Designation: F 1627 – 95

An American National Standard

Standard Specification for Tracheostomy Tubes–Pediatric Tracheostomy Tubes[1]

This standard is issued under the fixed designation F 1627; 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.

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 Use[2]

F 1054 Specification for Conical Fittings of 15 mm and 22 mm Sizes[2]

F 1242 Specification for Cuffed and Uncuffed Tracheal Tubes[2]

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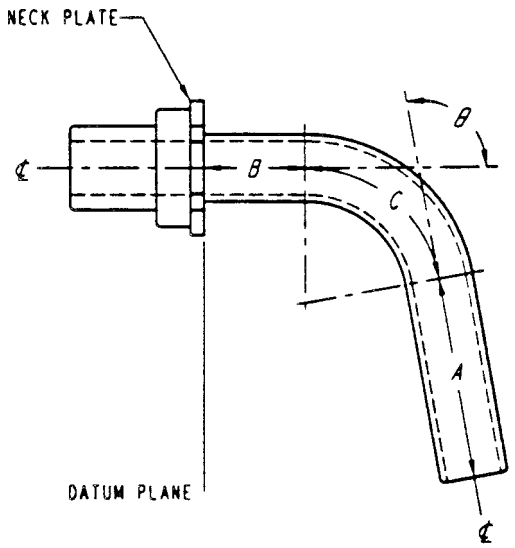
[2] *Annual Book of ASTM Standards*, Vol 13.01.

[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 ± 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.

