



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.*

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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

² Annual Book of ASTM Standards, Vol 13.01.

³ Available from American National Standards Institute, Department SD, 1430 Broadway, New York, NY 10018.

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

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

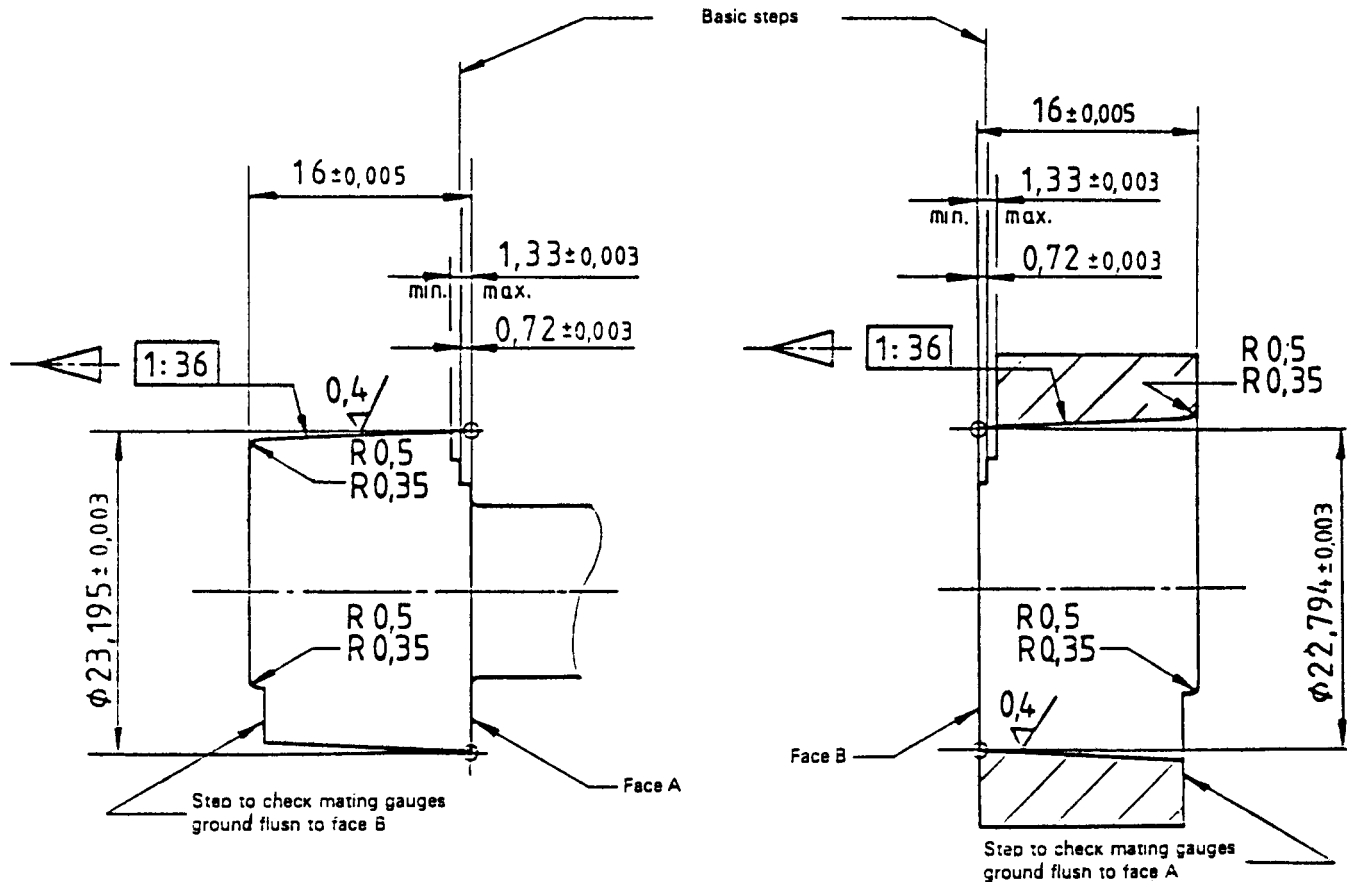
Name	Chemical Symbol	Color Identification			Cylinder Fill Pressure at 21°C (70°F) ^A		Contents When Full ^A
		CGA Colors ^B	Federal Standard 595a Color Numbers ^C	Pantone Color Numbers ^D	kPa	lb/in ²	(E Size Cyl.) Liters
Air		Yellow	23655	Yellow	13 100	1900	620
Carbon Dioxide	CO ₂	Gray	26492	428	5 800	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.



Notes:

- (1) Basic and mating gauge steps are optional.
- (2) Taper per unit of length on diameter: 0,0278 = 0,0002 units.
- (3) Dimensions in millimetres; surface roughness values in micrometres.

FIG. 1 23-mm Plug and Ring Gages

3.1.3 *enabling condition*—denotes a necessary, but not necessarily sufficient, condition to cause an action.

3.1.4 *flow-control system*—a device or assembly that controls and indicates the flow of gas.

3.1.5 *flowmeter*—a device that indicates the volume of gas passing through it in a unit of time.

3.1.6 *mixer (blender)*—a device for the precise mixing of O₂ and other gases, so that O₂ concentration may be regulated by the user.

