended masses~~	~~X~~		
~~Section Five—Protection Against Hazards from Unwanted~~ or ~~Excessive Radiation~~			
Section Five—Protection Against Hazards from UnwantedWarning statements, instructional messages, or ~~Excessive Radiation~~			
~~29. X-radiation~~	~~X~~		
~~30. Alpha, beta, gamma, neutron radiation~~ and ~~other particle radiation~~	~~X~~		
30. Alpha, beta, gamma, neutron radiation drawings affixed permanently and ~~other particle radiation~~	~~X~~		
~~31. Microwave radiation~~	~~X~~		
~~32. Light radiation (including 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 Anaesthetic Mixtures		
37. General	X	
38. Marking, 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	
45. Pressure vessels and parts subject legible to pressure	X	
46. Human errors		X
47. Electrostatic charges	X	
48. Materials in APPLIED PARTS in contact with the body of the PATIENT	X	
48. Materials in APPLIED PARTS in contact an operator with a visual acuity of the PATIENT	X	
49. Interruption of the power supply	X	
49. Interruption 1.0 (corrected if necessary) from a distance of the power supply	X	
Section Eight—Accuracy of Operating Data and Protection Against Hazardous Output **Section Eight—Accuracy 1 m at an ambient illuminance level of 215 lx, when viewing the information, markings, and Protection Against Hazardous Output**		
50. Accuracy of operating data (not used)		
51. Protection against hazardous output		X
Section Nine—Abnormal Operation and Fault Conditions; Environmental Tests **Section Nine—Abnormal Operation so forth, perpendicular to, and Fault Conditions; Environmental Tests**		
52. Abnormal operation and fault conditions	X	
52. Abnormal operation including 15° above, below, left, 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. Sustained pressure	X	
62. Gas leakage and sampling loss	X	
63. Connectors	X	
63. Connectors	X	right.

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

5. Clauses Containing Amendments, Additions, or Replacements to the Text in IEC 601-1:1988

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

4. *General Requirements and General Requirements for Tests*—Clauses 3 and 4 of the General Standard apply together with the following additions:

4.12 Test methods other than those specified in this draft specification, but of equal or greater accuracy, may 1—Care should be used taken to verify compliance with avoid directing the requirements of this draft specification. However, in the event of dispute, the methods specified in this draft specification shall be used light source so as the reference methods.

4.13 Components of the capnometer should be made of materials that are compatible with the gases and agents with which those components are designed to come into contact.

6. *Identification, Marking, and Documents* —The requirements given in Clause 6 of avoid glare.

6.1 d) If the General Standard apply together with the following additions and modifications:

(*1*) In the preamble to Clause 6, replace the first item under "clearly legible" by the following:

Warning statements, instructive statements, or drawings: affixed in a permanent location and legible to a user with a visual acuity of 1.0 (corrected if necessary) from a distance of 1 m at an illuminance level of 215 lx.

(*2*) In 6.1, replace item (*d*) by the following:

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: t

The name of the manufacturer, ~~a~~
A serial or lot or batch identifying number, and
Symbol 14 in Table D1 of the General Standard.

~~(3) In 6.1, add the following to item (f): a~~

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

~~(4) In 6.1, add the following to item (q): the~~

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

~~(5) In 6.1, add additional items as follows:~~

~~(zz) Marking on~~

6.1 cc) If applicable, the ~~capnometer shall additionally include the following:~~

~~(a) For capnometers not~~ words "Not for use with ~~inhalational anesthetic agents,~~ flammable anesthetics" or a symbol.

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

~~(b) If moisture has an adverse effect on performance, either a statement that the operator or user shall see the accompanying documents for the effect of moisture on accuracy, or Symbol 14 in Table D1.~~

~~(c) Abridged operating instructions for those capnometers that are intended as "free standing" types of devices.~~

~~(d) *Other Sources of Interference*—~~The 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 when exposed to electrocautery, electrosurgery, defibrillation, X-ray (gamma radiation) infra-red radiation, conducted transients, magnetic fields (that is, magnetic resonance imaging (MRI)), and radiofrequency interference known at the time of preparation of the accompanying documents.~~ 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:

~~(6) Clause 6.7 of the General Standard shall apply with the following modifications:~~

~~(a) Dot matrix, alphanumeric displays, and computer-generated graphics are not considered to be indicator lights.~~

~~(b) Compliance shall be checked by functional tests and inspections.~~

~~(7) In 6.8.2, add the following to item~~ (1) *Performance Specifications:*

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

~~(a) A description of the purpose and intended use of the capnometer.~~

~~(b) A description of the principles of operation of the measurement;~~

(a) The carbon dioxide reading range and the accuracy of measurement;

~~(b) In a diverting capnometer, including the relationship between gas concentration and its partial pressure, and the quantitative effects of humidity.~~

