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Anaesthetic and respiratory equipment — Supralaryngeal airways and connectors

Matériel d'anesthésie et de réanimation respiratoire — Canules supralaryngées et raccords

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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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).

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This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment* Subcommittee SC 2, *Airways and related equipment*.

This second edition cancels and replaces the first edition (ISO 11712:2009), which has been technically revised.

The main changes are as follows:

— the format of this document has changed to align with ISO 18190; and

— conformity checks for each requirement have been added.

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.

Introduction

A *supralaryngeal airway* is a medical device placed through the mouth, without passing through the vocal cords, intended to seal the supralaryngeal area to isolate the respiratory pathway from gases and liquids in the pharynx and to maintain airway patency to facilitate ventilation in anaesthetized or unconscious patients with or without delivery of anesthetic gases. Ventilation may be spontaneous, assisted or controlled. *Supralaryngeal airways* intended to provide a breathing airway and/or to simultaneously provide a guide for the intubation of tracheal tubes, bronchoscopes and suction devices are also included in the scope of this document, as are the *connectors* inserted into the *machine end* of these devices.

Examples of *supralaryngeal airways* are laryngeal masks, laryngeal tubes, airways and seals, cuffed oropharyngeal airways, and pharyngeal airways, and combination airway/oesophageal obturators.

The requirements of this document were developed using the hazard identification for risk assessment in Annex D.

The requirements for testing and disclosure apply to *supralaryngeal airways* introduced to the market after the publication of this document.

This document is written following the format of ISO 18190. The requirements in this document take precedence over any conflicting requirements in ISO 18190.

Anaesthetic and respiratory equipment — Supralaryngeal airways and connectors

1 Scope

NOTE There is guidance or rationale for this Clause in Annex A.2.

1.1 This document provides the essential requirements for the design of *supralaryngeal airways* and *connectors*. These devices are intended to provide a distinct respiratory pathway to the top of the larynx to provide an unobstructed airway in patients during spontaneous, assisted or controlled ventilation.

1.2 This document specifies the dimensions, basic properties and method of size designation of the available types of *supralaryngeal airways*. Airways devised for specialized applications are not specifically covered, although most may be classified by the sizing and dimensions (or other characteristics) required by this document.

1.3 The following devices are outside the scope of this document: nasal and oropharyngeal airways, anesthetic masks, oro- and naso-tracheal tubes, cricothyrotomy devices, dental appliances, tracheal stents, tracheal tubes, ventilating laryngoscopes, CPAP devices, esophageal obturators, bougies and devices that require surgical placement.

1.4 This document specifies dimensional disclosure so the operator will know which auxiliary devices, such as tracheal tubes and bronchoscopes will be size-compatible.

1.5 Flammability of airways, for example if used with certain flammable anesthetic gases, electrosurgical units or lasers, is a well-recognized hazard that is outside the scope of this document. (See E.1.7).

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 4135, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 18190, *Anaesthetic and respiratory equipment — General requirements for airways and related equipment*

ISO 18562-1, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications —Part 7: Connectors with 6 % (Luer) taper for intravascular or hypodermic applications*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135, ISO 18190 and the following 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
auxiliary ventilatory opening
secondary opening in the *ventilatory pathway* (3.11) intended for passage of ventilatory gases at or near the *patient end* (3.5)

3.2
cuff
compliant part permanently attached to the *supralaryngeal airway* (3.8) to position the device in the pharynx

3.3
external seal
seal that is positioned outside the patient

EXAMPLE A seal between a face mask and the face

3.4
machine end
end of the *supralaryngeal airway* (3.8) or the *supralaryngeal airway connector* (3.9) intended to connect to the breathing system

3.5
patient end
end of the *supralaryngeal airway* intended to be inserted into the patient

3.6
pressure drop
pressure differential at a specified flow

3.7
seating mechanism
part of the patient end that positions the *supralaryngeal airway*

3.8
supralaryngeal airway
device placed through the mouth, without passing through the vocal cords, which is intended to to provide a distinct respiratory pathway to the top of the larynx.

