Designation: F 1242 – 96$^{\epsilon 1}$

Standard Specification for Cuffed and Uncuffed Tracheal Tubes[1]

This standard is issued under the fixed designation F 1242; 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.

ϵ[1] NOTE—Editorial changes were made May 1997.

1. Scope

1.1 This specification covers the dimensions, rationale, labeling specifications, selected performance requirements, and test methods of cuffed and uncuffed Magill and Murphy-type tracheal tubes. These tubes are commonly used as airway catheters in human patients in the practice of anesthesiology and in respiratory care. This specification represents the state of the art at the time of publication and will be subject to periodic review.

1.2 This specification also provides test protocols to assess the performance and safety of cuffed oral and nasal tracheal tubes for prolonged use. Supporting rationale for the requirements is provided in Appendix X1, and references are included. Required safety and performance tests, together with availability of results, are relied upon in this specification, whenever possible, to allow a manufacturer the maximum use of technological alternatives in design and materials.

1.3 The values stated in SI units are to be regarded as standard.

1.4 The following precautionary caveat pertains to the test method portions, Annex A1 and Appendix X2, of this specification: *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.*

1.5 The following is a list of subject headings and subheadings included in this specification and the sections in which they appear:

[1] This specification is under the jurisdiction of ASTM Committee F-29 on Anesthetic and Respiratory Equipmentand is the direct responsibility of Subcommittee F29.12 on Airways.

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This specification, which is a consolidation and revision of ANSI Z79.14-1983 and ANSI Z79.16-1983, supersedes these older standards. No attempt has been made to delineate all types of tracheal tubes. This specification is not intended to inhibit innovation, variation, and future development.

2. Referenced Documents

2.1 *ASTM Standards:*

NOTE 1—This specification is intended to be used in conjunction with the following standards. When the standards referred to in this specification are superseded by an approved revision, the revision shall apply.

F 640 Test Methods for Radiopacity of Plastics for Medical Use[2]

F 813 Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices[2]

2.2 *ANSI Standards:*[3]

ANSI/HIMA MD70.1-1983 American National Standard for Medical Material—Luer Taper Fittings—Performance

ANSI Z79.14-1983 American National Standard For Anesthetic Equipment—Tracheal Tubes

ANSI Z79.16-1983 American National Standard for Anesthetic Equipment—Cuffed Oral Tracheal and Nasal Tracheal Tubes for Prolonged Use

3. Terminology

3.1 *Definitions:*

3.1.1 *bevel*—the slanted patient end of the tracheal tube (see Figs. 1 and 2).

3.1.2 *disposable*—an item intended for single use.

3.1.3 *inflation lumen*—the lumen within the wall of the tracheal tube for inflating the tracheal tube cuff.

3.1.4 *inflation tube*—the attached secondary tube for inflating the tracheal tube cuff (see Fig. 2).

3.1.5 *inflation valve*—a valve attached to the inflation system for inflating and deflating the cuff.

3.1.6 *machine end*—the end of the tracheal tube intended to project from the patient.

3.1.7 *Murphy eye*—a hole through the wall of a tracheal tube near the patient end and on the side opposite to the bevel. A Murphy type eye is illustrated in Fig. 3(*a*) to Fig. 3(*d*).

3.1.8 *patient end*—the end of the tracheal tube intended to be inserted into the patient's trachea.

3.1.9 *pilot balloon*—a small balloon attached to the inflation tube to indicate inflation or deflation of the tracheal cuff.

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

[3] Available from American National Standards Institute, 1430 Broadway, New York, NY 10018.

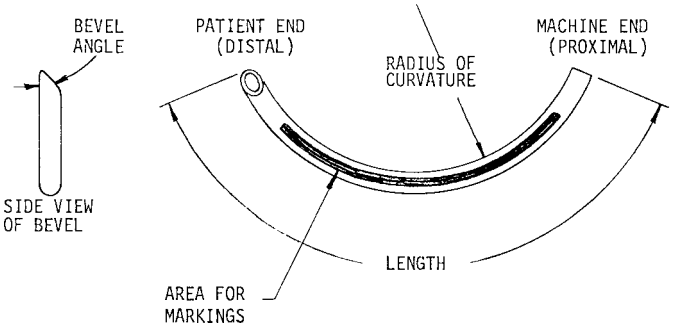

FIG. 1 Tracheal Tube

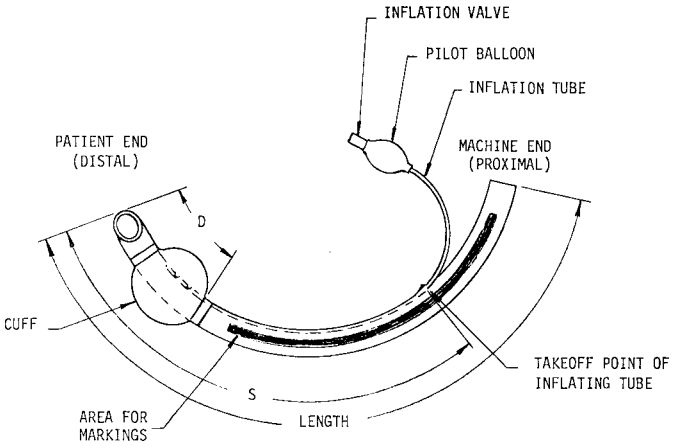

FIG. 2 Cuffed Tracheal Tube

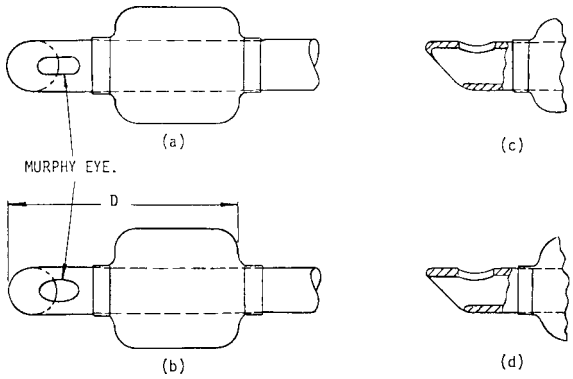

FIG. 3 Typical Murphy Tips

3.1.10 *tracheal tube*—a tube inserted either orally or nasally to convey gases or vapors to and from the trachea. This term shall be used rather than synonyms such as "endotracheal", "intratracheal", or "catheter". Typical tracheal tubes are illustrated in Figs. 1 and 2.

