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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment*.

This fifth edition cancels and replaces the fourth edition (ISO 5364:2008), which has been technically revised.

Throughout this International Standard, text for which rationale is provided in Annex A is indicated by an asterisk (*).

Major changes in this edition include new legibility test methods and requirements and a colour code to indicate designated size.

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.

Airway size is indicated by a legible marking and by a colour code, which are important to allow rapid identification and selection in emergencies.

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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 — Registered symbols*

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*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

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 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

[SOURCE: ISO 4135:2001, 6.1.1]

3.2
pharyngeal end
that end of an *oropharyngeal airway* (3.1) which is intended to be inserted into a patient's oropharynx

[SOURCE: ISO 4135:2001, 6.1.1.2]

3.3
flanged end
that end of an *oropharyngeal airway* (3.1) which is flanged and is intended to be external to the teeth or gums

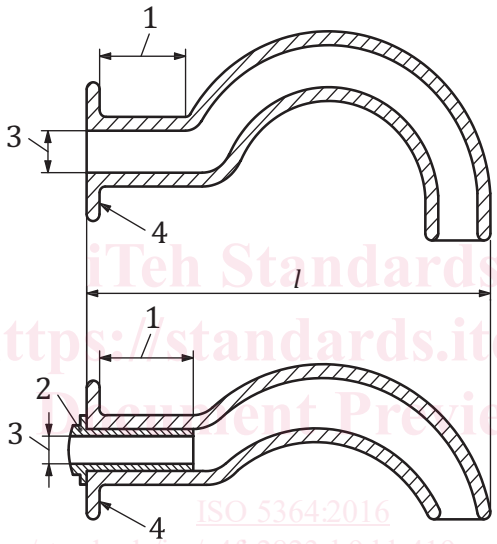
[SOURCE: ISO 4135:2001, 6.1.1.1]

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

NOTE 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) cm	Length and tolerance mm	Minimum inside dimension mm
3	30 ± 2,5	2,5
3,5	35 ± 2,5	3,0
4	40 ± 2,5	3,0
4,5	45 ± 2,5	3,0
5	50 ± 2,5	3,5
5,5	55 ± 2,5	3,5
6	60 ± 2,5	4,0
6,5	65 ± 2,5	4,0
7	$70\ ^{+5,0}_{-2,5}$	4,0
8	80 ± 5,0	4,5
9	90 ± 5,0	4,5
10	100 ± 5,0	5,0
11	110 ± 5,0	5,5
12	120 ± 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 patients 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 B, 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 C, the patency of the oropharyngeal airway lumen shall be maintained.

8 Sterility assurance

Oropharyngeal airways supplied and marked “STERILE” shall satisfy the requirements of EN 556-1:2001, 4.1.

9 Packaging of oropharyngeal airways supplied sterile

9.1 Each oropharyngeal airway supplied and marked “STERILE” shall be contained in an individual pack.

9.2 The pack shall serve as an effective barrier to the penetration of microorganisms and particulate material in accordance with ISO 11607-1.

9.3 The pack shall permit the aseptic extraction of the contents and shall not be capable of re-closure without clearly revealing that it has been opened.

9.4 The designated size of the airway shall be apparent on visual examination of the intact unit container.

9.5 Individual packs shall be contained within a shelf or multi-unit pack.

10 Marking

10.1 General

Marking of oropharyngeal airways, of unit packs and of shelf or multi-unit packs and information to be supplied by the manufacturer should comply with EN 1041.

10.2 Use of symbols

The requirements of 10.4 and 10.5 may be met by use of appropriate symbols as given in ISO 7000 or ISO 15223-1.

10.3 Marking of oropharyngeal airways

10.3.1 The flanged end of the oropharyngeal airway shall be marked with the following:

a) the designated size (nominal length, in centimetres) in accordance with 4.1 (see Figure 2);

b) the name and/or trademark of the manufacturer and/or supplier (see Figure 2);

c) an indication of the presence of natural rubber (latex), if present in the device.