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Standard Specification for Anesthesia Reservoir Bags¹

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1. Scope

1.1 This specification covers reservoir bags for use with anesthesia breathing systems. For purposes of this specification, the reservoir bag includes the neck, body, and neck bushing, if provided. Special-purpose bags, for example, bellows, evacuation, and self-expanding bags are excluded from the scope of this specification.

1.2 The following subjects are covered: material, construction, neck, size, compliance (pressure-volume relationship), electrical conductivity, marking and labeling, and test methods to substantiate compliance with the requirements. Alternative test methods may be employed provided they can be shown to be equivalent or better. (A rationale is given in Appendix X1.)

NOTE 1—This specification supersedes ANSI Standard Z 79.4–1974.

1.3 *This standard does not purport to address all of the safety concerns, 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 *ANSI Standard:*

ANSI/NFPA 99 Healthcare Facilities²

3. Terminology

3.1 *Definitions 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 *anesthesia reservoir bag*—collapsible container from which the patient may draw his tidal volume.

3.1.3 *compliance (pressure-volume relationship)*— a change of volume per change in pressure. Units of compliance are expressed as millilitres per kilopascals (millilitres per centimetre H₂O).

3.1.4 *conductive*—a property of an anesthesia reservoir bag

and any integrally attached components with electrical conductivity acceptable in accordance with the applicable test (see 9.1.1).

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

3.1.6 *hanging loop*—a loop for hanging which may be provided near the tail of the bag (used to facilitate drying).

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

3.1.8 *marking*—information directly on the device.

3.1.9 *neck*—the end of the anesthesia reservoir bag that connects with the anesthesia breathing system.

3.1.10 *nonconductive*—a property of an anesthesia reservoir bag and any integrally attached components with insufficient electrical conductivity to meet the requirements of the applicable test (see 9.1.1).

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

3.1.12 *size*—the size of the anesthesia reservoir bag is defined as the nominal or labeled capacity expressed in litres (L).

3.1.13 *tail*—the end of the bag opposite of the neck.

4. Material

4.1 *Requirements:*

4.1.1 The bag should be made of elastomeric material 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 Unless designated as disposable (for single use), the bag should be resistant to deterioration by methods of cleaning, disinfection, and sterilization as recommended by the manufacturer or the supplier. It is desirable that such products should withstand accepted methods of steam sterilization.

4.1.3 The material forming the body of the bag should be pliable to the extent that it remain elastic when the bag is inflated to its nominal size.

5. Construction

5.1 *Requirements:*

5.1.1 The bag shall not leak within a 10-s period when tested in accordance with 5.2.1.

5.1.2 The bag shall not be constructed in a manner such that the body or neck can cause a valve-like action (occlusion)

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² Available from American National Standards Institute, 1430 Broadway, New York, NY 10018.

under conditions of use.

5.1.3 The bag shall be free of visible defects or imperfections.

5.2 Test Procedure:

5.2.1 Inflate the bag with air to a pressure of 3.0 kPa (30 cm H₂O). Immerse the bag in a tank of water and observe for leakage as indicated by air bubbles. There shall not be air bubbles visible within a 10-s period.

5.2.2 Inflate the bag to its nominal size. Allow the bag to passively deflate (without assistance). Any indication of obstruction to flow as evidenced by failure of the bag to fully deflate is cause for failure.

5.2.3 Verify by visual inspection.

6. Neck

6.1 Requirements:

6.1.1 An integral neck bushing, if provided, shall be considered as part of the neck for purposes of this section.

6.1.2 The neck shall provide a secure fit on the nominal 22-mm plug gage shown in Fig. 1 such that it shall not disengage when tested in accordance with 6.2.2.

6.1.3 The axial length of the neck shall not be less than 25 mm.

6.2 Test Procedure:

6.2.1 Determine by inspection.

6.2.2 Disconnection Test—Lubricate the neck with distilled water and engage with the plug gage (see Fig. 1). The connection of the neck and gage shall be capable of withstanding a minimum tensile load of 15 N (3.4 lbf) applied on the body in any direction for a period of 1 min. The neck shall not become detached from the plug gage nor shall the bag detach from the bushing.

