



Standard Specification for Suction Catheters for Use in the Respiratory Tract¹

This standard is issued under the fixed designation F 1981; 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

This specification provides dimensions and requirements for suction catheters for use in the respiratory tract. The basis of this specification is ISO 8836: 1997. There are major differences in the addition of mandatory suction catheter “eyes,” removal of color coding, and inclusion of closed circuit suction catheters.

Size is designated by outside diameter, which is important when selecting catheters, because of its relationship to the ease with which the catheter can be passed through a tracheal or tracheostomy tube (see Specifications F 927, F 1242, F 1627, and F 1666 for details of requirements for tracheal tubes and tracheostomy tubes). Requirements for suction catheters made of rubber have been deleted because they are no longer in general use.

1. Scope

1.1 This specification provides requirements for suction catheters intended for use in suction of the respiratory tract.

1.2 Angled-tip suction catheters, for example, Coudé catheters, and closed circuit suction catheters are not considered to be specialized, and therefore, are included in this specification. Specialized suction devices are excluded from this specification.

1.3 Flammability of suction catheters, for example if flammable anesthetics, electrosurgical units, or lasers are used, is a well-recognized hazard that is addressed by appropriate clinical management and is outside the scope of this specification.

2. Referenced Documents

2.1 ASTM Standards:

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

F 927 Specification for Pediatric Tracheostomy Tubes²

F 1205 Specification for Anesthesia Breathing Tubes²

F 1242 Specification for Cuffed and Uncuffed Tracheal Tubes²

F 1627 Specification for Tracheostomy Tubes—Pediatric Tracheostomy Tubes²

F 1666 Specification for Adult Tracheostomy Tubes²

2.2 ISO Standards:

ISO 7000 Graphical Symbols for Use on Equipment—

Index and Synopsis³

ISO 8836–1997 Suction Catheters for Use in the Respiratory Tract³

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *adapter, n*—specialized connector to establish functional continuity between otherwise disparate or incompatible components.

3.1.2 *closed circuit suction catheter, n*—a suction catheter that is encased in a flexible, collapsible sleeve attached to a breathing circuit connector and intended to permit airway suctioning while maintaining the integrity of the breathing circuit.

3.1.3 *connector, n*—fitting to join together two or more components.

3.1.4 *eye, n*—lateral aperture near the patient end of the catheter.

3.1.5 *machine end, n*—end of the catheter intended to be connected to a source of vacuum.

3.1.6 *patient end, n*—end of the catheter intended to be inserted into the patient.

3.1.7 *residual vacuum, n*—negative pressure at the patient end of the suction catheter when the vacuum control device is in the relief position.

3.1.8 *shaft, n*—main part of the catheter, which is of uniform outside diameter.

3.1.9 *suction catheter, n*—flexible tube designed for introduction into a patient airway to remove material by suction.

¹ This specification is under the jurisdiction of ASTM Committee F29 on Anesthetic and Respiratory Equipment and is 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 (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

3.1.10 *terminal orifice, n*—central opening at the patient end of the suction catheter.

3.1.11 *tip, n*—the patient end of a suction catheter.

3.1.12 *vacuum control device, n*—means provided at or near the machine end of a suction catheter to control the flow of gases and entrained material.

4. Material

4.1 Suction catheters for use in the respiratory tract, in their ready-to-use state after any preparation for use recommended by the manufacturer, shall satisfy appropriate biological safety testing, as indicated in Specification F 813.

NOTE 1—It is recommended that the shaft be colorless and either transparent or translucent.

NOTE 2—The outside surface of the suction catheter should have characteristics, which would facilitate insertion through all types of plastic, rubber, and metal oro- and naso-tracheal tubes, tracheostomy tubes, and appropriate connectors.

NOTE 3—Suction catheters, under normal conditions of use, should be reasonably resistant to deterioration by anesthetic vapors and gases in clinical concentrations.