3.1.10.1 *Magill-type tracheal tube*—a Magill-type tracheal tube is illustrated in Fig. 1. Adult sizes of Magill tubes usually are provided with cuffs as illustrated in Fig. 2. A Magill tracheal tube does not have a Murphy eye.

3.1.10.2 *Murphy-type tracheal tube*—a tracheal tube that has a Murphy eye at the patient end as illustrated in Fig. 3(*a*) to Fig. 3(*d*). (See Refs **(1)**[4] and **(2)** for the original descriptions of Magill-type and Murphy-type tracheal tubes.)

3.1.11 *tracheal tube cuff*—an inflatable sleeve fastened to the patient end of the tracheal tube to provide an effective, leak-resistant fit between the tube and the trachea. A tracheal tube cuff is illustrated in Fig. 2.

3.1.12 *tracheal tube cuff resting diameter*—the diameter of the cuff when tested in accordance with A1.5.

4. Materials

4.1 *Inertness*:

4.1.1 Materials intended to be inserted into the patient shall be of a nontoxic substance compatible with human tissue, as

[4] The boldface numbers in parentheses refer to a list of references at the end of this specification.

determined by A1.1. Other tests may be used, including cell culture tests, provided they are shown to be equivalent. The biologic test procedure shall be applied to those portions of the finished product intended for insertion into the patient and in the form that they are supplied to the consumer. For tubes supplied sterile, the test shall be applied after sterilization. For tubes supplied nonsterile, the test shall be applied after the recommended method of sterilization. The test is designed to determine the suitability of formulations and is not intended to be used as a routine test for every lot.

4.1.2 Reusable tracheal tubes should be reasonably resistant both to deterioration by agents used in chemical cleansing and sterilizing and to deterioration from autoclaving, if steam sterilization is recommended.

4.1.3 Conditions of use require that all tracheal tubes be resistant to deterioration from anesthetic agents.

4.2 *Surface Characteristics*:

4.2.1 *Tubes*—The patient end of the tube shall be rounded without sharp points or rough edges. The tube surface should be smooth externally and internally. The external edge of the Murphy eye, if provided, and all bevel edges shall be smooth and well rounded. See Fig. 3.

4.2.2 *Cuffs*—The external surface should be smooth.

4.3 *Rigidity*—All sizes of tracheal tubes should be sufficiently flexible or should soften sufficiently at body temperature, to conform to the patient's airway anatomy without kinking.

4.4 *Integrity of Lumen*—The materials should be such as to allow construction of tracheal tubes with the thinnest possible walls, whose lumen will not be compromised by collapse under the inflated cuff at body temperature. Tubes shall be able to pass the tube collapse test (see A1.2).

5. Requirements for Tubes with Cuffs

5.1 *Cuffs*—The cuff shall be reliably attached to the tracheal tube. (See Ref **(3)** for information on cuff characteristics.) The maximum distance, *D*, from the tip of the tube to the machine end of the cuff shall be as illustrated in Figs. 2 and 3 and stated in Table 2. Upon visual inspection, the bonded edge of the cuff shall not encroach upon the Murphy eye, if present. The general requirement for tracheal tube materials shall also apply to cuff materials (see Section 4). The cuff position and size shall not cause the cuff to herniate over the tube tip under normal conditions of use (see Annex A1.4). The cuff shall inflate symmetrically (see Annex A1.3).

5.2 *Cuff Pressure, Volume, and Diameter Characteristics*—The manufacturer shall determine the resting diameter of the cuff. The diameter shall be stated in millimetres. (See Refs **(4), (5),** and **(6)** for background information on assessments of cuffs; see Refs **(7)** and **(8)** for reports on variations in sizes and shapes of human tracheas.) The cuff resting diameter shall be tested in accordance with A1.5 and be within ±15 % of the marked value referenced in Section 8.7.

5.3 *Inflation System*— The typical inflation system includes an inflation lumen in the wall of the tracheal tube, an external inflation tube, an optional pilot balloon, and an optional inflation valve (see Fig. 2). The inflation lumen within the wall of the tracheal tube shall not encroach upon the lumen of the tracheal tube and should not bulge outward. The external inflation tube shall not exceed 2.5 mm external diameter and should be attached to the tracheal tube at a small angle without undue projection. The external inflation tube shall be fitted, either with an inflation valve with an inlet that will mate with a male luer syringe tip or shall have a female end capable of accepting a standard luer syringe tip. (See ANSI/HIMA MD70.1.) The external inflation tube shall be attached to the tracheal tube at a distance *S* as described in Fig. 2 and stated in Table 2. The external inflation tube shall extend at least 3 cm beyond the machine end of the tracheal tube, in accordance with minimum tube length in Table 1, before any system is incorporated, for example, pilot balloon, valve, or connector. The pilot balloon, if provided, should give an indication of the degree of inflation or deflation of the cuff. The inflation system shall not leak when tested in accordance with X1.7. If the inflation tube is clamped, the lumen of the inflation tube should reopen after unclamping to enable the intentional deflation of the cuff.

