Designation: F 1205 – 88 (Reapproved 1999)

Standard Specification for Anesthesia Breathing Tubes [1]

This standard is issued under the fixed designation F 1205; 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 anesthesia breathing tubes, integrally attached end fittings, and integrally attached components for use with anesthesia breathing systems. Excluded are similar tubes for specific other purposes, such as those used with some breathing machines, pediatric anesthesia circuits, and gas scavenging tubes.

1.2 The following subjects are covered: terminology, dimensions, labeling and marking, selected performance requirements, and test methods to substantiate compliance with the requirements. Alternative test methods may be employed provided that they can be shown to be equivalent or better.

NOTE 1—This specification supersedes ANSI Standard Z 79.6-1975.

1.3 *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.*

2. Referenced Documents

2.1 *ASTM Standards:*

F 1054 Specification For Conical Fittings Of 15 mm and 22 mm Sizes[2]

2.2 *ANSI Standard:*

ANSI/NFPA 99 Healthcare Facilities[3]

3. Terminology

3.1 *Descriptions of Terms*—For the purpose of this specification, the following descriptions of terms shall apply:

3.1.1 *ambient temperature and pressure*—room temperature and pressure, dry gas (rtpd); indicates conditions of 20°C and 101.3 kPa (760 mm Hg) and dry gas.

3.1.2 *assembled end*—a fitting integrally attached by the manufacturer to the end of the tube.

3.1.3 *breathing tube*—a large-bore (greater than or equal to 15 mm) nonrigid tube, usually corrugated, used to convey gases or vapors, or both, to and from the patient.

3.1.4 *compliance* (pressure-volume relationship)—a change of volume per change in pressure. Units of compliance are expressed as millilitres per kilopascal (millilitres per centimetre H_2O) per metre length of tube.

3.1.5 *conductive*—a property of a breathing tube and any integrally attached components with electrical conductivity acceptable in accordance with the applicable test (see 10.1.1).

3.1.6 *disposable*—an item intended to be used once and discarded.

3.1.7 *flow resistance*—the pressure difference from inlet to outlet of a device caused by flow. Units of resistance are kilopascal per litre per second (centimetre of H_2O per litre per second) per meter length of tube.

3.1.8 *labeling*—information and literature accompanying the device, such as brochures, package inserts, and manuals.

3.1.9 *machine end*—that end of the breathing tube which is toward the machine.

3.1.10 *marking*—information directly on the device.

3.1.11 *nonconductive*—a property of a breathing tube and any integrally attached components with insufficient electrical conductivity to meet the requirements of applicable test (see 10.1.1).

3.1.12 *patient end*—that end of the breathing tube which is toward the patient.

3.1.13 *reusable*—an item intended for repeated use on one or more patients.

4. Material

4.1 *Requirements*:

4.1.1 Tubes should be made of materials suitable for the intended use and should function satisfactorily in the presence of anesthetic agents and gases commonly used and not elute toxic substances.

4.1.2 Reusable tubing should be able to withstand ordinary methods of cleaning, disinfection, and sterilization (see 12.1.1.1). It is desirable that such products should withstand accepted methods of steam sterilization.

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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 F29.12 on Airways.

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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.

5. Dimensions and Tolerances

5.1 *Requirements*:

5.1.1 *Measure System*—SI units shall be used.

5.1.2 *End Connectors*:

5.1.2.1 *Single Breathing Tube(s)*—Both ends of the tube shall mate with 22-mm male fittings which comply with Specification F 1054. The ends may be assembled, plain, cylindrical, or tapered.

5.1.2.2 *Assembled Sets* (integrally attached Y-piece and tubing, not intended to be disassembled):

(*a*) *Patient End*—The patient end of the Y-piece shall be a 22-mm/15-mm male/female coaxial fitting complying with Specification F 1054.

(*b*) *Machine End*—The machine end of both breathing tubes shall mate with 22-mm male fittings which comply with Specification F 1054. The ends may be assembled, plain, cylindrical, or tapered.

