International Standard

ISO 17256

First edition
2024-07

Anaesthetic and respiratory equipment — Respiratory therapy tubing and connectors

Matériel d'anesthésie et de réanimation respiratoire — Tubulures pour thérapie respiratoire et raccords

Reference number
ISO 17256:2024(en)

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

Published in Switzerland

Contents

Page

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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

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, *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

Respiratory tubing and connectors form the essential conduit between the *patient interface* and the gas supply device. The connectors specified in this document have been selected taking into consideration the risks of misconnection with other medical devices commonly used within the same environment. The requirements in this document were further developed and are to be circulated to all ISO/TC 121 subcommittees as recommendations.

Respiratory tubing and connectors are used extensively in healthcare facilities and increasingly in the home healthcare environment where medically trained personnel are not always in attendance. These environments have been carefully considered throughout the development of this document.

This document recognizes the significant use and the inherent safety of the EN 13544-2[1] specified nipple as the gas outlet on respiratory gas supply devices and therefore specifies a compatible elastomeric (funnel) connector as the inlet of the *respiratory tubing*. This document also recognizes the high risks associated with misconnection of the previously prescribed elastomeric (funnel) connector at the outlet (patient end) of the tubing and has therefore specified the new R2 respiratory small-bore connector as the outlet connector if the *respiratory tubing* is not integrated with the *patient interface* device (e.g. face mask, nasal cannula).

The concept of *extension tubing*, commonly used to provide flexibility of movement for the patient in home-care environments and hospital environments, such as MRI units, toilets and endoscopy units, has now been included in this document with particular emphasis on the connectors.

This document is adapted from EN 13544-2:2009[1] and has been modified as follows:

— the change of outlet from an elastomeric funnel to an R2 respiratory small-bore connector;

— requirements for *extension tubing*;

— requirements for *respiratory tubing* integrated with *patient interface* devices;

— a requirement to assess the biocompatibility of the materials of the devices that provide a gas pathway has been added;

— the dimensions of the nipple have been better defined;

— the option to specify a gas-specific threaded connection at the inlet of the *respiratory tubing* to replace the elastomeric funnel inlet connector has been made clearer;

— the gas-specific threaded inlet connectors now include gasses other than oxygen and air; and

— a hazard identification annex has been added (Annex C).

Anaesthetic and respiratory equipment — Respiratory therapy tubing and connectors

1 Scope

This document specifies requirements for the *respiratory tubing* and connectors used to convey respirable gases to a patient in the healthcare and homecare environments and provide a safe connection between the gas supply device and the *patient interface*. *Respiratory tubing* and connectors are mainly used for delivery of oxygen but can also be used for respirable air or oxygen/air mixtures and breathable medicinal gas mixtures such as oxygen/nitrous oxide or oxygen/helium mixtures. This document also specifies requirements for respiratory therapy *extension tubing*.

NOTE 1 The gas supply devices referred to in this document do not include anaesthetic machines/workstations and ventilators.

NOTE 2 This document does not cover breathing tubes for breathing systems. These are specified in ISO 5367.

This document is written following the format of ISO 18190, *General standard for airways and related equipment*. The requirements in this device-specific standard take precedence over any conflicting requirements in the General standard

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 20417, *Medical devices — Information to be supplied by the manufacturer*

ISO 21920-1, *Geometrical product specifications (GPS) — Surface texture: Profile — Part 1: Indication of surface texture*

ISO 80369-2, *Small-bore connectors for liquids and gases in healthcare applications — Part 2: Respiratory small-bore connectors*

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
extension tubing
flexible conduit with connectors to extend the connection between the *respiratory tubing* (3.4) and the *patient interface* (3.2)

3.2
patient interface
part connected to the patient

EXAMPLE Mask, nasal cannula or connectors thereof.

3.3
permanently attached
not removable without the use of a tool

Note 1 to entry: There is rationale for this definition in A.2.

3.4
respiratory tubing
flexible conduit with connectors to connect the gas supply device to the *patient interface* (3.2) or *extension tubing* (3.1)

4 General requirements

4.1 General

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

4.2 Test methods and conditions

The test methods included in this document are type tests and are carried out at (23 ± 2) °C; and at atmospheric pressure, unless otherwise specified.

NOTE Flowrates, volumes and leakage rates are expressed at Standard Temperature and Pressure, Dry (STPD).

5 Materials

5.1 General

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

5.2 Biological assessment of gas pathways

Respiratory tubing, *extension tubing* and connectors shall meet the requirements of ISO 18562-1.

Check conformance by inspection of the manufacturer's technical documentation.

6 Design requirements

6.1 General

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

6.2 Specific design requirements

6.2.1 *Respiratory tubing* and *extension tubing* shall:

a) withstand an axial force of (40 ± 1,5) N; and

b) be fitted with *permanently attached* inlet and outlet connectors.

