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Catheter systems for neuraxial application — Sterile and single-use catheters and accessories

Systèmes de cathéters pour application neuraxiale — Cathéters et accessoires stériles et à usage unique

Reference number
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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*.

Introduction

International Standards covering catheter systems for neuraxial applications do not exist; nevertheless, this class of medical devices is very broad and counts several million catheters inserted or implanted per year. For many of these applications (e.g. the ones targeting the brain or the spine) there are considerable clinical risks.

Incorrect delivery route of medication and other misconnections between medical devices have resulted in a greater awareness of the potential role of incompatible connectors in reducing these incidents. Connectors for neuraxial applications are described in ISO 80369-6.

The development of a dedicated standard for neuraxial application is addressed in this document.

Guidance on transition periods for implementing the requirements of this document is given in ISO/TR 19244.

Catheter systems for neuraxial application — Sterile and single-use catheters and accessories

1 Scope

This document specifies general requirements and test methods for catheter systems intended to be used in neuraxial applications.

This document specifies requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging and information supplied by the manufacturer, and tests to demonstrate conformity with these requirements.

Catheters for neuraxial applications are intended to administer medications directly into neuraxial sites, to deliver wound infiltration analgesia and to other regional analgesia procedures or to monitor or remove fluids from neuraxial sites for therapeutic or diagnostic purposes.

NOTE 1 Sites for the neuraxial application include the spine, intrathecal or subarachnoid space and the epi-, extra-, or peri-dural space (applications mentioned are just examples and not an exhaustive list). In neuraxial application, anaesthetics/analgesics can be administered regionally affecting a large part of the body, such as a limb, and include plexus blocks, such as the brachial plexus blocks or single nerve blocks. Neuraxial application procedures include continuous infusion of wounds with local anaesthetic agents.

NOTE 2 Local anaesthesia/analgesia injected hypodermically and systemic injection of anaesthetics are not considered neuraxial applications.

This document is applicable to the following types of devices:

— spinal/epidural catheter systems;

— spinal/epidural port catheter systems;

— peripheral nerve block catheter systems;

— wound infusion catheter systems (also known as catheters for Surgical Site Continuous Analgesia).

This document is not applicable to:

— pumps and other devices intended to deliver medications through these catheter systems;

— catheters generically intended to administer substances into the body which are not intended to interact directly with the nervous system, but which have an indirect effect on nervous system (e.g. cannula needles);

— drainage catheters for any other application than neuraxial.

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

ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

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

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

ISO 80369-6, *Small bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial 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:

— IEC Electropedia: available at https://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
catheter
tubular device designed to be partially or totally inserted or implanted into the body for administration and/or removal of fluids

3.2
distal end
end of the *catheter* (3.1) inserted furthest into the patient

3.3
hub
connector(s) at the proximal end of the *catheter* (3.1) which may either be integral with the *catheter* (3.1) or be capable of being securely fitted to the proximal end of the *catheter* (3.1)

Note 1 to entry: The proximal end is the end of the catheter to which connection can be made.

3.4
effective length
length of the *catheter* (3.1) that can be inserted into the body

Note 1 to entry: See Figures 1 and 2.

3.5
functional length
length of the *catheter* (3.1) between the tip and the most proximal hole

Note 1 to entry: Applies to catheters with side openings.

Note 2 to entry: See Figures 1 and 2.

3.6
total length
overall length of the *catheter* (3.1), including the catheter connector

Note 1 to entry: See Figures 1 and 2.

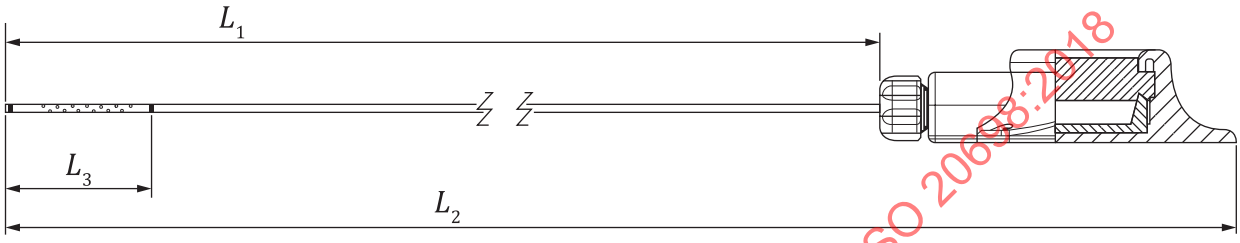
3.7
outside diameter
largest diameter of the *catheter* (3.1) along the *effective length* (3.4)