5.1.3 *Length*—The length of the breathing tube shall be designated as the nominal overall length when measured in the relaxed condition and shall be stated with a tolerance of ± 5 %.

5.2 *Test Procedure*:

5.2.1 Verify by inspection.

5.2.2 Test in accordance with 6.2.1.

5.2.2.1 (4.1.2.2(*a*)) Verify by inspection that the patient end fittings comply with Specification F 1054.

5.2.3 Verify by measuring.

6. Connections

6.1 *Requirements*:

6.1.1 All connections shall withstand a minimum tensile load of 15 N for 1 min in all directions, except the axial direction, which shall withstand a tensile load of 40 N for 1 min.

6.1.2 For breathing tubes with assembled ends, the joint between the tubing and assembled end fitting shall withstand an axial tensile load of 45 N for 1 min applied 250 mm from the end of the fitting. The breathing tube shall not become detached from the assembled end fitting.

6.2 *Test Procedure*:

6.2.1 Lubricate the mating surfaces of the end of the breathing tube with distilled water and engage with the appropriate plug gate (see Specification F 1054, Fig. 5 or Fig. 6). Apply a tensile load of 15 N at 45° to the axis for a period of 1 min. For the axial direction, apply a load of 40 N. Test each end separately. The breathing tube shall not become detached from the plug gage.

6.2.2 To test the integral joint between the assembled end fitting and the tube, affix the assembled end fitting and apply a 45-N axial tensile load to the tubing 250 mm from the joint for 1 min.

7. Leakage

7.1 *Requirements*:

7.1.1 When tested as specified in 7.2, leakage of one tube shall not exceed 25 mL/min at a pressure of 3.0 kPa (30 cm H_2O).

7.1.2 When tested as specified in 7.2, leakage of an assembled set as supplied by the manufacturer (two tubes plus integral Y-piece) shall not exceed 75 mL/min at a pressure of 3.0 kPa (30 cm H_2O).

7.2 *Test Procedure*:

7.2.1 The system shown in Fig. 1 is used to test for leakage of a single tube at ambient temperature and pressure (rtpd). Seal the end of the breathing tube and connect to the system as shown. Apply an airflow through the flowmeter (compensated for pressure) until the system pressure has stabilized at 3 kPa (30 cm H_2O). Record the flowmeter reading in millilitres per minute.

7.2.2 The system shown in Fig. 1 is used to test for leakage of an assembled set (two tubes plus Y-piece) as supplied by the manufacturer at ambient temperature and pressure (rtpd). Seal the end of the Y-piece and one end of one of the tubes of the assembled set and connect to the system as shown. Apply an airflow through the flowmeter (compensated for pressure) until the system pressure has stabilized at 3 kPa (30 cm H_2O). Record the flowmeter reading in millilitres per minute.

8. Flow Resistance

8.1 *Requirements*:

8.1.1 Resistance of a single tube shall not exceed 0.1 kPa (1.0 cm H_2O)/m of length at 1.0 L/s.

8.1.2 Resistance of the inspiratory pathway of an assembled set (two tubes plus Y-piece) as supplied by the manufacturer shall not exceed 0.1 kPa (1.0 cm H_2O)/m of length at 1.0 L/s.

8.1.3 Resistance of the expiratory pathway of an assembled set (two tubes plus Y-piece) as supplied by the manufacturer shall not exceed 0.1 kPa (1.0 cm H_2O)/m of length at 1.0 L/s.

8.2 *Test Procedure*:

8.2.1 The system shown in Fig. 2 or Fig. 3 is used to determine the pressure drop (resistance) across a single tube. A buffer chamber may be placed between the source and the flowmeter to minimize pressure fluctuation. Connect the single tube as shown and set the airflow to 1.0 L/s. Record the pressure drop (resistance) from the water manometer as kilopascals per litre per second per meter length (centimetre H_2O per liter per second per meter length).