TABLE 1 Tracheal Tube Dimensions

Inside Diameter, mm		Minimum Tube Length, mm	Precut Length, mm[A]
Size	Tolerance		
2.0	±0.15	140	110
2.5	±0.15	140	110
3.0	±0.15	160	120
3.5	±0.15	180	130
4.0	±0.15	200	140
4.5	±0.15	220	150
5.0	±0.15	240	160
5.5	±0.15	270	170
6.0	±0.15	280	190
6.5	±0.20	290	210
7.0	±0.20	300	230
7.5	±0.20	310	240
8.0	±0.20	320	250
8.5	±0.20	320	260
9.0	±0.20	320	270
9.5	±0.20	320	280
10.0	±0.20	320	280
11.0	±0.20	320	280

[A] Manufacturers desiring to market prepackaged sterilized oral tracheal precut tubes with connectors inserted may be guided by the lengths shown. However, the user is cautioned that anatomical variations, conditions of use, actual outside diameter of the tube, length of tube inserted, or other factors may well result in use of a tracheal tube either too long or too short for a given patient. Use of a tracheal tube precut to a standard length should not, under any circumstances, be substituted for expert clinical judgment in selecting tube size and length.

TABLE 2 Dimensions of Cuffed Tracheal Tubes

Size	Inflation Tube Take-Off Distance, (*S*), mm, ±10 mm[A]	Maximum Distance, (*D*), mm, from Tip to Machine End of Effective Cuff[B]
5.0	120	56
5.5	130	56
6.0	150	58
6.5	170	62
7.0	180	66
7.5	190	69
8.0	205	72
8.5	210	75
9.0	220	78
9.5	230	81
10.0	230	85
10.5	230	85
11.0	230	85

[A] See Fig. 2.
[B] See Figs. 2 and 3.

6. Dimensions and Permissible Variations of Tracheal Tubes

6.1 *Measurement System*—The SI (metric) system shall be the standard of measurement used.

6.2 *Size and Dimensions*—The size shall indicate the tube's inside diameter (ID) in millimetres, rather than be described by any other system, for example, French or Magill. The tube sizes with inside diameter tolerances, and the minimum tube lengths, shall be as listed in Tables 1 and 2.

6.3 *Radius of Curvature*—Both oral and nasal tracheal tubes shall have a radius of curvature of 140 ± 20 mm (see Fig. 1).

6.4 *Bevel*:

6.4.1 Tubes shall have a bevel angle of 38 ± 10° in relation to the long axis (see side view of bevel in Fig. 1).

6.4.2 The bevel opening of tubes shall be oriented as indicated in Figs. 1 and 2.

6.5 *Murphy Eye*—The area of a Murphy eye, if included, shall not be less than 80 % of the cross-sectional area of the tube lumen. The location of the eye shall be on the side of the tube opposite to the bevel (see Fig. 3(*a*) to Fig. 3(*d*). The size, shape, and location of the eye should not significantly weaken the patient end of the tube.

7. Product Marking

7.1 *Marking Materials*—Marking materials on the tracheal tube shall be nontoxic and tissue compatible (see A1.1). Marking materials on the tracheal tube should resist deterioration by anesthetic agents. The markings should not be easily rubbed off and should remain legible during use of the tube. If the tracheal tube is intended for reuse, the materials should also resist deterioration by recommended agents used in cleansing and sterilizing.

7.2 *Tracheal Tube Markings*—Markings should be of sufficient size and contrast to be clearly legible, shall be located on the bevel side of the tube within the shaded areas shown in Figs. 1 and 2, and shall read from left to right.

7.3 *Required Markings*:

7.3.1 Required markings shall include the word "Oral,"" Nasal," or "Oral/Nasal" as appropriate.

7.3.2 The size shall be marked in accordance with 6.2 and Table 1 and positioned between the cuff and take-off point, *S*, for cuffed tracheal tubes (see Fig. 2). For uncuffed tracheal tubes, size marking shall be towards the patient end and within the precut length (see Table 1).

7.3.3 For size 6.0 and smaller, the outside diameter (OD) shall be marked and that nominal marking shall be within 0.15 mm of the actual outside diameter. Marking of the outside diameter on larger tubes is optional.

7.3.4 The size markings shall be similar to one of the following specimens with the size marking inside diameter (ID) larger and bolder:

ID **6.0** Oral 8.4 OD
ID **6.0** Oral/Nasal 8.4 OD
ID **6.0** 8.4 OD Oral/Nasal
ID **6.0** Nasal 8.4 OD
ID **8.0** Oral
ID **8.0** Oral/Nasal
ID **8.0** Nasal

7.3.5 The name or trademark of the manufacturer or supplier shall be marked.

7.3.6 Tubes that comply with all requirements of this specification should be marked "F-29". Manufacturers shall state in their labeling the standard or standards for which the notation "F-29" indicates compliance.

7.3.7 Length (depth) markings in centrimetres, measured from the patient end, shall be provided.

7.3.8 Other markings not in conflict with required markings may be applied.

7.3.9 Individually packaged, sterile tubes being marketed as disposables shall be marked on the tube, "DO NOT REUSE," or" SINGLE USE ONLY," or equivalent.

7.3.10 *Radiopaque Marker*—A radiopaque marker shall be placed at the patient end or along the full length of the tube and the image of the tracheal tube marker shall have an optical density less than or equal to that of the aluminum comparison standard. The radiopaque marking shall be tested in accordance with A1.6.

