INTERNATIONAL STANDARD

ISO 8836

Fourth edition
2014-10-15

Suction catheters for use in the respiratory tract

Sondes d'aspiration pour les voies respiratoires

Reference number
ISO 8836:2014(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. www.iso.org/directives

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 2, *Airways and related equipment*.

This fourth edition of ISO 8836 cancels and replaces the third edition (ISO 8836:2007), of which it constitutes a technical revision.

Introduction

This International Standard specifies dimensions and requirements for **suction catheters** for use in the respiratory tract. It 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. Size is designated by outside diameter which 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][4]

Revisions in this fourth edition are intended to harmonize this International Standard with recent amendments in the European Medical Device Directive.

Major technical revisions in this edition include requirements for **closed suction catheters**, new requirements to harmonize this International Standard with requirements for critical care **ventilators**, and **risk management**.

Terms defined in Clause 3 of this International Standard or in ISO 4135[1] appear in **bold** type.

Throughout this International Standard, text for which a rationale is provided in Annex A is indicated by an asterisk (*).

Suction catheters for use in the respiratory tract

1 Scope

This International Standard specifies requirements for **suction catheters**, including **closed suction catheters**, made of flexible materials and intended for use in suctioning of the respiratory tract.

Angled-**tip suction catheters** (e.g. Coudé catheters) and **suction catheters** with aspirator collectors are not considered to be specialized and are therefore included in the scope of this International Standard.

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

NOTE See ISO/TR 11991 for guidance on airway management during laser surgery of the upper airway.[6]

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable to its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

*ISO 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

*ISO 594-2, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

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

ISO 5367:—[1)], *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*[2)]

ISO 10079-1, *Medical suction equipment — Part 1: Electrically powered suction equipment*

ISO 10079-2, *Medical suction equipment — Part 2: Manually powered suction equipment*

ISO 10079-3, *Medical suction equipment — Part 3: Suction equipment powered from a vacuum or positive pressure gas source*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

1) To be published. (Revision of ISO 5367:2000)

2) The graphical symbols in ISO 7000 are also available on line in the ISO web store. For more information, consult http://www.iso.org/iso/publications_and_e-products/databases.htm?=.

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

EN 556-1:2001, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices*

EN 1041, *Information supplied by the manufacturer of medical devices*

EN 15986, *Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates*

ASTM D3002:2007, *Standard Guide for Evaluation of Coatings Applied to Plastics*

ASTM F640, *Standard Test Methods for Determining Radiopacity for Medical Use*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135[1] and ISO 14971 and the following apply.

3.1
adaptor
specialized **connector** to establish functional continuity between otherwise disparate or incompatible components

[SOURCE: ISO 4135:2001, 4.2.3.1]

3.2
connector
fitting to join together two or more components

[SOURCE: ISO 4135:2001, 4.2.2.1]

3.3
***closed suction catheter**
suction catheter enclosed within a **protective sleeve** and **patient end adaptor** that allows its use within the airway without opening the **breathing system** directly to atmosphere

3.4
eye
side hole near the **patient end** of the **suction catheter**

[SOURCE: ISO 4135:2001, 8.3.6]

3.5
machine end
<suction catheter> that end of the catheter which is intended to be connected to a source of vacuum

[SOURCE: ISO 4135:2001, 8.3.2]

3.6
open suction catheter
suction catheter that is not enclosed within a **protective sleeve** and **patient end adaptor** or attached to a **VBS**

3.7
patient connection port
<closed suction catheter> opening at the **patient end** of a breathing system port of a **ventilator breathing system** intended for connection to an airway device

[SOURCE: ISO 4135:2001, 4.2.1.2]

3.8
patient end
<suction catheter> that end of the **suction catheter** which is intended to be inserted into a patient

[SOURCE: ISO 4135:2001, 8.3.3]

3.9
patient end
<closed suction catheter> the **patient connection port** of the **closed suction catheter patient end adaptor** intended to be connected to the conical **connector** of an artificial airway (e.g. tracheostomy or tracheal tube)

3.10
***patient end adaptor**
tubular **connector** with multiple ports, one of which is a **patient connection port**

3.11
protective sleeve
flexible barrier that encloses the **suction catheter** shaft to prevent contact with the user while connected to the **VBS**

3.12
residual vacuum
negative pressure at the **patient end** of the **suction catheter** when the **vacuum control device** is in the relief position

3.13
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO 14971:2007]

3.14
risk analysis
systematic use of available information to identify hazards and to estimate the **risk**

Note 1 to entry: **Risk analysis** includes examination of different sequences of events that can produce hazardous situations and harm (see ISO 14971:2007, Annex F).