3.1.7 *MTTF*—Mean Time to Failure is the mean, or average, length of time a component or system will operate before it experiences its first failure.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *kPa*—kilopascals (SI unit of pressure); 1 lbf/in² ≅ 6.9 kPa. All pressure values are gauge values unless otherwise stipulated.

3.2.2 *labeling*—denotes a requirement to furnish the specified information in the literature accompanying the device.

3.2.3 *lbf/in²*—pound-force per square inch (psi).

3.2.4 *marking*—denotes a requirement to furnish the specified information directly on a device.

3.2.5 *may*—denotes an optional feature.

3.2.6 *rtpd*—room temperature and pressure, dry gas; indicates measurements performed at 20°C (293.15°K) and 101.3

kPa (760 mm Hg) using dry gas.

3.2.7 *shall*—denotes a mandatory feature.

3.2.8 *should*—denotes a desirable but not mandatory feature.

4. General

4.1 *Requirements:*

4.1.1 The anesthesia machine shall comply with relevant standards or regulations for safety, explosion and fire hazards, electrical hazards, and with relevant standards for cylinders and pipeline fittings.

4.1.2 The design of casters and the weight distribution of components shall be such that the anesthesia machine conforms to the requirements for stability in Section Four IEC 601-1 (1977).

4.1.3 The faces of all scales and gauges shall be legible and all controls and indicators shall be visible at a distance of 1 meter (3.3 feet) and at a light level of 215 lux (20 footcandles) to an operator with 6-6 (20-20) vision (corrected), seated or standing in front of the anesthesia machine. The markings and calibrations should be readily identified with the controls, gauges, meters, or indicators with which they are associated. Flowmeters, gauges, controls, and other displays that need to be read most frequently should be grouped together.

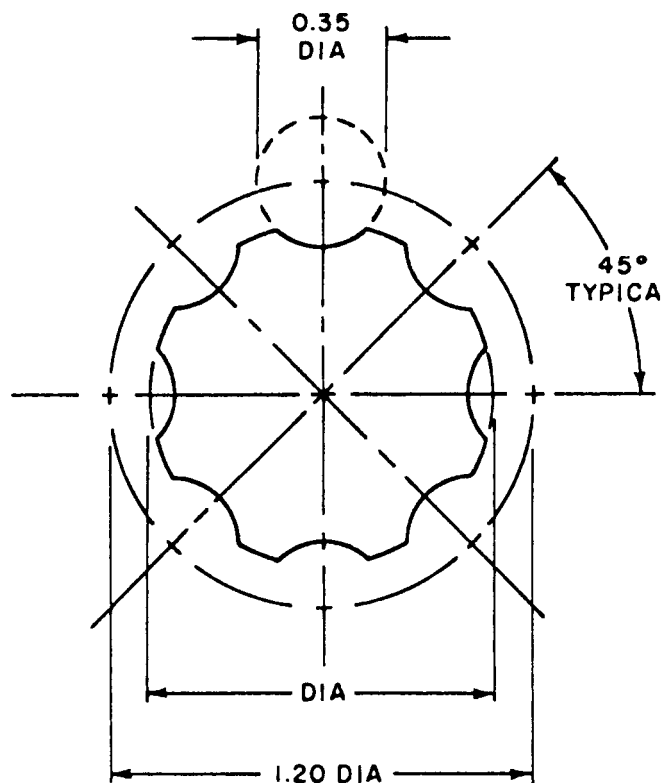


FIG. 2 Profile of Oxygen Flow-Control Knob

be placed as close as possible to the operator's field of vision when in the normal position for operating the anesthesia machine and observing the patient (see Appendix X2).

4.1.4 If components require periodic servicing, cleaning, sterilization or calibration by the users, the design should facilitate these operations, and the manufacturer shall recommend the intervals at which these services shall be performed.

4.1.5 Fragile components of the anesthesia machine, such as flowmeters, should be protected and secured to minimize accidental damage during normal use.

4.1.6 The anesthesia machine should be designed to facilitate cleaning. All exposed surfaces shall be able to withstand commonly used cleaning and disinfecting agents. The manufacturer shall recommend common methods for cleaning and disinfection.

4.1.7 The anesthesia machine should be free from sharp edges, and all accessible corners should be well-rounded or blunted.

4.1.8 An outline of operational checks to be carried out prior to use of the anesthesia machine shall be provided by the manufacturer and shall be located on the machine. See Fig. X1.1 and Fig. X1.2 for two general examples.

4.1.9 Anesthesia machines shall comply with applicable portions of IEC 601-1 and 62 D—Central Office N37 (Particular Requirements for the Safety of Anesthesia Machines).

4.1.10 All components of the anesthesia machine shall be made of materials that are compatible with the gases and agents with which those components are designed to come into contact (see Appendix X3).

4.2 Test Materials and Equipment:

4.2.1 *Materials Required*—The following materials will be

required when performing the tests described in this specification:

4.2.1.1 Filled cylinders of appropriate sizes, for yoke tests and circuit continuity tests.

4.2.1.2 Sources of gases supplied by standard hospital pipeline systems. These gases should be supplied through hoses recommended by the manufacturer of the anesthesia machine.