~~(tolerance;~~

(*b*) In a diverting capnometer, the gas diversion flow and its tolerance;
(*c*) A detailed specification including the following:
The carbon dioxide measurement range and the accuracy of measurement;
If gas diversion occurs, the gas diversion flow;
The stability of measurement accuracy;
The rise time;
The carbon dioxide level alarm range and its accuracy;
The operating and non-operating (storage) temperature ranges;
For sampling type capnometers, the gas diversion rate;
Power requirements; and
Time from switching on to obtaining specified operating performance.
(device will meet specifications;
(*c*) The minimum sample flow at which the device will meet specifications;
(*d*) Details of any adverse effect on stated function due to the following:
Humidity or condensate, including, for example, any adverse effects if an adaptor is provided to improve the function of the sensor in the presence of condensation or particulate water;
Interfering gases or vapors;
Mechanical shock;
Cyclic pressure;
Barometric pressure or pressure at the site of use of the capnometer;
Fluctuation in line or battery voltage; and
If automatic compensation for barometric pressure is not provided, then the accompanying documents shall contain an explanation that the readings in concentration units are correct only under the pressure at which the capnometer is calibrated.
(measurement accuracy;
(*d*) The stability of measurement accuracy;
(*e*) An illustration of the features of the capnometer, indicating the location of all operating controls, adjustments, and system components necessary for correct operation.
(*f*) Instructions for operation of the capnometer, including the following:
Checking total system response time;
(*e*) The rise time, and the total system response time;
(*f*) The carbon dioxide reading alarm limit range, its resolution, default setting(s), and calibration before use;
Routine inspection and testing; and
Recommended methods for cleaning and disinfection or sterilization.
(time from detection to activation;
(*f*) The carbon dioxide reading alarm limit range, its resolution, default setting(s), and time from detection to activation;
(*g*) A description of an in-service test using a recommended test gas as the calibration gas.
(temperature, atmospheric pressure, and humidity for operation and for storage;
(*g*) The ranges of temperature, atmospheric pressure, and humidity for operation and for storage;
(*h*) A de scri performance;
(*h*) The time from switching "ON" to obtaining specified operating performance;
(*i*) The int ion of the correct installation of the capnometer and a detailed description of sampling arrangements and any connecting tubing.

capnometer requires a sensor cable or sampling tubing for connection from the capnometer to the sensing area, the cable or tubing should be of sufficient length to reduce the likelihood of its being elongated beyond its elastic limit and being stressed at the poi

us Leakage Currents and Patient Auxiliary Currents—The requirements given in Clause 19 of maximum sample flow rate; and
(*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 General Standard apply except as follows: device is equipped with automatic barometric pressure compensation.
(*j*) A statement whether the device is equipped with automatic barometric pressure compensation.

(*1*) In item 19.1(*e*), add the following:
(*a*) For non-diverting capnometers at the sensor; and
(*b*) For diverting capnometers, at the junction of the sampling tubing and the body of the capnometer.

NOTE 4—Sampling tubing usually non-conducting. Input port most likely to represent an electrical hazard.

(*2*) Where national standards mandate more restrictive limits, these more restrictive limits shall apply.
21. *Mechanical Strength:*
(*1*) The requirements given in Clause 21) *Known Adverse Effects on Stated Performance asa Result of the General Standard are replaced by the following:*
21.1 Free-standing capnometers (that is, those not intended for use as an integral inseparable component of a larger system) and all separable components, such as sensors, shall be able to withstand mechanical shock and vibration, such that electrically live parts shall not become accessible.

(2) Compliance shall be checked by the test given in 21.7.

21.7 *Method of Test:* *Following:*

21.7.1 *Principle*

The accuracy

(a) Quantitative effects of the carbon dioxide reading, the rise time, and, if applicable, the alarm accuracy are determined after the capnometer and all separable components have been subjected to a mechanical shock.

21.7.2 *Procedure:*

(1) Attach the unpackaged items to be tested rigidly to a shock table machine. Apply three shocks in both directions along three mutually perpendicular axes of each test item (a total of 18 shocks to each item), taking care to ensure the following:

(a) That the shape of the shock pulse is in accordance with Fig. 2;

(humidity or condensate;

(a) Quantitative effects of humidity or condensate;

(b) That the acceleration amplitude (A) of the ideal half-sine pulse is 300 m/s2 (30 × gravity) and its duration (D) is 11 ms.

(vapors; (see also Clause 60.1);

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

(c) That the oscillogram of the shock pulse includes a time approximately 33 ms (3 × D) long;

(sampled gas;

(c) Leaks or internal venting of sampled gas;

(d) That the measured acceleration pulse is contained between the broken-line boundaries shown in Fig. 2;

() Mechanical shock;

(d) Mechanical shock;

(e) That the measured velocity change (which may be obtained by integration of the acceleration pulse) is within the limits Vi_ 0.1 Vi, where the velocity change associated with the ideal pulse is Vi 2 × A × D/3.1416 2 × 300 × 0.011/3.1416 2.1 m/s; and

() Cyclic pressure up to 10 kPa (100 cmH_2O);

(e) Cyclic pressure up to 10 kPa (100 cmH_2O);

(f) That the integration to determine velocity change extends from 4.4 ms (0.4 D) before the pulse to 1.1 ms (0.1 D) after the pulse.

) Quantitative effects of barometric pressure;

(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.

(2) Inspect the capnometer to check that the appearance and condition of the capnometer, including the enclosure and warning or display indications or markings, have not been damaged or have not deteriorated in such a way as to prevent normal operation of the capnometer and that no electrically live parts have become accessible.