[SOURCE: ISO 14971:2007]

3.15
risk assessment
overall process comprising a **risk analysis** and a **risk evaluation**

[SOURCE: SO 14971:2007]

3.16
risk evaluation
process of comparing the estimated **risk** against given **risk** criteria to determine the acceptability of the **risk**

[SOURCE: ISO 14971:2007]

3.17
risk management
systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring **risk**

[SOURCE: ISO 14971:2007]

3.18
risk management file
set of records and other documents that are produced by **risk management**

[SOURCE: ISO 14971:2007, 2.23]

3.19
shaft
main part of the **suction catheter** which is of uniform outside diameter

3.20
single-fault condition
condition in which a single means for reducing a **risk** is defective or a single abnormal condition is present

3.21
suction
application of vacuum to remove gas, liquids or solid particles

[SOURCE: ISO 4135, 8.1.2]

3.22
suction catheter
flexible tube designed for introduction into the respiratory tract or an airway device to remove material by suction

[SOURCE: ISO 4135]

3.23
***suction catheter connector**
connector at the **machine end** of the **suction catheter** that allows a connection to a vacuum source

3.24
terminal orifice
central aperture at the **tip** of the **suction catheter**

[SOURCE: ISO 4135:2001, 8.3.5]

3.25
tip
extremity of the **patient end** of a **suction catheter**

[SOURCE: ISO 4135:2001, 8.3.4]

3.26
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]

3.27
vacuum control device
means provided at or near the **machine end** of a **suction catheter** to control the flow of air and entrained material

[SOURCE: ISO 4135:2001, 8.3.9]

3.28
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** and the **exhaust port**[ISO 80601-2-12:2011,[8] 201.3.221, and ISO 4135:2001, 4.1.1, modified]

3.29
wiper
means for removing secretion residues from the surface of the **suction catheter**

4 *General requirements for open and closed suction catheters

4.1 Risk management

4.1.1 An established **risk management** process in accordance with ISO 14971 shall be applied to the design of the device.

Check compliance by inspection of the **risk management file**.

NOTE See Annex E.

4.1.2 The manufacturer shall apply a usability engineering process to assess and mitigate risks caused by usability problems associated with correct use and use errors.

EXAMPLES IEC 60601–1 and IEC 62366–1.

Check compliance by inspection of the usability engineering file.

4.1.3 Clinical evaluation shall be performed. Clinical evaluation is the assessment and analysis of clinical data pertaining to a medical device in order to verify the clinical safety and performance of the device.

Clinical data may be sourced from

— clinical investigation(s) of the device concerned, or

— clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated, or

— published and/or unpublished reports on other clinical experience with either the device in question or a similar device for which equivalence to the device in question can be demonstrated.

If required, clinical investigations shall be performed under the conditions for which performance is claimed and documented in the **risk management file**. The clinical studies shall comply with the requirements of ISO 14155.

Check compliance by inspection of the **risk management file**.

4.2 Safety

The manufacturer may use type tests different from those detailed within this International Standard, if an equivalent degree of safety is obtained. Alternative test methods shall be validated against the test methods specified in this International Standard.

5 Specific requirements for open and closed suction catheters

5.1 Size and length designations

5.1.1 The size of **suction catheters** shall be designated by the nominal outside diameter of the **shaft**, expressed in millimetres; it may additionally be expressed in French (Charriere) gauge size (see Table 1).

NOTE 1 For the purposes of this International Standard, 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 **suction catheter** outside diameter to the inside diameter of the tracheal or tracheostomy tube.

5.1.2 The size of the **suction catheter** shall also be designated by use of colour identification at the **machine end** in accordance with Table 1, for the designated sizes listed.

5.1.3 The use and choice of colour identification for designated sizes not listed in Table 1 are at the manufacturer's discretion.

5.1.4 The length of the **suction catheter** shall be designated by the nominal **shaft** length, expressed in millimetres.

5.2 *Dimensions

5.2.1 The outside diameter of the **shaft** shall be the designated nominal outside diameter, subject to a tolerance in accordance with Table 1.

5.2.2 The minimum inside diameter of the **shaft**, excluding the **tip**, shall be in accordance with Table 1.

5.2.3 The minimum inside diameter of the **terminal orifice** at the **tip** shall be not less than 90 % of the minimum inside diameter in accordance with Table 1.

