
Suction catheters for use in the respiratory tract

Sondes d'aspiration pour les voies respiratoires

STANDARDSISO.COM : Click to view the full PDF of ISO 8836:2019



STANDARDSISO.COM : Click to view the full PDF of ISO 8836:2019



COPYRIGHT PROTECTED DOCUMENT

© ISO 2019

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword.....	iv
Introduction.....	v
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 *General requirements.....	3
5 Materials.....	4
6 Design requirements.....	4
6.1 General.....	4
6.2 Size designations and dimensions.....	4
6.3 <i>Suction catheter tip</i>	5
6.4 <i>*Suction catheter connector</i>	6
6.5 Additional requirements for <i>closed suction catheters</i>	7
6.5.1 General design.....	7
6.5.2 <i>Closed suction catheter manifold and connectors</i>	8
6.5.3 <i>Protective sleeve</i>	9
6.5.4 <i>*Suction control device</i>	9
6.5.5 Flushing system.....	10
6.5.6 T-piece port.....	10
6.6 Performance requirements.....	10
6.6.1 Security of construction.....	10
6.6.2 <i>Shaft performance</i>	10
6.6.3 <i>Suction control device performance</i>	11
6.6.4 <i>*Leakage</i>	11
6.6.5 <i>*Resistance to flow</i>	11
7 Requirements for <i>suction catheters</i> supplied sterile.....	11
8 Packaging.....	11
9 Information supplied by the manufacturer.....	11
9.1 General.....	11
9.2 Marking.....	12
9.3 Instructions for use.....	13
Annex A (informative) Rationale.....	14
Annex B (normative) Test method for security of attachment.....	17
Annex C (normative) Measurement of residual vacuum.....	18
Annex D (normative) *Method of testing leakage.....	20
Annex E (informative) Hazard identification for risk assessment.....	21
Bibliography.....	24

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 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*.

This fifth edition cancels and replaces the fourth edition (ISO 8836:2014), which has been technically revised. The main changes compared to the previous edition are as follows:

- it is no longer a requirement to have only male-type *suction catheter connector* on the *suction catheter*;
- the female-type suction catheter connector has been reinstated following removal in the fourth edition of this document;
- the terms and definitions have been revised;
- the conditions for the measurement of *residual vacuum* in *closed suction catheters* have been revised.

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

This document is concerned with the basic requirements and method of size designation of both *open* and *closed suction catheters* made of flexible materials.

The method of describing tube dimensions and configuration has been devised in order to assist clinicians in the selection of the most suitable *suction catheter* for a particular patient. The size designation is important when selecting a catheter because of its relationship to the ease with which the catheter can be passed through a *tracheal or tracheostomy tube*^{[2][3]}.

Throughout this document the following print types are used:

- Requirements and definitions: roman type;
- *Conformance checks and 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;
- *defined terms: 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](#).

STANDARDSISO.COM : Click to view the full PDF of ISO 8836:2019

[STANDARDSISO.COM](https://standardsiso.com) : Click to view the full PDF of ISO 8836:2019

Suction catheters for use in the respiratory tract

1 Scope

This document specifies dimensions and requirements for both *open* and *closed suction catheters* made of flexible materials and intended for use in suctioning of the respiratory tract.

Suction catheters intended for use with flammable anaesthetic gases or agents, lasers or electrosurgical equipment are not covered by this document.

NOTE For guidance on airway management during laser surgery of the upper airway, see ISO/TR 11991^[4].

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*

ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

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 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

***closed suction catheter**

suction catheter (3.17) enclosed within a *protective sleeve* (3.8) that allows its use within the airway without opening the *breathing system* directly to atmosphere

3.2

***closed suction catheter manifold**

part of the *closed suction catheter* (3.1) that provides a connection to an airway device

3.3

connector

fitting to join together two or more components

[SOURCE: ISO 4135:2001, 4.2.2.1]

3.4

eye

side hole near the *patient end* (3.6) of the *suction catheter* (3.17)

3.5

machine end

that end of the catheter which is intended to be connected to suction tubing

3.6

patient end

that end of the *suction catheter* (3.17) which is intended to be inserted into a patient

[SOURCE: ISO 4135:2001, 8.3.3]

3.7

patient connection port

opening intended for connection to an airway device

3.8

protective sleeve

flexible barrier that encloses the *suction catheter* (3.17) *shaft* (3.15) to prevent contact with the user while connected to the *VBS* (3.23)

3.9

residual vacuum

negative pressure at the *tip* (3.21) of the *closed suction catheter* (3.1) when the *suction control device* (3.19) is in the relief position

3.10

risk

combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO 14971:2019, 3.18]

3.11

risk analysis

systematic use of available information to identify hazards and to estimate the *risk* (3.10)

[SOURCE: ISO 14971:2019, 3.19]

Note 1 to entry: *Risk analysis* includes examination of different sequences of events that can produce hazardous situations and harm (see ISO 14971:2019, 5.4).