3.8
junction
joining of one or more tubes with the rest of the *catheter* (3.1)/device, where the assembly of the tubes provide mechanical support in tension/compression during clinical use

3.9
stylet
flexible device inside the *catheter* (3.1) to assist the insertion of the *catheter* (3.1)

3.10
risk assessment
overall process comprising a risk analysis and a risk evaluation

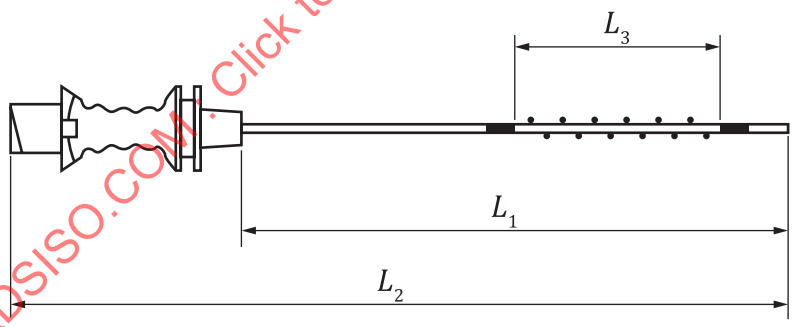
[SOURCE: ISO 14971:2007, 2.18]



Key

L_1 *effective length* (3.4)
L_2 *total length* (3.6)
L_3 *functional length* (3.5)

Figure 1 — Example of neuraxial catheter with identification of lengths and markings — Spinal/epidural port



Key

L_1 *effective length* (3.4)
L_2 *total length* (3.6)
L_3 *functional length* (3.5)

Figure 2 — Example of neuraxial catheter with identification of lengths and markings — Wound infusion catheter

4 Intended performance

The intended performance of a neuraxial catheter shall be described and documented by addressing the following, with particular regard to safety.

a) Intended purpose(s):

   In particular, it shall be clear:

   — which is the target destination of the catheter, and

   — the type of contact with the patient (e.g. totally/partially implantable, invasive).

b) Functional characteristics.

c) Intended conditions of use.

d) Intended lifetime and/or implant-time/duration time, if necessary.

The flow rate performance definition shall be given (see also 7.2.5).

5 Design attributes

5.1 Nominal size of the catheter

5.1.1 General

The nominal size of the catheter shall be designated as specified in 5.1.2 and 5.1.3.

5.1.2 Outside diameter

Unless otherwise specified in another part of this document for a particular type of catheter, the outside diameter shall be expressed as the nominal dimension in millimetres. Units of measurement systems other than those specified may additionally be used (e.g. a Gauge scale as defined in Annex E).

NOTE Designation of nominal dimension and number of significant digits after the decimal point can be provided according to risk assessment and manufacturing tolerances.

For devices that are not round by design the size shall be designated by the dimension of the largest axis. Where relevant, manufacturers may choose to report additional information regarding the device profile, such as the dimension of the second axis for an oval shape.

5.1.3 Catheter lengths

All catheter lengths (as defined in 3.4 to 3.6) shall be expressed in millimetres or centimetres.

NOTE This document does not specify tolerances to all lengths.

5.2 Catheter holes

The design, number and positioning of catheter holes shall be such as to minimize adverse effects on the catheter and trauma to the tissues.

5.3 Distal tip

The distal tip shall be smooth, rounded, tapered or similarly finished in order to minimize trauma to tissues during catheter insertion and use.

5.4 Surface

The external surface of the effective length of the catheter, including the distal end, shall be free from process and surface defects. The definition of the defects shall be determined by intended use requirements and risk assessment.

5.5 Hubs

If the catheter is supplied with either an integral or a separate hub it shall be a female hub that shall comply with ISO 80369-6.

The conformity of the hubs with ISO 80369-6 is also applicable to any accessories included in the device package that are intended to access the neuraxial site directly or indirectly.

5.6 Markings

Appropriate markings shall be provided on the catheter based on risk assessment and intended use.

See Figures 1 and 2 for examples of conforming catheter markings for different applications.

5.7 Filter

If a filter is included, an appropriate definition of its specification (e.g. nominal pore size) shall be defined.