5.2.4 The **shaft** length shall be the designated nominal **shaft** length subject to a tolerance of ±5 %.

Table 1 — Colour identification for designated size of suction catheter

Designated size		Outside diameter tolerance	Minimum inside diameter	Colour identification
French (Charriere) 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 Materials

6.1 **Open** and **closed suction catheters** for use in the respiratory tract, in their ready-to-use state after any preparation for use recommended by the manufacturer, shall satisfy appropriate biological safety testing, as indicated in ISO 10993-1.

6.2 **Open** and **closed suction catheters** for use in the respiratory tract, in their ready-to-use state after any preparation for use recommended by the manufacturer shall not contain natural rubber latex.

Check compliance by inspection of the technical documentation.

6.3 The outside surface of the shaft of the **suction catheter** shall be free from characteristics which would hinder easy insertion through all types of plastic, rubber and metal oro- and naso-tracheal tubes, tracheostomy tubes and appropriate **connectors**.

Check compliance by visual inspection.

6.4 **Suction catheters** and their markings should be resistant to deterioration by anaesthetic vapours and gases.

6.5 The marking of **suction catheters** shall be durable and legible

Check compliance by inspection, as indicated in 6.4.1 of ASTM D3002:2007 or in simulated use.

6.6 The mid-section of the **shaft** of **suction catheters** shall allow visualization of secretions removed from the respiratory tract.

Check compliance by visual inspection.

6.7 If phthalates as categorized in EN 15986 are incorporated in parts of the medical devices coming directly or indirectly into contact with the patient, the manufacturer shall identify the individual risks for the affected patient populations [see 10.3.2 i)].

Check compliance by inspection of the **risk management file**.

7 *Design

7.1 Lumen of the suction catheter

The inside diameter of the **shaft** at any point between the **suction catheter connector machine end** and the **eye** nearest to the **machine end** shall be not less than the inside diameter of the **shaft** at that **eye**.

7.2 Suction catheter tip

7.2.1 **Suction catheters** on which the **patient end** cannot be observed during use or which are for use with suction systems operating at a vacuum pressure > 3,92 kPa, (40 cmH_2O), shall have a **terminal orifice** and at least one **eye** within 2 cm of the **terminal orifice**.

NOTE The availability of one or more **eyes** reduces the **risk** and likelihood of injury.

7.2.2 **Suction catheters** that can be observed during use, or are for use with suction systems operated at vacuum from 0 cm H_2O to 40 cmH_2O (3,92 kPa), need not have an **eye**.

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

NOTE This is to minimize injuries of the tracheal epithelium.

Check compliance by visual inspection.

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

7.2.5 The axis of the **patient end** may be at an angle to the long axis of the **shaft** (see Coudé catheter **tip** in Figure 1).

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

7.3 *Suction catheter connector

7.3.1 A **suction catheter** shall be provided with a male **suction catheter connector** intended for connection to the end-piece of suction tubing attached to a collection container that complies with ISO 10079-1, ISO 10079-2, and ISO 10079-3.

A male **suction catheter connector** is required in order to comply with the ISO 10079-1, ISO 10079-2, and ISO 10079-3 requirement that connections for the suction tubing be so designed as to minimize the **risk** of wrong assembly when all parts are mated. The use of a male **suction catheter connector** also distinguishes the use of the **suction catheter** from urethral catheters, umbilical catheters, thoracic catheters, feeding tubes, and other catheters not designed for use in the respiratory tract.

7.3.2 The **suction catheter connector** shall be securely attached to the **shaft.**

Check compliance by testing in accordance with 8.1.1.

7.3.3 The **suction catheter connector** shall have an internal diameter equal to or greater than the internal diameter of the **shaft** to which it is attached.

7.3.4 The male end of the **suction catheter connector** shall be rigid or semi-rigid and shall fit inside semi-rigid or elastomeric tubing having an inside diameter of 6 mm (see Figure 1).

NOTE It is advantageous if the male end of the **suction catheter** fits inside elastomeric tubing with a larger inside diameter which can be used in an emergency to clear the airway.

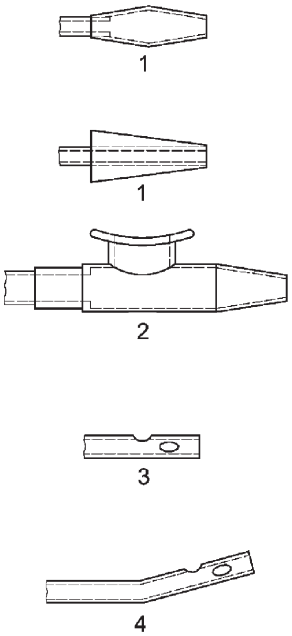
7.3.6 *The **suction catheter connector** shall not be compatible with any of the conical **connectors** specified in ISO 5356-1.

