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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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Foreword

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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.

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.

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.

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 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/

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.

5 Materials

5.1 General

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

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.

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

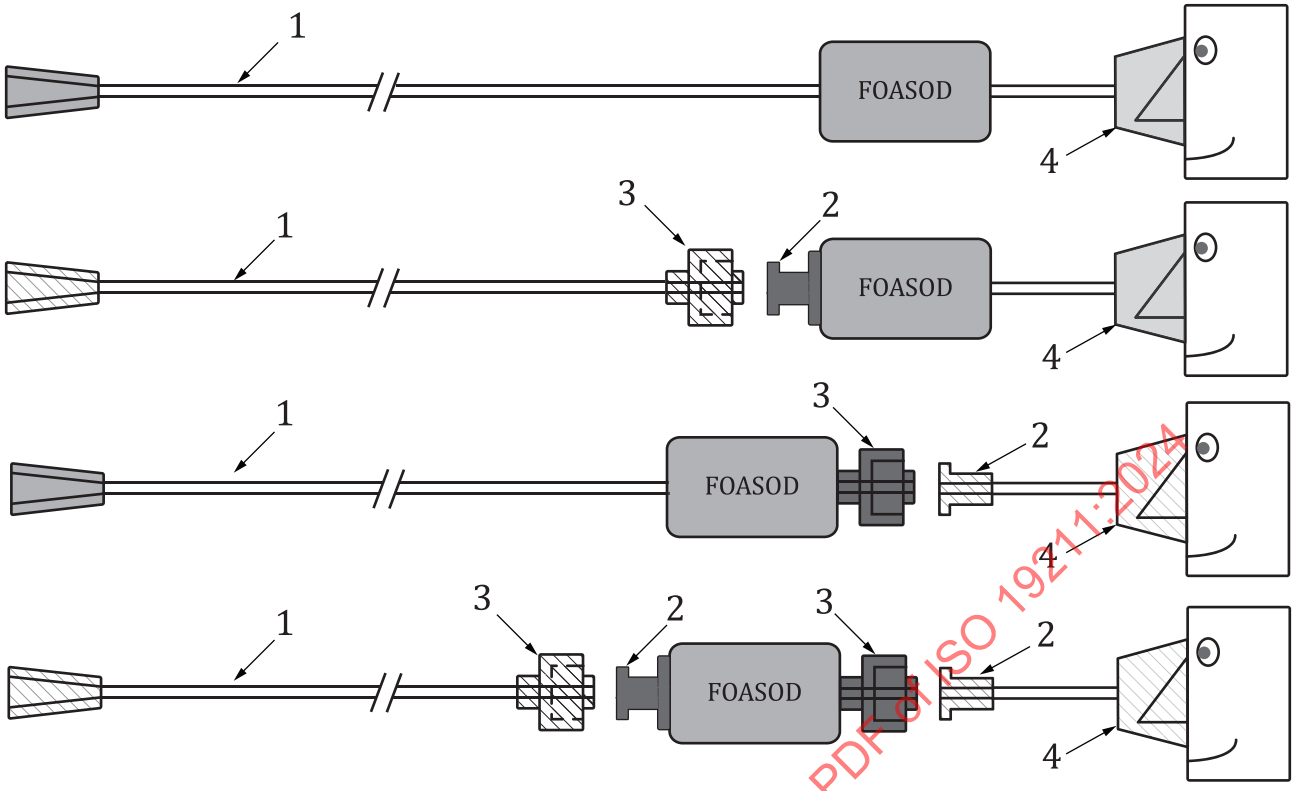
If the *fire activated oxygen shut-off device* is user-detachable, (i.e. detachable without the use of a tool), the inlet connector shall be an R2 socket, small-bore connector (see Figure 1).

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.



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

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

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.

Check conformance by the test given in B.4.3

NOTE There is rationale for this subclause in A.4.

6.8 Activation and prevention of flow of oxygen

NOTE There is rationale for this subclause in A.5.

6.8.1 *Fire activated oxygen shut-off devices* shall activate across the range of flows and oxygen concentrations specified by the *manufacturer,* [see 9.2 b)].

6.8.2 When activated, *fire activated oxygen shut-off devices* shall reduce the flow of oxygen to a maximum of 10 ml/min in the respiratory therapy tubing recommended by the *manufacturer* [see 9.2 j)] at static pressures of (600 ± 10) kPa and (20 ± 1) kPa.

Check conformance by the test given in B.4.4.

NOTE 1 Where the *fire activated oxygen shut-off device* relies on a supporting member melting to prevent the flow of oxygen, there can be a minimum required flow and concentration of oxygen to ensure effective valve closure.

