



Standard Specification for Minimum Performance and Safety Requirements for Components and Systems of Anesthesia Gas Machines¹

This standard is issued under the fixed designation F 1161; 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.

1. Scope

1.1 This specification covers the minimum performance and safety requirements to be used in the design of anesthesia gas machines for human use in order to enhance safety of the patient and operator. Intermittent-flow machines, which only deliver gas to the breathing system at varying rates in response to the patient's inspiratory efforts, draw-over vaporizers, and dental nitrous oxide-oxygen analgesia machines are not covered in this standard.

1.2 This standard supercedes ANSI Z79.8-1979. The sections in ANSI Z79.8-1979 covering Flowmeter-Controlled and Electrically-Heated Vaporizers have been omitted since they are no longer manufactured in the U.S.

1.3 This specification is based in part on actual user experience (see Appendix X1) and on relevant portions of MIL-STD-1472C (see Appendix X2).

1.4 Qualification test procedures to determine compliance with the requirements are also specified. Equivalent qualification test procedures to determine compliance with these requirements may be used. Correlation of paragraph numbering has been maintained between the subsections on requirements and the subsections containing the corresponding test procedures to enable the appropriate test to be easily located (for example, the test for the requirement stated in 5.1.1 is in 5.2.1, the test for the requirement stated in 7.1.4 is in 7.2.4, and so on).

1.5 The following safety hazards caveat pertains only to the test methods described in this specification: *This standard does not purport to address all of the safety problems, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

1.6 This specification is arranged as follows:

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TABLE 2 Alarms

Category	Priority	Auditory	Visual	Operator Response
I	High	Not II or III	Not II or III	Immediate
II	Medium	Not I or III	Not I or III	Prompt
III	Low	Not I or II	Not I or II	Awareness

Alarms
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2. Referenced Documents
2.1 ASTM Standards:

F 1054 Specification for Conical Fittings of 15 mm and 22 mm Sizes²

2.2 American National Standards:

ANSI Z79.2-1976 Tracheal Tube Connectors and Adapters³
 ANSI/CGA V-1-1977 (B57.1) Compressed Gas Cylinder Valve Outlet and Inlet Connections³
 ANSI/ASME B40.1-1985 Gauges—Pressure Indicating Dial Type—Elastic Element³
 ANSI/NFPA 99-1987 Health Care Facilities³
 ANSI S1.4-1983 Specifications for Sound Level Meters³
 ANSI Z79.10-1979 Requirements for O₂ Analyzers for Monitoring Patient Breathing—Mixtures³
 ANSI Z79.8-1979 Minimum Performance and Safety Requirements for Components and Systems of Continuous-Flow Anesthesia Machines for Human Use³

ANSI/UL 252-1984 Standard for Safety-Gas Pressure Regulators³

2.3 Compressed Gas Association Standards:

CGA C-9-1982 Standard Color Markings of Compressed Gas Cylinders Intended for Medical Use in the United States⁴

CGA V-5-1978 Diameter Index Safety System⁴

2.4 Military Standard:

MIL-STD-1472C Human Engineering Design Criteria for Military Systems, Equipment and Facilities, Notice 3, 17 March 1987⁵

2.5 IEC Standard:

IEC 601-1 Part 1: General Requirements for the Safety of Medical Electrical Equipment-1977³

NOTE 1—It is expected that additional related standards will be published (for example, Alarms, Capnometry). At that time the related sections of this document will be reconsidered.

3. Terminology
3.1 Definitions:

3.1.1 *common gas outlet*—that port through which the mixture dispensed from the anesthesia machine is delivered to the breathing system.

3.1.2 *DISS*—Diameter Index Safety System.⁶

⁴ Available from Compressed Gas Association, 1235 Jefferson Davis Highway, Arlington, VA 22202.

⁵ Available from Naval Publications and Forms Center, Code 3015, 5801 Tabor Avenue, Philadelphia, PA 19120.

⁶ See CGA V-5-1978, Diameter Index Safety System.

TABLE 1 Identifying Colors and Medical Gas Cylinder Capacities

Name	Chemical Symbol	Color Identification			Cylinder Fill Pressure at 21°C (70°F) ^A		Contents When Full ^A
		CGA Colors ^B	Federal Standard 595a Color Numbers ^C	Pantone Color Numbers ^D	kPa	lbf/in ²	(E Size Cyl.) Liters
Air		Yellow	23655	Yellow	13 100	1900	620
Carbon Dioxide	CO ₂	Gray	26492	428	5 800	838	1590
Carbon Dioxide-Oxygen Mixture	CO ₂ -O ₂	Gray-Green		428-363	13 100	1900	650
Helium	He	Brown		470	11 300	1600	490
Helium-Oxygen Mixture	He-O ₂	Brown-Green		470-363	13 100	1900	580
Nitrous Oxide	N ₂ O	Blue		292	5 100	745	1590
Nitrogen	N ₂	Black	37038 (Lusterless) 27038 (Semigloss)		13 100	1900	610
Nitrogen-Oxygen Mixture	N ₂ -O ₂	Black-Green		363	13 100	1900	620
Oxygen	O ₂	Green	14187	363	13 100	1900	650

^A Based on the CGA P-2 pamphlet's Draft 2, revised Sept. 29, 1986, values given are minimum for pressures indicated.

^B See CGA C-9—1982, Standard Color-Marking of Compressed Gas Cylinders Intended for Medical Use in the United States.

^C See Fed. Std. No. 595a, Colors, Vol I, Text and ½-by-inch Chips (for desk use). Published by Standardization Division, Federal Supply Service, General Services Administration, Washington, DC 20406.

^D See Pantone Color Specifier—Designers Edition of the Pantone Matching System. Published by Pantone Inc., 55 Knickerbocker Road, Moonachie, NJ 07074. Color numbers are listed for reference only. The hue and intensity of each color shall be adjusted for maximum background contrast to meet the intent of the CGA C-9—1982 Clause 4.6.