3.12

risk assessment

overall process comprising a *risk analysis* (3.11) and a *risk evaluation*

[SOURCE: ISO 14971:2019, 3.20]

3.13

risk management

systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring *risk* (3.10)

[SOURCE: ISO 14971:2019, 3.24]

3.14

risk management file

set of records and other documents that are produced by *risk management* (3.13)

[SOURCE: ISO 14971:2019, 3.25]

3.15**shaft**

main part of the *suction catheter* (3.17) which is of uniform outside diameter

3.16**single-fault condition**

condition in which a single means for reducing a *risk* (3.10) is defective or a single abnormal condition is present

3.17**suction catheter**

flexible tube designed for introduction into the respiratory tract or an airway device to remove material by suction

3.18***suction catheter connector**

connector (3.3) at the *machine end* (3.5) of the *suction catheter* (3.17) that allows a connection to suction tubing

3.19**suction control device**

means provided at or near the *machine end* (3.5) of a *suction catheter* (3.17) to control the level of suction in the *suction catheter*

Note 1 to entry: *Suction control devices* can be integrated into the *suction catheter connector* or be a stand-alone device that attaches to the *suction catheter connector*.

3.20**terminal orifice**

central aperture at the *tip* (3.21) of the *suction catheter* (3.17)

3.21**tip**

extremity of the *patient end* (3.6) of a *suction catheter* (3.17)

[SOURCE: ISO 4135:2001, 8.3.4]

3.22**vacuum**

pressure less than atmospheric pressure

Note 1 to entry: It is usually expressed as a difference from atmospheric pressure.

[SOURCE: ISO 4135:2001, 8.1.1]

3.23**ventilator breathing system****VBS**

inspiratory or expiratory pathways through which gas flows at respiratory pressures and bounded by the port through which fresh gas enters, the *patient connection port* (3.7) and the exhaust port

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

4 *General requirements

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

NOTE [Annex E](#) covers hazard identification for *risk assessment of suction catheters*.

5 Materials

5.1 The requirements of ISO 18190:2016, Clause 5 and the following apply.

5.2 The shaft of the suction catheter shall be constructed from materials which facilitate passage through an airway device.

NOTE Examples of airway devices are tracheal tubes, tracheostomy tubes, tracheobronchial tubes and supralaryngeal airways.

Check conformance by inspection of the technical file.

5.3 The *shaft* shall be transparent.

Check conformance by visual inspection.

5.4 *Suction catheters* shall also be evaluated for biocompatibility in accordance with ISO 18562-1.

Check conformance by inspection of the technical file.

6 Design requirements

6.1 General

The requirements of ISO 18190:2016, Clause 6 and the following apply:

6.2 Size designations and dimensions

6.2.1 Designated sizes of *suction catheters* shall be within the tolerances of the nominal outside diameters specified in [Table 1](#) and expressed in millimetres. The designated size can additionally be expressed in French (Charrière) gauge size.

NOTE 1 For the purposes of this document, the French gauge system of size (F) is based on the outside diameter of the *shaft* gauged in steps of thirds of a millimetre (1 mm corresponds to 3F).

NOTE 2 The French gauge size is not an SI unit. Size designation in millimetres facilitates matching the outside diameter of the *suction catheter* to the inside diameter of the tracheal or tracheostomy tube.

Check conformance by measurement.

6.2.2 *Suction catheters* shall have a colour identification at the *machine end*, to denote the designated size in accordance with [Table 1](#).

NOTE The use and choice of colour identification for designated sizes not listed in [Table 1](#) are at the manufacturer's discretion.

Check conformance by visual inspection.

6.2.3 The minimum inside diameter of the *shaft*, shall be in accordance with [Table 1](#) and shall not, at any point between the *suction catheter connector* and the *eye* nearest to the *machine end*, be less than the inside diameter of the *shaft* at that *eye*.

Check conformance by measurement.

6.2.4 The inside diameter of the *terminal orifice* shall be not less than 90 % of the minimum inside diameter of the *shaft*.

Check conformance by measurement.

6.2.5 The *shaft* length shall be within ± 5 % of the marked length.

Check conformance by measurement.

Table 1 — Designated size and colour identification

Designated size		Outside diameter tolerance	Minimum inside diameter	Colour identification
French (Charrière) equivalent (F)	Nominal outside diameter (mm)			
4	1,33	$\pm 0,10$	0,55	Purple
4,5	1,5	$\pm 0,10$	0,70	Blue
5	1,67	$\pm 0,10$	0,80	Grey
6	2,0	$\pm 0,10$	1,0	Light green
6,5	2,1	$\pm 0,10$	1,1	Yellow green
7	2,33	$\pm 0,10$	1,25	Ivory
7,5	2,5	$\pm 0,10$	1,45	Pink
8	2,67	$\pm 0,10$	1,50	Light blue
9	3,0	$\pm 0,15$	1,75	Turquoise
10	3,33	$\pm 0,15$	2,00	Black
12	4,0	$\pm 0,15$	2,45	White
14	4,67	$\pm 0,20$	2,95	Green
15	5,0	$\pm 0,20$	3,20	Brown
16	5,33	$\pm 0,20$	3,40	Orange
18	6,0	$\pm 0,20$	3,90	Red
20	6,67	$\pm 0,20$	4,30	Yellow

6.3 Suction catheter tip

6.3.1 Suction catheters for use with suction systems operating at a vacuum $>4,0$ kPa, shall have a *terminal orifice* and at least two *eyes* within 2 cm of the *terminal orifice*.