8. Packaging and Labeling

8.1 *Gas Effects*— Cuff volume or pressure may either increase or decrease due to diffusion of nitrous oxide, oxygen, or air. This shall be stated in the product labeling and recommendations shall be included for minimizing this effect, if applicable. (The rapidity with which this diffusion occurs is shown in Refs **(9)** through **(14)**.)

8.2 *Sterile Tubes*— The markings shall be clearly legible through the intact package. The size should also be marked clearly on the right-hand end of the package in print at least 10 mm high.

8.3 *Nonsterile Tubes*— When tracheal tubes are not supplied sterile, the package information shall recommend a suitable method or methods of sterilization.

8.4 *Disposable Tubes*— Packages for disposable tubes shall be marked "DO NOT REUSE," or "FOR SINGLE USE ONLY," or equivalent.

8.5 *Reusable Tracheal Tubes*—When tracheal tubes are supplied with the intention that they can be reused, this shall be stated in the package information. The package information also shall recommend a method or methods for cleaning, sterilizing, and inspecting.

8.6 *Storage Conditions*—The manufacturer shall caution against known conditions of storage likely to result in rapid deterioration of the tubes and cuffs, for example, high temperature, ultraviolet light, or fluorescent lighting.

8.7 *Cuff Diameter*—For cuffed tubes the marking of packages or package inserts shall included the cuff resting diameter expressed in millimetres as determined in A1.5.

ANNEX

(Mandatory Information)

A1. TEST METHODS

A1.1 *Implantation Test*—See Ref **(18).** Other test methods, including cell cultures, may be used, provided that they are shown to yield equivalent results. One acceptable alternate is Practice F 813.

A1.2 *Tube Collapse:*

A1.2.1 *Apparatus*—Suitable apparatus is illustrated in Fig. A1.1 and includes the following:

A1.2.1.1 *Tube*, made of glass or transparent plastics material. The length of the tube shall be about twice the effective length of the cuff. The inside diameter of the transparent tube is to be within 5 % of two times the tracheal tube size, plus 4 mm. This is approximately two times the outside diameter of the tracheal tube.

A1.2.1.2 *Water Bath*, thermostatically controlled at 40 ± 1°C.

A1.2.1.3 *Air Supply*.

A1.2.1.4 *Air-Pressure Indicating Device*.

A1.2.1.5 *Rigid Ball*, of diameter not less than 75 % of the nominal size of the tracheal tube undergoing test. (Not shown in figure.)

A1.2.2 *Determination of the Test Inflation Pressure*—The test inflation pressure shall be determined as follows:

A1.2.2.1 Set up the apparatus as illustrated in Fig. A1.1.

NOTE A1.1—Fig. A1.1 includes a pressure gage, but this could be isolated by a stopcock for this test.

A1.2.2.2 Place the patient end of the tracheal tube into the test tube so that the cuff is centrally located.

A1.2.2.3 Attach the inflating tube to the air supply.

A1.2.2.4 Inflate the cuff with air until it makes circumferential contact with the test tube.

A1.2.2.5 Immerse the tracheal tube and the test tube in a water bath that is thermostatically controlled at 40 ± 1°C.

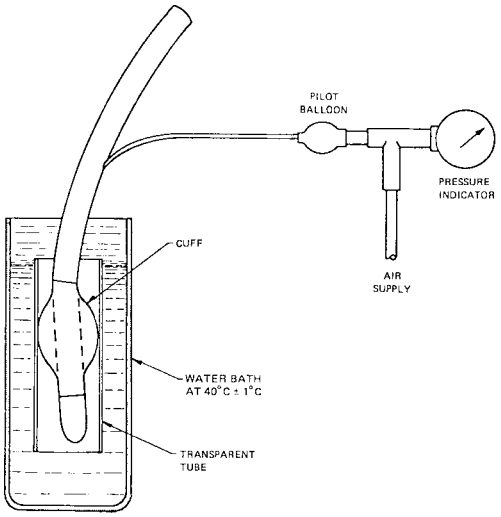

FIG. A1.1 Test for Tube Collapse (see A1.2)

A1.2.2.6 Periodically adjust the inflation volume of the air in the cuff so that circumferential contact is only just maintained.

A1.2.2.7 After 30 min in the water bath and with the inflation volume of air in the cuff adjusted so that minimum circumferential contact is maintained, record the inflation pressure of the cuff defined as the reference inflation pressure in Table A1.1. Select the test inflation pressure from Table A1.1.

A1.2.3 *Method of Test for Tube Collapse*—The following procedure shall be used to test for tube collapse:

A1.2.3.1 After determination of the test inflation pressure in accordance with A1.2.2, inflate the cuff with air at the test inflation pressure and leave for 24 h in the water bath at 40 ± 1°C. Regularly, check and maintain the test inflation pressure in the cuff during the test period.

A1.2.3.2 Check the patency of the lumen by means of a gravitational fall of a rigid ball having a diameter of not less than 75 % of the nominal size of the tracheal tube. This test is satisfied if the ball passes freely through the tube.

A1.3 *Cuff Symmetry*—The object of the test is to assess symmetrical expansion of the cuff in planes at right angles to the long axis of the tube. The following procedure shall be used to test cuff symmetry.

A1.3.1 Mount the tube on the test rig as illustrated in Fig. A1.2. The diameter of the mandrel shall be 1.0 mm less than the inside diameter of the tube. The mandrel may be designed to rotate on the base of the test rig.

A1.3.2 Inflate the cuff without external constraint until at least one diameter of the inflated cuff measures not less than 2.5 times the outside diameter of the tube. Note the inflation pressure and, if it is less than 4 kPa (30 mm Hg), continue the inflation until that pressure level is obtained.