8.2.2 The system shown in Fig. 2 is used to determine the inspiratory pathway pressure drop (resistance). A buffer chamber may be placed between the source and the flowmeter to minimize pressure fluctuation. Connect the assembled set (two tubes plus Y-piece) to the test set-up at the end of the tube on the inspiratory side and seal the expiratory end as shown and set the airflow to 1.0 L/s. Record the pressure drop (resistance)

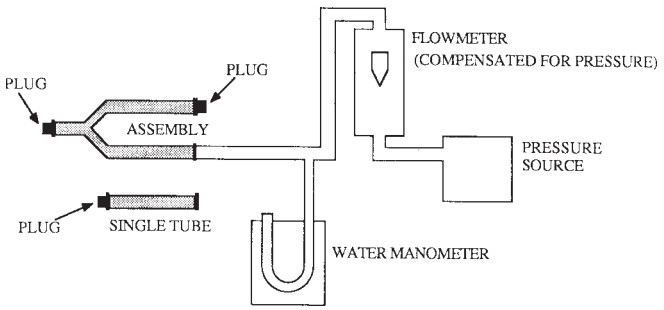

FIG. 1 Leakage Test Set-Up

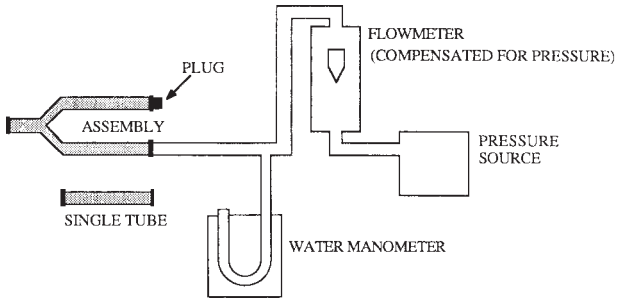

FIG. 2 Inspiratory Pathway Resistance Test Set-Up

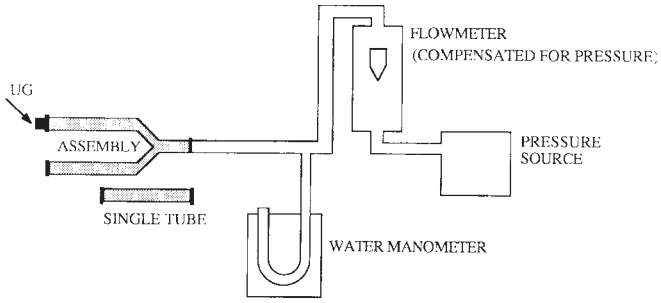

FIG. 3 Expiratory Pathway Resistance Test Set-Up

from the water manometer as kilopascals per litre per second per meter length (centimetre H_2O per litre per second per meter length).

8.2.3 The system shown in Fig. 3 is used to determine the expiratory pathway pressure drop (resistance). A buffer chamber may be placed between the source and the flowmeter to minimize pressure fluctuation. Connect the assembled set (two tubes plus Y-piece) to the test set-up at the end of the Y-piece and seal the inspiratory end as shown and set the airflow to 1.0 L/s. Record the pressure drop (resistance) from the water manometer as kilopascals per litre per second per meter length (centimetre H_2O per litre per second per meter length).

9. Internal Compliance

9.1 *Requirements*—The typical compliance shall be measured at 2.0 kPa (20 cm H_2O) and 4.0 kPa (40 cm H_2O) and shall be expressed in the labeling at 2.0 kPa (20 cm H_2O) and 4.0 kPa (40 cm H_2O) as millilitres per kilopascal (millilitres per centimetre H_2O) per meter of length of tube(s). For assembled sets, the total compliance at 2.0 kPa (20 cm H_2O) and 4.0 kPa (40 cm H_2O) should be expressed in the labeling.

9.2 *Test Procedure*:

9.2.1 The system shown in Fig. 4 is used to determine the internal compliance (pressure-volume relationship) of a single tube or an assembled set as supplied by the manufacturer. The tubing volume connecting the manometer should not be more than 1/100 of the volume of the test sample. Connect the single tube or assembled set as shown and seal all ends. Inject and record the volume of air necessary to create 2.0 kPa (20 cm H_2O) of pressure. Inject an additional volume of air until the pressure reaches 4.0 kPa (40 cm H_2O) and record the total volume necessary to reach 4.0 kPa (40 cm H_2O).