7.3.7 The **suction catheter connector** shall be designed to facilitate correct assembly to the suction tubing or marked to indicate correct assembly when all parts are mated in accordance with ISO 10079-1, ISO 10079-2, and ISO 10079-3.

NOTE Incorrect connections have frequently been a cause of misconnection to the vacuum source and/or a loss of suction.

7.3.8 *The **suction catheter** shall be provided with a **vacuum control device.**

Check compliance by inspection.



Key

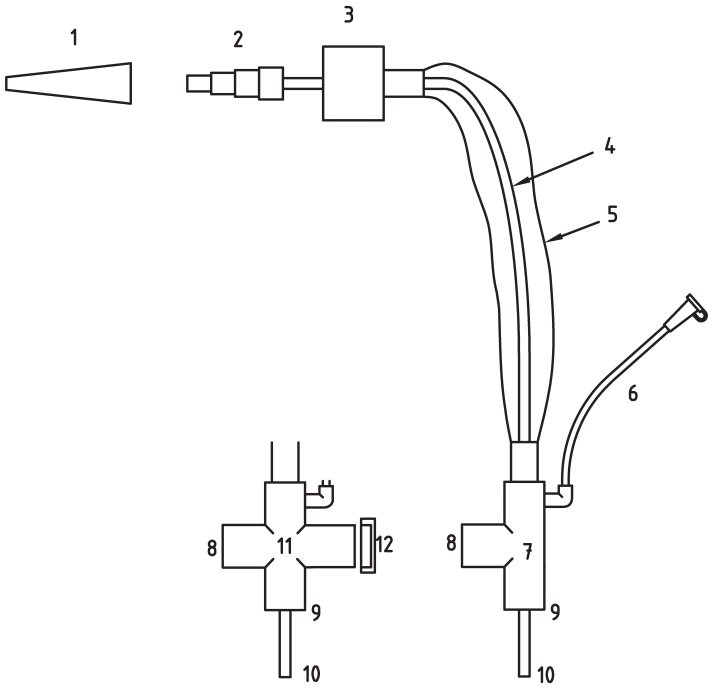
1 male **suction catheter connector**

2 male **suction catheter connector** with **vacuum control device**

3 **suction catheter tip** with **eyes**

4 Coudé **suction catheter tip** with **eyes**

Figure 1 — Examples of different designs for suction catheter connectors and suction catheter tips for use in the respiratory tract



Key

1	protective cap	7	**patient end adaptor**
2	**suction catheter connector**	8	**machine end** of the **patient end adaptor,** with a male conical **connector** to connect to the **breathing system** or **ventilator breathing system**
3	**vacuum control device**	9	**patient connection port** of the **patient end adaptor,** with a 15 mm female conical **connector** (connects to airway device)
4	**shaft** of the **suction catheter**	10	**suction catheter tip**
5	**protective sleeve**	11	**patient end adapter** as a T-piece
6	flushing line with non return valve, female Luer **connector**, and cap	12	T-piece cap

NOTE **Closed suction catheter** shown is an example only. Actual systems may consist of other arrangements and components not illustrated or listed

Figure 2 — Example of a closed suction catheter

7.4 Additional requirements for closed suction catheters

7.4.1 General design

In addition to the requirements for **suction catheters**, **closed suction catheters** shall be supplied with a **patient end adaptor** with a **patient connection port**, a **protective sleeve**, and **vacuum control device**. See example in Figure 2.

Check compliance by inspection.

7.4.2 *Patient end adaptor and connectors for the closed suction catheter

7.4.2.1 The **patient end** of the **patient end adaptor** shall be a **patient connection port** comprised of 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.

7.4.2.2 The **machine end** of the **patient end adaptor** shall be a 22 mm female or 15 mm male conical **connector** complying with ISO 5356-1.

7.4.2.3 The **connectors** should be free to rotate to minimize torsion on the airway device and breathing set.

NOTE See E.3 d).

7.4.2.4 The **patient end adaptor** shall contain a sealing mechanism to prevent leakage of gases from the airway into the area between the sleeve and the catheter shaft.

Check compliance by testing in accordance with 8.4.