3.9
supralaryngeal airway connector
component that provides the interface to connect a *supralaryngeal airway* (3.8) to a gas supply

3.10
ventilatory opening
opening in the *supralaryngeal airway* (3.8) near the *patient end* (3.5) and intended to allow passage of gases and/or devices such as a tracheal tube, suction catheter or endoscope

Note 1 to entry: A *supralaryngeal airway* can have more than one *ventilatory opening*.

3.11
ventilatory pathway
part of the *supralaryngeal airway* (3.8) through which gases are intended to pass

4 General requirements

4.1 General

The requirements of ISO 18190:2016, Clause 4 shall apply.

Annex D provides an informative list of identified hazards.

4.2 Test methods

Many of the test clauses within this document establish acceptance criteria for performance aspects. These acceptance criteria shall always be met. If the manufacturer chooses to specify, in the accompanying documents, higher performance levels than those specified within this document these manufacturer-specified levels become the acceptance levels and shall also be met.

Check conformity by inspection of the instructions for use and the manufacturer's technical documentation.

5 Materials

5.1 General

The applicable requirements of ISO 18190:2016, Clause 5 shall apply.

5.2 Biological safety testing

Supralaryngeal airways shall also be evaluated and tested in conformance with ISO 18562-1.

Check conformity by inspection of the manufacturer's technical documentation.

5.3 Guidance on materials specific to *supralaryngeal airways* and *connectors*

Annex E provides guidance on materials and design for *supralaryngeal airways* and *connectors.*

6 Design requirements

6.1 General

The applicable requirements of ISO 18190:2016, Clause 6 shall apply.

6.2 Ventilation positions of use

NOTE There is guidance or rationale for this subclause contained in Annex A.3.2.

6.2.1 *Supralaryngeal airways* shall permit ventilation in those head and neck positions, and in those patient positions for which the device is intended.

Check conformity by inspection of the manufacturer's technical documentation.

6.2.2 *Supralaryngeal airways* shall permit ventilation when the patient is in the supine position and the head and neck are at neutral positions and at least 30° of:

a) flexion;

b) extension;

c) right and left rotation;

d) right and left lateral flexion (tilt).

Check conformity by inspection of the manufacturer's technical documentation.

6.2.3 *Supralaryngeal airways* shall also permit ventilation in the following positions and in any position intended for use:

a) Trendelenburg's (head down, 10°);

b) sitting (45°).

NOTE See Annexes A and D.

Check conformity by examination of the mitigations described in a risk assessment and associated verification and validation studies in the manufacturer's risk management file.

6.3 Size designation

NOTE There is guidance or rationale for this subclause contained in Annex A.3.3.

Supralaryngeal airways shall be designated by size using the following convention:

a) the range of sizes may be from 0 to 6; the smallest increment permitted is 0,5;

b) sizes from 0 to 6 may be designated for the smallest to largest size devices;

NOTE The transition size from paediatric to adult is size 3.

Check conformity by visual inspection.

6.4 *Ventilatory openings*

NOTE There is guidance or rationale for this subclause contained in Annex A.3.4.

Ventilatory openings shall be provided at or near *patient ends* of *supralaryngeal airways*. *Auxiliary ventilatory openings* may be provided to reduce the risk of obstruction.

Check conformity by visual inspection.

6.5 Safeguards against collapse of the *ventilatory pathway*

NOTE There is guidance or rationale for this subclause contained in Annex A.3.5.

6.5.1 Means shall be provided to resist collapse of the *ventilatory pathway* from kinking or compression.

Check conformity by the test given in Annex C.

6.5.2 The resistance to compression shall be evaluated by examination of the mitigations described in a risk assessment and associated verification and validation studies.

Check conformity by inspection of the manufacturer's risk management file.

6.6 *Seating mechanisms*

NOTE There is guidance or rationale for this subclause contained in Annex A.3.5 and Annex B.

6.6.1 *Seating mechanisms* shall be integrally attached to the *supralaryngeal airway*.