4.2.1.3 Appropriate anesthetic agents for testing vaporizers.

4.2.2 *Equipment Required*—The following equipment will be required when performing the tests described in this standard:

4.2.2.1 *Flowmeters*—(a) Non-pressure-compensated flowmeter with inlet tubing to fit yoke nipple. The range of sensitivity should be suitable for measuring gas flowrate up to 200 mL/min rtpd; and (b) Non-pressure compensated flowmeter for attachment to the common gas outlet of the anesthesia machine. Calibration and sensitivity should cover a nominal flowrate from 0 to 100 L/min of oxygen. It is to be used to measure oxygen-flush flowrate.

4.2.2.2 *Flowmeter Test Kit*—A precision flowmeter, non-pressure-compensated, calibrated for specific gas services to the accuracy stated by the manufacturer, to verify the performance of anesthesia machine flowmeters. Range and conditions of calibration are to be as stated by the manufacturer.

4.2.2.3 *Pressure Gauges*:

(A) Gauge calibrated over a range of 0 to 27 600 kPa (0 to 4000 lbf/in.²) or equivalent units, with appropriate connections to verify the performance of cylinder pressure gauges. The accuracy shall be as specified in ANSI/ASME B40.1-1985.

(B) Gauge calibrated over a range of 0 to 1035 kPa (0 to 150 lbf/in.²) or equivalent units, with appropriate connection to verify the performance of the pipeline pressure gauges. The accuracy shall be as specified in ANSI B40.1.

(C) Gauge to monitor pressures at a nominal value of 100 cm H₂O above ambient pressure. The gauge inlet should be provided with appropriate connections to fit the filler inlet of the vaporizer to be tested. This pressure gauge shall be used to monitor the internal pressure of the vaporizer.

(D) Gauge to monitor pressure at a nominal value of 30 cm H₂O above ambient. Gauge inlet to be equipped with appropriate connection to fit the common gas outlet.

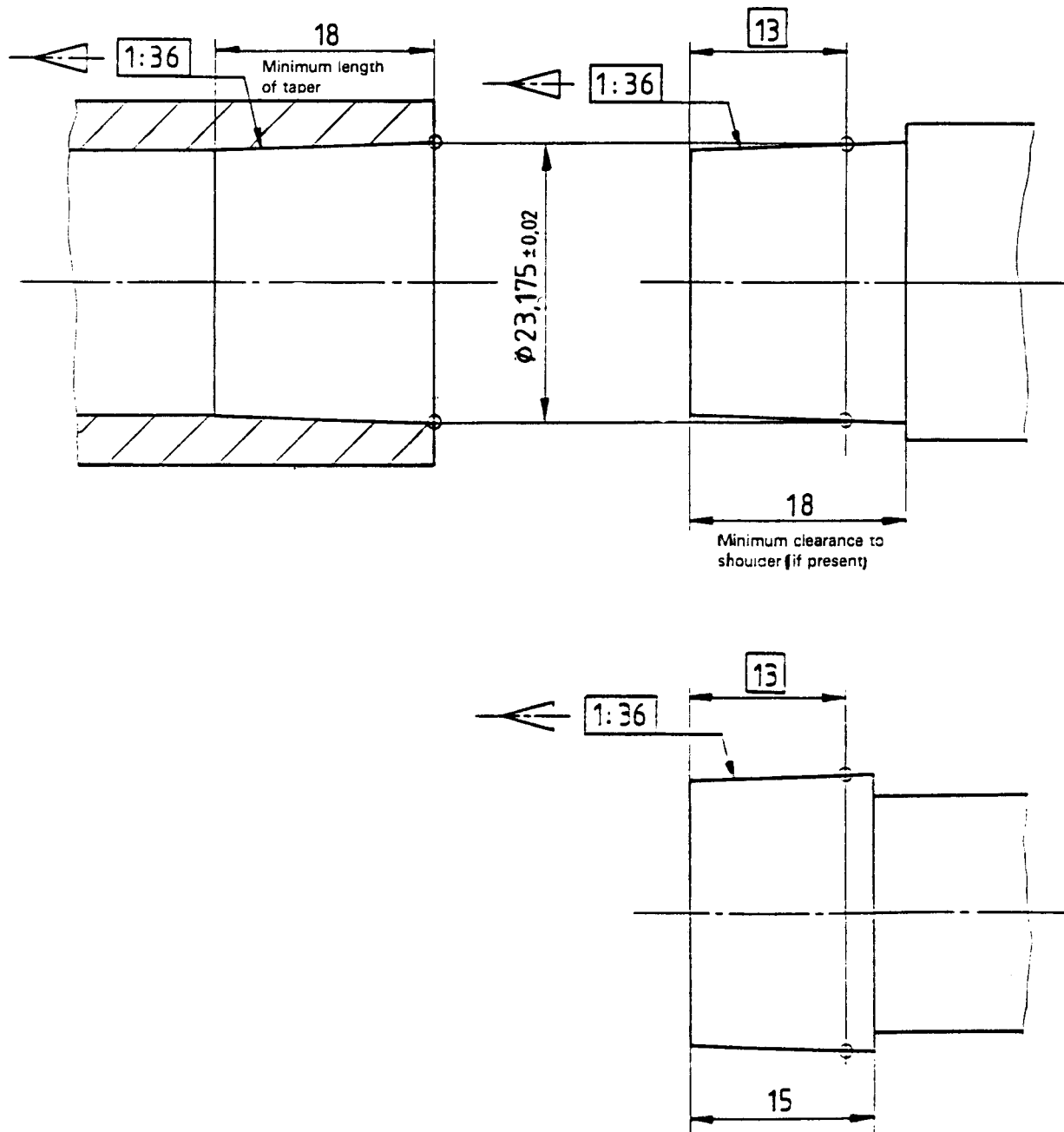
4.2.2.4 *Stop Watch or Electric Timer*—Capable of establishing time periods in minutes to an accuracy of ± 0.5 s.