(3) *Operation and Maintenance:*

(a) Calibration or verification, or both, before use and during use;

(b) Re a tting;

(b) Routine inspection and testing;

(c) Recommended methods for cleach any separable components to the number of these cycles;

(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 anging system;

(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) Reconductions.

(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 measurement accuracy correct operation.

6.8.2 ee) A description of an in-service test using a recommended test gas as described in Clause 50.2 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 sectimon of the General Standard apply, except as ~~described~~ follows:

19. *Continuous Leakage Currents and Patient Auxiliary Currents*—The requirements in Clause ~~50.5 and, if~~ 19 of the ~~capnometer is fitted~~ 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 ~~carbon dioxide level alarm,~~ nondiverting capnometer is the ~~test~~ sensor, and for ~~carbon dioxide level alarm set point~~ 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 ~~described~~ follows:

36. *Electromagnetic Compatibility*—The requirements in Clause ~~51.4.9.~~

~~21.7.3 *Expression 36 of Results*—~~Express the ~~results as described in~~ General Standard apply, with the ~~relevant subclauses~~ following addition:

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

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

All clause ~~51~~s and ~~report any damage or the accessibility~~ subclauses of ~~live parts.~~

~~26. *Vibration and Noise:*~~ *this section of the General Standard do not apply.*

~~26.1 *Noise Output*—If a capnometer is included~~

SECTION SEVEN—PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

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

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

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

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

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

An oxidant is present.

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

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

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

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

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

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

~~26.3 The A-weighted sound pressure level shall~~ patient. It is also recommended that the contents of AAMI HE-48 be ~~measured as follows:~~

~~26.3.1 *Measuring Instruments*~~ *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

~~—A precision sound level meter~~All clauses and subclauses of ~~Type 1,~~ this section of the General Standard apply, except as ~~specified in IEC Publication 651,~~ 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 ~~used. Measurements shall be made with~~ within ±12 % of the ~~A-weighted network in use and~~ test gas value or ±4 mm Hg whichever is greater, over the ~~"slow" meter characteristics selected. The sound level meter~~ full measurement range of the capnometer, corrected to one atmosphere (760 mm Hg).

Compliance shall be ~~calibrated~~ checked by the test given in ~~accordance~~ 51.5.4.

51.5.3 For capnometers with ~~the manufacturer's instructions.~~

~~26.3.2 *Test Environment*—Measurement~~ waveform display capabilities, noise shall be ~~made in a free field over a reflecting plane such~~ limited as ~~that specified in ISO 3744.~~ 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—~~Th~~Six standard deviations is ~~e~~equivalent to ±3.0 σ. This means that 99.73 % (about ~~399~~/400) of all ~~r~~yeadings occur within ±3.0 σ (=0.6 volume percent) from the mean reading. See rationale for details.

The ma~~y be~~nufacturer shall provide~~v~~ test methods and re~~s~~sults upon request.

51.5.4 *Test Metho~~m~~d:*

51.5.4.1 *Pri~~n~~cai~~p~~l~~l~~y~~e~~*—Carbon dioxide gas readings are determined at a ~~hard, flat surface outdoors, in~~ number of carbon dioxide gas levels spanning the carbon dioxide monitor measurement range after exposing the sampling site ten times to a ~~large room, or~~ cyclic pressure in ~~a smaller room~~ accordance with ~~sufficient sound absorptive materials on its walls and ceiling.~~

~~26.3.3 *Ambient Conditions*—At~~ Fig. 2.

51.5.4.2 *Test Gases*—Test gases shall be equal to or greater than 5 times more accurate (⅕ the ~~microphone positions,~~ error) than the ~~A-weighted sound pressure levels~~ required test unit accuracy. This is calculated as ⅕ (0.2) times the error tolerance of the ~~background noise shall be at least 10 dB below the sound pressure level to be measured.~~ essential requirement stated in Clause 51.5.2.

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

~~26.3.4 *Capnometer Installation*—The capnometer 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 capnometer 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 capnometer and at a radius of 1 m. At each setting, if the capnometer is intended for use~~ 7—Test gases with ~~a sampling tubing, 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. If the length of the sampling tubing does not allow this disposition, move the microphone toward the capnometer until the distance between it and the sampling tubing is 150 mm. If the manufacturer recommends or supplies attachments 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 attachments fitted. If any such attachment incorporates a port intended for connection to an endotracheal or tracheostomy tube, connect a tube of an internal diameter equal to our 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.~~

