
International Standard



5364

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Oropharyngeal airways

Canules oro-pharyngées

Second edition — 1986-07-01

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UDC 615.473

Ref. No. ISO 5364-1986 (E)

Descriptors : medical equipment, pharyngeal cannulae, specifications, dimensions, designation, marking, packing.

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 5364 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*.

This second edition cancels and replaces the first edition (ISO 5364:1980), of which it constitutes a minor revision.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

Oropharyngeal airways

0 Introduction

Because of wide variations in the size and anatomical configuration of the human oropharynx, various conditions of use, user preferences and cost, a reasonable latitude which does not decrease safety or serviceability of oropharyngeal airways seems desirable. Therefore, it is not the intent of this International Standard to prescribe an exact design with narrow limits of dimensions and tolerances, which would preclude serviceability or deter future development.

1 Scope and field of application

This International Standard specifies the size designation and certain basic requirements for oropharyngeal airways which may include but are not limited to the following types :

- Guedel's
- Phillip's
- Water's

2 Definitions

2.1 oropharyngeal airway : Device intended to maintain the patency of the respiratory passages through the oral cavity and pharynx.¹⁾

2.2 pharyngeal end : That end of the oropharyngeal airway which is intended to be inserted into the patient's oropharynx.

2.3 buccal end; flanged end : That end of the oropharyngeal airway which is flanged and is expected to fit between the teeth or gums at the lips.

3 Size designation

The size of oropharyngeal airways shall be designated by a number giving the nominal length, L , expressed in centimetres in accordance with the table. See figure 1.

4 Materials

4.1 Oropharyngeal airways may be manufactured from plastics or elastomeric materials or from combinations of these materials. A metal insert may be present (see figure 1).

NOTE — The user is reminded of the frequent association of trauma with metal oropharyngeal airways. Teeth are particularly subject to trauma from oropharyngeal airways.

4.2 All materials shall be non-toxic and compatible with the human tissues with which they are intended to be used.

4.3 All materials shall be resistant to changes or deterioration caused by anaesthetic gases and vapours, commonly used water-soluble lubricants and topical anaesthetics.

4.4 When a metal insert is used, it shall be of a suitable corrosion-resisting type or finished with a durable corrosion-resisting finish.

4.5 Unless the airway is intended for a single use, it shall be made of material capable of being resterilized.

5 Design

5.1 The airway shall have sufficient rigidity to keep the base of the patient's tongue in a forward position while the airway is in use.

5.2 The airway shall have sufficient rigidity at the buccal (flanged) end, by use of an insert if necessary, to prevent collapse when bitten by the patient.

1) Definition taken from ISO 4135, *Anaesthesiology — Vocabulary*.

5.3 Edges and corners that may come into contact with the patient's tissues shall have a minimum radius of curvature of 0,5 mm.

6 Finish

All surfaces shall be smooth and free of flash. Mould mismatch of surfaces shall not cause a depression of one surface relative to another by more than 0,15 mm in the event that the intended match was designed to produce a continuous surface.

7 Information to be provided by the manufacturer

Unless the airway is intended for single use, acceptable methods of sterilization shall be recommended by the manufacturer.

8 Marking

Each airway shall be permanently and clearly marked with the nominal size and the name or trademark of the manufacturer and/or supplier, as shown in figure 2.

9 Packaging

9.1 Oropharyngeal airways marketed for single use shall be individually prepackaged in a sterile, ready-to-use condition. The package shall be clearly marked :

"STERILE — FOR SINGLE USE"

and the size shall be readily apparent upon examination of the package.

9.2 Airways intended for re-use shall be packaged in accordance with accepted industry standards.

Table — Dimensions and tolerances

Dimensions in millimetres

Nominal size	Length, <i>L</i>	
		tol.
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

NOTE — This table is intended to relate nominal size to airway length (dimension *L*). Clinical practice neither suggests nor requires the availability of all nominal sizes given in the table.