4.2.2.5 *Refractometer, Gas Chromatograph, Mass Spectrometer, Interferometer, and the Like*—These are examples of the type of instruments necessary to verify the performance of anesthetic vaporizers. It is intended that they comply with the accuracy provisions of 4.2.4 with respect to both calibration and operation. The actual test set-up shall be in accordance with the manufacturer's recommendations.

4.2.2.6 *Gages*:

(A) *Twenty-three mm Plug and Ring Gages*—These gages, which are used to verify the inlet and outlet fittings utilized on vaporizers (see 12.1.5) that are not intended for use in the breathing circuit shall conform to Fig. 1.

(B) *Fifteen-mm and twenty-two-mm Plug and Ring Gages*—These gages shall conform to Specification 12.1.5.



Notes:

- (1) Maximum radius on the entrance to the female connector and on the leading edge of the male cone should not exceed 0.5 mm.
- (2) Dimensions in millimetres.

FIG. 3 Rigid Conical Fittings of 23-mm Size

4.2.2.7 *Sound Level Indicator*—This indicator shall be in accordance with ANSI S1.4-1983.

4.2.2.8 *Precision Flow-Control Valve*—This valve shall be suitable for setting a 10 mL/min flowrate and furnished with a male oxygen DISS inlet connection and standard 15-mm male and female outlet connections.

4.2.3 *Test Conditions*—Unless otherwise specified in this standard, all measurements shall be corrected to standard operating conditions, which are: (1) temperature, 20°C (293.15°K), (2) pressure, 101.3 kPa (760 mm Hg), and (3) humidity, 0 % absolute. Actual conditions at the time of the test

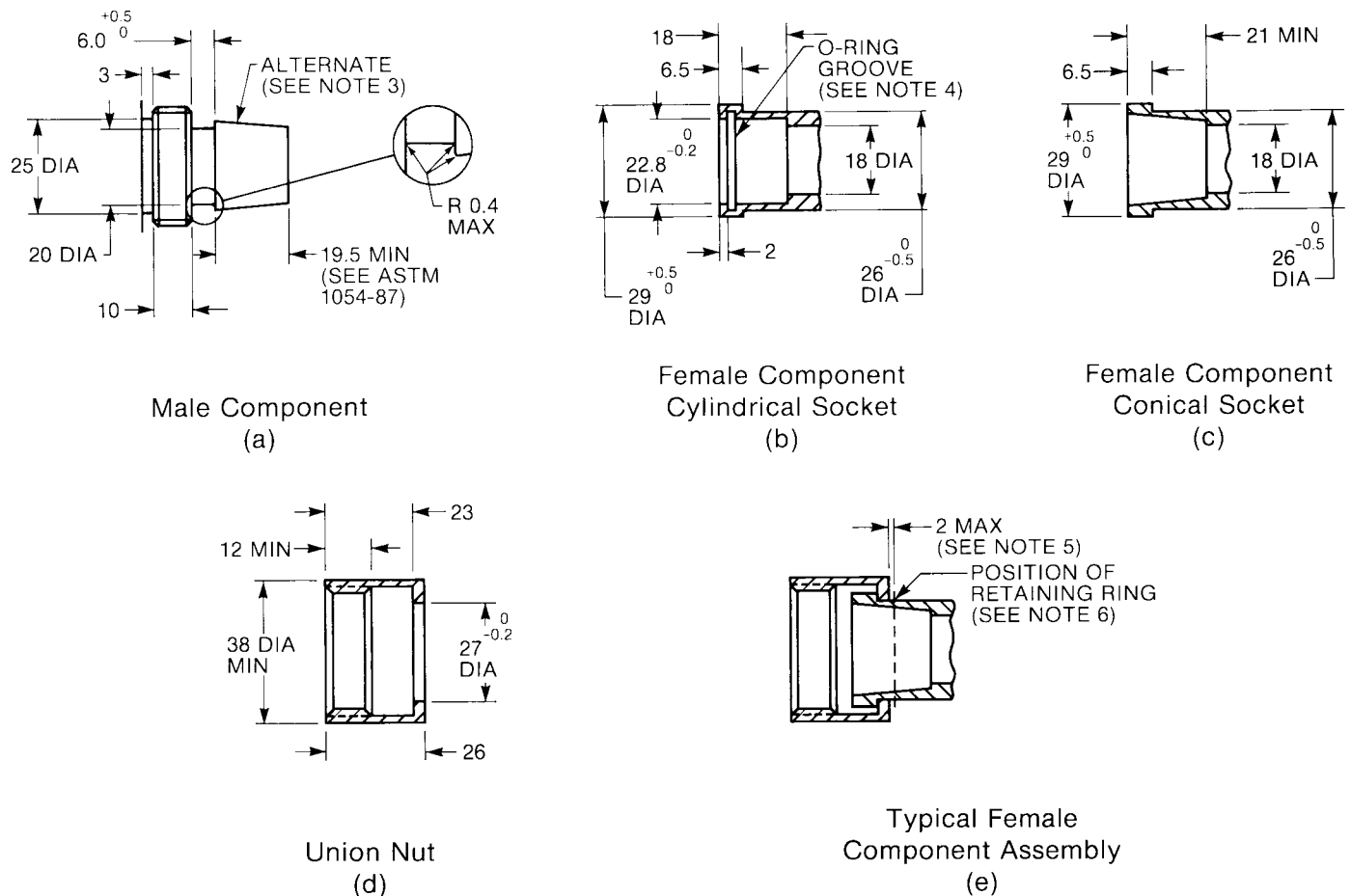
shall be measured and reported.