~~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.~~

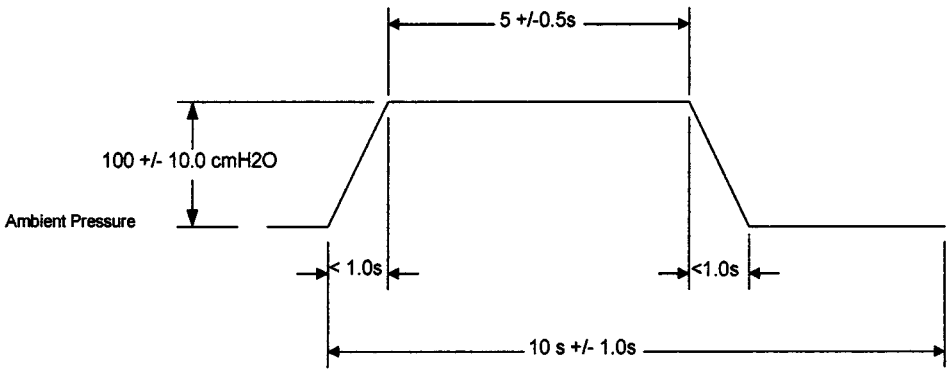


FIG. 2 Cyclic Pressure

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

43.4.2 *Procedure*—Place the capnometer in a room in which the air exchange is between 3 and 10 room volumes per hour. Set the oxygen flow through the capnometer so that it equals the maximum flows of oxygen and nitrous oxide under normal conditions. Switch off the mains supply, and measure the oxygen level in the enclosed compartment. Operate the capnometer 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. At least the following requirements shall be satisfied in normal and single fault condition:

(*1*) The surface temperature of components shall not exceed 300°C.

NOTE 8—If it can be shown that the component burns when subjected to overheating in 100 % oxygen but without propagating the fire, this component aforementioned accuracy may have a surface temperature that exceeds 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.

(*3*) Compliance shall be checked by the test given in 43.6.

43.6 Measure or calculate the voltages and currents in stead state conditions and measure the surface temperatures in normal condition and single fault condition.

44. *Overflow, Spillage, Leakage, Humidity, Ingress of Liquids, Cleaning, Sterilization and Disinfection*—The requirements given in Clause 44 of the General Standard apply, with the following additions:

44.8 *Condensation Effects*—The manufacturer shall disclose in the accompanying documents the effects of the test listed in 66.2.5 on the performance of the capnometer other than accuracy.

44.9 *Obstruction of the Sensing Area or Sampling Tubing:*

(*1*) The capnometer shall have a means of indicating obstruction of the sensing area or sampling tubing.

(*2*) Compliance shall be checked by the test given in 44.10.

44.10 *Test Method*—Totally obstruct the sensing area or sampling tubing at the sampling site, and verify that the requirements of 44.11 are met.

44.11 *Contamination of Breathing Systems*—It shall not be possible to reverse the direction of flow through the sampling tube in order to purge the capnometer.

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

46.1 Gas connections provided for calibration gases shall not be interchangeable with DISS or pin index systems, and cylinders shall be color-coded differently obtained from the colors used for medical gases.

50. *Accuracy of Operating Data*—Replace Clause 50 of the General Standard with the following:

50.1 *Measurement Accuracy:*

(*1*) The carbon dioxide reading shall be within ± 12 % of the actual test gas value manufacturers or ±4 mm Hg (0.53 kPa), whichever is greater, over the full range of the capnometer, corrected to one atmosphere (760 mm Hg).

(*2*) Compliance shall be checked by the test given in 50.2.

50.2 *Test Method:*

50.2.1 *Principle*—Carbon dioxide readings are determined at a number in-house production of carbon dioxide levels spanning the capnometer measurement range.

50.2.2 Test gases of an required test gas mixtures with accuracy of 0.03 % as determined verified by gravimetric other methods shall be used for these tests.

50.2.3 *Procedure*—The (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 gas mixtures as described in 50.2.4 and 50.2.5.

50.2.4 *Dry Gas Testing*—Conduct the tests using the mixtures and conditions gases given in Table 1.

50.2.5 *Saturated Gas Testing*—After 24 h of continuous operation with the capnometer connected to a simulated breathing system containing air fully saturated with water, at 37°C, and cycling at a frequency of 10 breaths/min between a pressure of ambient and 35 cm H_2O (3.5 kPa), perform an accuracy test using ambient temperature of 23 ± 2°C. For each numerically displayed carbon dioxide level, verify that the mixtures and conditions given in Table 2.

50.3 *Stability accuracy requirements of 51.5.2 are met.*

51.5.5 *Drift of Measurement Accuracy:*

(*1*) The

51.5.5.1 The capnometer shall meet the requirements specified in 50.1 51.5.2 for no less than 24 h when used in accordance with the accompanying documents.(2) Compliance shall be checked by the test given in 50.4.

50.4 *Test Method*—Repeat 51.5.6.

51.5.6 *Test Method:*

TABLE 1 DryGas Testing

ComposNitirogen	Carbon Dioxide, Range in Percent
Temperature	Humidity
Balance	0.0
Mixture No. 1	Carbon Dioxide:A 0 %,2.5,5.0, and10.0,balance nit
Balance	2.5,5.0, and10.0, balancenitrogen
23 ± 2°C	dry
Balance	5.0
Mixture No. 2	Carbon Dioxide: 0 %,2.5,5.0,and10.0,balance air
Balance	10.0, balance air

A Carbon dioxide shall be expressed at one atmosphere, 23°C, as dry gas.