NOTE The availability of one or more *eye(s)* reduces the *risk* and likelihood of injury.

Check conformance by visual inspection.

6.3.2 Suction catheters for use with suction systems operated at vacuum $\leq 4,0$ kPa shall have a *terminal orifice* but need not have an *eye*.

Check conformance by visual inspection.

6.3.3 The edges of the *tip*, *terminal orifice* and *eye(s)* shall be smooth.

NOTE This is to minimize injuries of the tracheal epithelium.

Check conformance by inspection.

6.3.4 The *eye(s)* shall not cause the *suction catheter* to kink or collapse during use.

Check conformance by inspection of the risk management file.

6.3.5 The axis of the *tip* can be at an angle to the long axis of the *shaft* (see Coudé *suction catheter tip*, key 7 in [Figure 1](#)).

NOTE This is to facilitate the introduction of the *suction catheter* into the left main bronchus.

6.4 *Suction catheter connector

6.4.1 *Suction catheters* shall be provided with a *suction catheter connector*, (see [Figure 1](#) for examples), intended for connection to the inlet port of suction tubing.

NOTE Requirements for suction tubing are specified in the ISO 10079 series of International Standards.

Check conformance by visual inspection.

6.4.2 *Suction catheter connectors* shall be securely attached to the *shaft*.

Check conformance by the performance requirements and test specified in [6.6.1](#).

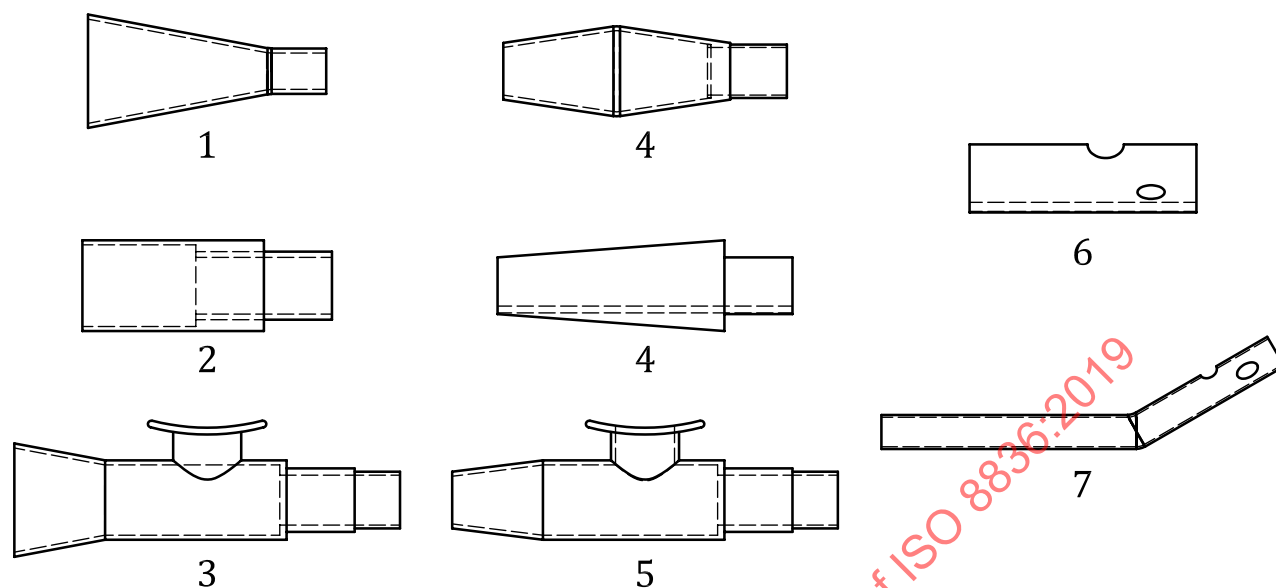
6.4.3 *Suction catheter connectors* shall have an internal bore diameter equal to or greater than the internal diameter of the *shaft* to which it is attached.

Check conformance by measurement.

6.4.4 Male *suction catheter connectors* shall be made from material with a modulus of elasticity either in flexure or in tension >70 MPa and shall be compatible with suction tubing having an inside diameter of 6 mm (see [Figure 1](#)).

Check conformance by inspection of the technical file.

6.4.5 *Suction catheters should be provided with a suction control device.



