भारतीय मानक

Indian Standard

IS 18460 : 2024
ISO 8836 : 2019

श्वसन पथ में उपयोग के लिए सक्शन कैथेटर

Suction Catheters for Use in the Respiratory Tract

ICS 11.040.10

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Anaesthetic, Resuscitation and Allied Equipment Sectional Committee, MHD 11

NATIONAL FOREWORD

This Indian Standard which is an identical to ISO 8836 : 2019 'Suction catheters for use in the respiratory tract' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendation of the Anaesthetic, Resuscitation and Allied Equipment Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

The text of the ISO standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are however not identical to those used in the Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words 'International Standard' appears referring to this standard, they should be read as 'Indian Standard'; and

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards, which are to be substituted in their places, are listed below along with their degree of equivalence for the editions indicated:

International Standard	*Corresponding Indian Standard*	*Degree of Equivalence*
ISO 5356-1 Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets	IS/ISO 5356-1 : 2015 Anaesthetic and respiratory equipment — Conical connectors: Part 1 Cones and sockets (*first revision*)	Identical
ISO 80369-7 Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications	IS/ISO 80369-7 : 2016 Small-bore connectors for liquids and gases in healthcare applications: Part 7 Connectors for intravascular or hypodermic applications	Identical

The Committee has reviewed the provisions of the following International Standards referred in this adopted standard and has decided that they are acceptable for use in conjunction with this standard:

International Standard/ Other Publication	*Title*
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

This standard also makes a reference to the BIS Certification Marking of the product, details of which is given in National Annex F.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test shall be rounded off in accordance with IS 2 : 2022 'Rules for rounding off numerical values (*second revision*)'

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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.

Indian Standard

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)	(mm)	(mm)	
4	1,33	±0,10	0,55	Purple
4,5	1,5	±0,10	0,70	Blue
5	1,67	±0,10	0,80	Grey
6	2,0	±0,10	1,0	Light green
6,5	2,1	±0,10	1,1	Yellow green
7	2,33	±0,10	1,25	Ivory
7,5	2,5	±0,10	1,45	Pink
8	2,67	±0,10	1,50	Light blue
9	3,0	±0,15	1,75	Turquoise
10	3,33	±0,15	2,00	Black
12	4,0	±0,15	2,45	White
14	4,67	±0,20	2,95	Green
15	5,0	±0,20	3,20	Brown
16	5,33	±0,20	3,40	Orange
18	6,0	±0,20	3,90	Red
20	6,67	±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* ≤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.

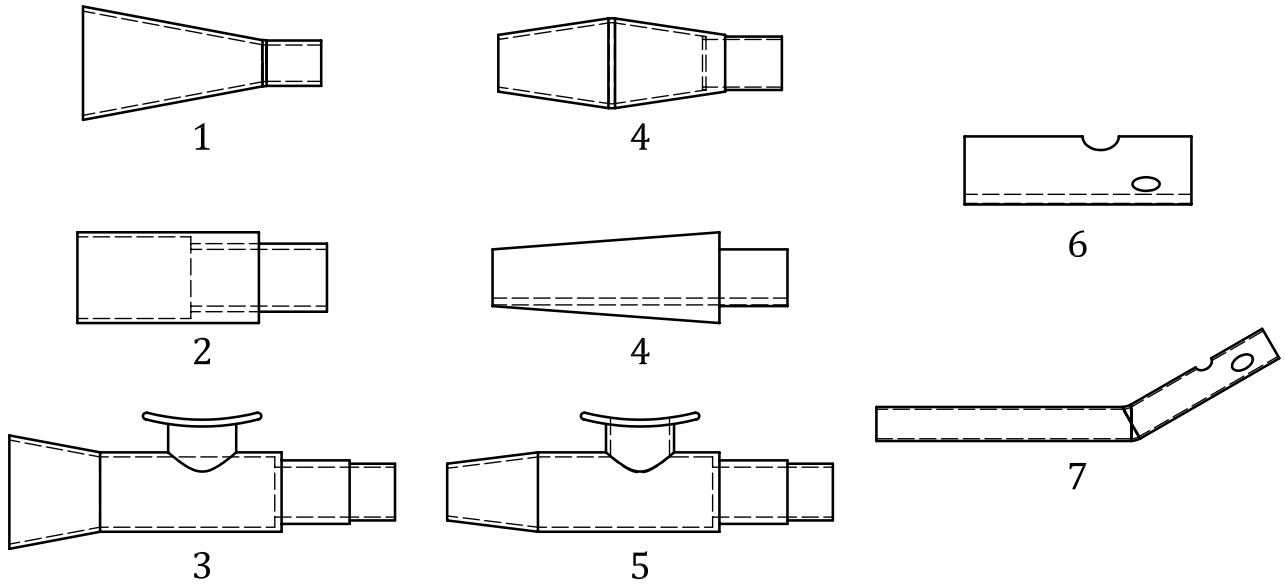
6.4.3 *Suction catheter connectors* shall have an internal bore diameter equal to or greater than the internal diameter of the *shaft* to which it is attached.

