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An American National Standard

Standard Specification for Adult Tracheostomy Tubes¹

This standard is issued under the fixed designation F 1666; 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 (€) indicates an editorial change since the last revision or reapproval.

€¹ NOTE—Editorial change was made to the title in October 1999.

1. Scope

1.1 This specification describes basic requirements for tracheostomy tubes made of plastic materials or rubber, or both; having inside diameters greater than 5.0 mm. Such tubes are primarily designed for adult 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 The following standards contain provisions which, through reference in this text, constitute provisions of this standard. All standards are subject to revision, and parties to agreements based on this specification are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below.

2.2 ASTM Standards:

F 640 Test Methods for Radiopacity of Plastics for Medical Use²

F 813 Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices²

F 1054 Specification for Conical Fittings of 15 mm and 22 mm sizes²

F 1242 Specification for Cuffed and Uncuffed Tracheal Tubes²

2.3 ISO Standards:

ISO 4135 Anesthesiology—Vocabulary³

ISO 5366-1 Tracheostomy Tubes—Part 1: Connectors³

ISO 7000 Graphical Symbols for Use on Equipment—Index and Synopsis³

2.4 ANSI Standard:

ANSI/HIMA MD70.1 Medical Material—Leur Fittings—Performance³

3. Terminology

3.1 Definitions:

¹ This specification is under the jurisdiction of ASTM Committee F29 on Anesthetic and Respiratory Equipment and is under 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, 11 W. 42nd St., 13th Floor, New York, NY 10036.

3.1.1 *angle of bevel*—acute angle between the plane of the bevel and the longitudinal axis of the tracheostomy tube at the patient end. (See Angle B in Fig. 1.)

3.1.2 *bevel*—slanted portion at the patient end of the tracheostomy tube.

3.1.3 *center-line length*—distance from the patient side of the neck-plate to the patient end of the outer tube along the center line.

3.1.4 *cuff*—inflatable balloon fitted near the patient end of the tracheostomy tube to provide a leak-resistant seal between the tube and the trachea.

3.1.5 *inflating tube*—tube through which the cuff is inflated.

3.1.6 *inner tube*—tube that fits closely to the inside contours of the outer tube (tracheostomy tube).

3.1.7 *introducer (obturator)*—specifically adapted stylet to facilitate the introduction of the outer tube into the trachea.

3.1.8 *machine end*—that end of the tracheostomy tube which is intended to project from the patient.

3.1.9 *neck-plate (shield)*—that part of the tracheostomy tube which approximates to the contour of the patient's neck and is used to secure the tube in position.

3.1.10 *outer tube*—that part of the tracheostomy tube which is normally in contact with the tissues.

3.1.11 *patient end*—that end of the tracheostomy tube which is intended to be inserted into the trachea.

3.1.12 *pilot balloon*—balloon fitted to the inflating tube to indicate inflation status of the cuff.

3.1.13 *tracheostomy (tracheotomy) tube*—tube designed for insertion into the trachea through a tracheostomy.

4. Materials and Manufacture

4.1 Tracheostomy tubes, including cuffs, in their ready-for-use state shall be compatible with the human tissues with which they are intended to be used. Compatibility shall be indicated by the implantation test given in Annex A1, a cell tissue culture test (see Practice F 813) or other tests that give an equivalent indication of freedom from biological hazard.

NOTE 1—See Annex A3 for guidance on materials and design.

5. Size and Dimensions

5.1 Designation of Tube Size:

5.1.1 The size designation of a single tracheostomy tube (no

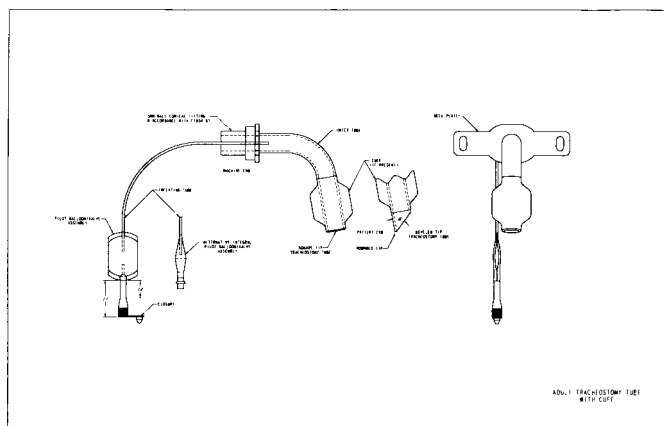


FIG. 1 Typical Tracheostomy Tube

inner cannula) shall be 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 6.5.1.