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

Check conformance by the following test:

a) Apply an axial force of (40 ± 1,5) N at a rate of (50 ± 5) mm/min between each connector, in turn and the *respiratory tubing*.

b) Verify that the tubing does not fracture and the connectors do not detach from the *respiratory tubing*.

6.2.2 *Respiratory tubing*, integrated with a *patient interface* device shall not become detached from the *patient interface* device when subjected to an axial force of (40 ± 1,5) N.

Check conformance by the following test:

a) Apply an axial disconnection force of (40 ± 1,5) N at a rate of (50 ± 5) mm/min between the *patient interface* device and the *respiratory tubing*.

b) Verify that the *respiratory tubing* does not detach from the *patient interface* device.

6.2.3 Elastomeric funnel connectors shall not detach from a test nipple, as specified in Figure 2 and Table 1, when subjected to an internal pressure of (200 ± 10) kPa.

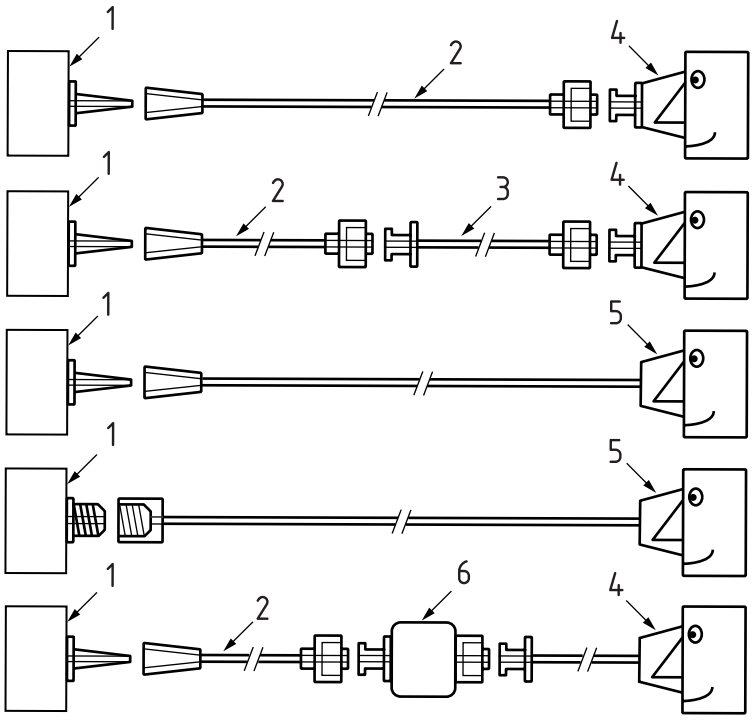
NOTE There is rationale for this subclause in A.4.

Check conformance by the following test:

a) Assemble the elastomeric funnel to a test nipple, complying with Figure 1, using an engagement axial force of (45 ± 1,5) N and a clockwise torque of (25 ± 5) N.cm at a rate not exceeding 20 $N.s^{-1}$.

b) Subject the assembled connectors to a static internal pressure of (200 ± 10) kPa for >30 s.

c) Verify that the elastomeric funnel does not detach from the test nipple.



Key

1 Gas supply device[a] with flow outlet connector[b]

2 *Respiratory tubing* with inlet connector[c] and outlet connector[d]

3 *Extension tubing* with inlet connector[c] and outlet connector[d]

4 *Patient interface* device [e]

5 Integral *respiratory tubing* with inlet connector and *patient interface* device

6 In-line medical device (MD) Example: oxygen consumption and activity recorder

[a] Examples of gas supply devices include: flowmeters, regulators with flow controls, nebulizer compressors.

[b] See Annex B.

[c] See 6.3.

[d] See 6.4.

[e] See 6.2.2.

NOTE Figure 1 does not show all the possible combinations.

Figure 1 — Examples of combinations of *respiratory tubing* and connectors

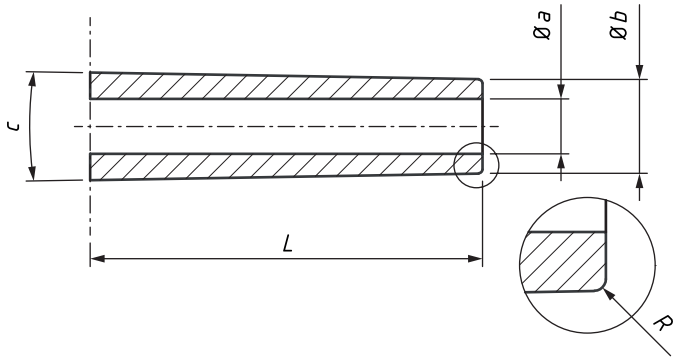


Figure 2 — Test nipple