4.2.4 *Accuracy of Test Apparatus*—All instruments and test equipment used in conducting the tests specified in this standard shall be such that the limits of error of the test equipment shall not exceed one-third the limits of tolerance of the variable to be measured, except where the tolerances for the test apparatus are specified in this standard.

5. Hanger Yokes

5.1 Requirements:

5.1.1 Each anesthesia machine shall be provided with



Notes:

- (1) All dimensions are shown in millimetres.
- (2) All screw threads are M33 X2 (as given in ISO 262-1973, General Purpose Metric Screw Threads—Selected Sizes for Screws, Bolts, and Nuts). Conical fittings shown are 22-mm. See Specification F 1054-87.
- (3) At the common gas outlet this may be a coaxial 22-mm male/15-mm female conical fitting.
- (4) Recommended size for O-ring groove is 25 mm, + 2.0 mm, - 0.0 mm diameter by 2.0 mm wide to suit O-ring of recommended size 22.1 mm inner diameter by 1.6-mm section.
- (5) Free axial movement of the union nut is 2.0 mm, maximum.
- (6) The union nut may be retained by a retaining ring.
- (7) All corner radii should not exceed 0.5 mm unless otherwise specified.

FIG. 4 Components for Screw-Threaded Weight-Bearing Fittings

hanger yokes accommodating medical gas cylinders having post-type valves. All anesthesia machines shall be provided with at least one hanger yoke for oxygen.

5.1.2 Each hanger yoke or group of interconnected yokes shall be provided with a suitable cylinder pressure gauge or other quantitative contents indicator. Each hanger yoke or group of interconnected yokes shall also be provided with a filter (100 μ m maximum) for the entrapment of particulate matter prior to delivery of the gas to a pressure regulator or a flow-control valve.

5.1.3 Each hanger yoke shall incorporate a clamping device with a 100° to 120° conical point of at least 7-mm (0.28-in.) diameter, by means of which the valve of a cylinder can be forced against the seal of the yoke, and a nipple of 6.35-mm (0.25-in.) nominal external diameter, which provides a gas conduit. The point and the nipple shall engage appropriate details on the cylinder valve, and a gasket shall be centered by the nipple. Each hanger yoke shall be provided with a pin index

safety system in order to prevent the connection of a cylinder of one gas to a hanger yoke intended for another. The pin index system and all other yoke details shall conform to ANSI/CGA V-1-1977.

5.1.4 Each hanger yoke should be fitted with a mechanism to prevent tightening of the clamping device until pins of the pin index safety system and the nipple are correctly engaged with appropriate recesses on the cylinder valve.

5.1.5 If two or more interconnected hanger yokes are provided for the accommodation of cylinders of the same gas on the anesthesia machine, a means shall be provided to limit to a rate of 200 mL/min the leakage from an open cylinder in one yoke at a pressure up to 15 180 kPa (2200 lbf/in²) through another yoke to an empty open cylinder or to atmosphere.

5.1.6 Each hanger yoke assembly shall be permanently identified with the name or chemical symbol of the gas it accommodates and should be identified by a label.

to the gas in the applicable color identification standard (see Table 1).

5.2 Test Procedures:

5.2.1 Verify by visual inspection, compliance with 5.1.1 and 5.1.2, and 5.1.6.

5.2.2 (5.1.3) With appropriate measuring instruments, confirm the configuration and size of the clamping device and the nipple described in 5.1.3. Then using a cylinder seal gasket install a cylinder of the appropriate gas (with a post-type valve installed in the cylinder) in each yoke to confirm the proper location of the index pins and the center conduit nipple of the yoke and to confirm noninterference between the cylinder as installed and any part of the anesthesia machine or its accessories.

5.2.3 (5.1.4) No test is required for 5.1.4.

5.2.4 (5.1.5) Verify that anesthesia machines with interconnected yokes comply with 5.1.5 by pressurizing each circuit from a yoke inlet with the appropriate gas at varying pressures from 1380 kPa (200 lbf/in.²) to the maximum available for that gas and measuring the leak from the other yoke(s) with the flowmeter described in 4.2.2.1(a).

5.2.5 For the test procedure for 5.1.6, see 5.2.1.

6. Pressure Gauges (Pressure Indicators)

6.1 *Requirements*—These requirements pertain to analog pressure gauges having a maximum pressure indication of 345 to 27 600 kPa (50 to 4000 lbf/in.²). Analog pressure gauges, definitions, and performance shall comply with ANSI B40.1.