5.8 Stylet

If a stylet is provided, it shall not protrude from the distal end or lateral holes of the catheter. If intended to be removable, the stylet shall be equipped with a handle allowing safe removal of the stylet from the catheter.

Removal of the stylet from the catheter shall not cause buckling by compression or tear the catheter.

5.9 Detectability

The catheter, or at least its effective length, shall be detectable by X-ray or by other means (ultra-sound, MRI, etc.), if required by the risk assessment.

5.10 Fixation devices

When a fixation device is provided, it shall not reduce the flow rate by more than 10 % in comparison with the flow rate without a fixation device.

6 Materials

6.1 General

Device materials shall be selected according to the properties required for the intended purpose. The selection shall also take into account the effects of manufacture, handling, sterilization and storage, as well as any treatment (chemical, electro-chemical, thermal, mechanical, etc.) applied to the surface or a part of the surface of the device material in order to modify its properties. Possible reactions or interactions shall be considered.

If the device includes any metallic parts that could be exposed to tissues or drugs, they shall be resistant to corrosion (see 7.2.4).

When a medicinal product is an integral part of a device, the medicinal product shall be assessed according to pharmaceutical principles.

6.2 Biocompatibility

Biocompatibility of the device shall be assessed in accordance with ISO 10993-1.

6.3 Drug and material compatibility

The materials used for the manufacturing of the catheter systems shall minimize the risk of interaction of the device with other materials, devices, or substances and gases that will be infused through or in contact with them.

7 Design evaluation

7.1 General

Design evaluation shall identify general safety and performance requirements of the medical device. Therefore, design evaluation shall introduce/address lifecycle risk management, clinical use, usability and post-market surveillance. Design evaluation shall identify methods and criteria for evaluating the benefit-to-risk ratio of the medical device under development, in manufacturing and post-market.

7.2 Pre-clinical evaluation

7.2.1 General

Based on general design evaluation methods, clinical and pre-clinical evaluation based on verification and validation shall be performed for each device. The pre-clinical evaluation shall adequately address the criteria listed in this clause. Verification and validation shall be performed using the device under ready-to-use conditions.

NOTE This subclause provides a non-exhaustive list of minimum requirements for the devices covered by this document.

7.2.2 Radiopacity

Conformance to radiopacity requirement, if applicable (see 5.9), shall be demonstrated by an appropriate test method.

NOTE Test methods such as ASTM F640 or DIN 13273-7 can be used.

7.2.3 Magnetic resonance compatibility

If applicable, the hazards of neuraxial devices in the magnetic resonance environment shall be evaluated by an appropriate method.

NOTE Test methods such as ASTM F2052, ASTM F2213, ASTM F2182 or ASTM F2119 can be used.

7.2.4 Corrosion resistance

When tested in accordance with the method given in Annex A, no implantable/invasive metallic components of the device shall show visible signs of corrosion.

If exposed external metallic components of the device could develop visible signs of corrosion, the level of corrosion shall be evaluated, with respect to intended use and risk assessment, by subjecting the catheter to the corrosion test described in Annex A.

A more rigorous test method may be applied in place of the method defined in Annex A depending on risk assessment (e.g. intended time contact).

NOTE See ISO 10555-1:2013, Annex A or ASTM F2129 for examples of more rigorous test methods.

7.2.5 Flow rate

The flow rate shall be determined in accordance with Annex B.

The length of the catheter tested shall be clinically relevant.

In case other flow performances are relevant and specified for the catheter these shall be determined with a specific appropriate test method.

NOTE This test is also intended to verify the patency of the system.

7.2.6 Freedom from leakage (design)

The hub or connection fitting assembly or any other part of the catheter shall not leak liquid when tested in accordance with the method given in Annex C.

7.2.7 Peak tensile force

Peak tensile force shall be tested in accordance with the method given in Annex D. Evaluation of the minimum acceptable peak tensile force shall be determined in the risk assessment of the device.

The peak tensile force test shall be carried out on the entire catheter system including, if applicable, the hub; alternatively, each single section of the catheter system may be tested independently. Verification of both tubular elements and catheter junctions shall be performed.

When a removable stylet is included, at a unit crosshead speed of 200 mm/min, the peak tensile force for separation of the handle and stylet shall not be less than 15 N.

7.2.8 Catheter kinking test

Catheter kinking characteristics shall be determined according to risk assessment and tested in accordance with applicable test method.

