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Anaesthetic and respiratory equipment — Respiratory therapy tubing and connectors

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

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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, *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.

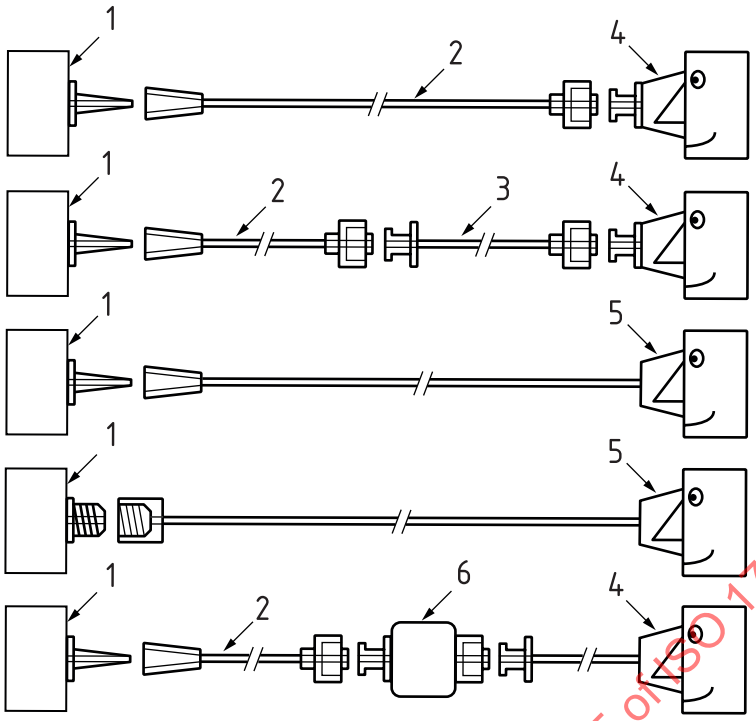
NOTE There is rationale for this subclause in A.4.

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

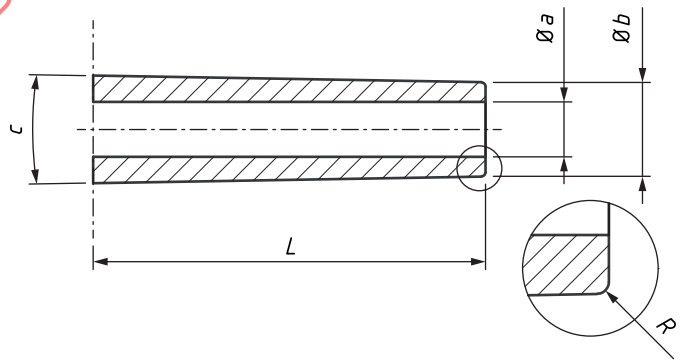


Figure 2 — Test nipple

Table 1 — Dimensions of test nipple

Key	Description	Dimensions and tolerances
Øa	Internal bore	3,5 mm[a]
Øb	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) according to ISO 21920-1.		
[a] The internal bore is optional.		
[b] The radius can be replaced by a 45° chamfer of length *R*.		

6.2.4 The resistance to flow shall not exceed 0,9 kPa/m at a flow of 4 l/min.

Check conformance by the following test:

a) Set a flow of (4 ± 0,2) l/min through a length of *respiratory tubing* or *extension tubing*, complete with its connectors.

b) Measure the pressure drop across the length of tubing.

c) Verify that the pressure drop is less than 0,9 kPa/m.

6.2.5 Flow shall not reduce by more than 25 % when the *respiratory tubing* and *extension tubing* is bent in a semicircle of diameter three times its nominal outside diameter.

Check conformance by the following test:

a) Determine the pressure drop required to maintain a flow of 10 l/min across a straight length of *respiratory tubing/extension tubing.*

b) Maintain this pressure while bending the tubing in a semicircle of diameter three times its nominal outside diameter.

c) Verify that the flow is >7,5 l/min.