Check conformity by inspection of the manufacturers technical file.

6.6.2 The *seating mechanism* shall position and help maintain the device in the airway to provide a respiratory gas pathway to the lungs.

Check conformity by inspection of the manufacturers technical file

6.6.3 *Seating mechanisms* shall not occlude the *ventilatory opening* nor collapse the *ventilatory pathway*.

Check conformity by a method chosen by the manufacturer based upon an examination of the mitigations described in a risk assessment and associated verification and validation study.

6.7 *Cuff* inflation/deflation system

6.7.1 *Cuff* inflation systems shall include an inflating tube, a pilot balloon or other device to indicate inflation or deflation of the *cuff*.

NOTE *Cuff* inflation systems can also serve as a pressure-indicating or pressure-limiting device.

Check conformity by visual inspection.

6.7.2 The free end of the inflation tube shall be either open or sealed with a closure device or self-sealing valve. If interface with an external inflation device is required, the inlet of the inflation tube shall be compatible with a cone Luer connector, complying with ISO 80369-7.

Check conformity by visual inspection and functional testing.

6.7.3 Intentional deflation of the *seating mechanism* shall not be prevented by the inflation tube, inflation valve or any closure device acting as a non-return valve.

Check conformity by functional testing.

6.8 Internal volume

NOTE There is guidance or rationale for this subclause contained in Annex A.3.7.

The internal volume of the *ventilatory pathway* shall be measured and declared in the instructions for use [see 9.4 c)].

Check conformity by inspection of the instructions for use and the following test method:

Cap one end of the ventilatory pathway. Measure the volume of water in millilitres required to fill the ventilatory pathway from the ventilatory opening up to and including the 15 mm connector at the machine end of the device.

6.9 Maximum device size

The maximum size of devices that will easily pass through the *ventilatory pathway* shall be declared by the manufacturer in the instructions for use [see 9.4 e)]. Devices may include (but are not limited to) tracheal tubes, suction catheters, fibreoptic scopes, bougies, etc.

Check conformity by functional testing and inspection of the instructions for use.

NOTE The device can be lubricated with water or water-soluble lubricant to assist the passage.

6.10 *Supralaryngeal airway connectors*

6.10.1 *Machine ends* of *supralaryngeal airway connectors* shall be a 15 mm cone complying with ISO 5356-1. Any transition in the inside lumen of the connector shall permit an adequate lead-in for smooth passage and removal of a device (see 6.9).

Check conformity by visual inspection and inspection of the manufacturer's technical documentation.

6.10.2 The opening at the *patient end* shall have a plane at 90° ± 5° to the long axis of the *patient end* of the connector.

Check conformity by visual inspection.

6.11 Cleaning, disinfection and sterilization

Supralaryngeal airways and *connectors* not intended for single use shall be designed to be suitable for cleaning and disinfection or sterilization by methods described in the accompanying documents [See 9.4 t)].

NOTE See Annex E.

Check conformity by inspection of the manufacturer's technical documentation.

7 Requirements for *supralaryngeal airways* and *connectors* supplied sterile

The applicable requirements of ISO 18190:2016, Clause 7 shall apply.

8 Packaging

The applicable requirements of ISO 18190:2016, Clause 8 shall apply.

9 Information supplied by the manufacturer

9.1 General

The applicable requirements of ISO 18190:2016, Clause 9 shall apply.

9.2 Marking on the *supralaryngeal airway*

9.2.1 Marking materials shall:

a) be nontoxic and tissue-compatible;

b) remain legible during the intended lifetime of the *supralaryngeal airway*

Check conformity by exposing the appropriate marking areas of the *supralaryngeal airways* to the applicable substances listed for a cumulative duration of time equivalent to the expected exposure duration in use:

— Drugs or chemicals which will contact the *supralaryngeal airways* in use and are listed in the Instruction for use (IFU).

— If applicable, artificial saliva

— If applicable, artificial mucus

— If applicable, artificial skin oil