INTERNATIONAL STANDARD

ISO 5364

Fourth edition
2008-07-15

Corrected version
2009-01-15

Anaesthetic and respiratory equipment — Oropharyngeal airways

Matériel d'anesthésie et de réanimation respiratoire — Canules oropharyngées

Reference number
ISO 5364:2008(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

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.

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.

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

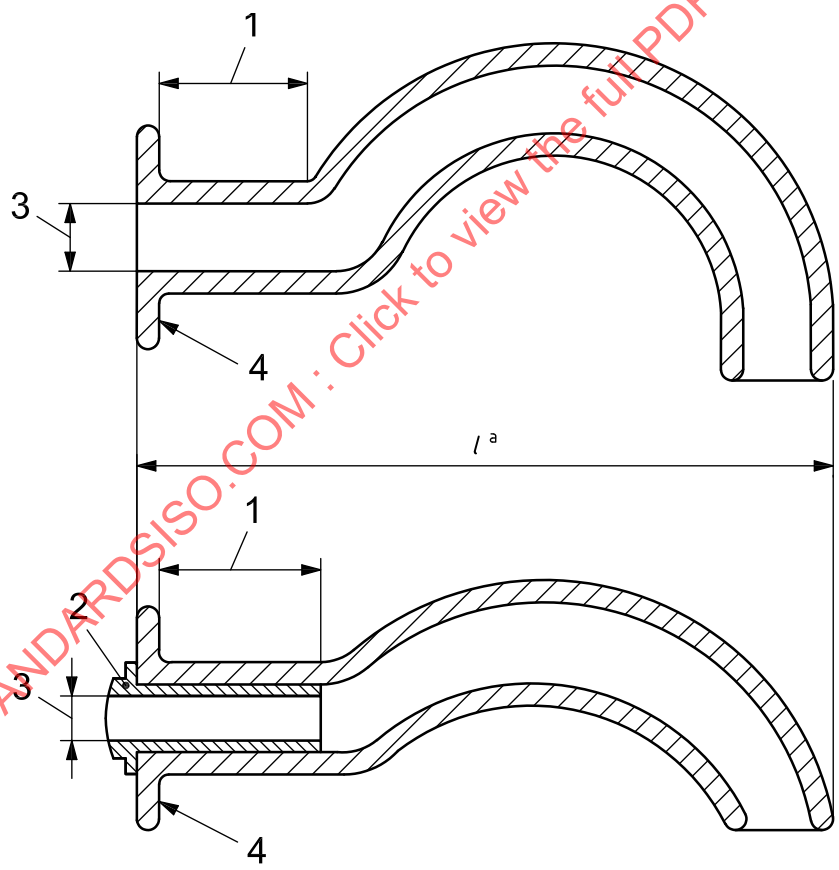
[ISO 4135]

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) cm	Length and tolerance mm	Minimum inside dimension 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.

8 Sterility assurance

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

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 micro-organisms 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 EN 980.

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 trade mark of the manufacturer and/or supplier (see Figure 2).

10.3.2 Markings in accordance with a) and b) shall be visible from the flanged end.

10.4 Marking of unit packs

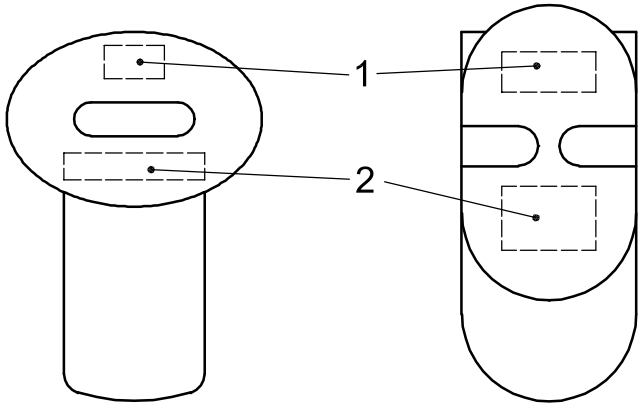
The marking of individual packs or a package insert shall include the following:

a) the word “STERILE”, if appropriate.

   It is recommended that the method of sterilization be given;

b) for oropharyngeal airways not intended for re-use, the words “single use” or equivalent;

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



Key

1 designated size

2 name and/or trademark of manufacturer or supplier

NOTE The designs shown in Figures 1 and 2 are intended to illustrate common types of oropharyngeal airway for the purpose of size designation and marking, but are for example only.

Figure 2 — Typical marking locations on flanged end of oropharyngeal airways

10.5 Marking of shelf or multi-unit packs

The marking of shelf or multi-unit packs shall include the following:

a) a description of contents;

b) the designated size in accordance with 4.1;

c) the name and/or trademark and address of the manufacturer and/or supplier;

d) the batch number;

e) the word “STERILE”, if appropriate;

It is recommended that the method of sterilization be given.

f) for oropharyngeal airways not intended for re-use, the words “single use” or equivalent;

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

11 Information to be supplied by the manufacturer

11.1 Unless the oropharyngeal airway is intended and marked as being for single use, the manufacturer shall recommend methods of cleaning and disinfection or sterilization.

11.2 The manufacturer shall indicate the presence of natural rubber (latex), if present in the device.

Annex A
(normative)

Test method for resistance to collapse of the buccal portion

A.1 Principle

The resistance of the buccal portion to collapse is tested by measuring the minimum inside dimension during compression.