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*

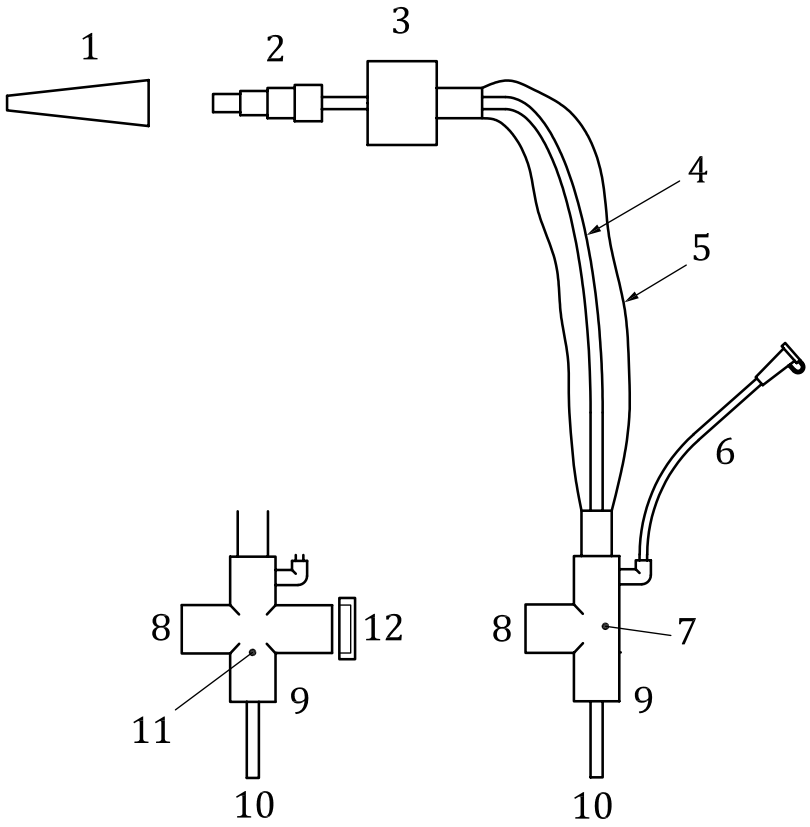
Figure 1 — Examples of designs for *suction catheter connectors* and *suction catheter tips*

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:

a) the designated size (see 6.2.1 and Table 1);

b) colour identification as specified in 6.2.2;

c) the length in mm (see 6.2.5);

d) *suction catheter connectors* attached to a *suction catheter* with an angled *tip* shall indicate the direction in which the *tip* points;

e) 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*;

f) 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;

g) 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.