5.1.2 The size designation of a tracheostomy tube with inner cannula shall be indicated by both the nominal inner diameter (ID) of the outer tube and the inner diameter (ID) of the inner tube expressed in millimetres. The two numbers shall be juxtaposed by a slash or by a hyphen (example: 8/7 or 8-7).

5.2 Outside Diameter:

5.2.1 The outside diameter (OD) of sections A and B (see Fig. 2) of the outer tube, other than at the cuff, if provided, shall be 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 2—The marked outside diameter relates to that portion of the tube intended to be within the wall and lumen of the trachea.

5.3 Length:

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

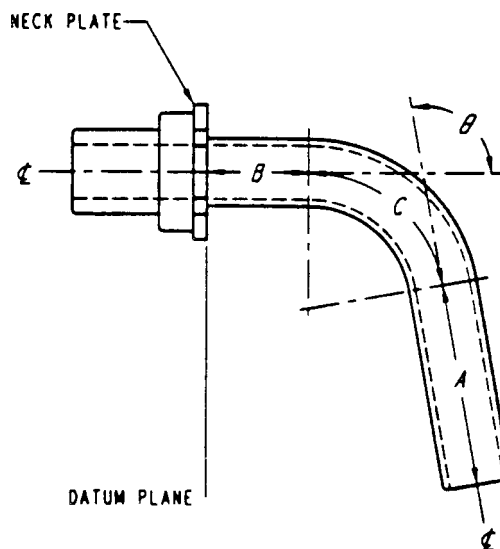
5.3.2 The actual center-line length shall not vary by more than 2.0 mm from the marked length.

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

TABLE 1 Size Range of Single Tracheostomy Tubes

NOTE 1—Dimensions and tolerances are in millimetres.

Designed Size (Nominal Inside Diameter, (ID))	Inside Diameter and Tolerance
5.0	5.0 $\pm$ 0.20
5.5	5.5 $\pm$ 0.20
6.0	6.0 $\pm$ 0.20
6.5	6.5 $\pm$ 0.20
7.0	7.0 $\pm$ 0.20
7.5	7.5 $\pm$ 0.20
8.0	8.0 $\pm$ 0.20
8.5	8.5 $\pm$ 0.20
9.0	9.0 $\pm$ 0.20
9.5	9.5 $\pm$ 0.20
10.0	10.0 $\pm$ 0.20
11.0	11.0 $\pm$ 0.20



BASIC DIMENSIONS OF TRACHEOSTOMY TUBES
FIG. 2 Basic Dimensions of Tracheostomy Tubes

NOTE 3—Dimensions A or B, or both, may be, or approach, zero.

5.3.4 For tubes with an adjustable neck-plate, the range of center-line lengths shall be expressed in millimetres.

5.4 Angle θ —The angle θ (see Fig. 2) shall be expressed in degrees.

NOTE 4—Angle θ is the obtuse angle formed between the tangents to the longitudinal axes of the tube at the machine and the 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.

6. Design

6.1 Machine End—The machine end of tracheostomy tubes shall comply with the requirements specified in Specification F 1054.

6.2 Neck-Plate:

6.2.1 A tracheostomy tube shall have a neck-plate (see Fig. 1 and Fig. 2).

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 Inner Tube—The inner tube shall extend to within 1.0 mm of the patient end and not more than 3.0 mm beyond the patient end of the tracheostomy tube with which it is provided.

6.4 Cuff:

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

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

6.5 Inflating Tubes for Cuffs:

6.5.1 Inflating Tube—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.