NOTE 2 The requirement in subclause 6.8.2 can only be considered a partial risk control. The risk of burn injury is still present as fabrics saturated with oxygen in the vicinity of the *fire activated oxygen shut-off device* can still ignite and burn vigorously and uncontrollably.

NOTE 3 There is rationale for this subclause in A.5.

6.9 Inadvertent disassembly

It shall not be possible to disassemble *fire activated oxygen shut-off devices* without the use of a tool.

Check conformance by inspection of the technical documentation.

7 Requirements for *fire activated oxygen shut-off devices* supplied sterile

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

8 Packaging

8.1 General

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

8.2 Protection during storage and transport

The packaging shall protect the *fire activated oxygen shut-off device* against damage during storage and transportation.

Check conformance by inspection of the technical documentation.

9 Information supplied by the *manufacturer*

9.1 General

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

9.2 Instructions for use

The instructions for use shall include the following:

a) a warning to the effect that smoking and naked flames are prohibited where oxygen therapy is administered;

b) the range of recommended flows of gases, and where relevant to effective operation, the oxygen concentrations, which enable the device to achieve its intended performance;

c) a warning to the effect that only respiratory therapy tubing and connectors complying with ISO 17256[2] should be used;

d) a warning to the effect that fire can arise from the use of lubricants not recommended by the *manufacturer*;

e) a warning to the effect that use of this device does not prevent fires (the risk of burn injury is still present as fabrics saturated with oxygen can still ignite and burn vigorously);

f) any limitations for the use of the *fire activated oxygen shut-off device* with oxygen therapy equipment;

g) any limitations on the *shelf-life* of the *fire activated oxygen shut-off device*;

h) a warning to the effect that use of this device does not stop the flow of oxygen if the respiratory therapy tubing is ignited between the *fire activated oxygen shut-off device* and the gas supply;

i) if applicable, a warning to the effect that the resistance to flow increases when the device is added to the respiratory therapy tubing; and

j) the respiratory therapy tubing recommended for use with the *fire activated oxygen shut-off device.*

Annex A
(informative)

Rationale

A.1 General

This annex provides a rationale for some requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this document necessitated by those developments.

A.2 Scope (see Clause 1)

Fire activated oxygen shut-off devices are intended to stop the flow of oxygen if the downstream respiratory therapy tubing is ignited. The question of the flammability of the respiratory therapy tubing is outside the scope of this document. By cutting off the supply of oxygen the risk of the fire propagating further along the respiratory therapy tubing back to the supply source and developing into a larger fire is reduced.

Fires related to oxygen therapy are relatively common and are often caused by patients smoking while receiving oxygen or oxygen-enriched air through a facemask or nasal cannula. This is particularly prevalent in situations where oxygen therapy is provided at the patient's home (domiciliary oxygen), though oxygen therapy-related fires do occur in hospitals and other healthcare facilities and can be initiated by other sources of ignition. Oxygen therapy-related fires in healthcare facilities such as hospitals, while less common, are potentially more severe in terms of the number of casualties and the cost of restoration.

In the US, the NFPA Fire Analysis and Research Division[5] estimates that there were an average of 222 home structure fires per year involving oxygen administration apparatus between 2006 and 2010. It is estimated that these fires led to 75 deaths and 113 injuries per year.

Fire activated oxygen shut-off devices are also commonly known as 'firebreaks' and have been required to be fitted by service providers in the United Kingdom under the Department of Health Home Oxygen Service Specification[6] since 2005. In July 2012 the Federal Institute for Drugs and Medical Devices (BfArM) in Germany[7] issued a recommendation to home oxygen service providers supplying oxygen concentrators to include a means to prevent encroachment of the fire into the oxygen concentrator and also a means to interrupt the delivery of oxygen into the respiratory therapy tubing as close to the patient as possible, in case of ignition.

A.3 Leakage to atmosphere under maximum static pressure (see 6.6)

It is a foreseeable risk that the respiratory therapy tubing between the *fire activated oxygen shut-off device* and the patient can become occluded. The *fire activated oxygen shut-off device* could then be subjected to a pressure of 600 kPa which is the maximum pressure, under normal conditions, before alarms are activated, for medical gas pipeline systems complying with ISO 7396-1.[3] A pressure of 900 kPa was selected to include a 50 % safety margin.

A.4 Leakage to atmosphere during normal use conditions (see 6.7)

The leakage limit is that used by *manufacturers* that have been manufacturing these devices for ten or more years.

A.5 Activation and prevention of flow of oxygen (see 6.8)

Concerns that fires could still propagate along the outside of the tube, and along carpets, clothes, fabrics and furnishings prompted a review of the title concentrating on the fundamental actions of the device.

