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Anaesthetic and respiratory equipment — Low-flow nasal cannulae for oxygen therapy

Matériel d'anesthésie et d'assistance respiratoire — Canules nasales à faible débit pour 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, *Airways 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).

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Introduction

Low-flow nasal cannulae are used to guide oxygen directly to the patient's nasal passageways via nasal prongs during the administration of *oxygen therapy*.

Several countries have introduced a fire-activated oxygen flow-stopping device for use with *oxygen therapy* systems especially in the home-care environment that prevents the proliferation of fire along the tubing if it catches light. It is recommended that these flow-stopping devices be fitted as close to the patient as possible.

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Anaesthetic and respiratory equipment — Low-flow nasal cannulae for oxygen therapy

1 Scope

This document specifies requirements for *low-flow nasal cannulae*, used in both home care and hospital environments for the administration of *oxygen therapy*.

This document does not include requirements to prevent the proliferation of fire within the tubing but does specify a user-detachable connection that can be used to fit a fire-activated oxygen shut-off device.

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 and semantics*

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,[1)] *Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for respiratory 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
inlet connector
connection on the *low-flow nasal cannula* (3.3) that connects to the outlet of the oxygen supply device or the outlet of the therapy tubing

3.2
integral nasal cannula
low-flow nasal cannula (3.3) and therapy tubing with no user-detachable connectors between the *inlet connector* (3.1) and the nasal prongs

3.3
low-flow nasal cannula
patient interface designed for use with flows ≤6 l/min for the administration of oxygen via nasal prongs

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