7.4.2.5 The **patient end adaptor** shall be sufficiently transparent to allow visualization of liquids and secretions on the surface of the catheter.

Check compliance by visual inspection.

7.4.2.6 The inside surfaces of the **patient end adaptor** and **connectors** should be smooth and free of sharp edges to minimize kinking and deformation of the **suction catheter**.

Check compliance by visual inspection.

7.4.2.7 *The internal volume of the **patient end adaptor** and, if provided, the extension tube shall be determined as the inside volume contained within the solid elements, when not pressurized, minus the inside volume of the male and female connectors.

7.4.3 Protective sleeve

7.4.3.1 The **protective sleeve** shall enclose the shaft of the **suction catheter** when not in use in a manner that prevents user or patient contact with the **suction catheter**.

7.4.3.2 The **protective sleeve** shall be sufficiently flexible to allow unimpeded insertion or removal of the **suction catheter** to its intended length and shall not detach, rupture, or tear under normal use.

Check compliance by conditioning the product in accordance with 8.1.1 and inspection.

7.4.3.3 The **protective sleeve** shall be sufficiently transparent to allow visualization of the **suction catheter** and the materials inside the **suction catheter** during the process of suctioning.

Check compliance by inspection.

7.4.4 **Vacuum control device** for **closed suction catheters**

7.4.4.1 **The vacuum control device** shall be securely attached. Check compliance by testing in accordance with 8.1.1.

7.4.4.2 *The **vacuum control device** shall not leak fluids in any position during normal use and single fault condition.

Check compliance by inspection of the risk management file.

7.4.4.3 The **vacuum control device** shall be designed such that

— the “off” position can be locked, and

— the “on” position cannot be locked.

Check compliance by functional testing.

7.4.5 Flushing system for closed suction catheters

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 capable of accepting a male conical fitting with a 6 % (Luer) taper complying with ISO 594-1 or ISO 594-2.

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, labelling and instructions for intended use.

7.4.6 T-piece cap

7.4.6.1 If the **patient end adaptor** is provided as a T-piece, a detachable end cap shall be provided. See example in Figure 2. When attached, the **patient end adapter** shall not leak when tested in accordance with 8.4.

7.4.6.2 The T-piece cap should be provided with a retention device to prevent it becoming misplaced when not attached to the **patient end adapter**.

8 Performance requirements

8.1 Security of construction

8.1.1 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.

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

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

8.1.2 When tested in accordance with Annex B, the force required to detach any component not securely attached shall be not less than that specified in Table 3.

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

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

8.2 Shaft performance

When the **machine end** of the **suction catheter** is connected to a vacuum source at 40 kPa (408 cmH_2O, or 300 mmHg) below ambient pressure for 15s at a temperature of (23 ± 2 °C) with the **patient end** occluded and, if present, the **vacuum control device** set to apply full vacuum, the **shaft** of the **suction catheter** shall not collapse.

Check compliance by functional testing.

8.3 *Vacuum control device performance

The **residual vacuum** of the **suction catheter** shall not exceed 0,33 kPa (3,4 cmH_2O).

Check compliance by testing **residual vacuum** in accordance with Annex C.

8.4 *Leakage

A **closed suction catheter** with integrally attached **patient end adaptor** shall comply with the leakage requirements for the patient category for which the device is intended for use (see Table 4).

Check compliance by testing in accordance with 5.4.3 of ISO 5367:— to the leakage limits in Table 4 below.

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

Patient category	**Intended delivered volume** (ml)	**Leakage limit** (ml/min)	**At pressure** (hPa) (cmH_2O)
Adult	≥300 ml	70	60
Paediatric	50 ml < 300 ml	40	60
Neonatal	≤50 ml	30	60

8.5 *Resistance to flow

The resistance to flow of a **patient end adaptor** integrally attached to a **closed suction catheter** shall conform to the limits for the patient category for which the device is intended for use.

Check compliance by testing in accordance with 5.5.2 of ISO 5367:— to the resistance limits in Table 5 below.

Table 5 — Resistance limit by patient category

Patient category	**Intended delivered volume (**ml**)**	**Maximum Resistance limit (**hPa/l/min**) (**cmH_2O**)/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

8.6 *Radiopacity

If an **open** or **closed suction catheter** is labelled as radiopaque, the radiopaque marker shall be radiographically distinguishable from that of the aluminium comparison standard.

Check compliance by inspection of the tube using test method B in ASTM F640 test methods, exposing the **suction catheter** and an aluminium comparison standard. The aluminium comparison standard shall be a piece of aluminium 1 by 1 by 10 mm, or equivalent.