A1.3.3 Visually inspect the inflated cuff for freedom from protuberances, obvious local areas of thinning or outpouching (bulging) (see Fig. A1.3). The presence of any of these defects shall constitute failure of this test.

A1.3.4 Adjust the height of the pointer to approximately midpoint of the cuff as in Fig. A1.2 and rotate the tube through 360° and measure the maximum distance, *B*.

A1.3.5 Without any further adjustment of the height of the pointer, rotate the tube relative to the pointer through 360° and

TABLE A1.1 Determination of the Test Inflation Pressure

Reference Inflation Pressure, kPa, (mm Hg)	Test Inflation Pressure, kPa (mm Hg)
Up to 16.6 (125)[A]	two times the reference inflation pressure or 2.7 (20), whichever is greater
Over 16.6 (125) to 33.3 (250)	33.3 (250)
Over 33.3 kPa (250)	the reference inflation pressure

[A] It is desirable that a cuff have a reference inflation pressure well below this figure, in the range of 10 to 20 mm Hg.

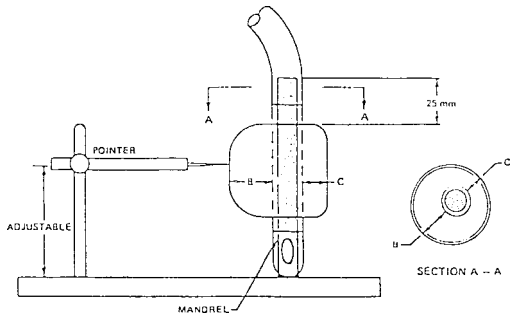

FIG. A1.2 Test Rig

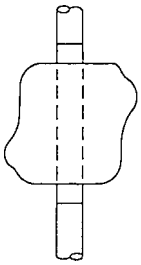

FIG. A1.3 Visual Inspection of Tube Cuff

measure the minimum distance, *C* , in Fig. A1.2.

A1.3.6 If the value calculated according to the formula, ((*B-C)/C*) × 100, is greater than 50, the tube failed the test.

A1.3.7 Readjust the height of the pointer away from the midpoint to the point between 25 and 75 % of the cuff length, where asymmetry appears greatest. Rotate the tube through 360° to measure distance *B* and repeat A1.3.5 and A1.3.6 (see Figs. A1.2 and A1.3).

A1.4 *Cuff Herniation:*

A1.4.1 *Apparatus*—Suitable apparatus is illustrated in Fig. A1.1 and Fig. A1.4 and includes the following:

A1.4.1.1 *Tube*, made of glass or rigid transparent plastics material. The length of the tube shall be about twice the effective length of the cuff. The inside diameter of the transparent tube is to be within 5 % of two times the tracheal tube size.

A1.4.1.2 *Water Bath*, thermostatically controlled at 40 ± 1°C.

A1.4.1.3 *Air Supply*.

A1.4.1.4 *Air-Pressure Indicating Device*.

A1.4.1.5 *100-g weight.*

A1.4.2 *Conditions*:

A1.4.2.1 Set up the apparatus as illustrated in Fig. A1.1, inflate the cuff with air at the Test Inflation Pressure determined in Table A1.1 and maintain that pressure in a water bath at 40 ± 1°C for 24 h.

A1.4.2.2 After 24 h, remove the inflated tracheal tube and transparent tube from the water bath. Invert and suspend the 100-g weight from the tracheal tube (see Fig. A1.4). Progressively deflate the cuff over a period of 10 s and continuously observe cuff conformation. No portion of the cuff shall encroach upon any part of the lumen at the patient end of the tube during the observation period up to the time when the tracheal tube falls freely from the transparent tube. Occlusion of a Murphy eye shall be ignored.

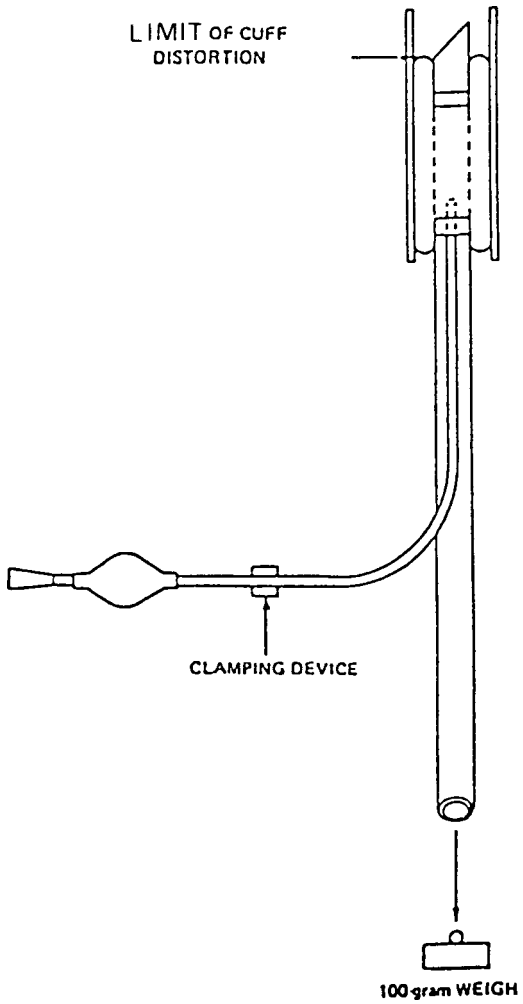

FIG. A1.4 Cuff Herniation Test

A1.5 *Cuff Diameter Assessment; and Tube Lumen Closure*—The following shall be completed to conduct this test protocol:

A1.5.1 Inflate the cuff with a 50-cm^3 syringe to an intracuff pressure of 2.0 kPa (20.4 cm H_2O) ±5 % and leave it to stabilize for 5 min at 23 ± 2°C, maintaining the pressure.

