



Designation: F 1573 – 95 (Reapproved 2000)

Standard Specification for Anesthetic Equipment—Oropharyngeal and Nasopharyngeal Airways¹

This standard is issued under the fixed designation F 1573; 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.

1. Scope

1.1 This specification covers minimum performance and safety requirements for oropharyngeal and nasopharyngeal airways for human use.

1.2 Size designations, dimensions, and tolerances; material compatibility; product marking and labeling; and packaging are considered.

1.3 Because of the wide variation in size and configuration of the human airway, various conditions of use, user preferences, and cost, this specification cannot cover all types of oropharyngeal and nasopharyngeal airways.

1.4 Standards for the types of airways not specifically addressed by this specification may be developed in the future.

1.5 This specification is not intended to limit the development of the other devices so long as the minimum safety and performance requirements stated herein are met.

2. Referenced Documents

2.1 ASTM Standards:

ANSI Z79.3-1983 Anesthetic Equipment—Oropharyngeal and Nasopharyngeal Airways²

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *buccal end (flanged end)*—the end of the airway that is flanged and is expected to fit between the teeth or gums or against the external nares.

3.1.2 *nasopharyngeal airway*—a device intended to maintain the patency of respiratory passages through the nasal cavity into the pharynx.

3.1.3 *oropharyngeal airway*—a device intended to maintain the patency of respiratory passages through the oral cavity into the pharynx.

3.1.4 *pharyngeal end*—the end of the airway that is intended to be inserted into the patient's pharynx.

3.1.5 *shall*—the word “shall,” as used in this specification, is to be understood as denoting a mandatory requirement.

3.1.6 *should*—the word “should,” as used in this specification, is to be understood as denoting a recommendation that is a sound safety practice: it does not denote a mandatory requirement.

4. Size Designation

4.1 *Measurement System*—The metric system shall be the standard of measurement used. Other units of measure may be provided as supplemental information.

4.2 Size:

4.2.1 *Oropharyngeal Airways*—The size of oropharyngeal airways shall be designated by a number giving the nominal length in centimetres in accordance with Table 1^{3,4} and Fig. 1(a) and (b).

4.2.2 *Nasopharyngeal Airways*—The size of nasopharyngeal airways shall be designated by a number expressing the inside diameter in millimetres as the primary dimension, in accordance with tolerances given in Table 2^{3,4,5} and Fig. 1(c).

5. Materials and Manufacture

5.1 Airways shall be fabricated from plastics, or elastomeric materials, or from combinations of these materials.

5.1.1 Airways shall be nontoxic and compatible with the human tissue with which they are intended to be used, as determined by the implantation test in the *U.S. Pharmacopeia*.⁶

NOTE 1—The designs shown in Fig. 1 and Fig. 2 are intended to illustrate typical common types of airways for the purpose of size designation and marking, but are not otherwise intended to form a part of this specification.

5.1.2 All material should be resistant to changes or deterioration from normal concentrations of substances encountered during routine use.

5.2 Reusable airways shall be made of material capable of being sterilized. The manufacturer shall supply recommended methods of sterilization.

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

³ Table 1 and Table 2 are intended to relate nominal size to the length (or diameter) of the airway. Clinical practice neither suggests nor requires the availability of all nominal sizes given in the tables.

⁴ Sizes not shown may be added by interpolation.

⁵ For nasopharyngeal airways, the actual outside diameter shall be designated on the product or the package label within ± 0.5 mm (see X1.1.2).

⁶ See *U.S. Pharmacopeia*, 12601 Twinbrook Pkwy., Rockville, MD 20852.

TABLE 1 Dimensions and Tolerances of Oropharyngeal Airways

Nominal Size of Airway	Length (L), mm	Tolerance, Length (L), mm
3	30	±2.5
3.5	35	±2.5
4	40	±2.5
4.5	45	±2.5
5	50	±2.5
5.5	55	±2.5
6	60	±2.5
6.5	65	±2.5
7	70	+5.0
...	...	-2.5
8	80	±5.0
9	90	±5.0
10	100	±5.0
11	110	±5.0
12	120	±5.0

TABLE 2 Dimensions and Tolerances of Nasopharyngeal Airways

Nominal Size of Airway	Inside Diameter, mm	Suggested Length, mm
5.0	5.0 ± 0.2	90
5.5	5.5 ± 0.2	100
6.0	6.0 ± 0.2	110
6.5	6.5 ± 0.2	120
7.0	7.0 ± 0.2	130
7.5	7.5 ± 0.2	140
8.0	8.0 ± 0.2	150
8.5	8.5 ± 0.2	160
9.0	9.0 ± 0.2	170

6.1.2 Oropharyngeal airways shall have sufficient rigidity at the buccal (flanged) end (by use of an insert, if necessary) to prevent collapse when bitten by the patient. Collapse shall have occurred when the airway has narrowed to the point of interfering with the passage of a correctly sized suction catheter or to a 25 % reduction in available airflow under incisor bite of 225 N. (See X1.1.5.1 and X2.1.2).