6.2.6 *Respiratory tubing* and *extension tubing*, including their connectors, shall not leak by more than 5 ml/min while being subjected to an internal pressure of (600 ± 10) kPa.

NOTE There is rationale for this subclause in A.5.

Check conformance by the following test:

a) With the outlet occluded subject a length of *respiratory tubing* or *extension tubing,* complete with connectors, to an internal pressure of (600 ± 10) kPa.

b) Measure the flow required to maintain this pressure.

c) Verify that this flow <5 ml/min.

6.3 Inlet connectors

6.3.1 *Respiratory tubing* inlet connectors shall be one of the following:

a) an elastomeric funnel compatible with the nipple shown in Figure B.1;

b) for use with oxygen, oxygen/air mixtures and other breathable medical mixtures such as oxygen/nitrous oxide or oxygen/helium, a nut and nipple complying with Figure B.2 a); or

c) for use with medical air, a nut and nipple complying with Figure B.2 b).

NOTE There is rationale for this subclause in A.6.

Check conformance by functional testing.

6.3.2 *Extension tubing* inlet connectors shall be R2 socket small-bore connectors complying with ISO 80369-2.

Check conformance by functional testing.

6.4 Outlet connectors

Respiratory tubing and *extension tubing* outlet connectors shall be R2 cone small-bore connectors complying with ISO 80369-2.

Check conformance by functional testing.

7 Requirements for *respiratory tubing*, *extension tubing* and connectors supplied sterile

The requirements of ISO 18190:2016, Clause 7, shall apply.

8 Packaging

The requirements of ISO 18190:2016, Clause 8, shall apply.

9 Information supplied by the manufacturer

9.1 General

The requirements of ISO 18190:2016, Clause 9 and ISO 20417 shall apply.

9.2 Information supplied by the manufacturer

Where recommended for use with a fire activated oxygen shut-off device the instructions for use shall include a warning statement to the effect – 'a fire activated oxygen shut-off device should be fitted between the *respiratory tubing* and the *patient interface* device'.

Annex A
(informative)

Rationale

A.1 General

This annex provides a concise rationale for the important requirements of this document and is intended for use by those who are familiar with the subject of this document but who have not participated in its development. An understanding of the reasons for the main requirements is considered essential for its proper application. Furthermore, as clinical practices and technologies change, it is believed that rationales for the present requirements will facilitate any revisions of this document.

A.2 Permanently attached (see 3.3)

Permanently attached has been defined as not being removable without the use of a tool. It is understood that nothing can be "permanently attached" in the true sense of the word but for the purposes of this document *permanently attached* is used to emphasise that the connectors should not be removable from the *respiratory/extension tubing* without rendering the *therapy/extension tubing* unusable.

A.3 Inlet and outlet connectors (see 6.2.1)

Requiring that tubing has *permanently attached* connectors at both ends is to prevent the use of cut-to-length tubing such as bubble tubing which can be misconnected to IV lines, urinary catheters, etc.

A.4 Test pressure for *permanently attached* funnel to *respiratory tubing* (see 6.2.3)

It was decided to have two separate test pressures in 6.2.1 and 6.2.3. In 6.2.3, which assesses the minimum retention characteristics of the elastomeric funnel to the test nipple, it was decided to use a test pressure of 200 kPa. The rationale for this is as follows:

— Firstly, in practice there existed an important and un-stated safety characteristic with this type of connection. Whereby if the *respiratory tubing* becomes occluded the increase in pressure within the system will cause the elastomeric funnel to detach automatically from the nipple defined in Annex B.

— Secondly, the test only assesses the retention when the elastomeric funnel is assembled with 45 N of force to the test nipple. This assembly force may not be adequate to ensure the funnel does not disconnect from the test nipple at full line pressures.

— Thirdly, a lower test pressure helps to ensure that the mechanical properties of the elastomeric funnel are not made too stiff and consequently too difficult for the user to connect and disconnect the elastomeric funnel from the nipple.