5. Size Designation and Dimensions

5.1 *Size Designation*—The size of suction catheters shall be designated by the following:

5.1.1 The nominal outside diameter of the shaft, expressed in mm. Additionally, it may be expressed in French (Charrière)-gauge size;

NOTE 4—For the purposes of this specification, the French (Charrière)-gauge system of size (F) is based on the outside diameter of the shaft gaged in steps of thirds of 1 mm. For example, 1 mm corresponds to 3F. The French (Charrière)-gauge size is not an SI unit.

5.1.2 The nominal shaft length, expressed in mm.

5.2 Dimensions:

5.2.1 The outside diameter and the minimum inside diameter of suction catheters, excluding the tip, shall be in accordance with Table 1.

5.2.2 The diameter of the terminal orifice shall not be less than 90 % of the minimum inside diameter specified in Table 1.

5.2.3 The actual shaft length shall be the marked shaft length ± 5 %. For closed circuit catheters, the marked length shall be the length that can be inserted into the patient’s airway.

TABLE 1 Basic Dimensions of Suction Catheters-Metric Sizes

Nominal Outside Diameter, mm	Designated Size		Minimum Inside Diameter, mm
	French (Charrière) Size Equivalent, F or Ch	Outside Diameter Tolerance, mm	
1.33	4	±0.1	0.55
1.5	4.5	±0.1	0.7
1.67	5	±0.1	0.8
2	6	±0.1	1.05
2.5	7.5	±0.1	1.45
2.67	8	±0.1	1.5
3	9	±0.15	1.75
3.33	10	±0.15	2
4	12	±0.15	2.45
4.67	14	±0.2	2.95
5	15	±0.2	3.2
5.33	16	±0.2	3.4
6	18	±0.2	3.9
6.67	20	±0.2	4.3

6. Design

6.1 *Lumen*—The inside diameter of the shaft at any point between the machine end and the eye nearest to the machine end shall be not less than the inside diameter of the shaft at that eye.

6.2 Patient End:

6.2.1 The suction catheter shall have a terminal orifice and one or more eyes.

NOTE 5—The use of a catheter with eye(s) reduces the likelihood of mucosal trauma during suctioning^{4,5} (see Appendix X1).

NOTE 6—The dimensions of the eye(s) should be such that they do not cause the suction catheter to kink or collapse in use.

NOTE 7—The edges of eye(s) and the terminal orifice of the suction catheter should be smooth and free from sharp edges.

NOTE 8—The tip should be well-rounded.

6.2.2 The axis of the patient end may be at an angle to the long axis of the shaft (see Coudé catheter tips in Fig. 1).

6.3 Machine End:

6.3.1 The machine end of the suction catheter shall be one of the following:

6.3.1.1 *Female*—Designed to receive a male-to-male adapter suitable for connection to a vacuum source that terminates in a female end;

6.3.1.2 *Male*—Designed for connection to a vacuum source that terminates in a female end; or,

6.3.1.3 A permanently-attached vacuum control device that terminates in either a male or female end.

6.3.2 Female ends shall be semi-rigid or elastomeric and shall be either conical or cylindrical (see Fig. 1) over a length of not less than 20 mm.

NOTE 9—Where a suction catheter with a female machine end is provided for use with a vacuum source with a female end, a male-to-male adapter is needed. The minimum inside diameter of the adapter should be not less than the minimum inside diameter of the suction catheter with which it is provided. The adapter should fit inside elastomeric tubing having an inside diameter of 6 mm.

6.3.3 Male ends shall be rigid or semi-rigid and shall fit inside elastomeric tubing having an inside diameter of 6 mm (see Fig. 1). The inside diameter of the male end shall not be less than the minimum inside diameter of the suction catheter with which it is provided.

NOTE 10—It is advantageous if the male end fits inside elastomeric tubing with a larger inside diameter, which may be used in an emergency to clear the airway.

6.3.4 The machine end of a suction catheter having an angled patient end, by a mark or other means, shall indicate the direction in which the tip points.

7. Performance Requirements

7.1 *Security of Construction*—When tested in accordance with Annex A1, the force required to detach any component permanently attached to the shaft shall be not less than that specified in Table 2.

⁴ Link, W. J., Spaeth, E. E., Wahle, W. M., Penny, W., and Glover, J. L., “The Influence of Suction Catheter Design on Tracheobronchial Trauma and Fluid Aspiration Efficiency,” *Anesthesia and Analgesia*, Vol 55, pp. 290–97, 1976.