A.2 Apparatus

A.2.1 Means of conditioning the oropharyngeal airway at (34 ± 2) °C and carrying out the test under the same conditions.

A.2.2 Means of applying a force of either (100 ± 10) N or (200 ± 20) N, as appropriate.

A.2.3 Means of measuring the minimum inside dimension of the buccal portion during compression, with an accuracy of $\pm$ 0,10 mm.

A.3 Test procedure

A.3.1 Condition the oropharyngeal airway at (34 ± 2) °C for 1 h and carry out the test under the same conditions.

A.3.2 Compress the middle of the buccal portion (see Figure 1) of the oropharyngeal airway using blocks with a $(60 \pm 2)°$ included angle and radius of curvature of $(1{,}0 \pm 0{,}5)$ mm to the mating surfaces and a width at least as great as that of the buccal portion of the airway being tested (see Figure A.1).

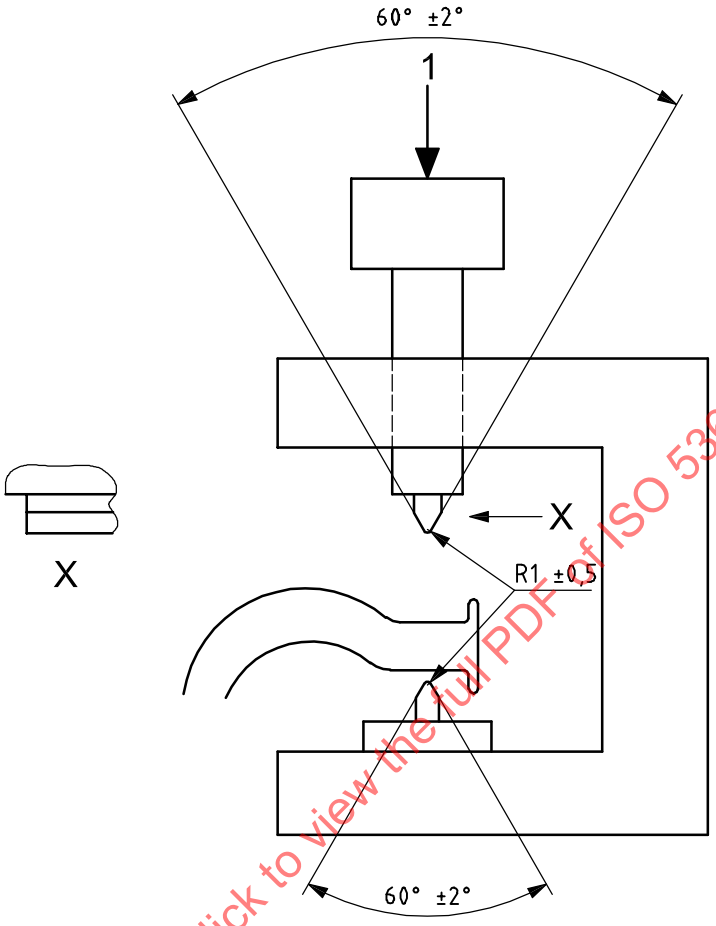
A.3.3 For oropharyngeal airways of designated size 5,5 or smaller, apply a force of (100 ± 10) N and maintain that force for 3 min whilst measuring the minimum dimension.

A.3.4 For oropharyngeal airways of designated size 6,0 or larger, apply a force of (200 ± 20) N and maintain that force for 3 min whilst measuring the minimum dimension.

A.4 Expression of result

Express the minimum inside dimension of the buccal portion during compression as a percentage of that value specified in Table 1 for the size of airway being tested.

Dimensions in millimetres



Key

1 compressive force applied as in A.3.3 or A.3.4

X width of blocks as great as buccal portion of airway being tested

R block tip radius of curvature of $(1 \pm 0{,}5)$ mm

Figure A.1 — Apparatus for testing resistance to collapse of the buccal portion

Annex B
(normative)

Test method for patency of lumen

B.1 Principle

The patency of the oropharyngeal airway lumen is tested by clamping the buccal portion, applying a force to the pharyngeal end, and passing a steel ball through the lumen of the oropharyngeal airway.

B.2 Apparatus

B.2.1 **Means of conditioning the oropharyngeal airway** at (34 ± 2) °C and carrying out the test under the same conditions.

B.2.2 **Clamp**, for suspending the oropharyngeal airway.

B.2.3 **Means of applying a force** of $(5{,}0 \pm 0{,}5)$ N.

B.2.4 **Steel ball**, of diameter 75 % of the minimum inside dimension of the oropharyngeal airway (see Table 1).

B.3 Test procedure

B.3.1 Condition the oropharyngeal airway at (34 ± 2) °C for 1 h and carry out the test under the same conditions.

B.3.2 Clamp the buccal portion of the oropharyngeal airway so that it does not move, and apply a force of $(5{,}0 \pm 0{,}5)$ N to the pharyngeal end, maintaining this force for not less than 1 min (see Figure B.1).

B.3.3 Pass a steel ball (B.2.4) through the lumen whilst the force is being applied.

B.4 Expression of results

Record whether or not the steel ball passes freely through the tube.