9 Requirements for suction catheters supplied sterile

9.1 Sterility assurance

Suction catheters supplied and marked as “STERILE” shall satisfy the requirements in 4.1 of EN 556-1:2001, ISO 11135, or, if applicable, ISO 11137-1.

9.2 Packaging of suction catheters supplied sterile

9.2.1 Each **suction catheter** supplied and marked as "STERILE" shall be contained in an individual pack.

9.2.2 The pack shall serve as an effective barrier to the penetration of microorganisms and particulate material in accordance with ISO 11607-1 and ISO 11607-2.

9.2.3 The pack shall permit the aseptic extraction of the contents and shall not be capable of reclosure without clearly revealing that it has been opened.

9.2.4 Individual packs shall be contained within a shelf or multi-unit pack.

10 Marking

10.1 Marking on suction catheters

10.1.1 Marking on **suction catheters** shall comply with EN 1041.

10.1.2 **Suction catheters** shall be marked with the outside diameter in accordance with 5.1. **Suction catheters** may, in addition, be marked with the French gauge (see Note 2 to 5.1.1).

10.1.3 The **suction catheter connector** attached to a **suction catheter** having an angled **patient end** shall, by a mark or other means, indicate the direction in which the **tip** points.

10.1.4 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**. See Figure 3.

10.1.5 For **suction catheters**, the **shaft** should have clearly visible markings at least every 2 cm along the length of the part inserted into the tracheal tube.

10.1.6 If provided, length marks shall be either in a single colour, such as black or blue, or in accordance with the colour code as shown in Table 6 and Figure 3

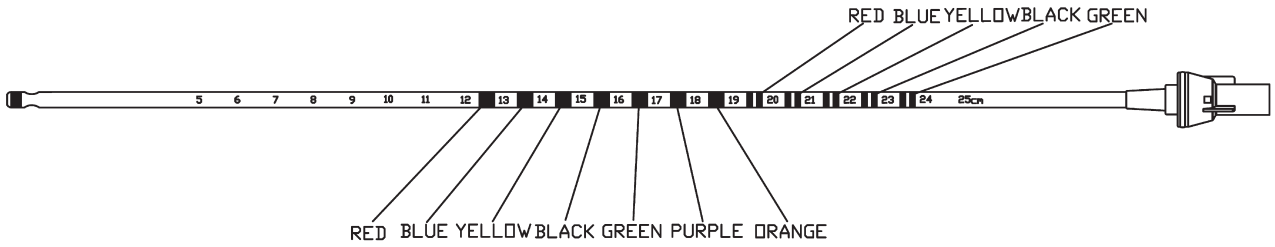


Figure 3 — Suction catheter length marks and associated colour code

Table 6 — Suction catheter length marks and associated colour code

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

10.2 Use of symbols

If required by a local competent authority, marking of **suction catheter** packages, inserts and information supplied by the manufacturer shall comply with EN 1041 and contain appropriate symbols from ISO 7000, ISO 15223-1, ISO 15223-2, EN 15986, and 6.4 of IEC 60601-1:2005.

10.3 Labelling of individual packs

10.3.1 Labelling of individual packs shall comply with EN 1041.

10.3.2 The labelling of individual packs shall include the following:

a) a description of the contents;

b) the designated size in accordance with 5.1.1, expressed in accordance with one of the following examples. Length may also be designated in centimetres:

   — 6 mm × 500 mm, or

   — 6 mm (18F) × 500 mm, or

   — diameter 6 mm (18 F), length 500 mm;

c) the name and/or trademark of the manufacturer and/or supplier;

d) the batch number preceded by the word “LOT”;

e) where appropriate, an indication of the date by which the catheter should be used, expressed as the year and month;

f) where appropriate, the word “STERILE” and the method of sterilization. Manufacturers shall be consistent in their indication that their device is sterile;

g) for **suction catheters** not intended for reuse, the words “single use” or equivalent;

h) for **closed suction catheters,** the internal volume of the **patient end adaptor** in accordance with 7.4.2.7;

i) If phthalates as categorized in EN 15986 are incorporated in parts of the medical devices coming directly or indirectly into contact with the patient, the medical device shall be labelled accordingly.

NOTE Attention is drawn to substances which are carcinogenic, mutagenic or toxic to reproduction.