Key

- 1 female conical suction catheter connector
- 2 female cylindrical suction catheter connector
- 3 female suction catheter connector with suction control device
- 4 male suction catheter connector
- 5 male suction catheter connector with suction control device
- 6 suction catheter tip with eyes
- 7 Coudé suction catheter tip with eyes

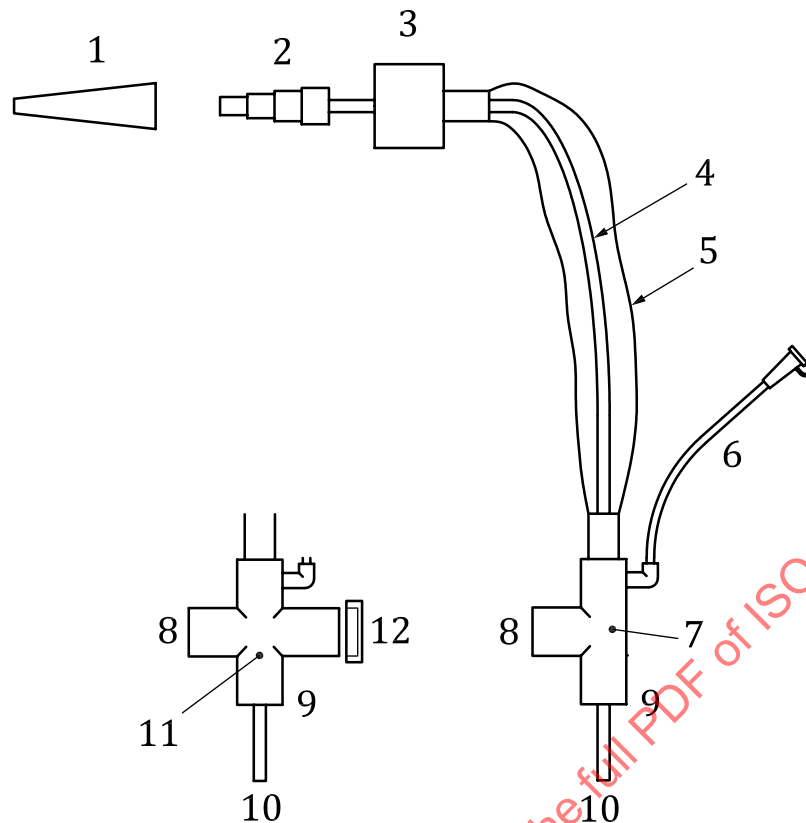
Figure 1 — Examples of designs for suction catheter connectors and suction catheter tips

6.5 Additional requirements for closed suction catheters

6.5.1 General design

In addition to the requirements for suction catheters, closed suction catheters shall be supplied with a closed suction catheter manifold, a protective sleeve, and a suction control device. (See [Figure 2](#)).

Check conformance by inspection.



Key

- | | |
|---|---|
| 1 protective cap | 7 closed suction catheter manifold |
| 2 suction catheter connector | 8 machine end of the closed suction catheter manifold |
| 3 suction control device | 9 patient connection port |
| 4 shaft of the suction catheter | 10 suction catheter tip |
| 5 protective sleeve | 11 closed suction catheter manifold as a T-piece |
| 6 flushing line with non-return valve, female Luer connector, and cap | 12 T-piece cap |

NOTE The closed suction catheter shown is an example only. Actual systems can consist of other arrangements and components not illustrated or listed.

Figure 2 — Example of closed suction catheter

6.5.2 Closed suction catheter manifold and connectors

6.5.2.1 The patient connection port shall be a female 15 mm conical connector complying with ISO 5356-1 and shall be in line with the suction catheter and the airway. (See [Figure 2](#)).

Check conformance by inspection of the technical file.

6.5.2.2 The machine end of the closed suction catheter manifold shall be a 22 mm female or 15 mm male conical connector complying with ISO 5356-1.

Check conformance by inspection of the technical file.

6.5.2.3 *The closed suction catheter manifold should be free to rotate to minimize torsion on the airway device and breathing set.

NOTE See E.2.4.

6.5.2.4 *Closed suction catheter manifolds* shall include a means to prevent leakage of gases into the area between the *protective sleeve* and the *shaft*.

Check conformance by the performance and test requirements specified in 6.6.4.

6.5.2.5 The *closed suction catheter manifold* shall be sufficiently transparent to allow visualization of liquids and secretions.

Check conformance by visual inspection.

6.5.2.6 Inside surfaces of *closed suction catheter manifolds* should be smooth and free of sharp edges to minimize kinking and deformation of the *suction catheter*.

6.5.2.7 *The internal volume at atmospheric pressure of the *closed suction catheter manifold* not including the volume of any female connectors shall be determined and stated in the instructions for use. (See 9.3.1.)

Check conformance by inspection of the technical file and the instructions for use.

6.5.3 Protective sleeve

6.5.3.1 The *protective sleeve* shall prevent direct user or patient contact with the *shaft*.

Check conformance by functional testing.

6.5.3.2 The *protective sleeve* shall be sufficiently flexible to allow unimpeded insertion or removal of the *suction catheter* to its intended length.

Check conformance by functional testing.