A.5 *Respiratory tubing* and *extension tubing* leakage (see 6.2.6)

In 6.2.6, which assesses the leak properties of the tubing and connectors, the pressure is set at 600 kPa as this is the typical maximum pressure the tube may receive if blocked or kinked.

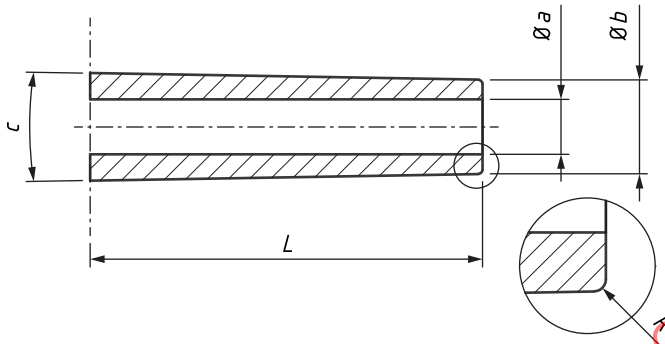
A.6 *Respiratory tubing* inlet connectors (see 6.3.1)

Because of the flexibility of the elastomeric funnel connector the dimensions are not defined. This is left to manufacturer's discretion as they need to assess the specified requirements for connection to the test nipple.

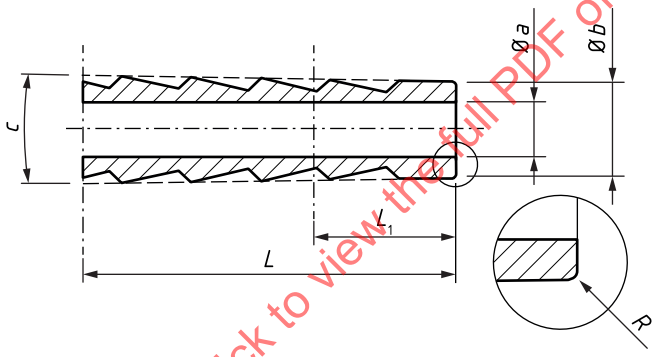
Recommendations for connectors on respiratory therapy devices are to be circulated to all ISO/TC 121 subcommittees for consideration during the development of their device specific standards. These recommendations specify that options for the outlet of the gas supply device includes both the nipple and threaded gas-specific connectors for air or oxygen. This document therefore includes the same alternatives for the inlet of the *respiratory tubing* and specifies the disconnection force for the elastomeric funnel connector from a test nipple.

Annex B
(normative)

Respiratory therapy equipment tubing connectors



a) Nipple profile



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

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

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

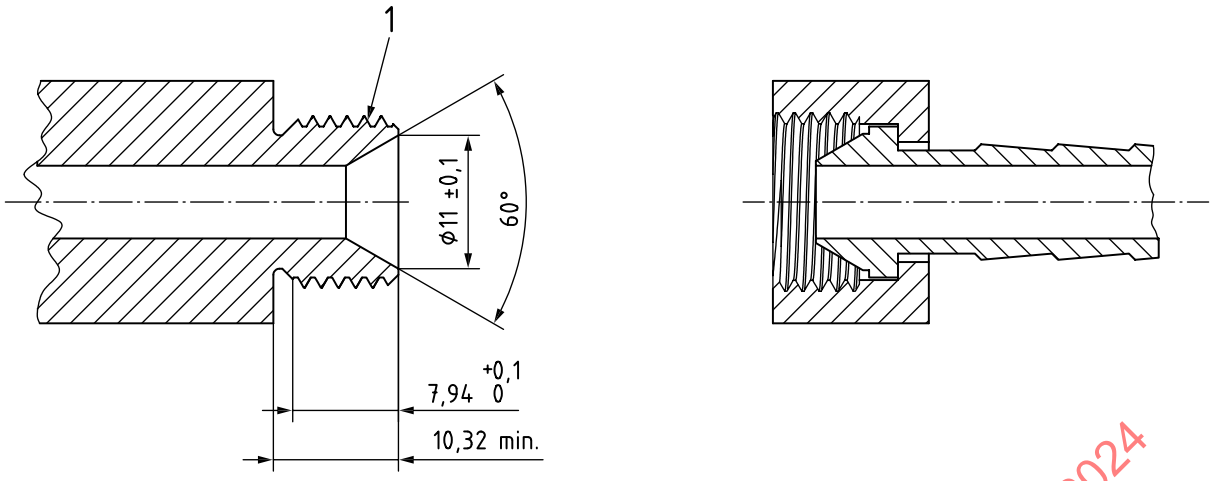
NOTE 1 The axis of the nipple can be curved.

