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An American National Standard

Standard Specification for Tracheostomy Tubes—Pediatric Tracheostomy Tubes¹

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INTRODUCTION

Pediatric tracheostomy tubes are primarily intended for use with infants and children who may require anesthesia, artificial ventilation, relief of upper airway obstruction, or other respiratory therapy.

An infant or child differs from an adult, not only in size but especially with regard to airway anatomy and respiratory physiology. Airway equipment for pediatric patients involves differences not only of size but also of basic design. The differences created a demand for a separate standard for tracheostomy tubes for pediatric use. It should be noted that, although this standard specifies some requirements for cuffs, cuffs are seldom provided on the smaller sizes of pediatric tubes.

This specification describes requirements for those characteristics of tracheostomy tubes that can be standardized and that are important for patient safety. It does not, however, limit the variety of tube designs necessary to conform to pediatric anatomy and the variety of lesions and space limitations encountered.

A tracheostomy tube may increase resistance to gas flow. For tubes with a given outside diameter, differences in wall thickness have a major influence on the resistance to gas flow, especially in the smaller sizes of pediatric tracheostomy tubes.

1. Scope

1.1 This specification describes basic requirements for tracheostomy tubes made of plastic materials or rubber, or both, having inside diameters less than 6.0 mm. Such tubes are primarily designed for pediatric patients who may require anesthesia, artificial ventilation or other respiratory support, but need not be restricted to these uses. Specialized tubes are excluded from the scope of this specification.

2. Referenced Documents

2.1 ASTM Standards:

F 640 Test Methods for Radiopacity of Plastics for Medical Use²

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

F 1242 Specification for Cuffed and Uncuffed Tracheal Tubes²

F 1666 Specification for Adult Tracheostomy Tubes

2.2 ISO Standards:³

ISO 7000 Graphical Symbols—Synopsis
ANSI/HEMA MD 70.1-Conical Fittings

3. Terminology

3.1 *Definitions*—For the purpose of this specification, the definitions given in Specification F 1666, together with the following definition, apply.

3.2 *pediatric tracheostomy tube*—tube designed for insertion into the trachea of an infant or child through a tracheostomy.

4. Size and Dimensions

4.1 Designation of Tube Size:

4.1.1 The size of a tracheostomy tube (outer tube) shall be designed by the nominal inside diameter (ID) of the tube expressed in millimetres, as measured at the minimum diameter, in accordance with Table 1, excluding any encroachment allowed by 6.6.1. When the ID of the tracheostomy (outer) tube does not fall within specified limits of the categories listed in Table 1, the actual ID may be used as the size designation with appropriate tolerances.

4.1.2 The size of a pediatric tracheostomy tube with inner cannula shall be designated in accordance with Specification F 1666.

4.2 Outside Diameter:

4.2.1 The outside diameter (OD) of sections A and B (see Fig. 1) of the tube, other than at the cuff if provided, shall be

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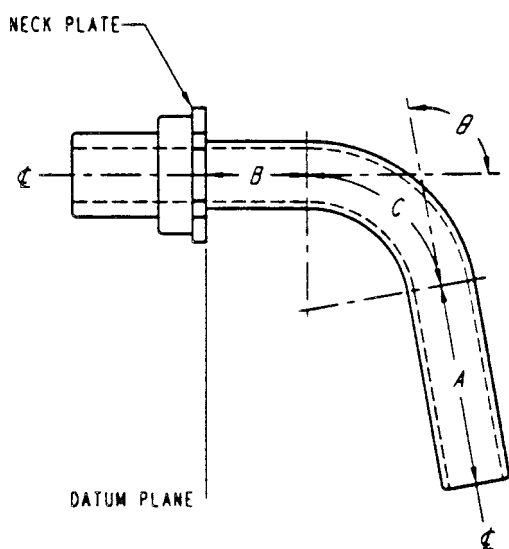
² *Annual Book of ASTM Standards*, Vol 13.01.