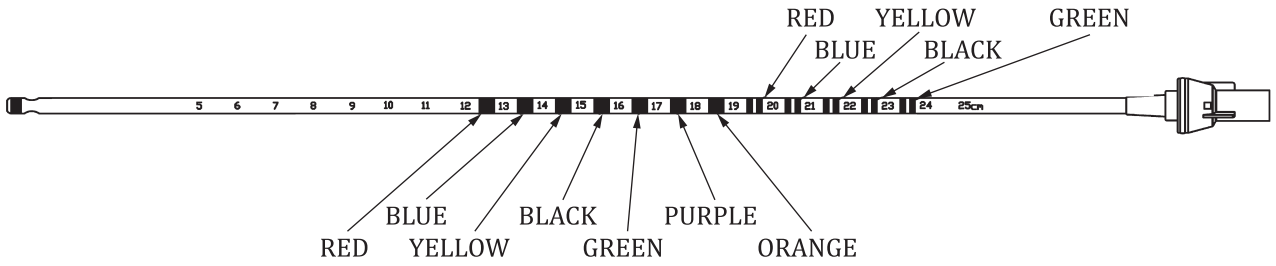


Figure 3 — *Suction catheter* length marks and associated colour code

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 ± 2) °C at (50 ± 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 ± 20) mm/min and measuring and recording the axial separation force applied.

B.3 Procedure

B.3.1 Condition the *suction catheter* at (23 ± 2) °C and at (50 ± 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 ± 20) 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 ±0,01 kPa.

C.3 Procedure

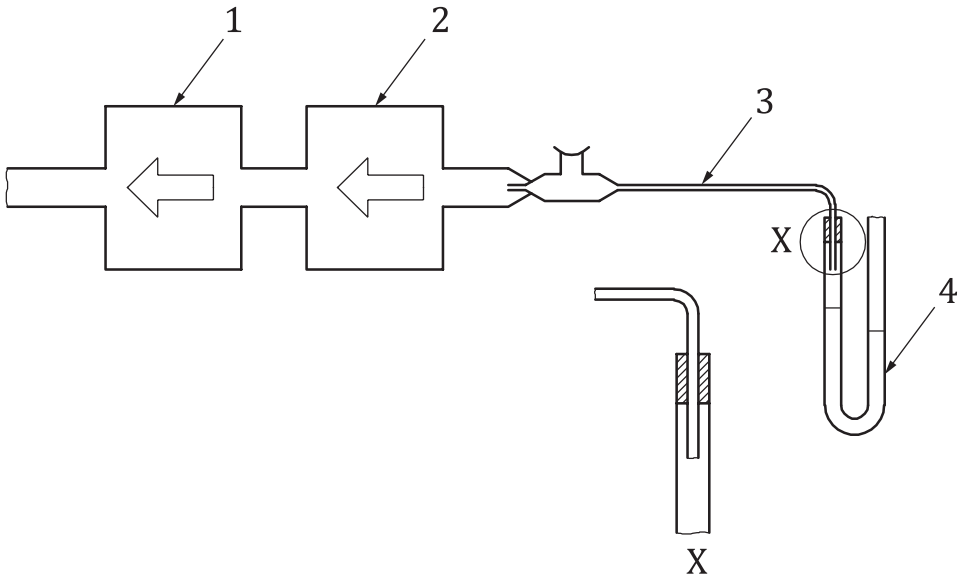
C.3.1 Assemble the apparatus, as shown in Figure C.1, with the flowmeter fitted to the exit of the vacuum pump, ensuring an airtight fit between the *suction catheter* and the manometer.

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

Annex D
(normative)

*Method of testing leakage

D.1 Principle

Leakage is tested by applying and maintaining an internal set pressure by introducing air into the *patient end* of the *patient connection port* of a *closed suction catheter* in the "off" position and all other connection ports blocked and recording the flow of air necessary to maintain that pressure.

D.2 Apparatus

D.2.1 Means of applying and maintaining for 5 min an internal gas pressure of (6 ± 0,3) kPa.

D.2.2 *Means of conditioning the *closed suction catheter*, and carrying out the test procedure at a temperature of (23 ± 2) °C and (42 ± 3) °C.

D.2.3 Means of recording the flow of air required to maintain the specified internal gas pressure in the *closed suction catheter* being tested, accurate to within ±5 % of the flows specified in 6.6.4.

D.3 Procedure

D.3.1 Carry out the test procedure at a temperature of (23 ± 2) °C and (42 ± 3) °C after the closed suction system has been conditioned for at least 1 h.

D.3.2 Attach the means of applying and maintaining an internal pressure according to D.2.1 to the *closed suction catheter.* Close the breathing system connections which are not used and the *suction control device*.

D.4 Expression of results

The flow required to maintain the specified internal gas pressure shall be expressed in $ml \cdot min^{-1}$.