6.2.3 Verify by inspection.

7. Size

7.1 Requirements:

7.1.1 The size shall be determined in accordance with 7.2.1.

7.1.2 The accuracy of the labeled size shall be within ± 15 % of the nominal size.

NOTE 2—The common nominal sizes are 0.5, 1.0, 2.0, 3.0, and 5.0 L.

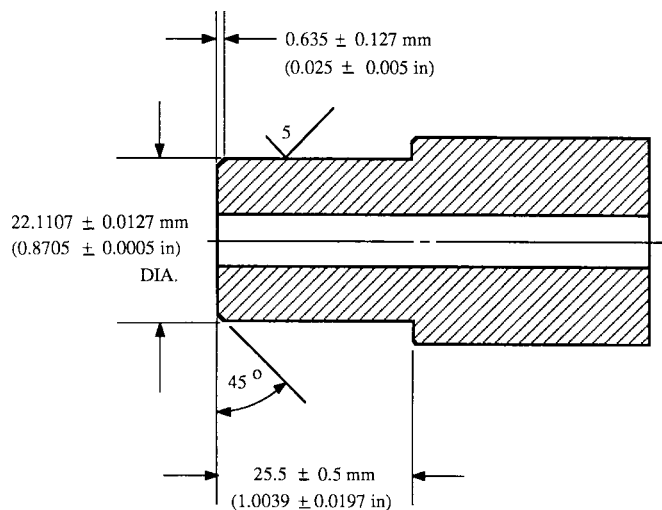


FIG. 1 22-mm Plug Gage

7.2 Test Procedure:

7.2.1 Size Test—Place the bag in a tank of water with the top rim of the neck held 25 mm above the water level. Seal lower opening of the bag (tail), if present. Fill the bag, held vertically, with water to the top rim of the neck. The water shall be at a temperature of 20 ± 3°C. Then remove the bag and measure the water volume. The measured volume is the size expressed in litres.

7.2.2 Verify by inspection.

8. Compliance

8.1 Requirements:

8.1.1 When tested in accordance with either 8.2.1 or 8.2.2, the bag shall expand uniformly. For bag sizes 1.5 L and smaller, the pressure shall not be less than 3.0 kPa (30 cm H₂O) nor shall it exceed 5.0 kPa (50 cm H₂O) when the bag is expanded to four times its size. For bag sizes greater than 1.5 L, the pressure shall not be less than 3.5 kPa (35 cm H₂O) nor shall it exceed 6.0 kPa (60 cm H₂O) when the bag is expanded to four times its size. After this test, the bag should revert to its original measured size within a tolerance of + 10 %, - 0 %. See Note 3.

8.2 Test Procedure:

8.2.1 Water Test—Seal the lower opening of the bag, if present. Place the bag in a tank of water with the neck held 25 mm above the water level. Fill the bag with water to the top rim of the neck. Insert an appropriately sized stopper into the neck of the bag. Insert a tube through the stopper to the water level in the tank. The bore of the tube shall not be less than 10 mm and it shall be of sufficient length to provide a pressure head of 6.0 kPa (60 cm H₂O). Add water through the tube until a total of four times the size of the bag is reached. Measure the pressure head when the water in the tube has reached a maximum height and has stabilized. The duration of the test shall not exceed 5 min with a water temperature of 20 ± 3°C. Measure the pressure to an accuracy of ± 0.1 kPa (± 1.0 cm H₂O).

8.2.2 Air Test (Optional)—Connect the bag to a pressure source with in-line flowmeter (compensated for pressure) and water manometer. Introduce air into the bag at a constant rate of two times nominal size per minute for a period of 2 min. Allow the system to stabilize. Record the pressure indicated on the manometer. The flow rate shall be accurate to within ± 5.0 % with air temperature at 20 ± 3°C. Measure the pressure to an accuracy of ± 0.1 kPa (± 1.0 cm H₂O).

NOTE 3—The electrical conductivity of a conductive reservoir bag which has undergone either of these tests may be reduced. The bag may not meet electrical resistance requirements appropriate to new products.

9. Electrical Conductivity

9.1 Requirements:

9.1.1 The electrical characteristics of bags and integral neck bushings made of conductive material shall be as specified and tested in accordance with the requirements of ANSI/NFPA 99.

9.1.2 Bags and integral neck bushings made of conductive materials shall be marked “CONDUCTIVE.”

9.1.3 Black bags and black integral neck bushings made of nonconductive materials shall be marked “NONCONDUCTIVE.”