⁵ Lomholt, N., “Design and Function of Tracheal Suction Catheters,” *Acta Anaesthesiologica Scand.* Vol 29, pp. 1–3, 1982.

a

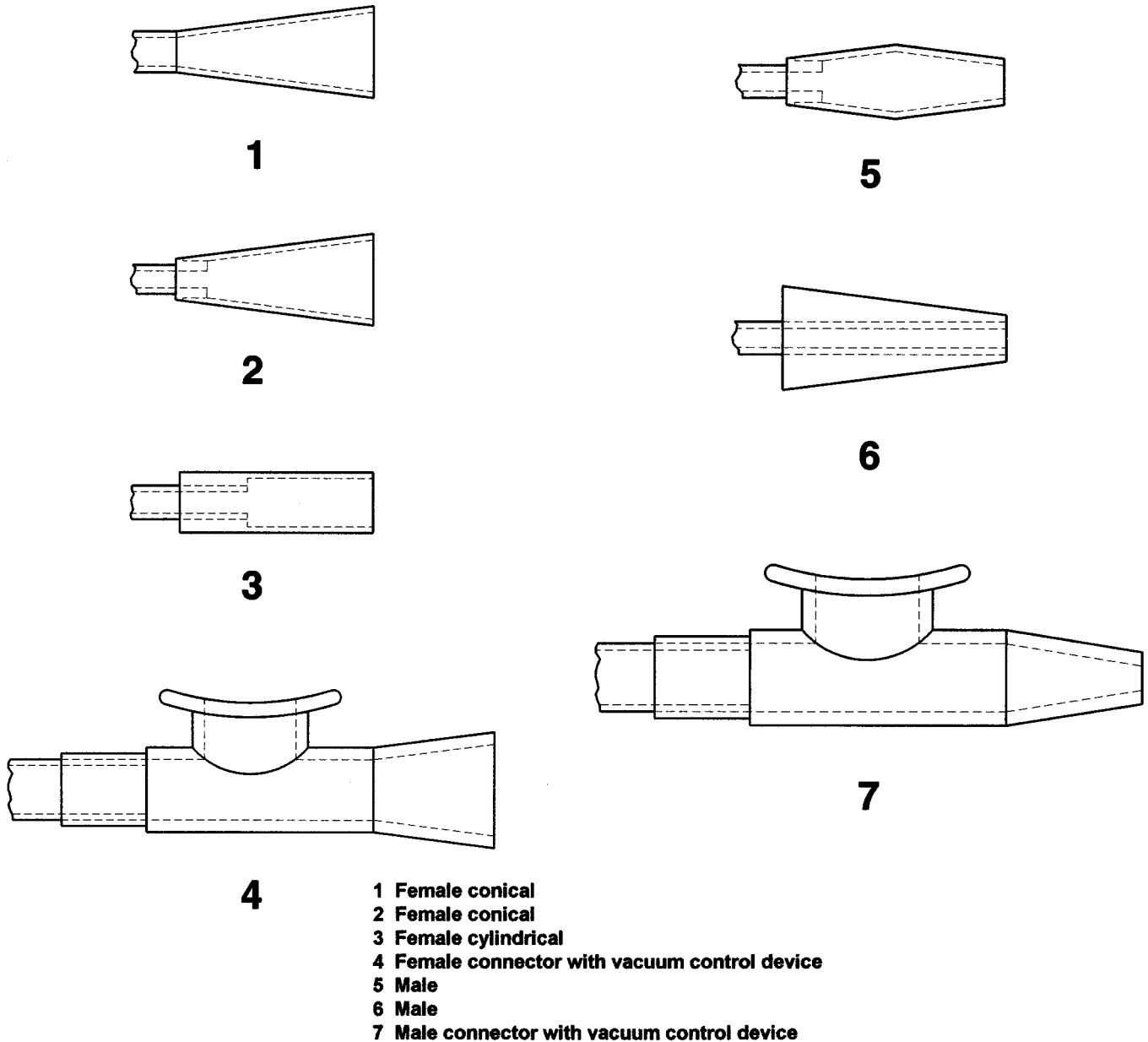


FIG. 1 Examples of Different Designs for a) Machine Ends, and b) Patient Ends of Suction Catheters for Use in the Respiratory Tract

7.2 *Shaft*—When the machine end of the suction catheter is connected to a vacuum source at 40 kPa below ambient pressure for 15 s at a temperature of $23 \pm 2^\circ\text{C}$ with the patient end openings occluded and the vacuum control device, if present, occluded, the shaft shall not collapse.