A1.5.2 Measure the largest diameter (cross-sectional dimension) in a plane perpendicular to the axis of the tube at rotated intervals of 45°. Calculate the arithmetic mean of the measurements obtained and express the results in millimetres.

A1.6 *Radiopaque Markers*—Using Test Method B in Test Methods F 640, expose the tracheal tube and an aluminum comparison standard. The aluminum comparison standard shall be a piece of aluminum 1 by 1 by 10 mm, or equivalent. The radiopaque marker on the tracheal tube shall meet the requirements stated in 7.3.10.

A1.7 *Leak Test*—Inflate the cuff to a pressure of 75 cm H_2O or to a diameter of 1½ times the resting diameter with a syringe or other inflating device conforming to ANSI/HIMA MD70.1. Detach the syringe or other inflating device. Submerge the entire inflation system of the tube in water and observe for bubbles for a period of not less than 10 s. No bubble shall be noted over the 10-s interval.

APPENDIXES

(Nonmandatory Information)

X1. RATIONALE FOR REQUIREMENTS

NOTE X1.1—This rationale is provided for the requirements in this specification. The section and subsection numbers given in parentheses at the end of each paragraph refer to the correspondingly numbered sections and subsections in the specification.

X1.1 *Tubes*—Sharp points or rough edges on the patient end of the tracheal tube, the bevel, and the eye may cause mucosal damage, particularly to the posterior nasopharynx during nasal intubations and to the cords. The internal edge of a Murphy eye is excluded because it is much less important compared with the external edges and much more difficult to round during the manufacturing process. (See 4.2.1.)

X1.2 *Rigidity*—Tracheal tube design is a trade-off of many factors; kinking and laryngeal loading are only two. (See 4.3.)

X1.3 *Integrity of Lumen*—Tube collapse due to cuff inflation is documented in Refs **(16)** and **(17)**. (See 4.4.)

X1.4 *Cuffs*—If the distance from the machine end of the cuff to the tip of the tube is too great, the tip of the tube may rest on the carina while the cuff impinges on the vocal cords. (See 5.1).

X1.4.1 Cuff and eye placement are important so that the cuff attachment sleeve does not encroach upon the eye, producing a knife-edge-like projection. (See 5.1.)

X1.4.2 The pressure versus volume and pressure versus diameter data are considered to be valuable in selecting a low-pressure cuff. Simply stated, a low-pressure, high-volume cuff must have a diameter greater than the diameter of the trachea into which the tube is to be placed. (See 5.2.)

X1.4.3 *Inflation System*—An unusually large inflation tube may project from the tracheal tube and may possibly exert pressure on airway structures. The 2.5-mm size limits this projection while allowing adequate size for the proper function of the cuff inflating system. (See 5.3.)

X1.5 *Size*—A standard system of size markings enables the user to readily select the desired tube. The tracheal tube lumen must be circular in shape to maximize cross-sectional area and reduce the potential of kinking. (See 6.2.)

X1.6 *Radius of Curvature*—A radius of curvature of about 14 cm seems to facilitate intubation. Clinical practice for more than 50 years with this curvature has proved satisfactory. Clinical data are not available to establish exact tolerance for the 14-cm requirement, but ASTM Committee F-29 consensus of ±2 cm allows considerable variation. (See 6.3.)

X1.7 *Bevels:*

X1.7.1 Although a longer bevel (smaller angle) may facilitate passage through the nares, it increases the risk of occlusion. Tracheal tubes with shorter bevels (larger angles) may be more difficult to pass through the nares or larynx. This wide tolerance on bevel angle allows for a tube to have an angle of 30° for nasal intubation or 45° for oral intubation. (See 6.4.1.)

X1.7.2 The required placement of the bevel provides better visibility during intubation because the cords can be seen before passing the bevel through. (See 6.4.2.)

X1.8 *Murphy Eye*—Although the clinical benefit of a Murphy eye has not been proven, the eye, if included, should be safe, that is, it should be placed and sized so that it does not weaken the tip, and should be large enough so that it would not impose too much resistance to flow if required to pass respiratory gases. (See 6.5.)

X1.9 For tubes used in pediatrics, outside diameter is paramount in sizing the tube for tracheal seal and for passage with minimum trauma. (See 7.3.3.)

X1.10 It is required that the inside diameter marking be particularly prominent to distinguish it as *the* number that designates size. (See 7.3.4.)

X1.11 *Identification of Tubes*—It was the intention of the committee that tubes manufactured to meet all the requirements of this specification should be identified by "F-29." ASTM Committee F-29 felt that the confusing and sometimes misleading "F-29/IT" should not be used and particularly wanted to make it clear that the markings" F-29/IT" would not indicate compliance with this specification. (See 7.3.6.)

X1.12 *Sterile Tubes*—Bold type designating the inside diameter on the package is necessary so that tube size may be rapidly determined under emergency conditions where lighting may be less than ideal. (See 8.2.)

X2. DISCONTINUED TEST PROTOCOLS

NOTE X2.1—The following test protocols have been retained in this specification for informational purposes only. These tests came from predecessor documents ANSI Z79.14-1983 and Z79.16-1983. This appendix is numbered in accordance with ASTM form and style. This also applies to the numbering of figures. The numbers in parentheses at the end of each paragraph refer to the original numbering of sections used in ANSI Z79.14-1983 and Z79.16.-1983.