6.5.3.3 The *protective sleeve* shall not detach, rupture, or tear under normal use.

Check conformance by the performance requirements and tests specified in 6.6.1, and the leakage requirements and tests specified in 6.6.4.

6.5.3.4 The *protective sleeve* shall be sufficiently transparent to allow visualization of the *shaft* and of its contents during the process of suctioning.

Check conformance by visual inspection.

6.5.4 *Suction control device

6.5.4.1 The *suction control device* shall be securely attached to the *shaft* and the *protective sleeve*.

Check conformance by the performance requirements and tests specified in 6.6.1.

6.5.4.2 The *suction control device* shall not leak fluids in any position during normal use and single-fault condition.

Check conformance by the performance and test requirements specified in 6.6.4.

6.5.4.3 The *suction control device* shall be designed such that

- a) the “off” position can be locked, and

b) the “on” position cannot be locked.

Check conformance by functional testing.

6.5.5 Flushing system

If provided, the free end of the flushing *connector* shall be sealed when not in use with a closure device, non-return valve, or Luer-activated valve, but in all instances, it shall be compatible with a male small-bore connector complying with ISO 80369-7.

CAUTION — Attention is drawn to the *risk* of misconnection with intravascular devices. Additional *risk* controls are required including, but not limited to, disclosure of specific warnings on the labelling and in the instructions for use.

Check conformance by functional testing and inspection of the risk management file.

6.5.6 T-piece port

T-piece ports shall be provided with a retained, detachable end cap. (See [Figure 2](#)).

Check conformance by visual and functional testing.

6.6 Performance requirements

6.6.1 Security of construction

6.6.1.1 When tested in accordance with [Annex B](#), the force required to detach securely attached components shall be not less than that specified in [Table 2](#).

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

Table 2 — Minimum force needed to detach any securely attached component

Designated size (mm)	Minimum force (N)
1,33 to 2,67	5
3 to 4,67	15
>5	20

6.6.1.2 When tested in accordance with [Annex B](#), the force required to detach any component not required to be securely attached shall be not less than that specified in [Table 3](#).

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

Table 3 — Minimum force required to detach any component not required to be securely attached

Designated size (mm)	Minimum force (N)
to 3,0	0,5
>3,0	1

6.6.2 Shaft performance

The *shaft* shall not collapse when subjected to a pressure ≤ 40 kPa below atmosphere for ≤ 15 s at a temperature of (23 ± 2) °C with the *tip* occluded and if present, the *suction control device* set to maximum.

Check conformance by functional testing.

6.6.3 Suction control device performance

The *residual vacuum* of the *suction catheter*, if provided with a *suction control device*, shall be $<0,33$ kPa.

Check conformance by the tests given in [Annex C](#).

6.6.4 *Leakage

Closed suction catheters shall conform with the leakage requirements for the patient category for which the device is intended for use (see [Table 4](#)).

Check conformance by the tests given in [Annex D](#) to the leakage limits in [Table 4](#).

Table 4 — Leakage limit of closed suction catheters by patient category

Patient category	Intended delivered volume (ml)	Leakage limit (ml/min)	At pressure (hPa)
Adult	≥ 300 ml	70	60
Paediatric	50 ml $<$ 300 ml	40	60
Neonatal	≤ 50 ml	30	60

6.6.5 *Resistance to flow

The resistance to flow of a *closed suction catheter* shall conform to the limits for the patient category for which the device is intended for use. (see [Table 5](#))

Check conformance by testing using the test principles in ISO 5367:2014, 5.5.2, to the resistance limits in [Table 5](#).

Table 5 — Resistance limit by patient category

Patient category	Intended delivered volume (ml)	Maximum resistance limit (hPa/l/min)	At flow (l/min)
Adult	≥ 300 ml	0,03	30
Paediatric	50 ml $<$ 300 ml	0,07	15
Neonatal	≤ 50 ml	0,4	2,5

7 Requirements for suction catheters supplied sterile

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

8 Packaging

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

9 Information supplied by the manufacturer

9.1 General

The applicable requirements of ISO 18190:2016, Clause 9 and the following apply.

9.2 Marking

9.2.1 *Suction catheters* shall be marked with the following:

- the designated size (see 6.2.1 and Table 1);
- colour identification as specified in 6.2.2;
- the length in mm (see 6.2.5);
- suction catheter connectors* attached to a *suction catheter* with an angled *tip* shall indicate the direction in which the *tip* points;
- smaller sizes of *suction catheters* for paediatric use shall be provided with length marks, beginning at least 5 cm from the *tip*, to represent the distance, in centimetres or parts thereof, from the *patient end*;
- for *suction catheters*, the *shaft* should have clearly visible marking at least every 2 cm along the length of the part inserted into the airway device;
- length marks shall be either in a single colour, such as black or blue, or in accordance with the colour code as shown in Figure 3 and Table 6.

