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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

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.

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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.

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/

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