Annex B
(normative)

Test methods

B.1 General

B.1.1 *Manufacturers* may use type tests different from those detailed within this document if an equivalent degree of safety is obtained. Alternative test methods shall be validated against the test methods specified in this document.

Check conformance by inspection of the technical documentation.

B.1.2 The test methods described are type tests and shall be performed sequentially.

B.1.3 Tests shall be carried out in ambient conditions using oxygen.

NOTE Non-medical quality gas is acceptable to use as the test gas, provided it is of at least the same analytical quality.

B.1.4 Flows shall be corrected to *ATPS* (23 °C and 101,3 kPa).

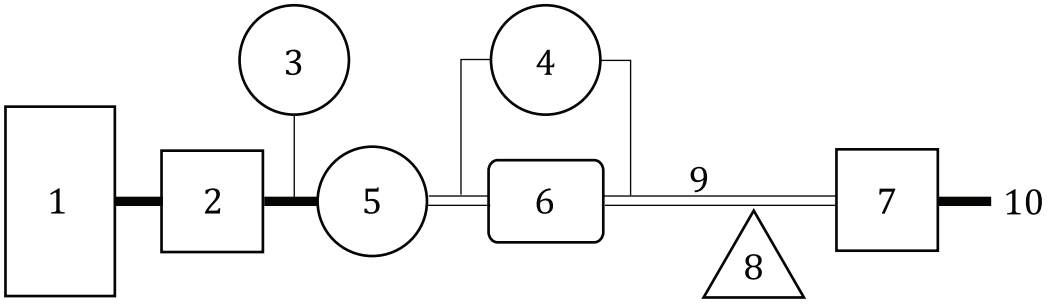
B.2 Principle

The *fire activated oxygen shut-off device* is tested for resistance to flow and leakage to atmosphere under normal use conditions. And when subjected to the maximum static pressure. It is then tested to check that it activates across the range of flows and oxygen concentrations specified by the *manufacturer* [see 9.2b)] after which it is tested for flow through the valve after activation.

B.3 Apparatus

The resolution and accuracy of all measuring devices used for testing shall be appropriate for the values to be measured.

See Figure B.1 for a schematic of the test apparatus.



Key

1 Test gas supply with:
- variable O_2 concentration 100 % V/V to lowest given by the *manufacturer* (40 % V/V);
- variable pressure 900 to 20 kPa.

2 Flow measurement device with flow control.

3 Pressure measurement device.

4 Differential pressure measurement device capable of measuring less than 1 kPa.

5 Flow measurement device capable of measuring form (4 to 10) l/min.

6 *Fire activated oxygen shut-off device* under test.

7 Shut-off valve.

8 Ignition means.

9 Respiratory therapy tubing complying with ISO 17256.[2]

10 To atmosphere

Figure B.1 — Schematic diagram of the test apparatus

B.4 Procedure

B.4.1 Resistance to flow

a) Connect the pressure measurement devices, flow measurement devices and test gas supply to the inlet of the *fire activated oxygen shut-off device* using the respiratory therapy tubing recommended by the *manufacturer*.

b) Set the flow of the test gas to (4 ± 0,2) l/min and record the pressure.

c) Convert the pressure recorded to *ATPS* and calculate the resistance to flow.

d) Verify that the resistance to flow is less than 0,9 kPa.

B.4.2 Leakage to atmosphere under maximum static pressure

a) Occlude the outlet of the *fire activated oxygen shut-off device* and increase the pressure in the device to (900 ± 10) kPa and hold that pressure for ≥1 min.

b) Verify that the leakage to atmosphere does not exceed 10 ml/min.

B.4.3 Leakage to atmosphere during normal use conditions

a) With the outlet still occluded increase the pressure in the *fire activated oxygen shut-off device* to (20 ± 0,5) kPa and hold that pressure for ≥1 min.

b) Verify that the leakage to atmosphere does not exceed (1 ± 0,1) ml/min.

B.4.4 Activation and prevention of flow of oxygen

a) Remove the occlusion and attach a short length (0,25 to 0,5) m of respiratory therapy tubing specified by the *manufacturer* [see 9.2 j)] to the outlet of the *fire activated oxygen shut-off device*.

b) Set the minimum flow recommended by the *manufacturer* through the device.

c) Ignite the oxygen respiratory therapy tubing connected to the outlet.

d) Observe the fire propagating along the respiratory therapy tubing towards the oxygen source.

e) Verify that the fire goes out and the flow through the device is reduce to below 10 ml/min.

f) Repeat this test at the medium and maximum flows specified by the *manufacturer*.