SLOVENSKI STANDARD
oSIST prEN ISO 5367:2021

01-julij-2021

Anestezijska in dihalna oprema - Dihalni seti in priključki (ISO/DIS 5367:2021)

Anaesthetic and respiratory equipment - Breathing sets and connectors (ISO/DIS 5367:2021)

Anästhesie- und Beatmungsgeräte - Atemsets und Verbindungsstücke (ISO/DIS 5367:2021)

Matériel d'anesthésie et de réanimation respiratoire - Ensembles respiratoires et raccords (ISO/DIS 5367:2021)

Ta slovenski standard je istoveten z: **prEN ISO 5367**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

oSIST prEN ISO 5367:2021 **en,fr,de**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 5367

ISO/TC **121**/SC **2**

Secretariat: **ANSI**

Voting begins on:
2021-03-30

Voting terminates on:
2021-06-22

Anaesthetic and respiratory equipment — Breathing sets and connectors

Matériel d'anesthésie et de réanimation respiratoire — Systèmes respiratoires et raccords

ICS: 11.040.10

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 5367:2021(E)

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Published in Switzerland

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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 ISO/TC 121, *Anaesthetic and respiratory equipment* Subcommittee SC 2, *Airways and related equipment*.

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.

This sixth edition cancels and replaces the fifth edition (ISO 5367:2014), which has been technically revised.

The main changes compared to the previous edition are as follows:

- the layout now follows the format of ISO 18190:2016 *General standard for airways and related equipment*;
- the general requirements such as risk management, usability, clinical investigation and some common marking requirements have been removed as they are now in ISO 18190 and cross-referenced in the appropriate clauses of this document.
- the list of normative references, many of which are cited in ISO 18190 has been updated.
- Requirements for hose systems for neonatal applications were added, e.g. the 11.5mm conical connector according to ISO 5356-1 was added

Introduction

This document contains requirements for *breathing sets*, *breathing tubes* and connectors that are intended to function as accessories to anaesthetic and respiratory equipment. *Breathing sets* and *breathing tubes* are characterized by certain design requirements such as a means of connection and leakage limits. Disclosure requirements for conformance and flow resistance values allow the user to make an informed choice when connecting these accessories to a breathing system. These design requirements are intended to allow operation within the limits of performance of the *anaesthetic breathing systems* and *ventilator breathing systems* with which the accessories are intended to operate.

This document includes requirements for both single-use and reusable *breathing sets* and *breathing tubes*. Re-usable *breathing sets* and *breathing tubes* are intended to comply with the requirements of this document for the recommended service life.

Certain tests are performed under constant pressure to simplify the test methodology. It is recognized that this does not reflect clinical use, where pressure is intermittent and peak pressures occur for short periods. The limits in the test methods take this into account. While such test methods do not address product variability, the limits required also take this into account.

Throughout this document, all pressures are denoted in SI units of hPa with corresponding cmH_2O equivalent values rounded to the nearest whole cmH_2O.

NOTE The unit cmH_2O is not an SI notation and is not used in ISO documents; rounded cmH_2O values are given for information only to allow comparison to medical literature and related breathing system standards.

Throughout this document the following print types are used:

— requirements and definitions: roman type;

— *conformance tests: 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: *italic* type.

Anaesthetic and respiratory equipment – Breathing sets and connectors

1 *Scope

This document specifies minimum requirements for *breathing sets* and *breathing tubes* intended to be used with *anaesthetic breathing systems*, *ventilator breathing systems*, humidifiers or nebulizers. It applies to *breathing sets* and *breathing tubes* and *patient end adaptors* supplied already assembled and to those supplied as components and assembled in accordance with the manufacturer's instructions.

This document is applicable to *breathing sets* which include special components (e.g. water traps) between the *patient end* and *machine end* which are supplied already assembled.

Provision is made for coaxial and related bifurcated, double-lumen, or multiple-lumen *breathing sets* and *breathing tubes* suitable for use with *patient end adaptors*.

NOTE: Examples of various types of *breathing sets* with *patient end adaptors* are depicted in Annex A.

This document is not applicable to *breathing sets* and *breathing tubes* for special purposes.

EXAMPLE 1: Ventilators having special *compliance*, pressure or breathing frequency requirements.

Requirements for breathing system components such as exhalation valves, exhaust valves, *adjustable pressure-limiting (APL) valves*, heat and moisture exchangers (HMEs), breathing filters, and reservoir bags, are not covered by this document but can be found in ISO 80601-2-12, ISO 80601-2-13, ISO 9360-1[3], ISO 23328-2[4], and ISO 5362[1]. Requirements for heated *breathing tubes* can be found in ISO 80601-2-74[2].

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 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

IEC 60601-1:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135 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

147 **3.1**

148 **anaesthetic breathing system**

149 inspiratory and expiratory gas pathways through which anaesthetic gas flows at respiratory pressure
150 between the fresh-gas inlet, the *connection port* (3.9) and an exhaust valve or exhaust port

151 [SOURCE: ISO 80601-2-13:2011, 201.3.203]

152 **3.2**

153 **antistatic**

154 property of a material or procedure that disperses or inhibits the accumulation of electrostatic charges

155 **3.3**
156 **APL valve**
157 **adjustable pressure-limiting valve**

158 pressure-limiting valve which releases gas over an adjustable range of pressures

159 [SOURCE: ISO 4135:2001, 4.3.6, modified]

160 **3.4**

161 **assembled end**

162 end of a *breathing tube* (3.7) incorporating an *adaptor* (3.1)

163 **3.5**

164 **breathing set**

165 assembly of *breathing tubes*, (3.6) connectors and components that form the gas pathways of a
166 *breathing system* between the ventilator and the patient's airway device

167 Note 1 to entry: The exhaust valve, APL valves, heat and moisture exchanger (HME), breathing system filter, and
168 reservoir bag are not included.