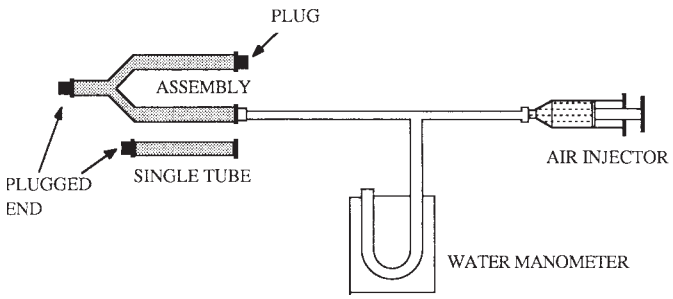

FIG. 4 Compliance Test Set-Up

10. Electrical Conductivity

10.1 *Requirements*:

10.1.1 The electrical characteristics of tubes and any integrally attached components made of conductive material shall be as specified and tested in accordance with the requirements of ANSI/NFPA 99.

10.1.2 Breathing tubes and integrally attached nonmetal components made of conductive materials shall be marked "CONDUCTIVE.''

10.1.3 Black breathing tubes and black components made of nonconductive materials shall be marked "NONCONDUCTIVE.''

10.2 *Test Procedure*:

10.2.1 Test in accordance with ANSI/NFPA 99.

10.2.2 Verify by visual inspection.

10.2.3 Verify by visual inspection.

11. Marking

11.1 *Requirements*:

11.1.1 *Reusable Tubing*:

11.1.1.1 The name, trademark, or unique identifying mark of the manufacturer shall be marked on or affixed to the tubing.

NOTE 2—The manufacture of reusable tubing without the name, trademark, or unique identifying mark of the manufacturer is permitted for 2 years after the initial publication of this specification.

11.1.1.2 Conductive tubes shall be marked "CONDUCTIVE.''

11.1.1.3 The month and year of manufacture or equivalent code should be marked on or affixed to the tubing.

11.2 *Test Procedure—Reusable Tubing*:

11.2.1 Verify by visual inspection.

11.2.2 Verify by visual inspection.

12. Labeling

12.1 *Requirements*:

12.1.1 *Reusable Tubing*:

12.1.1.1 When tubes are supplied with the intention that they can be reused, this shall be indicated. Information shall be provided to recommend acceptable methods for cleaning, disinfection, and sterilization.

12.1.1.2 The typical compliance as determined in Section 9 shall be stated.

12.1.1.3 Tubing length as determined in 5.1.3 shall be stated.

12.1.1.4 The name or trademark of the manufacturer shall be stated.

12.1.1.5 If the tubing is conductive as determined in Section 10, this shall be stated.

12.1.1.6 The month and year of manufacture or equivalent code shall be stated unless it is marked on or affixed to the tubing.

12.1.2 *Disposable Tubing*:

12.1.2.1 The unit package shall be labeled as such, for example, "Disposable.''

12.1.2.2 The typical compliance as determined in Section 9 shall be stated.

12.1.2.3 Tubing length as determined in 5.1.3 shall be stated.

12.1.2.4 The name or trademark of the manufacturer shall be stated.

12.1.2.5 If the tubing is conductive as determined in Section 10, this shall be stated.

12.1.2.6 The month and year of manufacture or equivalent code shall be stated unless it is marked on or affixed to the tubing.

12.2 *Test Procedure:*

12.2.1 *Reusable Tubing*—For requirements in 12.1.1.1 through 12.1.1.6, verify by visual inspection.

12.2.2 *Disposable Tubing*—For requirements in 12.1.2.1 through 12.1.2.6, verify by visual inspection.

13. Keywords

13.1 anesthesia; flow and flow rate; anesthesia equipment; leak testing; anesthesia equipment; pressure testing; medical equipment; pressure-volume relationship compliance; resistance; flow water test