Annex E
(informative)

Hazard identification for risk assessment

E.1 General

Identified hazards listed in E.3 and E.4 below represent those associated with the use of *suction catheters* published by the American Association for Respiratory Care (AARC)[5] and a comprehensive review of clinical articles published between January 1990 and October 2009 using MEDLINE, CINAHL, and Cochrane Library databases, and a total of 114 clinical trials, 62 reviews and 6 meta-analyses on endotracheal suctioning.

NOTE This list is not intended to be comprehensive for all devices within the scope of this document, but it provides guidance for *risk assessment*. Not all hazards will apply to each type of *suction catheter*.

E.2 Patient harm associated with the use of *suction catheters*

E.2.1 Patient harm associated with the placement, removal and use of *suction catheters*

a) Decrease in dynamic lung compliance and functional residual capacity;

b) Atelectasis;

c) Hypoxia/hipoxemia;

d) Tissue trauma to the tracheal and/or bronchial mucosa;

e) Bronchoconstriction/bronchospasm;

f) Increased microbial colonization of the lower airway;

g) Changes in cerebral blood flow and increased intracranial pressure;

h) Hypertension;

i) Hypotension;

j) Cardiac dysrhythmias;

k) Alteration of ventilation conditions;

l) Aspiration of a portion of the *suction catheter* into the airway if the *suction catheter* is not fully removed from the tracheal tube before the tracheal tube is cut to length.

E.2.2 Patient harm associated with routine use of normal saline instillation and *suction catheters*

a) Excessive coughing;

b) Decreased oxygen saturation;

c) Bronchospasm;

d) Dislodgement of the bacterial biofilm colonizing the tracheal tube into the lower airway;

e) Pain, anxiety, dyspnea;

f) Tachycardia;

g) Increased intracranial pressure;

h) Excessive mucus carried by the *suction catheter* into the airway causing blockage or inner diameter restriction.

E.2.3 Patient or user harm associated with toxicity

a) Allergy, including allergy to natural rubber latex;

b) Tissue sensitivity, inflammation or necrosis;

c) Systemic absorption of toxic substances;

d) Pollution of the immediate surrounding environment;

e) Leakage of ventilatory gas or anaesthetic gases and vapours.

E.3 Hazardous situations and hazards associated with the use of *suction catheters*

E.3.1 Loss of function caused by the following:

a) obstruction of the lumen, debris or fluid in the lumen;

b) kinking;

c) fracture of the *shaft* of the *suction catheter*;

d) failure of the *suction control device;*

e) undetected leak;

f) excessive resistance;

g) elevated temperature leading to softening of materials, weakening connections, leakage.

E.3.2 Incorrect size for a specific patient caused by the following:

a) inadequate or incorrect disclosure of size requirements by manufacturer;

b) patient variability.

E.3.3 Loss of ventilator function and/or accuracy:

a) undetected leak;

b) excessive breathing resistance;

c) rebreathing of exhaled gases due to excessive internal volume;

d) ventilator damage;

e) ventilator cycle false triggering.

E.3.4 Connections

Difficulty of connection and disconnection of swivel connectors might conflict with the requirements for security of connection.

NOTE See ISO 14971 for additional information on harm, hazardous situations, and hazards in the *risk analysis* process.

Bibliography

[1] ISO 5361, *Anaesthetic and respiratory equipment — Tracheal tubes and connectors*

[2] ISO 5366, *Anaesthetic and respiratory equipment — Tracheostomy tubes and connectors*

[3] ISO 80601-2-74, *Medical electrical equipment — Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment*

[4] ISO/TR 11991, *Guidance on airway management during laser surgery of upper airway*

[5] AARC, Clinical Practice Guidelines-Endotracheal Suctioning of Mechanically Ventilated Patients with Artificial Airways. *Respir. Care*. 2010, **55** (6) pp. 758–764

[6] ISO 10079 (all parts), *— Medical suction equipment*

[7] ISO 80601-2-12:2011, *Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*

[8] ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

[9] ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

NATIONAL ANNEX F
(*National Foreword*)

F-1 BIS CERTIFICATION MARKING

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the BIS Act, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

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