X2.1 *Test Protocol One—Tracheal Seal, Slope Pressure, and Lumen Closure Conditions*—The test apparatus (see Fig. X2.1) shall consist of a vertically mounted model trachea (Fig. X2.2), a test lung (or equivalent), mechanical ventilator, a pressure tap for measuring airway pressure, and a means for maintaining a specified temperature at 37 ± 1°C and relative humidity at 90± 10 %. Tracheal seal ventilation shall be defined as a condition in which a leak not to exceed 5 % of the tidal volume is evident in the flowmeter during mechanical ventilation. Conditions for mechanical ventilation shall consist of the ventilator and test lung settings necessary to produce a compliance of 150 to 350 mL/kPa (15.3 to 35.7 mL/cm H_2O), a resistance of 1 to 3 kPa/L/s (10.2 to 30.6 cm H_2O/L/s), a tidal volume of 500 mL, a frequency of 20/min, and a peak pressure of 3 to 4 kPa (30.6 to 40.8 cm H_2O). The inspiratory to expiratory ratio (I:E ratio) may be adjusted to meet these conditions, but shall not exceed 1:1 (8.1, 8.1.1).

X2.2 *Test Procedure*—The following steps shall be completed to conduct test protocol one (8.1.2):

X2.2.1 Assemble the test apparatus (see Fig. X2.1) in the following manner:

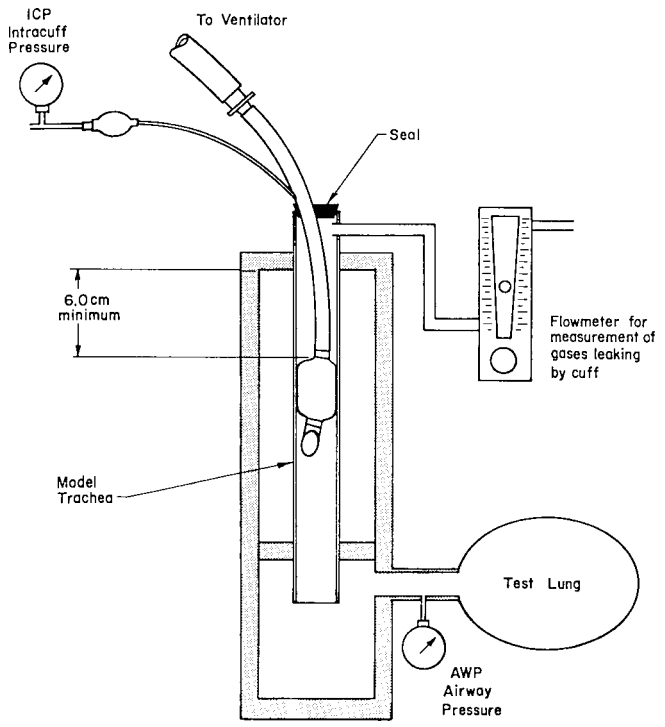

FIG. X2.1 Schematic of Cuffed Tracheal Tube in Model Trachea Mounted Vertically in Test Apparatus

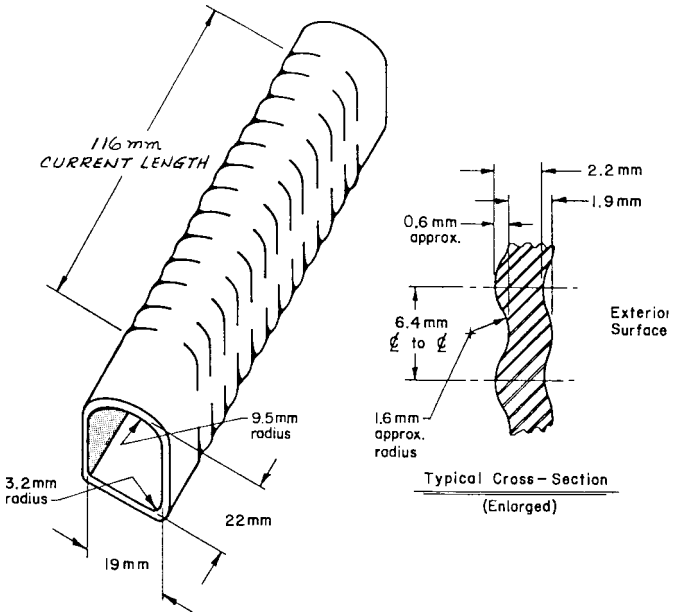

FIG. X2.2 Clear Polyvinyl Chloride (PVC) Adult Model Trachea

X2.2.1.1 Connect the pressure indicator to test apparatus at the junction with the test lung to determine airway pressure (AWP). (Record the accuracy and frequency response of the indicator.)

X2.2.1.2 Attach tubing and flowmeter for measurement of gases leaking past cuff.

X2.2.2 Place the size 8.0 cuffed tracheal tube in the model trachea for 4 h under specified conditions (see 8.1), prior to the test. Position the tube so that the upper margin of the cuff is at least 6 cm below the lower margin of the seal of the test apparatus. Seal the upper margin of the test apparatus.

X2.2.3 Connect the ventilator to the tracheal tube. Under specified conditions (see 8.1), ventilate the model trachea and test lung with heated, humidified air for 10 min with cuff deflated.

X2.2.4 Determine the intracuff volume and pressure necessary for tracheal seal ventilation in the following manner:

X2.2.4.1 Inflate cuff. Carefully adjust the cuff pressure until the desired leak is obtained. This pressure is defined as the intracuff pressure (ICP) for tracheal seal ventilation and the volume is defined as the intracuff volume (ICV) for tracheal seal ventilation. Record the ICP and the ICV, and the maximum and minimum AWP. Repeat this procedure on the same tube four additional times.

