
**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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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 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).

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For an explanation of 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 www.iso.org/iso/foreword.html.

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).

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

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

1) Under preparation. Stage at time of publication ISO/DIS 80369-2:2022.

3.4

oxygen therapy

supplemental oxygen administered to a patient at atmospheric pressure

3.5

user-detachable nasal cannula

low-flow nasal cannula (3.3) with connections between the *inlet connector* (3.1) and the nasal prongs that can be detached by the user

4 General requirements

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

5 Materials

5.1 General

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

5.2 Biological safety of gas pathways

Gas pathways of *low-flow nasal cannulae* shall be assessed for biological safety according to ISO 18562-1.

Check conformance by inspection of the technical file.

6 Design requirements

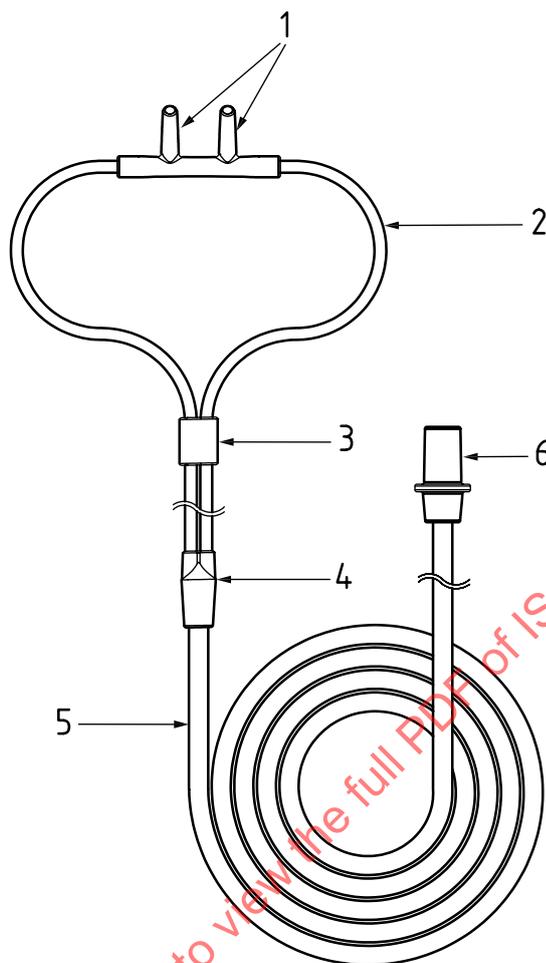
6.1 General

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

6.1.2 *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.

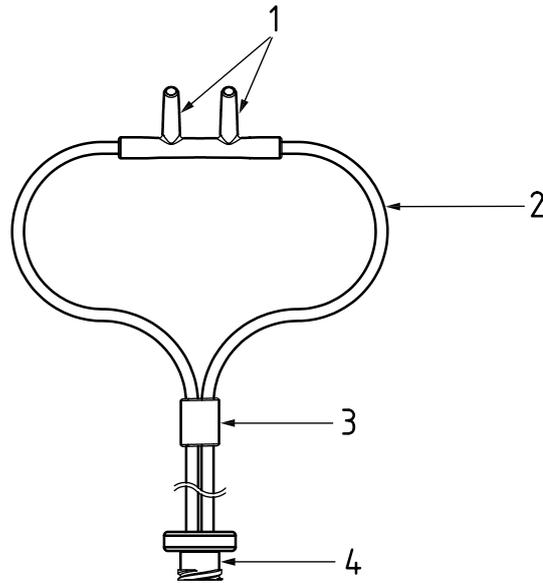
Check conformance by inspection.



Key

- | | |
|--------------------------------------|-----------------------------|
| 1 nasal prongs | 4 bifurcation/wye connector |
| 2 headset tubing/headset loop | 5 therapy tubing |
| 3 toggle/slide/slide bolo (adjuster) | 6 inlet connector |

Figure 1 — Example of integral nasal cannula



Key

- | | | | |
|---|-----------------------------|---|--|
| 1 | nasal prongs | 3 | toggle/slide/slide bolt (adjuster) |
| 2 | headset tubing/headset loop | 4 | R2 respiratory small-bore socket connector |

Figure 2 — Example of user-detachable nasal cannula

6.1.3 A low-flow nasal cannula shall operate normally, i.e. within its specification, at flows ≤ 15 l/min. Check conformance by inspection of the technical file.

6.2 Resistance to flow

6.2.1 The resistance to flow of the therapy tubing shall not exceed 0,9 kPa/m at a flow of 4 l/min for adult sizes, 3 l/min for paediatric sizes and 2 l/min for neonatal sizes.

Check conformance by the test given in [Annex A](#).

6.2.2 The resistance to flow of the headset shall not exceed 10 kPa at a flow of 4 l/min for adult sizes, 3 l/min for paediatric sizes and 2 l/min for neonatal sizes.

NOTE The resistance to flow through headsets is based on testing of devices on the market. It is higher than that for therapy tubing as headset tubing can be markedly smaller particularly if it bifurcates. This is not seen as detrimental to patients as they receive oxygen from both tubes.

Check conformance by the test given in [Annex A](#).