10.4 Labelling of shelf/multi-unit packs

10.4.1 Labelling of shelf/multi-unit packs shall comply with EN 1041.

10.4.2 The labelling of shelf/multi-unit packs shall include the following:

a) a description of the contents;

b) the designated size in accordance with 5.1.1, expressed in accordance with one of the following examples. Length may also be designated in centimetres:

— 6 mm × 500 mm, or

— 6 mm (18F) × 500 mm, or

— diameter 6 mm (18 F), length 500 mm;

c) the name and/or trademark and address of the manufacturer and/or supplier;

d) the batch number preceded by the word “LOT”;

e) where appropriate, an indication of the date by which the catheter should be used, expressed as the year and month;

f) appropriate instructions on preparation for use;

g) where appropriate, the word “STERILE” and the method of sterilization;

h) where applicable, instructions for cleaning and disinfection or sterilization, and the maximum number or period of reuses shall be marked on the **suction catheter** package or on an insert;

i) for **suction catheters** not intended for reuse, the words “single use” or equivalent.

Annex A
(informative)

Rationale

General

This annex provides a concise rationale for the important requirements of this International Standard and is intended for use by those who are familiar with the subject of this International Standard 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 International Standard necessitated by those developments.

The clauses and subclauses in this annex have been so numbered to correspond to the clauses and subclauses in this International Standard to which they refer. The numbering is, therefore, not consecutive.

Clause 2 **Normative references**

ISO 594-1 and ISO 594-2 are intended to be replaced by ISO 80369-7.[7]

Subclause 3.3 **closed suction catheter**

Closed suction catheters are used for endotracheal or artificial airway suctioning 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) and reduce the risk of contamination with secretions.

At the time of publication of this International Standard, it was common practice in critical care areas to use a **closed suction catheter** during simultaneous 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 is in contrast to the use of a traditional **open suction catheter** which require the opening or disconnection of the **VBS** before the application of the subatmospheric pressure on the respiratory tract.

When used as intended, an in-line or **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 **suction catheter adaptor**, the **connector** at the **patient end** of the **closed suction catheter adaptor** becomes the 'new' **patient connection port** of the **VBS**.

Subclause 3.10 **patient end adaptor**

All **closed suction catheters** are enclosed within a **protective sleeve** and a **patient end adaptor** designed to connect to the **airway** and the **breathing set** of the **VBS.**

For **closed suction catheters**, examples of **patient end adaptors** may 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 also Figure 2.

Subclause 3.23 **suction catheter connector**

In this edition, 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 previous edition, i.e. ISO 8836:2007. Consolidation of these confusing terms is intended to clarify the requirement of this International Standard.

Clause 4 **General requirements for open and closed suction catheters**

Suction catheter devices 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**. The need for a **risk management file** is a well recognized process through which the manufacturer of a medical device 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 may 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.

Attention is drawn to the consideration of disclosure of specific labelling and instructions for intended use that might deviate from the currently accepted medical practice.

Subclause 5.2 **Dimensions**

The materials used for the manufacture of **suction catheters** should allow construction of a **suction catheter** with the thinnest possible wall, which at the same time maintains resistance to collapse and kinking.

Subclause 7.3.6 **Suction catheter connector**

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 International Standard. 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 7.3.8 **Vacuum control device**

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

Subclause 7.4.2.7 **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 7.4.4.2 **Vacuum control device leakage**

Clinicians have noted the transmission of fluids from the **vacuum 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 **vacuum control device** may be a 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** may 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 vacuum control valve remains leak-free in all positions, even when the machine end is blocked and positive pressure applied to the **patient end**.

Subclauses 8.3 and 8.4

Test methods of **vacuum 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 International Standard are sufficient to meet needs at the time of publication.

Subclauses 8.4 and 8.5

Requirements have been added to reduce the risk associated with low delivered tidal volumes which are attributed to leakage, resistance, and internal volume of **VBS accessories**. Because the **closed suction catheter** is an **accessory** of a **breathing system**, the same functional performance requirements that apply to the **breathing set** also apply to the **closed suction catheter**.

See ISO 5367 and ISO 80601-2-12:2011, Annex A (rationale) for more information.

Subclause 8.4 **Leakage**

Leakage limits are approximately 30 % of the **ventilator** and **anaesthetic breathing system** limits and 100 % of the breathing set limit.

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 International Standard 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 8.5 **Resistance to flow**

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

Subclause 8.6 **Radiopacity**

The requirement for radiopaque markers is intended to allow visualization of the **suction catheter** when verification of the depth of intubation is required.

Subclause 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 8185.[5]

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 as appropriate, 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 as appropriate, has been reached.