NOTE 2—Pressure gauges cannot accurately indicate the quantitative contents of cylinders containing liquefied gas.

6.1.1 Each gas supplied from a cylinder shall be monitored by a cylinder pressure gauge or pressure indicator.

6.1.2 If more than one cylinder hanger yoke is supplied for a gas, one gauge may be provided for each yoke, or one gauge may be provided for the group of yokes. In the latter case, it shall be possible to determine the pressures in the separate cylinders.

6.1.3 Anesthesia machines shall be provided with gauges to indicate pressures of each gas supplied by a pipeline.

6.1.4 Analog gauges shall comply with Accuracy Grade B as specified in ANSI B40.1.

6.1.5 All cylinder and pipeline pressure gauges of a circular, analog type shall be mounted so that the lowest pressure indication is at the same position, between 6 and 9 on the clock-face, of the gauges.

6.1.6 The indicating end of the pointer shall be immediately apparent and shall contrast with the background. The tail end of the pointer shall be shorter than the indicating end, and should either blend with the background or be masked from the user's view.

6.1.7 Analog gauges shall have a scale length of not less than 50 mm (2 in.) and, if circular, shall be at least 38 mm (1.5 in.) in diameter. The gauge or its surroundings shall be clearly and permanently marked with the name or chemical symbol of the gas it monitors and should be identified by the color assigned to that gas in the applicable color identification standard (see Table 1).

6.1.8 Units of calibration (units of measure) shall be kilo-

pascals (according to ANSI B40.1), and shall be marked unambiguously on the dial. The dials also may be calibrated in pound-force per square inch (psi).

6.1.9 The gauge shall be designed and constructed in such a manner that in the event of pressure-sensing-element failure, no parts shall be expelled free of the gauge enclosure when a gas pressure equal to the maximum pressure indicated on the dial is applied.

6.1.10 The gauge may be furnished with restrictors in the inlet pressure connection, and the gauge case may have a venting means to prevent internal pressure buildup, in accordance with ANSI B40.1. If employed, vent covers not secured to the gauge case shall be designed to open at a suitable low pressure and shall be of a resilient material that will not cause bodily injury.

6.1.11 All gauges used on anesthesia machine shall comply with the Cleanliness Level IV or higher, as outlined for oxygen gauges in ANSI B40.1.

6.2 Test Procedures:

6.2.1 Verify by visual inspection that the full-scale markings on the dials equal or exceed the minimum full-scale gauge pressures given in Table 1 and that operating pressure is also marked.

6.2.2 Verify compliance with 6.1.2 by visual inspection and by manipulation of the valves.

6.2.3 Pressurize a yoke of each system having a hospital pipeline pressure gauge and note the pressure indication on its cylinder pressure gauge. Verify that the hospital pipeline pressure gauge shows zero pressure. Now pressurize the hospital pipeline inlet connections and verify that hospital pipeline pressure gauges indicate the pressure in the hose. Verify by visual inspection that the full-scale marking on the pipeline supply gauges equals or exceeds 520 kPa (75 psi).

6.2.4 Verify that the accuracy of the gauges complies with ANSI B40.1 using equivalent production gauges. When a cylinder of known charge is installed and cylinder pressure is applied to the gauge, the gauge shall indicate the charge pressure within the stated tolerance. With zero pressure applied, the gauge pointer shall return to the lowest indicated pressure or below.

6.2.5 Verify by visual inspection the position of the lowest pressure indication of all gauges to confirm compliance with 6.1.5.

6.2.6 Verify by visual inspection that the pointers comply with 6.1.6.

6.2.7 Using a ruler, check that the gauge scale lengths or diameters comply with 6.1.7. Verify that the markings and colors, if used, comply with Table 1.

6.2.8 Verify by visual inspection that the units of calibration comply with 6.1.8.

6.2.9 Evidence of compliance with 6.1.9 shall be provided by the manufacturer of the anesthesia machine upon request.

6.2.10 Verify by visual inspection that the gauge case venting described in 6.1.10, if employed is in accordance with ANSI B40.1.

6.2.11 Verify by visual inspection that the gauges on the anesthesia machine comply with 6.1.11.

7. Pressure Regulators

7.1 Requirements:

7.1.1 The anesthesia machine shall be equipped with an automatic pressure-reducing regulator system for each gas supplied to the machine at a pressure in excess of 690 kPa (100 lbf/in²) from a source at 25°C (77°F). Each system may consist of one automatic pressure-reducing regulator or of two or more automatic pressure-reducing regulators in series.

7.1.2 The regulators shall be so adjusted that the anesthesia machine uses only the gas supply from the pipeline when the machine pipeline inlet pressure gauge reads 345 kPa (50 psi) or greater. An acceptable forward flow through the regulator shall be 10 mL/min or less when the outlet pressure at the regulator is 345 kPa (50 lbf/in²).

7.1.3 An O₂ flow of 2 L/min shall be restored to 2 ± 0.1 L/min within a period of 2 s after each operation of the oxygen flush valve.