TABLE 2 Gas TMixturesting F foltr Cowmbing Use ind Ga Sims Acculated Breacy Testhing System

Carbompos n Dition xide	RangeNin PercentTemperatoure	Humidity
Mixture No. 1Carbon Dioxide:A 0 %, 2.5, 5.0, and 10.0, balance nitrogen		
Mis Oxture No. 1	Carbon Dide A	Oxygen
37 ± 2°C	1balance	300 %
5.0	balance	30
Mixture No. 2	Carbon Dioxide: 0 %, 2.5, 5.0,and 10.0, balance air	37 ± 2°C100 %
5.0	balance	37 ± 2°C 160

A Carbolf n-dioxide shall be expt fore ussed at amb wieth nit pressours oxide, 37°C, sat uratsed w nith water vaporgen.

51.5.6.1 With the tests given capnometer set up, calibrated, and operated in 50.2 at accordance with the end 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.

501.5.7 *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 50.6 (both increase and decrease in concentration), and 51.5.8.

For diverting-type monitors, the manufacturer shall also disclose the gas diversion flow required to meet 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.

501.65.8 *Test Method:*

(*1*) The

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

Connect the carbon dioxide signal output of the capnometer to a suitable recording device with a resolution within 1 %, reproducibility within 1 %, and a time constant equal to or less than one-tenth of device.

With the expected rise time of the capnometer.

(*2*) Pass dry air at ambient temperature and at a flow of 10 L/min through the test apparatus and the capnometer with the capnometer switched to normal function. By means of the three-way tap, a dry calibrated gas at ambient temperature containing approximately 5 % (V/V) of carbon dioxide is passed through gas mixture from Table 1, cycle the apparatus valve(s) and record the rise time is calculated. time. Repeat the above procedure, switching from 5 % (V/V) carbon dioxide to air.

50.7 *Procedure*—Hold for this gas mixture 20 times and determine the ambient temperature of the average rise time.

51.5.9 *Combined Gas Accuracy Testing:*

51.5.9.1 The capnometer constant to within _2°C of a nominal value within the operating range specified shall be set up and calibrated in accordance with the accompanying documents. G and tested using thera test gases given in Table 2, at least four stable carbon dioxide readings an ambient temperature of 23 ± 2°C. For each numerically displayed anesthetic gas, verify that span the range accuracy requirements of the alarm system in approximately equal steps by varying the carbon 51.5.2 are met.

51.6 *Displays*—Carbon dioxide level delivered to the sensor, or by electrically stimulating the sensor, or by adjusting the calibration control.

50.8 *Displays*—Carbon dioxide (CO_2) level displays shall be marked continuously or on operator demand with kPa, V/V %, kilopascals, percent, or mm Hg. Units millimetres of mercury. If the units of measure shall can be marked changed by (adjacent to) the display, or operator from the user-selected default units of measure, the units of measure shall be displayed on demand. continuously.

NOTE 9—Displays should not 8—User-selected default units of measure may be obscured by the hand normally adjusting same as the control(s) associated with the display.

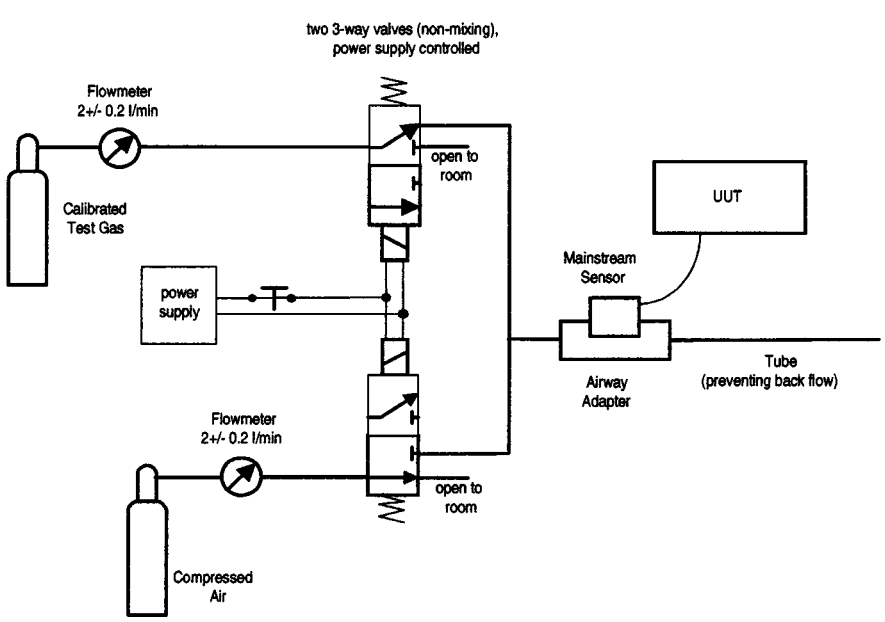
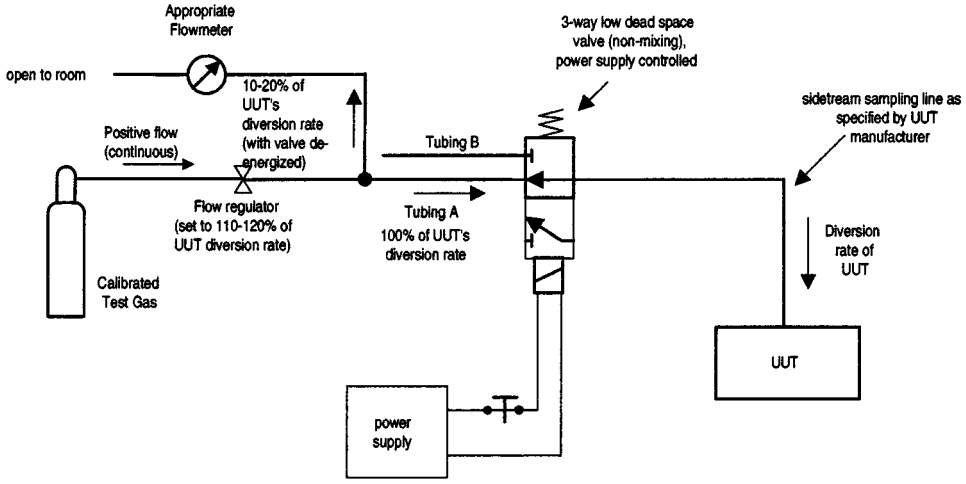