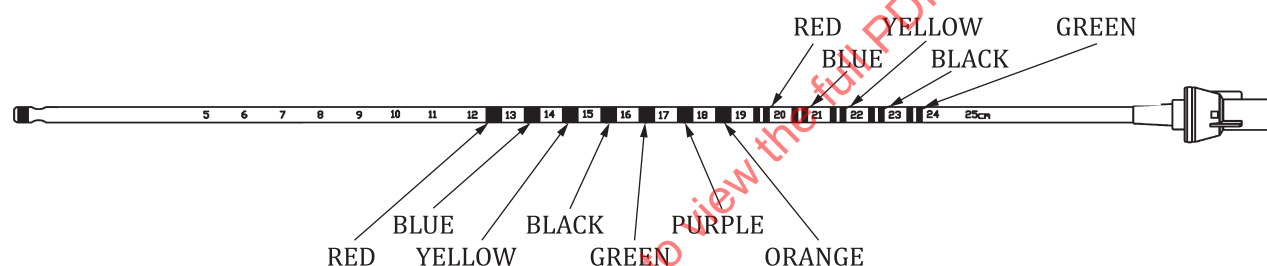


Figure 3 — *Suction catheter* length marks and associated colour code

Table 6 — *Suction catheter* length marks and associated colour code

Length mark (cm)	Colour identification between length marks
13	Red
14	Blue
15	Yellow
16	Black
17	Green
18	Purple
19	Orange
20	Double-Red
21	Double-Blue
22	Double-Yellow
23	Double-Black
24	Double-Green

9.2.2 Individual packs shall be marked with the following:

- a) the designated size and the length in accordance with [6.2.1](#) and [6.2.5](#) respectively, expressed in accordance with one of the following examples. Length can also be designated in centimetres:
 - 1) 6 mm × 500 mm,
 - 2) 6 mm (18F) × 500 mm, or
 - 3) diameter 6 mm (18 F), length 500 mm.
- b) for *closed suction catheters*, the internal volume of the *closed suction catheter manifold* in accordance with [6.5.2.7](#).

9.2.3 Shelf/multi-unit packs shall be marked with the designated size in accordance with [6.2.1](#) and [6.2.5](#) respectively, expressed in accordance with one of the following examples. Length can also be designated in centimetres:

- a) 6 mm × 500 mm,
- b) 6 mm (18F) × 500 mm, or
- c) diameter 6 mm (18 F), length 500 mm.

9.3 Instructions for use

9.3.1 The instructions for use shall state the internal volume at atmospheric pressure of the *closed suction catheter manifold* not including the volume of any female connectors.

9.3.2 For *suction catheters* intended to be used with tracheal tubes, the instructions for use shall contain a warning to the effect that the *suction catheter* is to be fully removed from the tracheal tube before the tracheal tube is cut to length.

Annex A (informative)

Rationale

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 necessitated by those developments.

Subclause 3.1 *Closed suction catheter*

Closed suction catheters are used for endotracheal or airway suctioning on patients with artificial airways to minimize disturbance of the VBS. *Closed suction catheters* are provided with a *protective sleeve* to protect the user and the immediate environment (room surfaces, room air) by reducing the risk of contamination with secretions.

It is common practice in critical care areas to use a *closed suction catheter* during mechanical ventilation of a *patient*. Use of a *closed suction catheter* allows uninterrupted mechanical ventilation without disconnection of the VBS from the tracheal tube, tracheostomy tube or other airway device. This contrasts with the use of a traditional *suction catheter* which requires the opening or disconnection of the VBS before the application of the subatmospheric pressure to the respiratory tract.

When used as intended, a *closed suction catheter* and related suction equipment become an accessory to the ventilator and an extension of the VBS. When a VBS is equipped with a *closed suction catheter*, the *connector* at the *patient end* of the *closed suction catheter manifold* becomes the 'new' *patient connection port* of the VBS.

Subclause 3.2 *Closed suction catheter manifold*

All *closed suction catheters* are enclosed within a *protective sleeve* and include a *closed suction catheter manifold* designed to connect to the airway and the VBS.

Examples of *closed suction catheter manifolds* can include a T-piece adaptor, Y-piece adaptor, a 3-way breathing system *connector*, a swivel adaptor, and other specialized adaptors for co-axial, multiple tubes, and bifurcated tubes. (See [Figure 2](#)).

Subclause 3.18 *Suction catheter connector*

In the 4th edition of this document (ISO 8836:2014), the new term *suction catheter connector* replaces what was described previously with many different terms as the *machine end*, the adaptor, the male end or the *connector* in various subclauses of the 3rd edition (ISO 8836:2014). Consolidation of these confusing terms is intended to clarify the requirements of this document.

Clause 4 General requirements for open and closed suction catheters

Suction catheters should be designed in such a way that satisfies the performance, safety, clinical, and usability needs of patients and users.

This section has been revised to include basic safety and essential performance and *risk management* principles associated with *suction catheters* through reference to ISO 18190:2016, Clause 4. The need for a *risk management file* is a well recognized process through which the manufacturer can identify hazards associated with a medical device, estimate and evaluate the *risks* associated with these hazards, control these *risks*, and monitor the effectiveness of that control. Clinical evaluation might also be necessary to confirm the adequacy of the controls. See ISO 14971 for additional information.

