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Anaesthetic and respiratory equipment — Oropharyngeal airways

*Matériel d'anesthésie et de réanimation respiratoire — Canules
oropharyngées*

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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. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 5364 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Tracheal tubes and other equipment*.

This fourth edition cancels and replaces the third edition (ISO 5364:2001), which has been technically revised.

In this corrected version of ISO 5364:2008 Figure 1 has been replaced with an illustration in which the position given in key 3 is corrected.

ISO 5364:2008

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Introduction

This International Standard specifies dimensions and other requirements for oropharyngeal airways.

Airway size is designated by length, which is important when selecting an oropharyngeal airway to hold forward the base of the tongue to prevent obstruction of the airway by the soft tissues.

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Anaesthetic and respiratory equipment — Oropharyngeal airways

1 Scope

This International Standard specifies requirements for oropharyngeal airways of plastics materials and/or rubber, including those with a reinforcement insert made of plastics materials and/or metal.

This International Standard is not applicable to metal oropharyngeal airways, nor to requirements concerning flammability of oropharyngeal airways.

Flammability of oropharyngeal airways, for example if flammable anaesthetics, electrosurgical units or lasers are used, is a well-recognized hazard. It is addressed by appropriate clinical management, which is outside the scope of this International Standard.

This International Standard is not applicable to supralaryngeal airways without an internal, integral sealing mechanism.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

EN 556-1:2001, *Sterilization of medical devices — Requirements for medical devices to be designated “STERILE” — Part 1: Requirements for terminally sterilized medical devices*

EN 980, *Graphical symbols for use in the labelling of medical devices*

EN 1041, *Information supplied by the manufacturer with medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

oropharyngeal airway

device intended to maintain a gas pathway through the oral cavity and pharynx

[ISO 4135]

3.2

pharyngeal end

that end of an oropharyngeal airway which is intended to be inserted into a patient's oropharynx

[ISO 4135]

3.3

flanged end

that end of an oropharyngeal airway which is flanged and is intended to be external to the teeth or gums

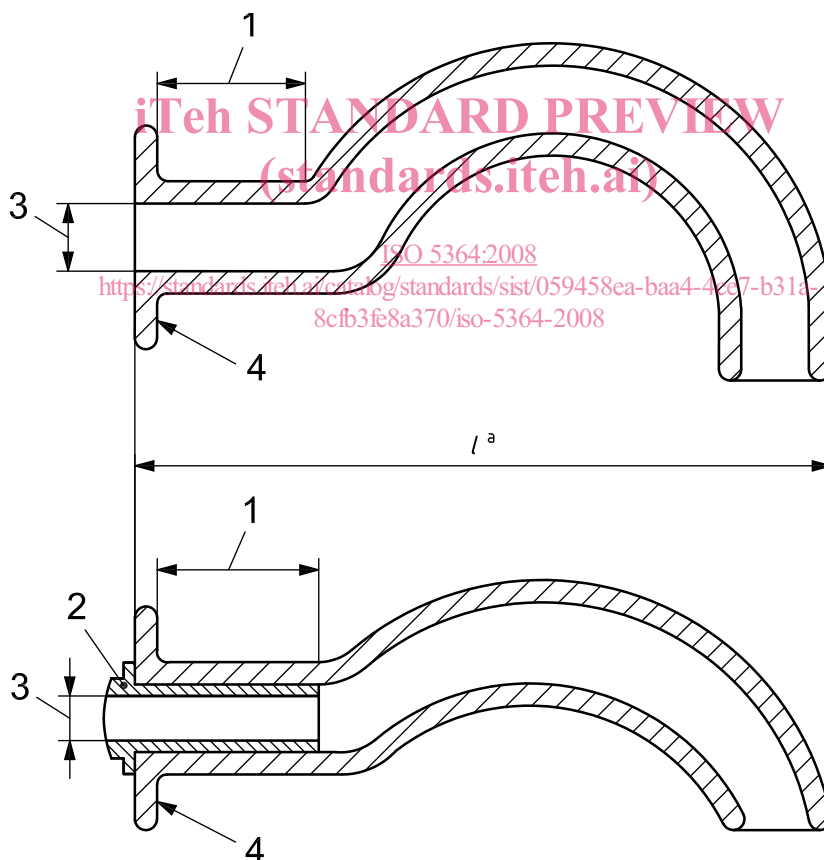
[ISO 4135]

4 Size designation and dimensions

4.1 Size designation

The size of oropharyngeal airways shall be designated by the nominal length (see l , Figure 1) expressed in centimetres, in accordance with Table 1.

NOTE The manufacturer's own size designation may additionally be given, but this is not recommended.



Key

- 1 buccal portion
- 2 reinforcement insert, if provided
- 3 position for measuring minimum inside dimension (see Table 1)
- 4 flanged end

^a For l see 4.1 and 4.2.1.

Figure 1 — Dimensions for size designation of oropharyngeal airways

Table 1 — Size designation of oropharyngeal airways — Dimensions and tolerances

Designated size (nominal length)	Length and tolerance	Minimum inside dimension
cm	mm	mm
3	$30 \pm 2,5$	2,5
3,5	$35 \pm 2,5$	3,0
4	$40 \pm 2,5$	3,0
4,5	$45 \pm 2,5$	3,0
5	$50 \pm 2,5$	3,5
5,5	$55 \pm 2,5$	3,5
6	$60 \pm 2,5$	4,0
6,5	$65 \pm 2,5$	4,0
7	$70^{+5,0}_{-2,5}$	4,0
8	$80 \pm 5,0$	4,5
9	$90 \pm 5,0$	4,5
10	$100 \pm 5,0$	5,0
11	$110 \pm 5,0$	5,5
12	$120 \pm 5,0$	5,5

4.2 Dimensions

4.2.1 The length (see l , Figure 1) shall be in accordance with Table 1.

4.2.2 The minimum inside dimension at any point along the length of the airway shall be not less than that specified in Table 1.

NOTE This dimension is relevant to the ability to pass other devices, e.g. a suction catheter, through the airway.

5 Materials

Oropharyngeal airways, in their ready-for-use state after any preparation for use recommended by the manufacturer, shall satisfy appropriate biological safety testing, as indicated in ISO 10993-1.

6 Design

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

7 Performance requirements

7.1 Resistance to collapse of the buccal portion

When tested in accordance with Annex A, the minimum inside dimension of the buccal portion of the airway shall be not less than 75 % of that given in Table 1 for the size of the airway being tested.

7.2 Patency of lumen

When tested in accordance with Annex B, the patency of the oropharyngeal airway lumen shall be maintained.