FIG. 3 Nondiverting Monitor—Rise Time Test Apparatus



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

51. *Protection Against Hazardous Output* —The requirements given in Clause 51 manufacturers' default units of the General Standard are replaced measure.

Compliance shall be checked by the following:

51.1 *Control Function inspection of markings and Position:*

(*1*) If 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.

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

NOTE 109—User-operable function checks, other than "power on" for test controls; such as battery condition or signal operation, should automatically 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 11—All other controls 10—The audible components of alarm signals should also include means be designed to prevent inadvertent changes from allow silencing until 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, capnometer is placed in use (that is, connected to the right, or in patient) to reduce nuisance alarm signals.

51.8.3 There shall be a clockwise direction visual indication that an audible alarm signal has been silenced. The visual indication shall increase remain until the control function. Movement downwards, to operator re-enables the left, or in an anti-clockwise direction 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 control function.

(*2*) Rotary gas flow controls displayed alarm limits are exempt changed by the operator from thie user-deqfault alarm limits, the changed alarm limits shall be displayed for at least 15 s. If alarm limits can be hidden, the alarm limits shall be displayed on operator demand.

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

NOTE 12—The separation between control knobs, switches, toggles, pinwheels, or push buttons should conform 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 recommendations given lower priority alarm signal.

51.8.9 If operator-adjustable change in ISO 7249 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 ISO 7250. 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 13—Controls and their associated markings should be visible or legible, or both, to a user having a visual acuity (corrected, if necessary) 12—Components of at least 1.0 when the user is located at least 1 m in front of the capnometer and the illuminance level is 215 lx. Markings should be identified clearly with their associated controls.

51.3 *Alarms:*

51.3.1 *Alarm Prioritization*—The alarm characteristics made of monitors specified in this specification shall be grouped in three categories: high priority, medium priority, and low priority (see Table 3).

51.3.1.1 The audible materials that are compatible with the gases with which those components of these alarms should be are designed to allow silencing until the capnometer is placed in use (that is, connected to the patient) in order to reduce nuisance alarms.

51.3.1.2 There shall be come into contact, thus minimizing health risks as a visual indication that an audible alarm has been silenced.

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

TABLE 3 AlTest Concentrations of Interm fering Gases or Vapors, % (V/V)

AlGas orm C Vategpory	OpLervel, % (V/V)	
Hator Response	Audible I4	
Halothane	4	
Endicators[A]	5	
Enflurane	5	
Indicator ColorB	Flashing Frequency (Hz)[C]	
Isoflurane	5	
High priority	immediate	5
Sevoflurane	immediate	5
not medium or low priority I	red5	
Desflurane	5	
Ethanol	1.4 to 2.8 Hz (F_2)	
Ethanol	specified by the manufacturer	
Medium priority	pro mpturer	
Acetone	specified by the manufacturer	
nothigh or low priority	ye manufacturer	
Methane	specified by the manufacturer	
Hellow	0.4 to 0.8 Hz (F_1)	
Helium	50	
Low priority	awareness	1
Tetrafluoroethane[A] (Freon 134a)	awareness	1
not highor medium priority	yellow	constant (on)
Dichlorofluromethane[A] (Freon 21)	yellow	constant (on)1

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

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 substance leached from the visual signals specified capnometer in 51.3.3 and 51.3.4.

51.3.2.2 There shall be a simultaneous audible indication of use.

56.12.1 If 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 capnometer has cleared.

51.3.3 *Medium Priority: Alarms*

51.3.3.1 There shall be a visual indication of additional modes, other than the medium priority alarm. It shall be different and distinguishable from standard operating mode, the visual signals specified in 51.3.2 and 51.3.4.

51.3.3.2 There current mode shall be a simultaneous audible indication of the medium priority alarm. indicated continuously. This audible indication shall be different legible.

NOTE 13—AAMI HE-48 *Human Factors Engineering Guidelines and distinguishable from Preferred Practices for 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 Design 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 There may be a simultaneous audible indication of the low priority alarm. This audible indication, if provided, shall be a low priority alarm. This audible indication shall be different and distinguishable from the audible signals specified in 51.3.2 and 51.3.3.

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

51.4 *Alarm Characteristics: Medical Devices*

51.4.1 The capnometer shall have a high carbon dioxide reading alarm contains information concerning implementation of these alternative modes.

