SLOVENSKI STANDARD
oSIST prEN ISO 23368:2019

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Anestezijska in dihalna oprema - Nosni kateter za kisikovo terapijo (ISO/DIS 23368:2019)

Anaesthetic and respiratory equipment - Low flow nasal cannulae for oxygen therapy (ISO/DIS 23368:2019)

Anästhesie- und Beatmungsgeräte - Nasenbrillen für die Atemtherapie (ISO/DIS 23368:2019)

Matériel d'anesthésie et de réanimation respiratoire - Canules nasales à faible débit pour oxygénothérapie (ISO/DIS 23368:2019)

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

Matériel d'anesthésie et de réanimation respiratoire — Canule nasale pour thérapie oxygène

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Contents

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.

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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee *121, Anaesthetic and respiratory equipment* Subcommittee SC 2, *Airways and related equipment* and is based on the *General Standard for airways and related devices* ISO 18190:2016.

This is the first edition.

Throughout this International Standard the following print types are used:

- Requirements and definitions: roman type;
- *Test specifications: italic type;*
- Informative material appearing outside of tables, such as notes, examples and references: smaller type. The normative text of tables is also in smaller type;
- *terms defined in clause 3: green italics.*

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

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 should it catch light. It is recommended that these flow-stopping devices be fitted as close to the patient as possible. Whilst this standard does not mandate the inclusion of a fire-activated oxygen flow-stopping device as part of the *low flow nasal cannula* it does specify a user-detachable connection close to where the *low flow nasal cannula* bifurcates to allow the fitting of such a device.

Anaesthetic and respiratory equipment – Low flow nasal cannulae for oxygen therapy

1 Scope

This device-specific standard 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 such as that specified in ISO 19211 [1].

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 4135:2001, *Anaesthetic and respiratory equipment- Vocabulary*

ISO 17256:201x. *Anaesthetic and respiratory equipment - Therapy tubing and connectors*

ISO 18190:2016, *Anaesthetic and respiratory equipment — General requirements for airways and related equipment*

ISO 18562-1:2017, *Biological evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process*

ISO 18562-2:2017, *Biological evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter*

ISO 18562-3:2017, *Biological evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds (VOCs)*

ISO 18562-4:2017, *Biological evaluation of breathing gas pathways in healthcare applications – Part 4: Tests for leachables in condensate*

ISO 80369-2:201x, *Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for breathing systems and driving gases 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 terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
inlet connector
connection on the *low flow nasal cannula* 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 and therapy tubing with no user-detachable connectors between the *inlet connector* 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

3.4
oxygen therapy
supplemental oxygen administered to a patient at atmospheric pressure

3.5
user-detachable nasal cannula
low flow nasal cannula with connections between the *inlet connector* and the nasal prongs that can be detached by the user

4 General requirements

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

5 Materials

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

In addition:

The gas pathways of *low flow nasal cannulae* shall be assessed for biological safety according to ISO 18562 parts 1 to 4 inclusive.

Check compliance by inspection of the technical file.

6 Design requirements

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

In addition:

6.1 General

6.1.1 *Low flow nasal cannulae* shall either be:

a) an integral part of the therapy tubing with a minimum length of 1,8 m (see Figure 1);

or

b) user-detachable from the therapy tubing with an *inlet connector* within 100 mm of the bifurcation, (see Figure 2) or if not bifurcated within 500 mm of the nasal prongs.

Check compliance by inspection.