Some elements of device design, as appropriate, may be evaluated using biophysical or modelling research whose validity has been established. Biophysical or modelling research includes the application of physics and engineering to biological processes and may include anatomical modelling or other means to simulate clinical use.

The materials used should allow construction of a *suction catheter* with the thinnest possible wall, whilst at the same time maintaining resistance to collapse and kinking.

Subclause 6.4 Suction catheter connector

The gender of the outlet connector on the *suction catheter* has not been specified as it needs to take into account compatibility with the suction tubing to which it will be connected. Suction tubing is specified in ISO 10079-1, ISO 10079-2 and ISO 10079-3, but these International Standards only specify the inner diameter of the tubing and do not specify the gender of the tubing inlet connector which could therefore be male or female.

It is understood that small-bore *connector* systems cannot be designed to overcome all chances of misconnection or to eliminate deliberate misuse. For example, the possibility of the misconnection of a small-bore *connector* to a specialized patient-access port can still exist. Specialized patient-access ports often require the use of flexible materials which are intended to permit access by a range of medical devices or accessories, such as endoscopes, bronchoscopes and surgical instruments. These access ports can permit interconnection with some small-bore *connectors*. The *risks* associated with the use of these specialized patient-access ports are not addressed by this document. Manufacturers of medical devices or accessories and the committees responsible for the development of standards for medical devices or accessories that incorporate these specialized patient-access ports will need to assess these *risks*.

Subclause 6.5.2.3 Closed suction catheter manifold rotation

The placement of the *closed suction catheter adapter* between the airway device and the breathing set can impart torsional stress on the airway device and the breathing set. To minimize this effect the ability of the *closed suction catheter adapter* to rotate independently of the airway device and the breathing set will minimize this *risk*. It is typical practice for users to apply an axial force and a rotation force when assembling and disconnecting *connectors*. Having a manifold that rotates can reduce the user's ability to apply a rotation force when disconnecting the *closed suction catheter manifold* from the airway device and breathing set. This can lead to difficulty in separation of the components. The design of the *closed suction catheter manifold* needs to account for both the *risk* of torque and the *risk* of difficulty in separation.

Subclause 6.5.2.7 Internal volume

Internal volume is important because the design of the *patient connection port* should minimize dead space to reduce the volume of rebreathed gases. The design of the *patient connection port* should also minimize the accumulation of secretions.

Subclause 6.5.4 Suction control device

To reduce the hazards associated with *residual vacuum*, all *suction catheters* used in the respiratory tract should be provided with a *suction control device*.

Subclause 6.6.4 Leakage

Clinicians have noted the transmission of fluids from the *suction control device* during use. Fluids can contain pathogens. It is important, therefore, that these devices should not leak potentially contaminated fluids into the environment during their use. The *suction control device* might be the site of such a leak in the closed position, the open position, and during transition between the two states. The positive pressure from the ventilator can potentially force contaminated fluids through the valve, particularly in the setting of a blockage in the suction line. A static leak test only assesses leakage in the closed position. The manufacturer should ensure that the *suction control device* remains leak-free in all positions, even when the *machine end* is blocked and positive pressure is applied to the *patient end*.

Leakage limits are approximately 30 % of the anaesthetic and *ventilator breathing system* limits and 100 % of the breathing set limit. (See ISO 5367, ISO 80601-2-12:2011 and ISO 80601-2-74^[3].)

[Table 4](#) recognizes that manufacturers use statistical methods in developing and testing their devices, and that almost all devices in a manufacturing run have a leakage much lower than those shown in the table. Furthermore, the variability in leakage from the assembled system is proportional to the square root, rather than the sum of the number of devices placed in the circuit. Most failures attributable to leaks occur as a result of a fault condition in the system, rather than a stacking of individual leaks. While it is necessary to have some figure against which a manufacturer can test their products, this document recognizes the variability inherent in the manufacturing process, and that it is statistically unlikely that every device placed in the *VBS* will leak at the maximum allowable rate, and thus exceed the ventilator budget. These values have been placed at 30 % of the ventilator budget, being approximately the square root of 10, so that it is unlikely that even if 10 devices were placed in the circuit that the budget would be exceeded.

Subclause 6.6.5 Resistance to flow

Resistance limits are 15 % of the anaesthetic and *ventilator breathing system* limits and 100 % of the breathing set limit.

Annex D

Test methods of *suction control device* performance on *closed suction catheters* are based on historical methods developed by manufacturers of these devices. ISO/TC 121/SC 2 discussed at length alternate test methods to assess leakage in simulated clinical conditions. ISO/TC 121/SC 2 agreed that the test methods described in this document are sufficient to meet needs at the time of publication.

D.2.2

Temperature conditions are the same as the normal operating and test conditions for breathing sets and heated humidifiers. See ISO 5367 and ISO 80601-2-74^[3].

