International Standard

ISO 19211

Anaesthetic and respiratory equipment — Fire-activated oxygen shut-off devices for use during oxygen therapy

Matériel d'anesthésie et de réanimation respiratoire — Dispositif de coupure de l'oxygène activé par le feu pendant une oxygénothérapie

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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, *Airway devices and related equipment*.

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.

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Introduction

Fire activated oxygen shut-off devices are used to minimise the severity of fires associated with oxygen therapy. These devices automatically cut off the supply of oxygen in the respiratory therapy tubing and isolate the oxygen supply as the fire propagates towards the source of supply from the normal ignition site at the patient interface. It is therefore important that the operating characteristics be specified and tested in a defined manner.

This document pays particular attention to:

— safety;

— cleanliness;

— performance;

— suitability of materials;

— testing;

— identification; and

— information supplied.

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Anaesthetic and respiratory equipment — Fire-activated oxygen shut-off devices for use during oxygen therapy

1 Scope

This document specifies requirements for *fire activated oxygen shut-off devices* that stop the flow of oxygen in respiratory therapy tubing when activated by fire.

NOTE 1 Typical arrangements for *fire activated oxygen shut-off devices* are shown in Annex C.

NOTE 2 Respiratory therapy tubing is covered by ISO 17256[2].

NOTE 3 Use of *fire activated oxygen shut-off devices* in medical devices or accessories is not mandated in this document.

The *fire activated oxygen shut-off devices* specified in this document are not suitable for use with oxygen therapy systems with flows in excess of 20 l/min).

NOTE 4 There is rationale for this clause in A.2.

The requirements in this device-specific standard take precedence over any conflicting requirements in the general standard for airway devices (ISO 18190). All the common requirements that appear in the general standard for airway devices have been removed from this document.

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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.

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ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 18190:2016, *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 80369-2, *Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for respiratory applications*

IEC 60601-1-11:2015+AMD1:2021, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135 and 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/

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3.1
ATPS
volume of gas saturated with water vapour at ambient temperature and barometric pressure

3.2
fire activated oxygen shut-off device
FAOSOD
device that stops the flow of oxygen in respiratory therapy tubing when activated by fire

3.3
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his or her own name, regardless of whether these operations are carried out by that person or on his or her behalf by a third party

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.55, modified — the notes to entry have been deleted.]

3.4
shelf-life
maximum period of time that an item can be stored prior to its first use under the conditions described in its labelling and remain suitable for use

[SOURCE: IEC 60601-1-11:2015, 3.3]

4 General requirements

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

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5 Materials

5.1 General

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

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5.2 Biological assessment of gas pathways

Fire activated oxygen shut-off devices shall meet the requirements of ISO 18562-1.

Check conformance by inspection of the technical documentation.

5.3 Oxygen compatibility

Materials that come in contact with oxygen, during normal use, shall be resistant to corrosion and compatible with oxygen in the environmental conditions specified in 5.4.

NOTE 1 Corrosion resistance includes resistance against moisture and surrounding materials.

NOTE 2 Compatibility with oxygen involves both combustibility and ease of ignition. Materials that burn in air burn violently in an oxygen-enriched atmosphere. Many materials that do not burn in air will do so in an oxygen enriched atmosphere, particularly under pressure. Similarly, materials that can be ignited in air require lower ignition energies in oxygen.

NOTE 3 ISO 15001[1] contains information on selection of metallic and non-metallic materials and other aspects of compatibility of equipment with oxygen.

Check conformance by inspection of the technical documentation.

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5.4 Environmental conditions

Fire activated oxygen shut-off devices shall meet the requirements of IEC 60601-1-11:2015+AMD1:2021, 4.2.

Check conformance by inspection of the technical documentation.

6 Design requirements

6.1 General

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

6.2 Specific design requirements

Inlet and outlet connectors shall not detach from the body of the *fire activated oxygen shut-off device* when subjected to an axial force of (50 ± 1,5) N and a torque of (5 ± 0,5) Nm for a minimum of 1 min.

6.3 Inlet connector

If the *fire activated oxygen shut-off device* is user-detachable, (i.e. detachable without the use of a tool), the inlet connector shall be an R2 socket, small-bore connector (see Figure 1).

Check conformance by functional testing

6.4 Outlet connector

If the *fire activated oxygen shut-off device* is user-detachable, (i.e. detachable without the use of a tool), the outlet connector shall be an R2 cone, small-bore connector (see Figure 1).

Check conformance by functional testing.