7.1.4 To ensure the safety of the anesthesia machine and adjacent structures and personnel, the single regulator of a system, or the first of a series of regulators in the system, shall meet either of the following requirements:

7.1.4.1 The regulator shall be equipped with a relief valve that opens at not more than four times the normal delivery pressure of that regulator and at not more than two-thirds of the minimum burst pressure of the diaphragm. The relief valve shall also be capable of venting the regulator at a maximum relief pressure not exceeding the minimum burst pressure of the diaphragm when a pressure 50 % greater than the normal supply pressure of the corresponding gas is applied.

7.1.4.2 The regulator shall be designed to ensure rupture of its diaphragm, without hazard to its environment due to flying fragments, at a pressure not greater than 2760 kPa (400 lbf/in²). The diaphragm shall not rupture at pressures less than 1380 kPa (200 lbf/in²).

7.2 Test Procedures:

7.2.1 Visually inspect the circuitry of the anesthesia machine to confirm that each gas circuit, where the inlet pressure may normally exceed 690 kPa (100 lbf/in²), contains one or more pressure regulators.

7.2.2 Perform the following test to confirm that the pressure regulator complies with 7.1.2 (These tests must be performed first with oxygen. After completing the test with oxygen, the oxygen supply must be left connected and O₂ lines pressurized to 345 ± 10 kPa ($50 \pm$ lbf/in²) before proceeding with the tests for other gases):

7.2.2.1 Close all flow control valves and flush valves and shut off all other gas-consuming devices;

7.2.2.2 Connect a compressed gas supply at a pressure of at least 90 % of the cylinder filling pressure (see Table 1) to one cylinder inlet connection; seal all other cylinder and pipeline inlet connectors for the gas.

7.2.2.3 Verify that there is no leakage by opening the cylinder valve for a few seconds and then reclosing; adjust connections until the cylinder pressure gauge reading does not fall discernibly within 1 min after valve closing.

7.2.2.4 Open the cylinder valve and open the flow control valve to obtain a flowrate of 1 ± 0.05 L/min; record the cylinder pressure, P_1 .

7.2.2.5 Close the cylinder valve and measure the time t_1 (in seconds) required for the cylinder pressure to fall to a value P_2 , which is between 10 and 20 % of P_1 .

7.2.2.6 Connect the pipeline inlet of the anesthetic machine to a supply of gas at 345×10 kPa and reset the flowrate to 1 ± 0.05 L/min.

7.2.2.7 Open the cylinder valve and record the cylinder pressure, P_3 .

7.2.2.8 Close the cylinder valve and record the time t_2 (in seconds) required for the cylinder pressure to decrease to a value P_4 , which is 75 to 84 % of P_3 .

7.2.2.9 Compute the forward flow, Q , in mL/min according to the following:

$$Q = 16.67 \times [(P_3 - P_4)/(P_1 - P_2)] \times (t_1/t_2) \quad (1)$$

This shall not exceed 10 mL/min.

NOTE 3—A derivation of this formula is given in Appendix X4.

7.2.3 Using an indicated oxygen flow of 2 L/min, operate the flush valve for ten cycles of 10-s duration, with a pause of 5 s between flushes. Check that the flow is restored to 2 ± 0.1 L/min within 2 s after each flush.

7.2.4 The regulator shall meet the tests specified in ANSI/UL 252-1984.

8. Gas Machine Piping

8.1 Requirements:

8.1.1 The gas machine piping comprises the piping connecting the high-pressure gas supply to the pressure regulators and the flow control valves (or gas-mixing device), as well as the piping connecting the flowmeters and vaporizers (if fitted) to the common gas outlet. This gas piping system shall withstand four times the intended service pressure without rupture.

8.1.2 Joints and unions in the system shall not loosen in normal use. The maximum permissible leakage on each gas service, between the cylinders or the pipeline inlet and the flow-control valves, shall be 10 mL/min at normal operating pressure. (Venting of air or oxygen from fluidic or pneumatic components shall not be covered by this requirement.) The maximum permissible leakage rate on all gas services between the flow-control valves and the common gas outlet shall be 30 mL/min at a pressure of 30 cm H₂O, with the vaporizers (fitted to the machine by the manufacturer) in both the ON and OFF position.

8.1.3 The manufacturer shall include in the maintenance manual instructions for testing for correct assembly of each gas supply system, including any vaporizers fitted to the machine.

8.1.4 Except where the connectors of gas piping are noninterchangeable, the gas content of the anesthesia machine piping shall be readily identifiable by appropriate marking at each junction or where the piping joins a component, for example, a valve. The name, chemical symbol, or appropriate color code shall be used at each junction.

8.2 Test Procedures:

8.2.1 Perform the following test to ensure that the gas piping system complies with 8.1.1:

8.2.1.1 Pressurize an equivalent production piping system with four times the intended service pressure from the hanger yoke(s).

8.2.1.2 Pressurize the low pressure system from the pipeline

inlet to four times the intended service pressure.

8.2.1.3 Pressurize between the flow-control valves and the common gas outlet to 35 kPa (5 lbf/in²), including all accessories commonly installed on the machine.

8.2.1.4 No rupture of the piping shall occur under these conditions.

8.2.2 Circuit leak tests shall be performed to ensure that the anesthesia machine piping complies with 8.1.2. First inspect the circuitry to confirm that joints and unions are tightened sufficiently to prevent in-service loosening. Turn off all vaporizers fitted to the machine by the manufacturer and test the assembly for leaks according to the procedures described in 8.2.2.1 through 8.2.2.3. These tests shall be repeated with each vaporizer turned on, one at a time.