56.12.2 Operator-adjustable controls used for both inspired and exhaled carbon dioxide.

51.4.2 The capnometer should have a low carbon dioxide reading alarm for exhaled carbon dioxide.

51.4.3 Alarm set points for both high and (if provided) low carbon dioxide reading alarms calibration shall be operator-adjustable.

51.4.4 When the capnometer is switched on, the high carbon dioxide reading alarms for carbon dioxide shall be include a medium priority alarm.

51.4.5 If a low carbon dioxide reading alarm is provided, it shall be a medium priority alarm.

51.4.6 If the capnometer has an operator-adjustable high carbon dioxide reading alarm priority control, it shall allow the operator means to change the alarm priority between medium and high priority only after the capnometer is switched on.

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

(*1*) Compliance shall be checked by inspection.

51.4.8 The difference between the alarm set point and the carbon dioxide reading when the alarm is activated shall not exceed 0.2 volumes percent (1.4 mm Hg at 760 mm Hg barometric pressure, BTPS) carbon dioxide.

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

51.4.9 Generate at least four stable carbon dioxide readings that span prevent unintentional changes from 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).

(*1*) For each carbon dioxide 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 carbon dioxide reading at which the alarm is activated. The difference between the alarm set point and the corresponding carbon dioxide reading shall not exceed 0.2 volumes percent.

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.

(*1*) 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, it shall require deliberate action on the part of the operator. The visual indication shall remain until the alarming condition no longer exists.

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

6. Additional intended position.

5. Additional Requirements Specifically Related to Capnometers

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

60.1 The Effects—The manufacturer shall disclose in the accompanying documents any adverse interference documents, known effects on carbon dioxide gas readings (if any) caused by the gases and vapors given at the nominal (±20 %) concentrations listed in Table 4.

60.2 Compliance 3 (see Clause 6.8.2). The manufacturer shall be tested as follows:

60.2.1 *Principle*—The accuracy of make available upon request the carbon dioxide reading test methods used to make such determination.

Compliance is determined in the presence checked by inspection of the interfering gases and vapors given in Table 4.

60.2.2 *Test Gases*—Test gases shall be dry pre-mixtures of 5 % carbon dioxide (nominal), balance nitrogen, and the interfering gas or vapor at the level given in Table 4. Carbon dioxide levels shall be known to within ±2 % (V/V) of the specified value used.

60.2.3 *Procedure*—Calibrate the capnometer according to the instructions for use, and then expose the sensor to the test gas for a continuous period of 2 h, ensuring that both the capnometer and the sensor are maintained in the same condition during the whole period. Repeat the procedure for each application mixture in Table 4.

60.2.4 *Expression of Results*—Correct the carbon dioxide readings for changes in barometric pressure, if the errors due to this effect equal or exceed ±0.1 % (V/V) carbon dioxide, and report the corrected readings. accompanying documents.

61. *Sustained Pressure:*

61.1 Capnometers shall either:

(*1*) Meet the requirements givenGas Leakage and Sampling Loss—The rate of leakage for a nondiverting capnometer in 50.3 both the ready-for-use and 50.7 following exposure to "OFF" configuration shall not be greater than 10 mL/min at a sustained positive pressure of 10 6 kPa (100 (60 cm H_2O).

Compliance shall be checked by using a negative pressure of 1.5 gage having an accuracy to within ±0.6 kPa (15 (6 cm H_2O) for 30 s; or

(*2*) Be marked with the warning "not for use in breathing systems," and a similar warning flow metering device having an accuracy within ±2 mL/min.

Tests shall ~~appear in the accompanying documents.~~

~~(3) Compliance with (1) shall~~ be ~~checked by the test given~~ performed in ~~61.2.~~

~~61.2 Compliance shall be tested as follows:~~

~~61.2.1 *Principle*—The accuracy of~~ both the ~~carbon dioxide reading~~ ready-for-use and OFF configuration. Assemble the ~~rise time are determined after exposure of~~ capnometer so that the ~~sensor to sustained pressure.~~

~~61.2.2 *Procedure*—Expose the~~ sampling site is installed in a dimensionally suitable port of a test apparatus containing an inlet fitting to which a ~~sustained positive~~ test gas and airflow metering device are attached. Connect the pressure ~~with respect~~ gage to ~~ambient~~ a third port of ~~10 ± 1~~ a test apparatus. Slowly adjust the flow to raise the pressure in the test apparatus to 6 kPa ~~(100 ± 10~~ (60 cm H_2O~~) and a sustained negative pressure with respect~~O). Determine the flow necessary to ~~ambient of 1.5 ± 0.2 kPa (15 ± 2 cm H_2O), in turn, for not~~ maintain this pressure. This leakage flow shall be less than ~~30 s each. Repeat this procedure four times, and then conduct the test for measurement accuracy as described in Clause 50.2 and the test for rise time as described in Clause 50.6.~~ 10 mL/min.

