SLOVENSKI STANDARD
oSIST prEN ISO 5364:2014

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Anestezijska in dihalna oprema - Ustno-žrelne (orofaringealne) dihalne cevke (ISO/DIS 5364:2014)

Anaesthetic and respiratory equipment - Oropharyngeal airways (ISO/DIS 5364:2014)

Anästhesie- und Beatmungsgeräte - Oropharyngealtuben (ISO/DIS 5364:2014)

Matériel d'anesthésie et de réanimation respiratoire - Canules oropharyngées (ISO/DIS 5364:2014)

Ta slovenski standard je istoveten z: **prEN ISO 5364 rev**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

oSIST prEN ISO 5364:2014 **en**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 5364

ISO/TC **121**/SC **2** Secretariat: **ANSI**

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Anaesthetic and respiratory equipment — Oropharyngeal airways

Matériel d'anesthésie et de réanimation respiratoire — Canules oropharyngées

[Revision of fourth edition (ISO 5364:2008)]

ICS: 11.040.10

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Reference number
ISO/DIS 5364:2014(E)

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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, *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 a new legibility test methods and requirements, and a colour code to indicate designated size.

Major changes in this International Standard are highlighted in a BLUE box during the Enquiry phase only. These highlights will be removed during the approval and publication phases.

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 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*

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

[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

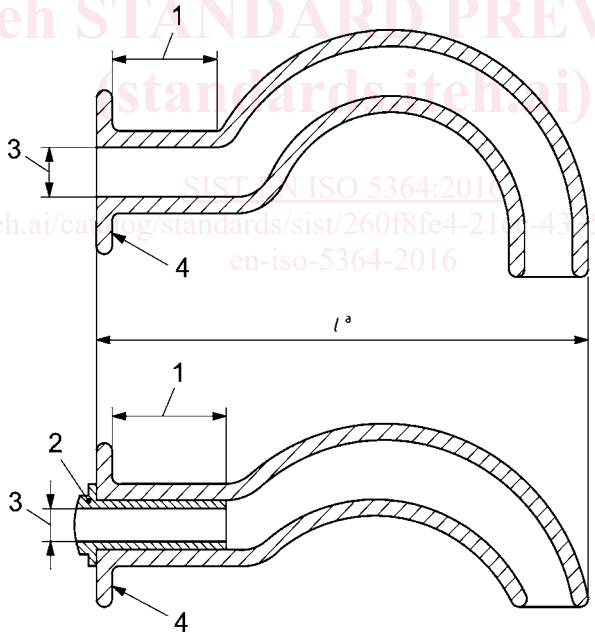
[ISO 4135]

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.



1 buccal portion

2 reinforcement insert, if provided

3 position for measuring minimum inside dimension (see)

4 flanged end

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.