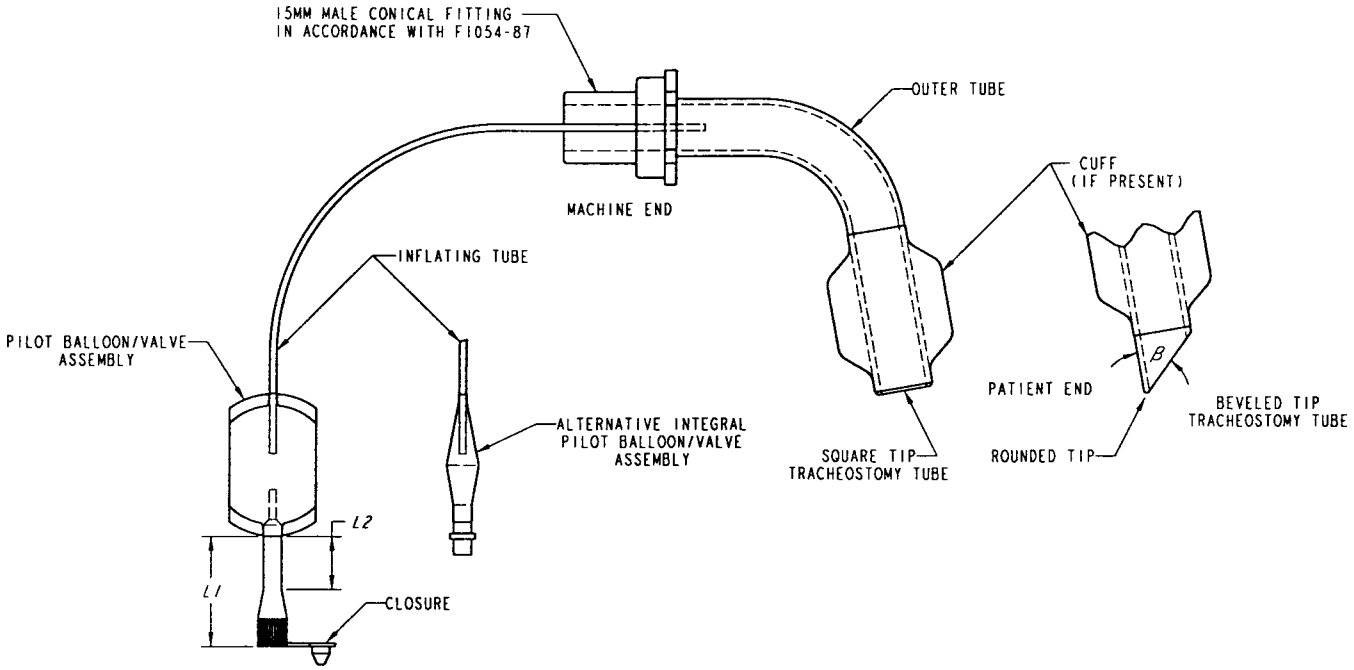


FIG. 2 Typical Tracheal Tube

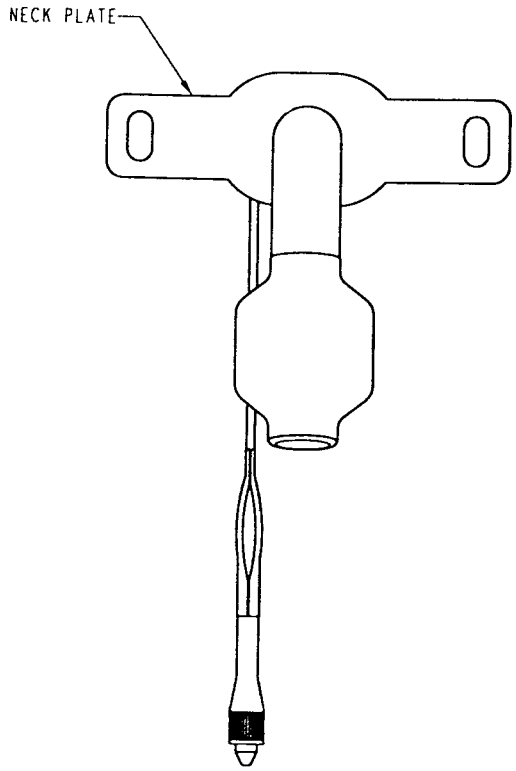


FIG. 2 *(continued)*

6.4.2.2 Neither the inflating tube nor any device shall act as a non-return valve to prevent the intentional evacuation of the cuff.

6.4.3 *Free End of Inflating Tubes for Cuffs*:

6.4.3.1 The end of the inflating tube may be open or sealed with a closure device or inflation valve, but in all instances it shall be capable of accepting a male conical fitting with a 6 % taper (Luer), complying with the requirements specified in ANSI/HEMA MD 70.1. The length, Fig. 2, Dimension L1 of the free end of the inflating tube shall not be less than 40 mm unless an inflation valve or closure device is provided.

6.4.3.2 If an inflation valve or closure device is provided, the length (Fig. 2, Dimension L2) between the pilot ballot (or other device) and the 6 % conical fitting shall not be less than 10 mm unless the pilot balloon and valve or closure device are integral.

6.5 *Patient End*:

6.5.1 The patient end may be square, beveled or of other configuration.

6.5.2 If a bevel is present, the angle of the bevel β shall be not less than 45° (see Fig. 2).

6.6 *Introducer (Obturator)*:

6.6.1 Provision of an introducer is optional.

6.6.2 The introducer shall be smooth and facilitate rapid intubation.

6.6.3 The introducer shall be easily inserted and removed.

6.6.4 When correctly seated the introducer should not fall out of the tracheostomy tube under its own weight when the tube is held by the neck-plate with the patient end uppermost.

7. Packaging and Labeling

7.1 *Unit Package*— The following information shall be apparent on visual examination of the intact unit package:

7.1.1 The size and shape of the tube;

7.1.2 Whether a cuff is provided; and

7.1.3 Whether a connector or adaptor is provided.

NOTE 5—The unit package may be transparent and the tube visible, or a drawing to scale, preferably full scale may be used. If a drawing is provided, product dimensions may be included.

7.2 The following information shall be provided either on the unit package or on an insert with the unit package:

7.2.1 A description of the contents;

7.2.2 The designated size expressed in millimetres in accordance with 4.1;

7.2.3 The nominal outside diameter expressed in millimetres (see 4.2);

7.2.4 The nominal center-line length expressed in millimetres (see 4.3). For tubes with an adjustable neck-plate, the range of center-line lengths shall also be given;

7.2.5 The name or trademark, or both, of the manufacturer or supplier, or both;

7.2.6 The batch number;

7.2.7 If relevant, instructions for cleaning and disinfection or sterilization;

7.2.8 The word “STERILE” or “NON-STERILE”, as appropriate; and

7.2.9 For tubes not intended for re-use, the words “SINGLE PATIENT USE” or equivalent.

NOTE 6—Symbol no. 1051 (“Do not re-use”) given in ISO 7000 should additionally be used (see Fig. 3).

7.2.10 If an inner tube is provided in the unit package, the nominal inside diameter of the inner tube.

7.2.11 The expiration date.

NOTE 7—For cuffed tubes, the resting diameter of the cuff, determined in accordance with Annex A1-Annex A3, and expressed in millimetres may be marked or may be readily available from the manufacturer.

NOTE 8—The angle θ, expressed in degrees may be made available upon request from the manufacturer.