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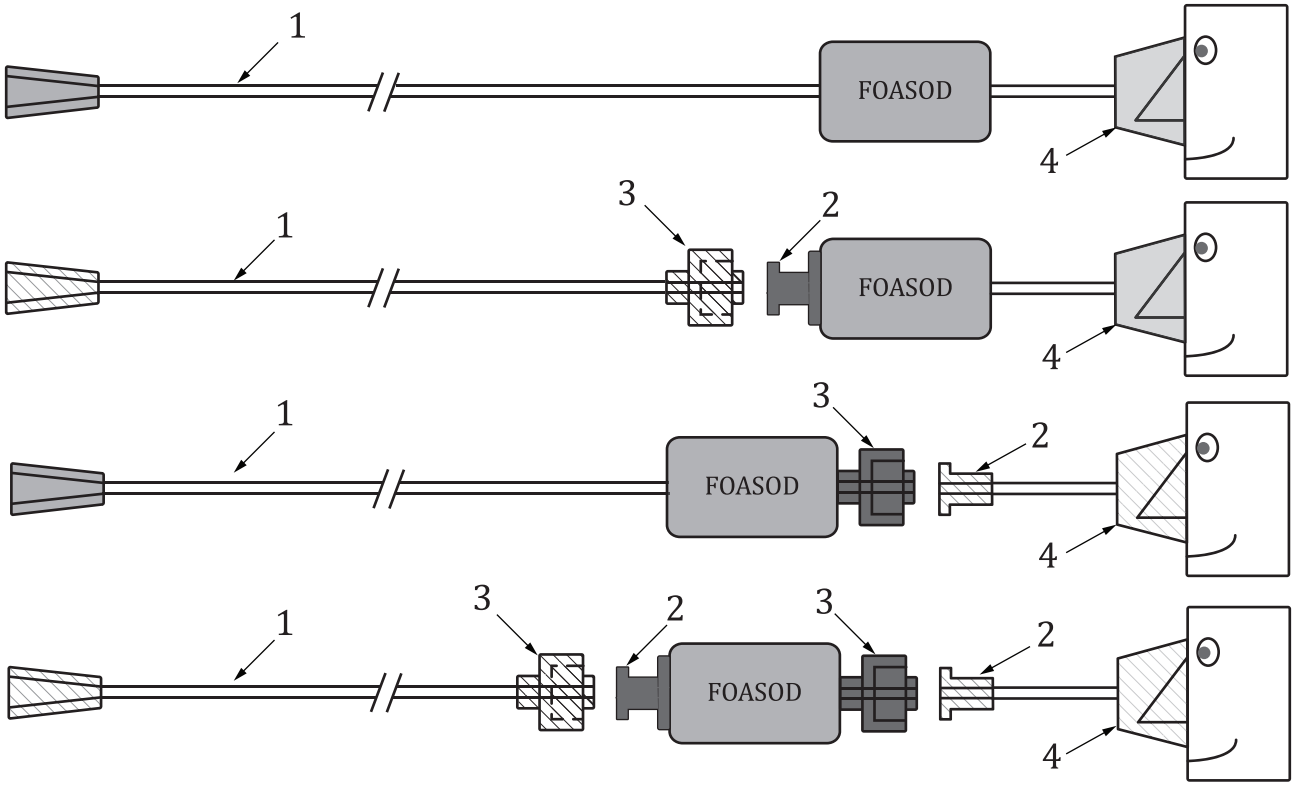

Key

1 respiratory therapy tubing
2 R2 socket small-bore connector conforming with ISO 80369-2
3 R2 cone small-bore connector conforming with ISO 80369-2
4 patient interface device e.g. nasal cannula, facemask

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Figure 1 — Configurations showing user-detachable inlet and outlet connectors

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6.5 Resistance to flow

The resistance to flow shall not exceed 0,9 kPa at a flow of (4 ± 0,2) l/min.

NOTE 0,9 kPa is equivalent to the worst-case resistance to flow per metre length of respiratory therapy tubing at a flow of 4 l/min according to ISO 17256.[2]

Check conformance by the test given in B.4.1.

6.6 Leakage to atmosphere under maximum static pressure

The leakage to atmosphere shall not exceed 10 ml/min when the *fire activated oxygen shut-off device* is subjected to a static pressure of (900 ± 10) kPa applied over a period ≥1 min.

Check conformance by the test given in B.4.2.

NOTE There is rationale for this subclause in A.3.

6.7 Leakage to atmosphere during normal use conditions

The leakage to atmosphere shall not exceed 1 ml/min when the *fire activated oxygen shut-off device* is subjected to a static pressure of (20 ± 0,5) kPa applied over a period ≥1 min.

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