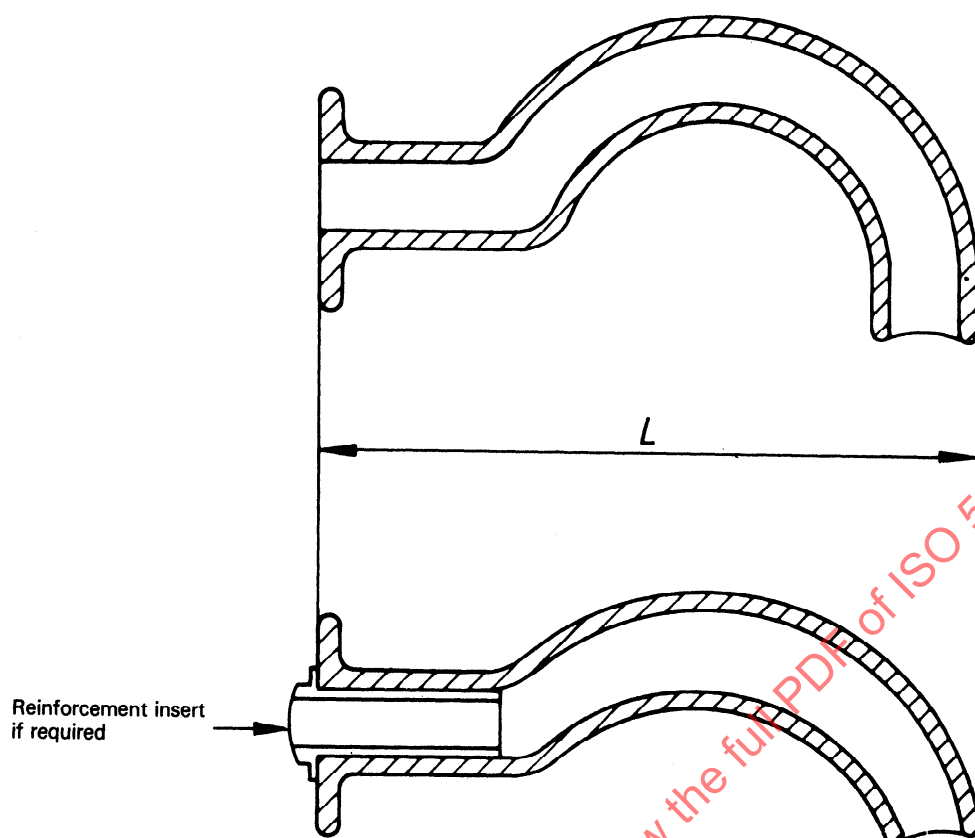


Figure 1 — Length for size designation of airways

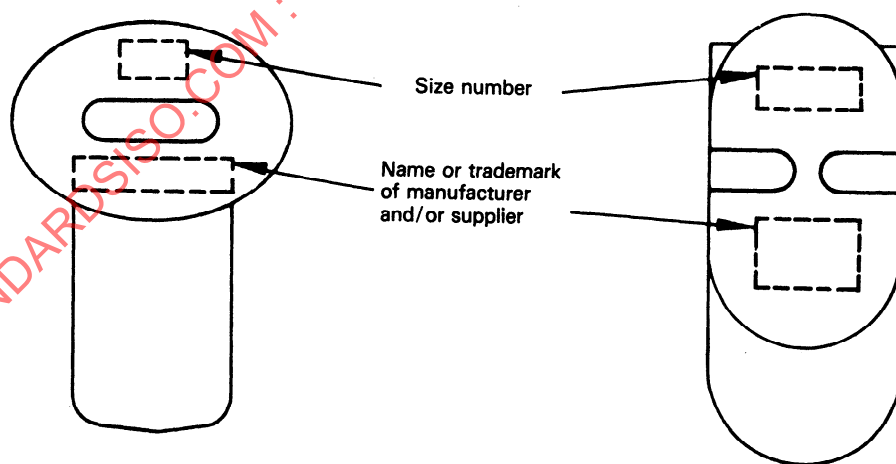


Figure 2 — Marking of airways

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

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