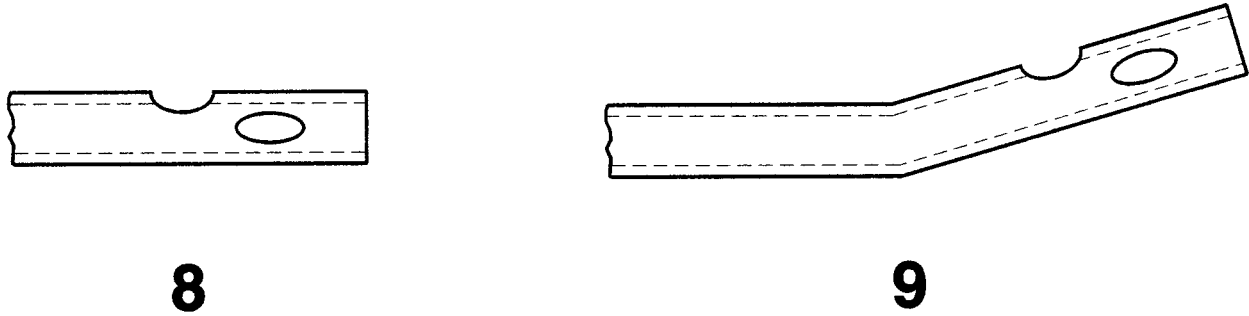
NOTE 11—Occlusion of the vacuum control device is intended for control devices that normally are open to atmosphere and require occlusion to apply the vacuum. Catheters that have vacuum control

devices, which normally are closed and require opening to apply the vacuum, should be placed in the fully open position for this test.

7.3 *Residual Vacuum*—When a suction catheter fitted with a permanently-attached vacuum control device is tested in accordance with Annex A2, the residual vacuum shall not exceed 0.33 kPa.

7.4 *Leakage for Closed Circuit Suction Catheter Systems*—Closed circuit systems must meet the leakage requirements for

b



8 Catheter tip with eyes
9 Coudé catheter tip with eyes

FIG. 1 Examples of Different Designs for a) Machine Ends, and b) Patient Ends of Suction Catheters for Use in the Respiratory Tract (continued)

TABLE 2 Minimum Force Needed to Detach Any Component Permanently Attached to Shaft

Designated Size (Outside Diameter), mm	Minimum Force, N
1.33 to 2.67	5
3 to 4.67	15
≥5	20

breathing tubes (see Specification F 1205) when tested with the suction catheter fully retracted, vacuum applied to the catheter sleeve as specified in Annex A2, and with the relief control device in the suction relief/cutoff position (see Appendix X1.2).

8. Packaging and Labeling

8.1 *Marking of Suction Catheters:*

8.1.1 Suction catheters that are not individually packaged shall be marked with the nominal outside diameter in accordance with 5.1.

8.1.2 Suction catheters that are individually packaged may be marked with the nominal outside diameter, expressed as millimeters or French (Charrière)-gauge (see 5.1).

NOTE 12—Manufacturers of the smaller sizes of suction catheters for pediatric use are encouraged also to mark the distance, in cm or parts thereof, from the patient end.

8.2 *Marking of Individual Packs*—The marking of individual packs shall include the following:

8.2.1 A description of contents;

8.2.2 The designated size in accordance with 5.1.1, expressed in accordance with one or both of the following examples:

8.2.2.1 6 mm (18 F) × 500 mm; or,

8.2.2.2 6 mm (18 Ch) × 500 mm;

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

8.2.4 The batch number;

NOTE 13—It is strongly recommended that the “use by” date be given.