Annex B (normative)

Test method for security of attachment

B.1 Principle

The security of attached components is tested by applying an axial separation force to the components.

B.2 Apparatus

B.2.1 Means of conditioning the *suction catheter* at $(23 \pm 2) ^\circ\text{C}$ at $(50 \pm 20) \%$ relative humidity and carrying out the test under the same conditions.

B.2.2 Means of separately securing the components under test and separating the two at a rate of $(200 \pm 20) \text{ mm/min}$ and measuring and recording the axial separation force applied.

B.3 Procedure

B.3.1 Condition the *suction catheter* at $(23 \pm 2) ^\circ\text{C}$ and at $(50 \pm 20) \%$ relative humidity for 1 h and carry out the test under the same conditions.

B.3.2 Separate the components under test at a rate of $(200 \pm 20) \text{ mm/min}$ and observe whether the component under test becomes detached from the other component before the appropriate minimum force given in [Table 2](#) or [Table 3](#) has been reached.

B.4 Expression of results

Record whether the components become detached before the appropriate minimum force given in [Table 2](#) or [Table 3](#) has been reached.

Annex C (normative)

Measurement of residual vacuum

C.1 Principle

The effectiveness of the *suction control device* as a means of relieving vacuum at the *patient end* is tested by measuring the *residual vacuum* at the tip of the *suction catheter* with the *suction control device* in the relief position, while suction is applied to the machine end of the catheter.

C.2 Apparatus

C.2.1 Flowmeter, capable of measuring a flow of 30 l/min to an accuracy of within ± 5 % and a resistance to flow of less than 0,1 kPa at 30 l/min.

C.2.2 Adjustable vacuum pump.

C.2.3 Manometer, with an accuracy of $\pm 0,01$ kPa.

C.3 Procedure

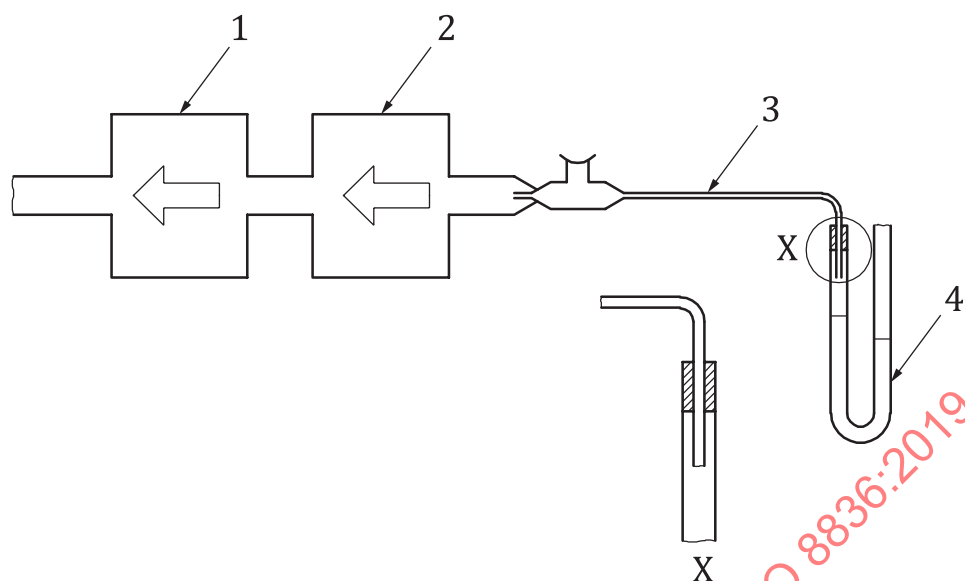
C.3.1 Assemble the apparatus, as shown in [Figure C.1](#), with the flowmeter fitted to the exit of the vacuum pump, ensuring an airtight fit between the *suction catheter* and the manometer.

C.3.2 Open the *suction control device* to the *vacuum relief* position. Switch on the vacuum pump and adjust the applied *vacuum* until a flow of 30 l/min is indicated on the flowmeter.

C.3.3 For *closed suction catheters*, detach the manometer, open the *suction control device*, switch on the vacuum pump and adjust the applied *vacuum* until the flow in [Table C.1](#) is indicated on the flowmeter; then close the *suction control device* and attach the manometer.

C.4 Expression of results

Express the residual vacuum, in kilopascals, as indicated by the reading on the manometer.

**Key**

- 1 flowmeter
- 2 vacuum pump
- 3 suction catheter with suction control device
- 4 manometer
- X detail of suction catheter shaft sealed to a manometer

Figure C.1 — Apparatus for residual vacuum test**Table C.1 — Suction catheter designated size and minimum vacuum flow**

Designated size	Minimum vacuum flow (l/min)
1,33 and 1,5	0,5
1,67	1
2,0	5
2,1	6
2,33	7
2,5	8,5
2,67	10
3,0	11,5
3,33	13
4,0	18
4,67	28
5,33 or larger	30