



Designation: F 1456 – 01

## Standard Specification for Minimum Performance and Safety Requirements for Capnometers<sup>1</sup>

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 ( $\epsilon$ ) 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<sup>2</sup>

**F 1463** Specification for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care<sup>2</sup>

##### 2.3 IEC Standards:

**IEC 60079-4:1975** Electrical Apparatus for Explosive Gas Atmospheres—Part 4: Method of Test for Ignition Temperature<sup>3</sup>

**IEC 60601-1:1988** Safety of Medical Electrical Equipment—Part I: General Safety Requirements Including Amendment 1 and Amendment 2<sup>3</sup>

**IEC 60601-1-2:1992** Medical Electrical Equipment: Collateral Requirements Electromagnetic Compatibility<sup>3</sup>

##### 2.4 ISO Standards:

**ISO 4135:1995** Anaesthesiology—Vocabulary<sup>3</sup>

**ISO 7000-1989** Graphical Symbols for Use on Equipment—Index and Synopsis<sup>3</sup>

**ISO 7504:1984** Gas Analysis—Vocabulary<sup>3</sup>

##### 2.5 Other Standards:

**AAMI ES-1:1993** Safe Current Limits for Electromedical Apparatus<sup>4</sup>

<sup>1</sup> 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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<sup>2</sup> *Annual Book of ASTM Standards*, Vol 13.01.

<sup>3</sup> Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.

<sup>4</sup> Association for the Advancement of Medical Instrumentation, 1110 N. Globe Rd., Suite 220, Arlington, VA 22201-4795.

**AAMI HE-48:1993** Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices<sup>4</sup>

**CGA C-9-1982** Standard Color Markings of Compressed Gas Cylinders Intended for Medical Use<sup>5</sup>

**NFPA 53M** Fire Hazards in Oxygen-Enriched Atmospheres—1990 Edition<sup>6</sup>

### 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<sub>2</sub> concentration at the sampling site to the achievement of 10 % of the final CO<sub>2</sub> value in the capnometer (see Fig. 1).

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

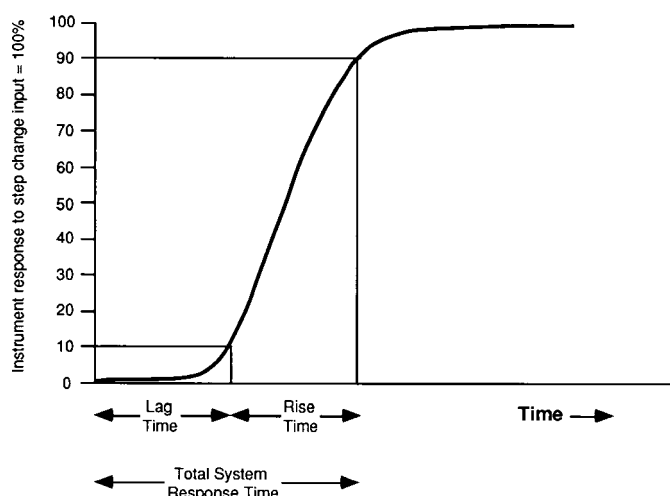


FIG. 1 Delay Time(Lag Time), Rise Time Total System Response Time

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<sub>2</sub> value in the capnometer when a step function change in CO<sub>2</sub> 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.

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.

<sup>5</sup> Available from Compressed Gas Association, 1235 Jefferson Davis Highway, Arlington, VA 22202.

<sup>6</sup> Available from National Fire Protection Association (NFPA), 470 Atlantic Ave., Boston, MA 02210.

#### 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 as a 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<sub>2</sub>O);
- (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.