8.2.5 The word “STERILE,” if appropriate;

8.2.6 For suction catheters not intended for reuse, the words “single use,” or the equivalent.

8.3 *Marking of Shelf or Multi-Unit Packs*—The marking of shelf or multi-unit packs shall include the following:

8.3.1 A description of contents; and

8.3.2 The designated size in accordance with 5.1.1, expressed in accordance with one or both of the following examples:

8.3.2.1 6 mm (18 F) × 500 mm; or,

8.3.2.2 6 mm (18 Ch) × 500 mm;

8.3.3 The name or trademark, or both, and the address of the manufacturer or supplier, or both;

8.3.4 The batch number;

NOTE 14—It is strongly recommended that the “use by” date be given.

8.3.5 The word “STERILE,” if appropriate;

8.3.6 For suction catheters intended for reuse, instructions for cleaning and sterilization shall be given. For suction catheters supplied nonsterile, appropriate instruction on preparation for use shall be provided.

8.3.7 For suction catheters not intended for reuse, the words “single use,” or the equivalent.

8.4 *Use of Symbols*—The requirements of 8.2 and 8.3 may be met by the use of appropriate symbols as given in ISO 7000.

ANNEXES

(Mandatory Information)

A1. TEST FOR SECURITY OF CONSTRUCTION

A1.1 *Principle*—The security of attachment of any component permanently attached to the shaft is tested by applying an axial separation force to the component relative to the shaft of the suction catheter.

A1.2 *Apparatus:*

A1.2.1 Means of conditioning the suction catheter at $23 \pm 2^\circ\text{C}$ and $50 \pm 20\%$ relative humidity and carrying out the test under the same conditions.

A1.2.2 Means of separately securing the component under test and the shaft of the suction catheter and separating the two at a rate of 250 ± 20 mm/min and measuring and recording the axial separation force applied.

A1.3 *Procedure:*

A1.3.1 Condition the suction catheter at $23 \pm 2^\circ\text{C}$ and $50 \pm 20\%$ relative humidity for 1 h and carry out the test under the same conditions.

A1.3.2 Separate the component under test and the shaft of the catheter at a rate of 250 ± 20 mm/min and observe whether the component becomes detached from the shaft before the appropriate minimum force given in Table 2 has been reached.

A1.4 *Expression of Results*—Record whether the component becomes detached from the shaft before the appropriate minimum force given in Table 2 has been reached.

A2. MEASUREMENT OF RESIDUAL VACUUM

A2.1 *Principle*—The effectiveness of the vacuum control device as a means of relieving vacuum at the patient end is tested by measuring the residual vacuum at the tip of the catheter with the vacuum control device in the relief position and with suction being applied to the machine end of the catheter. Vacuum control devices, which rely on cutoff mechanisms, cannot be tested effectively by this test method; therefore, these devices are excluded from this test method.

NOTE A2.1—More stringent requirements are provided in 7.4 regarding leakage for closed circuit suction catheter systems.

A2.2 *Apparatus:*

A2.2.1 *Flowmeter*, capable of measuring a flow of 30 L/min with an accuracy of $\pm 5\%$ and a resistance to flow of less than 0.1 kPa at 30 L/min.

A2.2.2 *Adjustable Vacuum Pump.*

A2.2.3 *Manometer*, with an accuracy of ± 0.01 kPa.