NOTE 2 The external diameter of all the corrugations falls on the profile of the nipple as shown in Figure B.1. The shape of the corrugations is given as an example.

NOTE 3 The dimension *Øb* (outside diameter at tip) is essential to avoid misconnection with the small-bore connectors specified in the ISO 80369 series.

Figure B.1 — Nipples for respiratory therapy equipment

Dimensions in millimetres

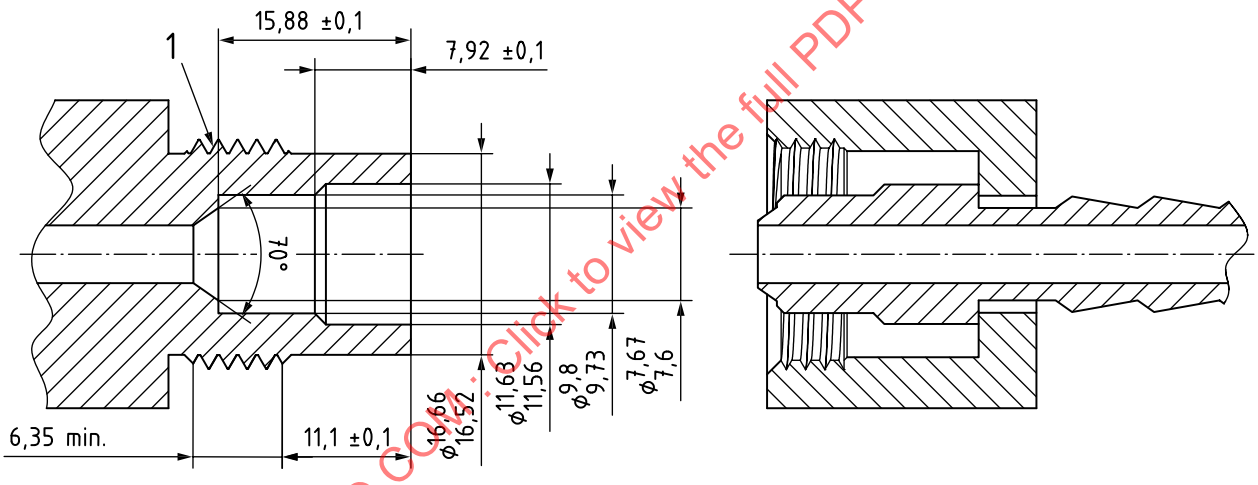


Key

1 ASME/ANSI 9/16-UNF-2A-RH

a) Oxygen screw-threaded inlet connector

Dimensions in millimetres



Key

1 ASME/ANSI 3/4-16 UNF-2A-RH

b) Air screw-threaded inlet connector

NOTE 1 Dimensions and tolerances of all components of the oxygen and air gas-specific connectors, are specified in CGA V-5:2005[2], connection n. 1240.

NOTE 2 The inlet connectors are only the nuts and nipples. The threaded mating connector is only shown to provide the mating dimensions as given in CGA V-5:2005[2].

Figure B.2 — Gas-specific inlet connectors