6.2.3 Flow shall not reduce by more than 25 % when the therapy tubing of the low-flow nasal cannula is bent in a semicircle of diameter three times its smallest outside diameter at flows of 4 l/min for adult sizes, 3 l/min for paediatric sizes and 2 l/min for neonatal sizes.

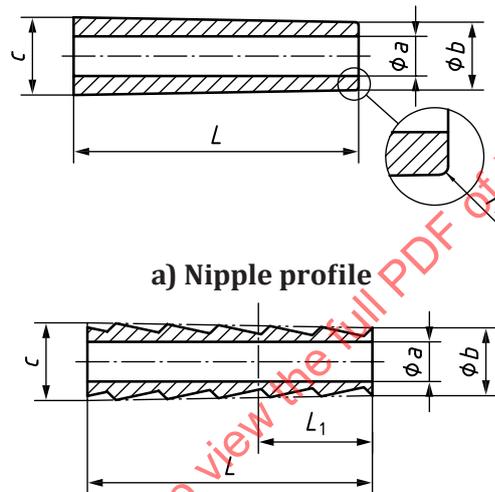
Check conformance by the test given in [Annex A](#).

6.3 Inlet connectors

6.3.1 *Inlet connectors* for *integral nasal cannulae* [see 6.1.2, a)] shall be compatible with the nipple specified in Figure 3 and shall not become detached from a test nipple as specified in Figure 4 when subjected to an internal static pressure of (200 ± 10) kPa for 30 s.

Check conformance by performing the following test:

- attach the *inlet connector* to a test nipple, complying with Figure 3, using an engagement axial force of $(45 \pm 1,5)$ N and a clockwise torque of (25 ± 5) N·cm at a rate not exceeding $20 \text{ N}\cdot\text{s}^{-1}$;
- subject the assembled connectors to a static internal pressure of (200 ± 10) kPa for > 30 s; and
- observe that the *inlet connector* does not detach from the test nipple.



b) Example of nipple with corrugations within the nipple profile in Figure 3 a)

See Table 1 for the dimensions of the nipple.

Figure 3 — Nipples for respiratory therapy equipment

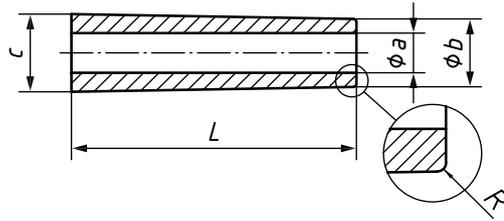
Table 1 — Dimensions of nipple

Key	Description	Dimension and tolerance
ϕa	Internal bore	(3,50 to 3,66) mm
ϕb	Outside diameter at tip	$(6,00^{-0,00}/_{+0,35})$ mm
c	Inclusive angle	$(2,0 \pm 0,1)^\circ$
L	Length	(12 to 40) mm
R	Radius at tip ^a	$(0,25 \pm 0,10)$ mm
L_1	Datum with a minimum of two corrugations within this length	$(10 \pm 1,0)$ mm

^a The radius can be replaced with a 45° chamfer of length R .

NOTE 1 The axis of the nipple can be curved.

NOTE 2 The external diameter of all the corrugations falls on the profile of the nipple as shown in Figure 3 a), the shape of the corrugations is given as an example.



See [Table 2](#) for the dimensions of the nipple.

Figure 4 — Test nipple

Table 2 — Dimensions of test nipple

Key	Description	Dimension and tolerance
$\varnothing a$	Internal bore	3,5 mm ^a
$\varnothing b$	Outside diameter at tip	(6,00 ^{-0,00} / _{+0,05}) mm
c	Inclusive angle	(2,0 ± 0,1)°
L	Length	(25 ⁻⁰ / ₊₅) mm
R	Radius at tip ^b	(0,25 ± 0,10) mm

The test nipple shall be made from stainless steel with an N6 (fine-ground surface finish). N6 is equivalent to a roughness value, Ra, of 0,8 µm and 32 µin.

^a The internal bore is optional.

^b The radius can be replaced by a 45° chamfer of length R .

6.3.2 The *inlet connector* for a *user-detachable nasal cannula* [(see [6.1.2](#), b)] shall be within 100 mm of where the *low-flow nasal cannula* bifurcates and shall be an R2 respiratory small-bore socket connector complying with ISO 80369-2.

NOTE Specifying a connection at this position allows a fire-activated oxygen shut-off device to be fitted as close to the patient as practicably possible. The respiratory small-bore connector has been specified to replace the previous elastomeric funnel connector found on therapy tubing to prevent misconnections to, for example, intravenous (IV) cannulae.

Check conformance by functional testing.

6.3.3 *Inlet connectors* shall not become detached from the therapy tubing or headset tubing when subjected to a static axial force of (40 ± 1,5) N.

Check conformance by the test given in [Annex B](#).

6.4 Nasal prongs

6.4.1 The outer surface of the nasal prongs shall be smooth and free of sharp edges.

Check conformance by inspection of the risk management file.

6.4.2 Nasal prongs shall not become detached from the headset tubing when subjected to a static axial force of (50 ± 1,5) N.

Check conformance by the test given in [Annex B](#).