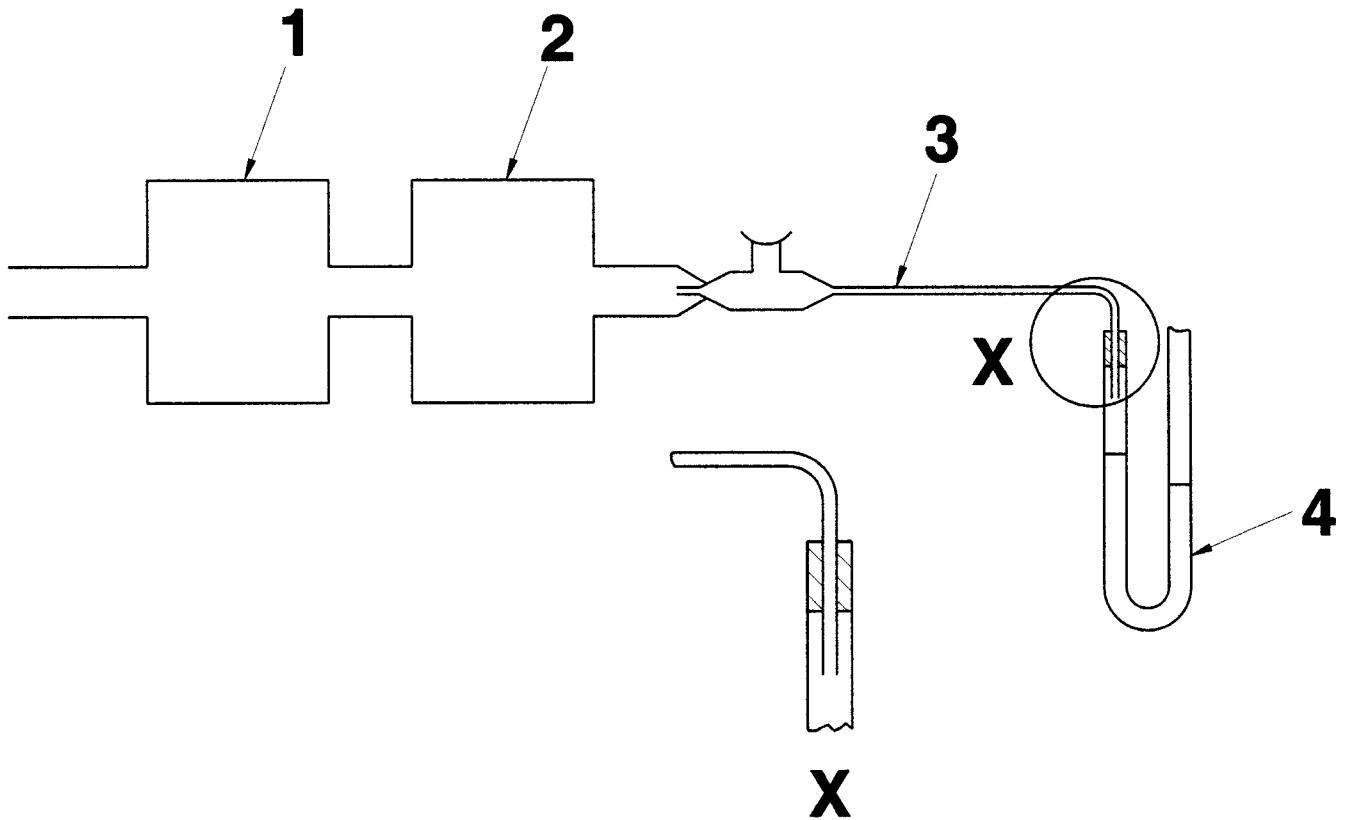
A2.3 *Procedure:*

A2.3.1 Assemble the apparatus, as shown in Fig. A2.1, with the flowmeter fitted to the exit of the vacuum pump, ensuring an airtight fit between the catheter and the manometer.

A2.3.2 Place the catheter vacuum control device in the relief position.

A2.3.3 Switch on the vacuum pump and adjust the applied vacuum until a flow of 30 L/min is indicated on the flowmeter.

A2.4 *Expression of Results*—Express the residual vacuum, in kilopascals, as indicated by the reading on the manometer.



- 1 Flowmeter**
- 2 Vacuum pump**
- 3 Suction catheter with vacuum control device**
- 4 Manometer**

FIG. A2.1 Apparatus for Residual Vacuum Test

APPENDIX

(Nonmandatory Information)

X1. RATIONALE FOR REQUIREMENTS

X1.1 The requirement for a minimum of one eye, in addition to the terminal orifice, is included because suction catheters with only a terminal orifice have been shown to cause more mucosal damage than those with eyes.

X1.2 The rationale for the requirements provided in 7.4 is that closed circuit suction catheters are intended to remain a part of the breathing circuit; therefore, a cross-reference to the breathing tube standard, Specification F 1205, is included.

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