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



TABLE 1 Size Range of Pediatric Tracheostomy Tubes

Dimensions and Tolerances, mm	
Designated Size (nominal inside diameter, ID)	Inside Diameter and Tolerance
2.0	2.0 + 0.20 -0
2.5	2.5 + 0.20 -0
3.0	3.0 + 0.20 -0
3.5	3.5 + 0.20 -0
4.0	4.0 + 0.20 -0
4.5	4.5 + 0.20 -0.10
5.0	5.0 ± 0.20
5.5	5.5 ± 0.20
6.0	6.0 ± 0.20



BASIC DIMENSIONS OF TRACHEOSTOMY TUBES

NOTE 1—The angle θ is an obtuse angle formed between the tangents to the longitudinal axes of the tube at the machine and patient ends. As dimensions A or B, or both, approach or equal zero, the angle θ shall be the obtuse angle formed between the tangents (planes perpendicular) to the longitudinal axes.

FIG. 1 Basic Dimensions of Pediatric Tracheostomy Tubes

expressed in millimetres, subject to a tolerance of ± 0.20 mm. Section C of the outer tube shall have a tolerance of ± 0.50 mm.

NOTE 1—The marked outside diameter relates to that portion of the tube intended to be within the wall and lumen of the trachea.

4.3 Length:

4.3.1 The center-line length (dimension A + B + C in Fig. 1) shall extend from the patient side of the neck-plate to the patient end of the outer tube including to the tip of the bevel, if present (see Fig. 2 Fig. insert) and expressed in millimetres.

4.3.2 The actual center-line length shall not vary by more than 1.5 mm from the marked length for tubes with a marked inside diameter of less than 4.5 mm, or by more than 2 mm for tubes with a marked inside diameter of 4.5 mm or greater.

4.3.3 Dimensions A, B and C shall be expressed in millimetres.

NOTE 2—Dimensions A or B, or both, may be, or approach, zero.

4.3.4 For tubes with an adjustable neck-plate, the range of measurements for center-line lengths shall be expressed in centimetres.

4.4 Angle θ :

4.4.1 The angle θ (see Fig. 1) shall be expressed in degrees. The angle θ shall be the obtuse angle formed between the tangents (planes perpendicular) to the longitudinal axes.

5. Materials

5.1 The materials of pediatric tracheostomy tubes shall comply with the requirements specified in Specification F 1666.

6. Design

6.1 Inner Tube:

6.1.1 The inner tube, if provided, shall extend to within 0.5 mm of the patient end of the tracheostomy (outer) tube and not more than 3.0 mm beyond the patient end.

6.1.2 The machine end of the inner tube shall be a 15-mm male connector conforming with the requirements of Specification F 1054. It shall not prevent the tracheostomy (outer) tube connector or adaptor, if provided, from mating with the breathing system of an anaesthetic machine or ventilator.

6.1.3 If the connector is attached to the inner cannula, a mechanism must be provided to fasten the inner cannula to the outer tube.

6.2 Neck-plate:

6.2.1 A tracheostomy tube shall have a neck-plate (see Fig. 1).

6.2.2 The neck-plate shall be provided with holes or other means to permit attachment to the patient.

6.2.3 If a tracheostomy tube has an adjustable neck-plate, it shall be securable to the tube, but not removable.

6.3 Cuff:

6.3.1 The cuff, if provided, shall be permanently attached to the tube.

6.3.2 Cuffs of tracheostomy tubes shall comply with the requirements specified in Specification F 1242.

6.3.3 The labeled cuff resting diameter shall be within $\pm 15\%$ of the normative value when determined in accordance with Annex A1-Annex A3.

6.4 Inflating Tubes for Cuffs:

6.4.1 Inflating Tubes:

6.4.1.1 The inflating tube, if fitted, shall have an outside diameter of not more than 2.5 mm. The secondary (inflation) lumen shall not encroach on the lumen of the tracheostomy tube by more than 10% of the inside diameter of the tracheostomy tube.

NOTE 3—The wall around the secondary (inflation) lumen should not project substantially on the outside surface of the tracheostomy tube.

6.4.2 Pilot Balloon:

6.4.2.1 The inflating tube shall have a pilot balloon or other means, or both, to indicate inflation status of the cuff.

NOTE 4—This (these) device(s) may also serve as a pressure indicating or limiting device.