8.2.2.1 High Pressure Leak Test:

- (1) Install cylinders in all yokes.
- (2) Shut off gas outflow from the anesthesia machine.
- (3) Open all cylinder post-type valves and record the readings of the cylinder pressure gauges.
- (4) Close cylinder post-type valves, remove the cylinders, and quickly insert yoke plugs.
- (5) Monitor the pressure gauges for 5 min, record the change in pressure, and apply Boyle's law to the pressure drop. The leakage rate shall not exceed 10 mL/min.

8.2.2.2 Low Pressure Leak Test:

- (1) Connect a 0 to 30 mL flowmeter to the common gas outlet and set the flow of the anesthesia machine to 30 mL/min.
- (2) Disconnect the flowmeter and replace it with a manometer that is calibrated for monitoring pressure at a nominal value of 30 cm H₂O.
- (3) If the reading on the manometer reaches or exceeds 30 cm H₂O, the leakage rate is acceptable.

8.2.2.3 If due to the design of the anesthesia machine the manufacturer cannot perform the test described in 8.2.2.2, the manufacturer shall state in the labeling how to verify the requirements of 8.1.2.

8.2.3 Verify the correct assembly of the gas supply systems and of any vaporizers by means of the procedures provided in the maintenance manual.

8.2.4 Verify by visual inspection that the gas content of the piping is identifiable, in compliance with 8.1.4.

9. Flow-Control Systems

9.1 *Requirements*—A flow-control system for each gas shall be provided. Where a mixing device is used in addition to, or instead of, independent control of flow of different gases, there shall be an indication of the gases controlled, the concentration of oxygen in the mixture, and the total flow (or delivered minute volume). Only one flow adjustment control for each gas delivered to the common gas outlet shall be provided.

9.1.1 Each flow-control system shall maintain any set rate of the allowable rates of flow within $\pm 10\%$ of the setting or ± 10 mL/min, whichever is greater, whenever the supply pressures (pipeline or cylinder) and pressures at the common gas outlet vary within the normal limits specified by the manufacturer.

9.1.2 Any device of a flow-control system which is intended to shut-off the flow of a gas shall permit the appropriate number of operational cycles as stated by the manufacturer

before a leakage through the device exceeds 5 mL/min at 345 kPa (50 lbf/in²) supply pressure.

9.1.3 For a rotary style flow adjustment control, a counter-clockwise rotation shall cause an increase in flow and conversely, a clockwise rotation shall cause a decrease in flow. The rotation required for adjustment through the upper 90 % of flowrate values shall be at least 90°.

9.1.4 Each flow adjustment control shall be adjacent to or identifiable with its associated flowmeter or indicator. The flow adjustment control or its surroundings shall be marked with the name or chemical formula of the gas or gases it controls, and may be identified by the color assigned to that gas in the applicable color identification standard (see Table 1).

9.1.5 For rotary style flow adjustment controls, the oxygen knob shall have the physically distinguishable profile in accordance with Fig. 2. All other flow adjustment control knobs shall be round. The oxygen knob may project beyond the knobs controlling other gases when grouped. Its diameter shall not be less than the diameter of the knobs controlling other gases. The surface finish serrations for these other knobs shall have a depth not exceeding 0.5 mm (0.02 in.). Spacing between the knobs should not be less than 25 mm (1 in.) to ensure adequate finger space.

9.1.6 Flow adjustment controls should be so designed as to minimize their unintentional change from a preset position.

9.1.7 Flow adjustment controls shall be visible at a light level of 215 lux (20 footcandles) to an operator with 6-6 (20-20) vision (corrected) seated or standing 1 m (3.3 ft) in front of the anesthesia machine.

9.1.8 Where a device of the flow control system requires a direct rotational motion by the operator for flowrate adjustment, then the device shall be so designed that either continuation of rotation will not cause "disassembly" of the device, or rotation is prevented prior to the point where "disassembly" would occur, or that the rotation required to reach the point of "disassembly" is at least five full turns or double the number required to effect adjustment over the upper 90 % of the flow span, whichever is greater.

9.2 Test Procedure:

9.2.1 Attach a flowmeter test kit to the common gas outlet of the anesthesia machine or follow the manufacturer's instruction for flowrate verification. Select any flowrate of the available flowrates for a specific gas. Vary the supply pressures and the outlet pressures to the extremes of their normal limits to determine compliance with 9.1.1.

9.2.2 Cycle a statistically significant sample of devices to achieve the desired MTTF (Mean Time To Failure) goal with a confidence of 90 %. Measure the leakage by volume displacement to determine compliance with 9.1.2.

9.2.3 Operate the rotary flow adjustment control and observe the flowmeter readings to determine compliance with 9.1.3.

9.2.4 Verify by visual inspection that the location, marking, and color identification (if used) of the flow adjustment controls complies with 9.1.4.

9.2.5 Verify by visual inspection and measurement that rotary flow adjustment controls comply with 9.1.5 and Fig. 2.

9.2.6 Adjust lighting to a level of 215 lux (20 footcandles).