169 **3.6**

170 **breathing tube**

171 non-rigid tube used to convey gases and/or vapours between components of a breathing system

172 [SOURCE: ISO 4135:2001, 4.1.2]

173 **3.7**

174 **compliance**

175 volume added per unit pressure increase when gas is added to an enclosed space, expressed at the
176 temperature and humidity of that enclosed space and at ambient atmospheric pressure

177 [SOURCE: ISO 4135:2001, 3.1.5]

178 **3.8**

179 **patient connection port**

180 opening intended for connection to an airway device

181 Note to entry: e.g. tracheal or tracheostomy tube, face mask, supralaryngeal airway

182 [SOURCE: ISO 4135:2001, 4.2.1.2, modified]

3.9

machine end

end of the *breathing set* (3.5) or *breathing tube* (3.6) intended to be connected to the anaesthetic workstation, ventilator or other breathing system component furthest from the patient

[SOURCE: ISO 4135:2001, 4.2.3.2, modified]

3.10

patient end

end of the *breathing set* (3.5) or *breathing tube* (3.6) which is intended to be connected to the *patient end adaptor*, *Y-piece* or other appropriate component near the patient

3.11

patient end adaptor

tubular connector with multiple ports, one of which is a patient *connection port* (3.8)

Note 1 to entry: Examples of *patient end adaptors* include a *Y-piece*, (3.16) a *swivel adaptor*, (3.14) and other specialized *adaptors* (3.1) for coaxial, multiple tubes, and bifurcated tubes. See also Annex A, Figures A.1 to A.5.

3.12

plain end

end of a *breathing tube* (3. 6) designed to fit directly over a male conical connector complying with ISO 5356-1

3.13

swivel adaptor

specialized *adaptor* (3.1) which allows variation in the position of its ports relative to each other

3.14

ventilator breathing system

VBS

inspiratory or expiratory gas pathways through which gas flows at respiratory pressures and bounded by the port through which fresh gas enters, the patient *connection port* (3.8) and the exhaust port

[SOURCE: ISO 80601-2-12:2011, 201.3.221]

4 General requirements

4.1 General

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

NOTE: An informative list of identified hazards is contained in Annex B.

4.2 Test methods

Manufacturers may use type tests different from those detailed within this document, if an equivalent degree of safety is obtained. However, in the event of dispute, the methods specified herein shall be used as the reference methods.

4.3 Recommended service life

Re-usable *breathing sets* and *breathing tubes* shall comply with the requirements of this document throughout the recommended service life as required in 9.3.4.

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

5 Materials

5.1 General

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

5.2 Biological safety testing

Breathing sets shall also be evaluated and tested in conformance with ISO 18562-1.

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

6 Design requirements

6.1 General

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

6.2 Designated length

6.2.1 The length of *breathing tubes* shall be designated by their nominal overall length, expressed in metres, when measured in the resting condition (without extension), lying on a horizontal surface.

Breathing tubes intended to be extended when used shall be designated by both the unextended and extended lengths.

Check conformance by functional testing.

6.2.2 The designated length of *breathing tubes* provided securely attached to a *Y-piece* or *patient end adaptor* shall include the length of the *patient end adaptor* and any *assembled ends*.

Check conformance by functional testing.

6.2.3 The actual length shall be within ± 10 % of the designated length.

Check conformance by functional testing.

6.3 Means of connection

6.3.1 General

6.3.1.1 *Breathing tubes* shall have *plain ends* complying with 6.3.2 or *assembled ends* with *adaptors* incorporating 22 mm, 15 mm or 11,5 mm conical connectors complying with ISO 5356-1.

Check conformance by inspection.

6.3.2 *Plain ends* of *breathing tubes*

6.3.2.1 The axial length [l_1 in Figure 1 a)] of the *plain ends* of *breathing tubes*, excluding those specified in 6.3.2.2, shall be not less than 21 mm for *breathing tubes* intended to engage with 22 mm male cones or not less than 14 mm for *breathing tubes* intended to engage with 15 mm male cones compliant with ISO 5356-1 or shall be not less than 10,5 mm for breathing tubes intended to engage with 11,5 mm male conical connectors.

Check conformance by functional testing.

6.3.2.2 The axial length [l_2 in Figure 1 a)] of the *plain ends* of *breathing tubes* that incorporate an internal ridge [see Figure 1 b)], intended to engage with the recess at the base of a 22 mm male cone as specified in ISO 5356-1, shall be not less than 26,5 mm.

Check conformance by functional testing.

6.3.2.3 *Plain ends* of *breathing tubes* shall not become detached from a 22 mm or 15 mm ISO 5356-1 compliant male cone at a force of less than 40 N or shall not become detached from an 11,5mm ISO 5356-1 compliant male cone at a force of less than 25 N.