6.1.3 Edges and corners that may come in contact with the patient's tissues should have a minimum radius of curvature of 0.5 mm.

6.1.4 The oropharyngeal airway (or its package or package insert) should be clearly marked with the designation, "DO NOT USE AS A BITE BLOCK" to prevent incisor luxation that is a common sequel to such use of oropharyngeal airways.

6.2 Nasopharyngeal Airways:

6.2.1 The nasopharyngeal airway shall be constructed to prevent kinking in use. Kinking shall have occurred when the airway, bent into the same curvature as the human nasopharynx, has flattened to the point of interfering with the passage of a steel ball that is 50 % of the diameter of the airway lumen. (See X1.1.5.1 and X2.1.2)

6.2.2 Nasopharyngeal airways that have been preformed into the correct anatomical curvature shall be straightened for testing and shall not kink or interfere with the passage of the steel ball described in 6.2.1.

6.2.3 The diameter of the flange shall be at least twice the outside diameter of the tube.

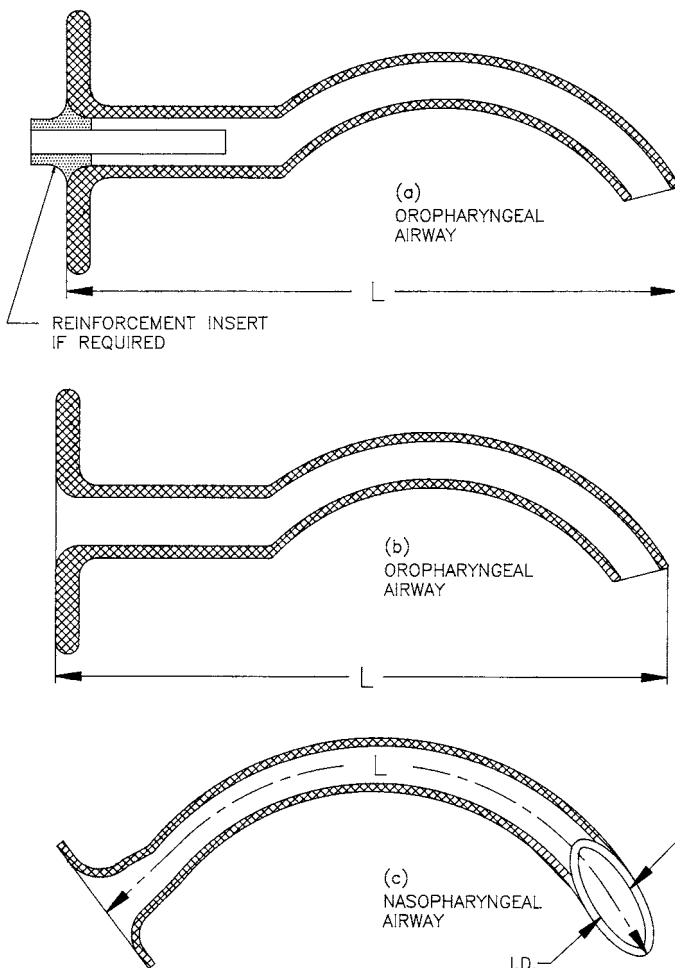
7. Workmanship, Finish, and Appearance

7.1 Mismatch of surfaces produced by molds shall not cause a depression of one surface relative to another by more than 0.15 mm, if the surfaces were designed to produce a continuous surface. All surfaces shall be generally smooth and free of flash.

8. Product Marking

8.1 Each oropharyngeal airway shall be permanently and clearly marked with nominal size and name or trademark of the manufacturer as shown in Fig. 2(a) and 2(b). The nominal size should be further suffixed by the abbreviation, "cm" (centimetres).

8.2 Each nasopharyngeal airway shall be permanently and clearly marked with the nominal size as shown in Fig. 2(c). The manufacturer's name or trademark shall also be clearly marked on the



5.3 Airways intended for single use or packages containing such airways shall be marked "Single Use Only" or "Do Not Reuse" (see 8.4 and 9.4).

6. Design

6.1 Oropharyngeal Airways:

6.1.1 Oropharyngeal airways should have sufficient rigidity to keep the base of the tongue in a forward position while the airway is in use.