



**International  
Standard**

**ISO 5364**

**Anaesthetic and respiratory  
equipment — Oropharyngeal  
airways**

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

**Sixth edition  
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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 document 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](http://www.iso.org/directives)).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at [www.iso.org/patents](http://www.iso.org/patents). ISO shall not be held responsible for identifying any or all such patent rights.

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airway devices and related equipment*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This sixth edition cancels and replaces the fifth edition (ISO 5364:2016), which has been technically revised.

The main changes are as follows:

- this document has been rewritten to follow the format of ISO 18190;
- the temperature of testing the lumen of the buccal portion and patency has changed from 34 °C to 40 °C to reflect the ambient conditions that can be reached in emergency use in some countries.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

## Introduction

This document 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.

NOTE The terms defined in [Clause 3](#) are denoted throughout the document in *italic font*.

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# Anaesthetic and respiratory equipment — Oropharyngeal airways

## 1 Scope

This document specifies requirements for *oropharyngeal airways*.

This document is not applicable to metal *oropharyngeal airways*, nor to requirements concerning flammability of *oropharyngeal airways*.

This document is not applicable to supralaryngeal airways, which are covered by ISO 11712<sup>[1]</sup>.

The requirements that are also applicable to other airway devices have been removed from this document as they now appear in the general airway device standard (ISO 18190).

The requirements in this device-specific standard take precedence over any conflicting requirements in the general standard for airway devices (ISO 18190).

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 18190:2025, *Anaesthetic and respiratory equipment — General requirements for airway devices and related equipment*

## 3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

### 3.1

#### ***oropharyngeal airway***

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

[SOURCE: ISO 4135:2022, 3.8.2.2]

### 3.2

#### ***pharyngeal end***

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

[SOURCE: ISO 4135:2022, 3.8.2.5]