X2.2.4.2 Calculate the mean and standard deviation of at least these five determinations.

X2.2.5 Determine the overinflation slope-pressure curve and lumen patency as follows:

X2.2.5.1 Disconnect ventilator and test lung; remove the base of the test apparatus.

X2.2.5.2 Inflate the cuff to tracheal seal ventilation pressure, ±0.05 kPa (±0.5 cm H_2O), and record the volume in the cuff.

X2.2.5.3 Further inflate the cuff in 1.0-mL increments until a larger volume (either two times the tracheal seal ventilation

volume or two times the testing volume) is reached. Check lumen patency by means of the free gravitational fall of a steel ball having a diameter of not less than 75 % of the nominal marked inside diameter of the tracheal tube.

X2.2.5.4 Record the ICV and ICP at each point.

X2.2.5.5 Perform this procedure four additional times on the same tube.

X2.2.5.6 Calculate the mean ±1 standard deviation of X2.2.5.4.

X2.3 *Ability to Conform to Human Anatomy and Resistance to Kinking*—Ten size 6.0-mm tubes and 10 size 8.0-mm tubes shall be used to determine the force (mean value ±1 standard deviation) required to achieve conformity. By placing the pegs on the test board so that the closest point to the tube is given by the coordinates in Table X2.1, the desired anatomical configuration is defined by both size 6.0 and 8.0 tubes. Other equivalent systems may be used (see Fig. X2.3) (8.2).

X2.3.1 *Storage Conditions*—With cuff removed or deflated, store each tube (unstressed) in a conditioning environment of 24 ± 1°C and 60 % relative humidity (RH)± 10 % RH for at least 60 ± 10 min (8.2.1).

X2.3.2 *Test Procedure*— Immediately after removing the tube from the conditioning environment, place the tube on the test board (see Fig. X2.3), with the cuff area placed under Peg F. Follow the tube's natural curvature for this placement. For reference in subsequent tube positioning, mark the most vertical uppermost surface at each end of the tube and mark the portion of the tube resting directly over Peg J (8.2.2).

X2.3.2.1 Loop a 1-cm-wide strap around the tube midway between Pegs J and K. Attach the strap to a force gage.

X2.3.2.2 Lift the tube 0.5 mm with the strap, pulling only in the direction of the *Y* axis. Record the force required to move the tube this distance.

X2.3.2.3 Immediately after the measurement, relax tension on the strap, and check the patency of the tube lumen by means of the free gravitational falls of a steel ball having the diameter of not less than 75 % of the labeled internal diameter of the tracheal tube. This test is performed with the test board's *Y* axis parallel to the force of gravity.

TABLE X2.1 Coordinates for Positioning Pegs on Test Board (Force Necessary to Conform to Human Anatomy)

Peg[A]	*X*-Coordinate, mm	*Y*-Coordinate, mm
A	−102	44
B	−92	44
C	−66	10
D	−53	5
E	−38	2
F	80	6
G	−96	−10
H	−82	−30
I	−50	−18
J	0	0
K	20	0

[A] Peg placements represent anatomical structures that establish limits on the positions a tracheal tube may occupy in human airways.

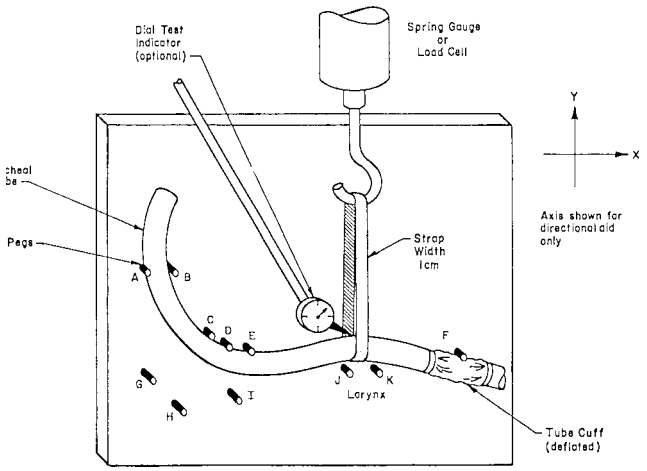

FIG. X2.3 Test Board

X2.3.2.4 Store each tube to be tested on the test board or on a fixture with an equivalent positional restraint(s), in an environment of 37 ± 1°C and 90 ± 10 % RH for a period of 60 ± 10 min or until thermal equilibrium is reached. If the tube is transferred from the test board to another fixture, maintain the same orientation with respect to the tube's natural curvature, using the indexing marks specified in this procedure, and, with the same orientation, return the tube to the test board after environmental conditioning.

X2.3.2.5 Repeat X2.3.2.1-X2.3.2.3, inclusive. Again, be careful to maintain the same orientation with respect to the tube's natural curvature, using the indexing marks specified in this procedure.

X2.4 *Tracheal Seal:*

X2.4.1 For size 8.0 tubes, the manufacturer shall make available upon request the intracuff pressure and volume (mean values ± one standard deviation (SD) necessary to provide a seal in the model trachea. (See Refs **(2), (3),** and **(4)** for background information.)

X2.4.2 The tracheal seal shall be tested in accordance with the method in X2.1.

X2.5 *Cuff Slope Pressure Effects:*

X2.5.1 For size 8.0 tubes, the manufacturer shall make available upon request a plot of pressure versus volume as determined in the model trachea for volumes ranging from tracheal seal ventilation volume (see X2.2) to a larger volume (either two times the tracheal seal ventilation volume or two times the resting volume (see section 8.1.2) (A1.5).

X2.5.2 Slope pressure effects shall be tested in accordance with the method in X2.1.

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