Annex C
(normative)

Measurement of residual vacuum

C.1 *Principle

The effectiveness of the **vacuum control device** as a means of relieving vacuum at the **patient end** is tested by measuring the **residual vacuum** at the **tip** of the catheter with the **vacuum 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**, to an accuracy of ±0,01 kPa (0,1 cmH_2O).

C.3 Procedure

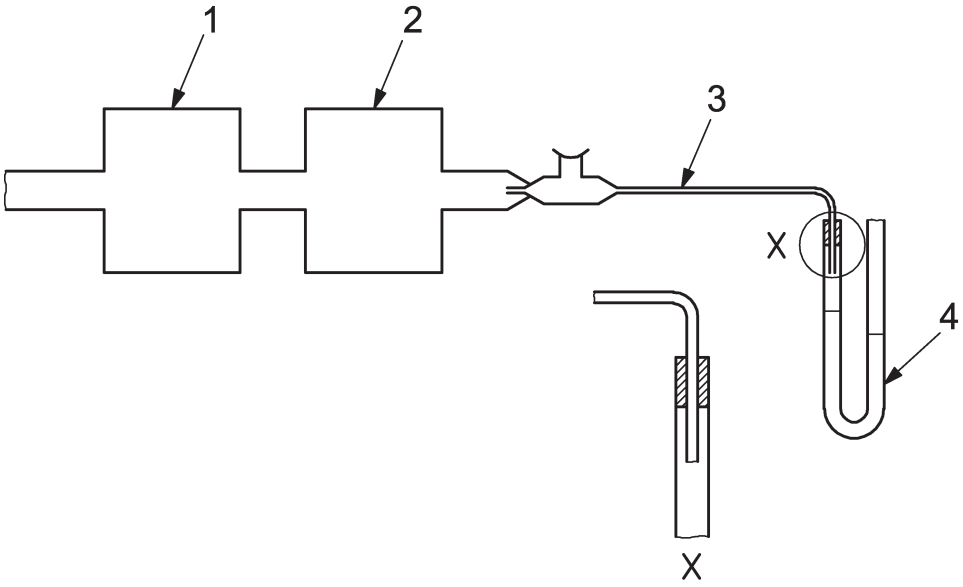
C.3.1 Assemble the apparatus, as shown in Figure C.1, with the flowmeter fitted to the exit of the vacuum pump, ensuring an airtight fit between the catheter and the manometer.

C.3.2 **For open suction catheters, o**pen the catheter **vacuum 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 vacuum control device, switch on the vacuum pump and adjust the applied vacuum until a flow of 30 l/min is indicated on the flowmeter, then close the vacuum 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 **vacuum control device**
4 manometer
X detail of **suction catheter shaft sealed to manometer**

Figure C.1 — Apparatus for residual vacuum test

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 [(60 ± 3) cmH_2O].

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 8.4.

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 respiration and patient connections which are not used and the **vacuum 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.2 and E.3 below represent those associated with the use of **suction catheters** published by the American Association for Respiratory Care (AARC) and RESPIRATORY CARE in 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.[9]

NOTE This list is not intended to be comprehensive for all devices within the scope of this International Standard, 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/hypoxemia

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

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

E.2.3 Patient or user harm associated with toxicity

a) Allergy, including allergy to natural rubber latex

b) Tissue sensitivity, inflammation, necrosis

c) Systemic absorption of toxic substances

d) Pollution of the immediate surrounding environment

e) Leakage of ventilatory gas or aesthetic gases and vapours

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

a) Loss of function caused by:

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

   2) kinking;

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

   4) failure of the suction valve;

   5) undetected leak;

   6) excessive resistance;

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

b) Incorrect size for a specific patient caused by:

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

   2) patient variability

c) Loss of **ventilator** function and/or accuracy:

   1) undetected leak;

   2) excessive breathing resistance;

   3) rebreathing of exhaled gases due to excessive internal volume.

d) Connections

Difficulty of connection and disconnection of swivel connectors may 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 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

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

[3] ISO 5366-1, *Anaesthetic and respiratory equipment — Tracheostomy tubes — Part 1: Tubes and connectors for use in adults*

[4] ISO 5366-3, *Anaesthetic and respiratory equipment — Tracheostomy tubes — Part 3: Paediatric tracheostomy tubes*

[5] ISO 8185, *Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems*

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

[7] ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications*[3)]

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

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

3) To be published.

ICS 11.040.25; 11.040.10
Price based on 27 pages