Designation: F 1452 – 01

Standard Specification for Minimum Performance and Safety Requirements for Anesthetic Gas Monitors[1]

This standard is issued under the fixed designation F 1452; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

The measurement of the concentration of inhaled anesthetic gases is becoming common practice. This specification establishes minimum safety and performance requirements for anesthetic gas monitors that are achievable within the limits of existing technology.

The appendix contains rationale for some of the important requirements. It is included to provide additional insight for the reasoning that led to the requirements and recommendations that have been incorporated in this specification.

This specification uses IEC 60601-1:1988 including Amendment 1 and 2 (hereafter called the General Standard) for many of the general requirements for safety. Additional requirements specific to anesthetic gas monitors 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 anesthetic gas monitors used with adults, children, and neonates.

1.1.2 It does not apply to devices intended for use in laboratory research applications, nonhuman applications, or for calibration of anesthetic agent vaporizers.

1.1.3 This specification does not apply to anesthetic gas monitors intended for use with flammable anesthetic mixtures.

2. Referenced Documents

2.1 The following standards contain provisions, which through reference in this specification constitute provisions of this specification. At the time of publication of this specification, the editions indicated were current. All standards are subject to revision, and parties using this specification are encouraged to investigate the possibility of applying the most recent editions of the standards listed as follows.

2.2 *ASTM Standards:*

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

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

2.3 *IEC Standards:*[3]

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

IEC 60601-1:1988 Medical Electrical Equipment—Part 1: General Requirements for Safety. Including Amendment 1 and Amendment 2

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

2.4 *ISO Standards:*[3]

ISO 4135: 1995 Anaesthesiology—Vocabulary

ISO 7000-1989 Graphical Symbols for Use on Equipment—Index and Synopsis

ISO 7504:1984 Gas Analysis—Vocabulary

2.5 *Other Documents:*

NFPA 53M Fire Hazards in Oxygen-Enriched Atmospheres—1990 Edition[4]

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

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

[3] Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.

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

AAMI HE-48:1993 Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices[5]

AAMI ES-1:1993 Safe Current Limits for Electromedical Apparatus[5]

CGA C-9-1982 Standard Color Markings of Compressed Gas Cylinders Intended for Medical Use[6]

3. Terminology

3.1 Clause 2 of the General Standard applies together with ISO 4135 and the following additions:

3.1.1 *accuracy*—the quality that characterizes the ability of a device to give indications approximating to the true value of the quantity measured.

3.1.2 *alarm condition*—a condition that occurs when a variable that is being monitored by an alarm system equals or falls outside the set alarm limits.

3.1.2.1 *Discussion*—The monitored variable may be displayed or internal.

3.1.3 *alarm limit(s)*—value(s) that 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 *anesthetic gas level*—the concentration (volume percent) of anesthetic gas in a gaseous mixture.

3.1.7 *anesthetic gas monitor*—a device for the measurement of the concentration (volume percent) of anesthetic gas(es) in a gaseous mixture.

3.1.7.1 *Discussion*—The anesthetic gas monitor consists of all equipment, including accessories, sensor, and sampling tube (if a diverting type), specified by the manufacturer for the intended use of the anesthetic gas monitor.

3.1.8 *anesthetic gas reading*—the measured anesthetic gas level as indicated by the monitor display.

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

3.1.9 *anesthetic gas scavenging systems*—complete systems that collect and remove excess gases and vapors released from equipment used in administering anesthesia, or exhaled by the patient for the purpose of conveying these gases and vapors to an appropriate place of discharge.

3.1.10 *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.

3.1.11 *delay time (lag time)*—the time from a step function change in anesthetic gas concentration (volume percent) at the sampling site to the achievement of 10 % of the final anesthetic gas value in the monitor (see Fig. 1).

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

3.1.13 *diverting (sidestream) anesthetic gas monitor*—a monitor that transports a portion of ventilatory gases from the sampling site through a sampling tube to the sensor, which is remote from the sampling site.

3.1.14 *drift*—(from ISO 7504:1984) change of the anesthetic gas level display of a monitor for a given level of concentration over a stated period of time under reference conditions that remain constant.

3.1.15 *interference with measurement accuracy*—the difference between the anesthetic gas readings in the presence and absence of an interfering gas(es).

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

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

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

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

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

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

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

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

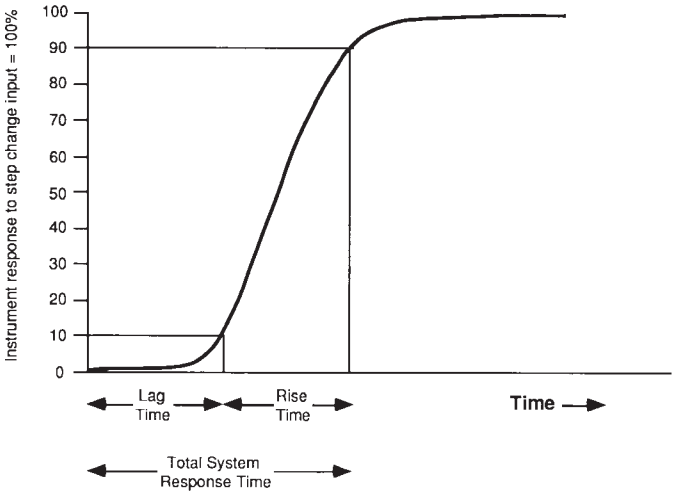

FIG. 1 Delay Time (Lag Time), Rise Time, and Total System Response

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

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

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

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

4. General Requirements and General Requirements for Tests

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

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

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

Under "clearly legible," the first sentence shall be modified to read as follows:

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 anesthetic gas monitor does not permit the complete marking as specified throughout this clause, at least the following shall be marked on the anesthetic gas monitor:

The name of the manufacturer,

A serial or lot or batch identifying number, and

Symbol 14 in Table D 1 of the General Standard.

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

6.1 bb) 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 anesthetic gas monitor.

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 anesthetic gas monitor in the correct operating condition, as well as a description of those adjustments and replacements that can be performed by the user.

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

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

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

6.1 ff) 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 anesthetic gas monitor 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.

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

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).

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

6.8.2 *Instructions for Use:*

6.8.2 aa) A description of the purpose and intended use of the anesthetic gas monitor.

6.8.2 bb) A description of the principles of operation of the anesthetic gas monitor.

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

(*1*) *Performance Specifications:*

TABLE 1 Colors for Color Coding of Anesthetic Agents

Anesthetic Agent	Color	Federal Standard 595a	Pantone Color	Munsell Color
Halothane	red	11105	200 C	5R4/14
Enflurane	orange	22510	151 C	2,5YR6/16
Isoflurane	purple	N/A[A]	245 C	7,5P4/12
Sevoflurane	yellow	N/A	108 C	6,25Y8,5/12
Desflurane	blue	N/A	3015 C	10B4/10

[A] N/A = Not available.