7.3 *Marking*:

7.3.1 *Neck Plate*—The following information shall be marked on the neck-plate and shall be visible from the machine end of the tube:

7.3.1.1 The designated size (nominal inside diameter) expressed in millimetres in accordance with 4.1;

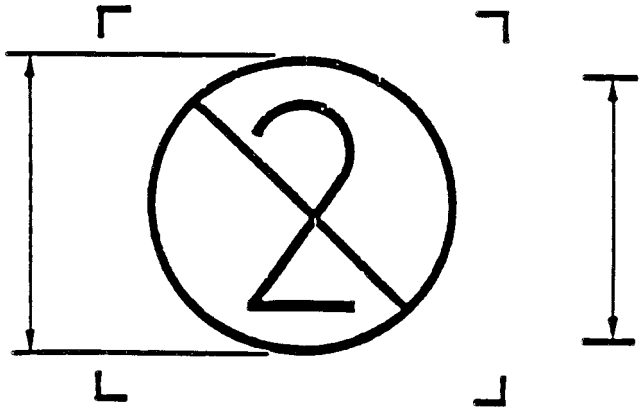


FIG. 3 ISO Symbol 7000/1051 “Do Not Re-Use”

7.3.1.2 The nominal outside diameter expressed in millimetres (see 4.2);

NOTE 9—The center-line length (or the maximum length for tubes having an adjustable neck-plate) expressed in millimetres (see 4.3) may also be marked.

7.3.1.3 The name or trade mark, or both, of the manufacturer.

7.3.2 *Labelling of Inner Tube Unit Packages*—Inner tube unit packages shall be clearly labelled to indicate the following information:

7.3.2.1 A description of contents;

7.3.2.2 The designated size (nominal inside diameter) of the tracheostomy tube (outer tube) into which it is designed to fit (see 4.1);

7.3.2.3 The nominal inside diameter of the inner tube;

7.3.2.4 The name or trademark, or both, of the manufacturer or supplier, or both;

7.3.2.5 The batch number;

7.3.2.6 The expiration date.

7.3.2.7 If relevant, instructions for cleaning and disinfection or sterilization;

7.3.2.8 The word “STERILE” or “NON-STERILE”, as appropriate;

7.3.2.9 For inner tubes not intended for re-use, the words “SINGLE PATIENT USE” or equivalent;

NOTE 10—Symbol no. 1051 (“Do not re-use”) given in ISO 7000 should additionally be used (see Fig. 3).

7.3.3 *Shelf or Multi-unit Packs*—Shelf or multi-packs shall be marked with the following information:

7.3.3.1 A description of the contents;

7.3.3.2 Size designation in accordance with 4.1;

7.3.3.3 Nominal outside diameter expressed in millimetres (see 4.2); and

7.3.3.4 The nominal center-line length expressed in millimetres (see 4.3);

NOTE 11—For tubes with an adjustable neck-plate, the range of center-line lengths should also be given.

7.3.3.5 The name and address of the manufacturer or supplier;

7.3.3.6 The batch number;

7.3.3.7 The word “STERILE” or “NON-STERILE”, as appropriate; and

7.3.3.8 For tubes not intended for re-use, the words“ SINGLE PATIENT USE” or equivalent.

NOTE 12—Symbol no. 1051 (“Do not re-use”) given in ISO 7000 should also be used (see Fig. 3).

7.3.3.9 The expiration date.

ANNEXES

(Mandatory Information)

A1. IMPLANTATION TEST

A1.1 See Specification F 1666.

A2. METHOD FOR DETERMINING THE RESTING DIAMETER OF THE CUFF

A2.1 *Principle*:

A2.1.1 The resting diameter of the cuff is measured when the cuff is inflated with a pressure which removes creases but minimizes stretching of its walls.

A2.2 *Apparatus*:

A2.2.1 Means to inflate the cuff with sufficient air to create an intracuff pressure of 2.0 kPa (20 cm H_2O) ±5 %.

A2.3 *Procedure*:

A2.3.1 Inflate the cuff with sufficient air to create an intracuff pressure of 2.0 kPa (20 cm H_2O) ±5 % and leave to stabilize for 5 min at (23 ± 2)°C, maintaining that pressure.

A2.3.2 Measure the maximum cuff diameter in a plane perpendicular to the axis of the tube at intervals of 45°.

A2.4 *Expression of Results*:

A2.4.1 Calculate the arithmetic mean of the measurements obtained in A2.3.2 and express the result in millimetres.

A3. GUIDANCE ON MATERIAL DESIGN AND FINISH

A3.1 See Specification F 1666.