62. *Sample Gas ~~Leakage and Sampling Loss:~~*

~~62.1 The rate of leakage for a non-diverting capnometer shall not be greater than 20 mL/min under the test conditions.~~

~~NOTE 14—The rate at which a sampling capnometer withdraws gas from a breathing system (the gas diversion rate) should not exceed 1.15 times the value stated in the accompanying documents.~~

~~NOTE 15—This requirement ensures that when fitted to a breathing system, the capnometer's rate of leakage at a continuous pressure of 3.0 kPa (30 cm H_2O) does not exceed more than 20 mL/min.~~

~~(1) Compliance shall be checked by the test given in 62.2.~~

~~62.2 Compliance shall be tested as follows:~~

~~62.2.1 *Apparatus*—A pressure gage having~~ Exhaust Port—For all diverting capnometers, an ~~accuracy to within ±0.3 kPa and a flow metering device having an accuracy within ± 2 mL/min shall be used.~~

~~62.2.2 *Procedure*—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 gage to a third port of a test apparatus. Slowly adjust the flow to raise the pressure in the test apparatus to 3 kPa. Determine the flow necessary to maintain this pressure. This leakage flow shall be as specified in Clause 62.1.~~

~~62.3 The rate at which a sampling capnometer withdraws gas from a breathing system (the gas diversion rate) shall not exceed 1.15 times the value stated in the accompanying documents.~~

~~(1) Compliance shall be checked by the test given in 62.4.~~

~~62.4 *Method of Test:*~~

~~62.4.1 *Principle*—The rate at which a sampling capnometer withdraws gas from a simulated breathing system is measured.~~

~~62.4.2 *Test Gas*—Pressurized air at room temperature shall be used.~~

~~62.4.3 *Apparatus*—A pressure gage having an accuracy to within ±0.3 kPa, and a flow or volume measurement device having an accuracy to within ±2.5 % of the rate at which the capnometer withdraws gas from the breathing system as stated in the accompanying documents.~~

~~62.4.4 *Procedure*—Assemble the apparatus as described in 62.2.2 but using the flowmeter specified in 62.4.3. Adjust the pressurized air source to 3.0 kPa and monitor the flow reading for 1 min.~~

62.5 An exhaust port shall be provided to collect or route the ~~diverting~~ diverted gas from the ~~capnometer, and this exhaust~~ capnometer. This port shall be incompatible with the sample gas inlet port ~~of~~ on the capnometer~~.~~ and shall not be a Luer type (~~1~~see Clause 6.8.2 cc)~~–~~.

Compliance shall be checked by inspection.

63. ~~*Breathing System Connections*—If a~~Minimum Sampling Flow—A diverting capnometer ~~is intended~~ shall have a means to ~~be connected to~~ indicate when the ~~breathing system~~ flow through ~~a T-piece,~~ the ~~breathing system connection ports~~ sampling tube has fallen below the manufacturer's specified minimum (see Clause 6.8.2 cc).

Compliance is checked by gradual reduction of the ~~T-~~ 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 ~~a 15 or 22 mm, or both, conical connector~~ conducted with the capnometer operating in accordance with ~~Specification F 1054-88 (or ISO 5356/1:1987). The sampling gas and outlet ports~~ the accompanying documents.

64. *Contamination ~~of a diverting capnometer~~ Breathing Systems*—It shall not be ~~interchangeable with~~ possible to reverse the ~~breathing system connection port~~ direction of ~~a breathing system.~~

~~NOTE 16—Annexes A to M given in~~ flow through the ~~General Standard, together with Appendix X1~~ sampling tube in ~~this draft specification, apply.~~ a diverting capnometer.

Compliance is checked by inspection.

5. Keywords

5.1 capnometers; performance requirements; safety requirements

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X36.1 Capnometers*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. The test voltages data.

Rationale for Clause 43—Reports of 8 kV 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 discharges and 3 kV 100 % oxygen environments. The minimum ignition temperature may be critically dependent upon the concentration of the oxidant present. If ignition temperatures for contact discharges other materials or oxygen concentrations are required, these may be determined using the IEC 801-2:1991 network methods and procedures are adequate 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 conditions most potent form of energy in which capnometers are used. 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 interyface between sparking conductors or their surroundings so that sustained burning occurs but there is at present no documented evidence as to limit the a 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 accessible parts, since to allow 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 application requirements to minimize fire risk are based on limitation of charges 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 d 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. I Ultimately, electrical energy is reasonable only significant in respect of its ability to raiseq the temperature of ignitable materials and this in turn depends upon the particular configuration and the proximity of any person opening ignitable materials.

Under single-fault conditions in a typical electrical circuit the possible number of failure modes is very high. In this case, foull 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 exercise both common sense ensure that temperatures remain below the minimum air ignition temperature under normal conditions and seal compartments or add forcepd ventilation to ensure that the oxygen content d woes not exceed that of ambient airk under single-fault condition.

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

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

X*Rationale for Clause 50.1–.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 50 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 ±1.0 σ (standard deviation) from the mean
95.45	% of all the readings occur within ±2.0 σ from the mean
99.73	% of all the readings occur within ±3.0 σ from the mean
99.9937	% of all the readings occur within ±4.0 σ from the mean

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

The fact that the deviations of readings are easily quantifiable (by calculation of the standard deviation) then allows for simple methods to be used to establish limits of clinical acceptability. 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 ±3.0 σ (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.