NOTE Test methods such as EN 13868 can be used.

7.2.9 Surface

When examined by normal or corrected to normal vision, with a minimum ×2,5 magnification, the external surface of the effective length of the catheter shall appear free from extraneous matter.

7.3 Clinical evaluation

Where a clinical investigation is carried out, it shall be performed in accordance with the requirements of ISO 14155.

8 Sterilization

8.1 General

Neuraxial catheter systems that are sterile shall have a sterility assurance level (SAL) of 10^{-6}. As an addition/amendment thereto the following shall be considered:

— the catheter system shall have been sterilized by an appropriate validated method, and shall be verified for safety and performance after sterilization (see also Clause 7).

8.2 Sterilization residuals

Testing for residuals of sterilization shall be in accordance with the principles set out in ISO 10993-1. If applicable, the level of residuals of ethylene oxide shall not exceed the limits specified in ISO 10993-7.

The microbial residuals after sterilization (e.g. pyrogens) shall be appropriately verified, in particular for fluid delivery into the spine.

NOTE Some regional legislation recommends a maximum acceptable pyrogen level, e.g. EUPH and USP.

9 Packaging

The packaging shall comply with ISO 11607-1.

10 Information to be supplied by the manufacturer

10.1 Marking on the device

In order to ensure traceability, if the device is intended to be totally implanted, the following information shall appear on the device:

— manufacturer's name or trade mark;

— batch code (lot number) or serial number.

If the marking would affect the intended performance, or if the implant is too small or the physical properties of the implant prevent legible marking, the information required shall be given on the label or by other means to provide traceability.

10.2 Information on instructions for use and/or packaging

The packaging and/or instructions for use shall contain, at least, information on the following:

a) the details strictly necessary to identify the device (including relevant design attributes as defined in Clause 5, and the contents of the packaging;

b) intended performance (see Clause 4);

c) where appropriate or locally required, a unique device identification;

d) if applicable, description of any additives or coating materials;

e) if applicable, where special claims are made because of the presence of an additive or coating:

   — a description of the additive or coating material;

   — the duration of effectiveness in use;

   — any contra-indications, warnings and precautions based on the additive or coating material(s);

f) if applicable, information on holes (number and position), functional length and tip configuration;

g) if applicable, explanation of any catheter marking;

h) information relative to flow rate (see 7.2.5), including catheter length tested;

i) any limitation in syringe size or other fluid administration method that should not be used with the device;

j) if applicable, any special recommendations concerning the use of filters, or pre-filtering of medicinal products.

Annex A
(normative)

Test method for resistance to corrosion

A.1 Principle

The device is immersed in sodium chloride solution, then in boiling distilled or deionized water, and afterwards examined visually for evidence of corrosion.

A.2 Reagents

A.2.1 **Saline solution**, comprising a solution of analytical reagent grade sodium chloride in freshly prepared distilled or deionized water, [c(NaCl) = 0,15 mol/l].

A.2.2 **Distilled** or **deionized water**.

A.3 Apparatus

A.3.1 **Borosilicate glass beakers**.

A.4 Procedure

A.4.1 Immerse the device in the saline solution (A.2.1) in a glass beaker (A.3.1) at (22 ± 5) °C for 5 h.

A.4.2 Remove the test specimen and immerse it in boiling distilled or deionized water (A.2.2) for 30 min.

A.4.3 Allow the water and the test specimen to cool to (37 ± 2) °C, and maintain them at this temperature for 48 h.

A.4.4 Remove the test specimen and allow it to dry at room temperature.

A.4.5 Disassemble specimens that have two or more components, which are intended to be separable in use. Do not strip away or cut open any coatings on metallic components. Inspect the specimen visually for signs of corrosion.

NOTE Additional testing can be performed using alternate durations and temperatures depending on appropriate risk-based clinical justification.

A.5 Test report

The test report shall include the following information:

a) a reference to this document, i.e. ISO 20698:2018;

b) identity of the device;

c) statement as to whether corrosion occurred during the test;

d) any deviations from the procedure;

e) any unusual features observed;

f) the date of the test.

Annex B
(normative)

Determination of flow rate through catheter

B.1 Principle

Water is allowed to flow through the catheter system and the amount of flow is measured either volumetrically or gravimetrically.

B.2 Reagent

B.2.1 **Distilled** or **deionized water** or **other clinically relevant media**

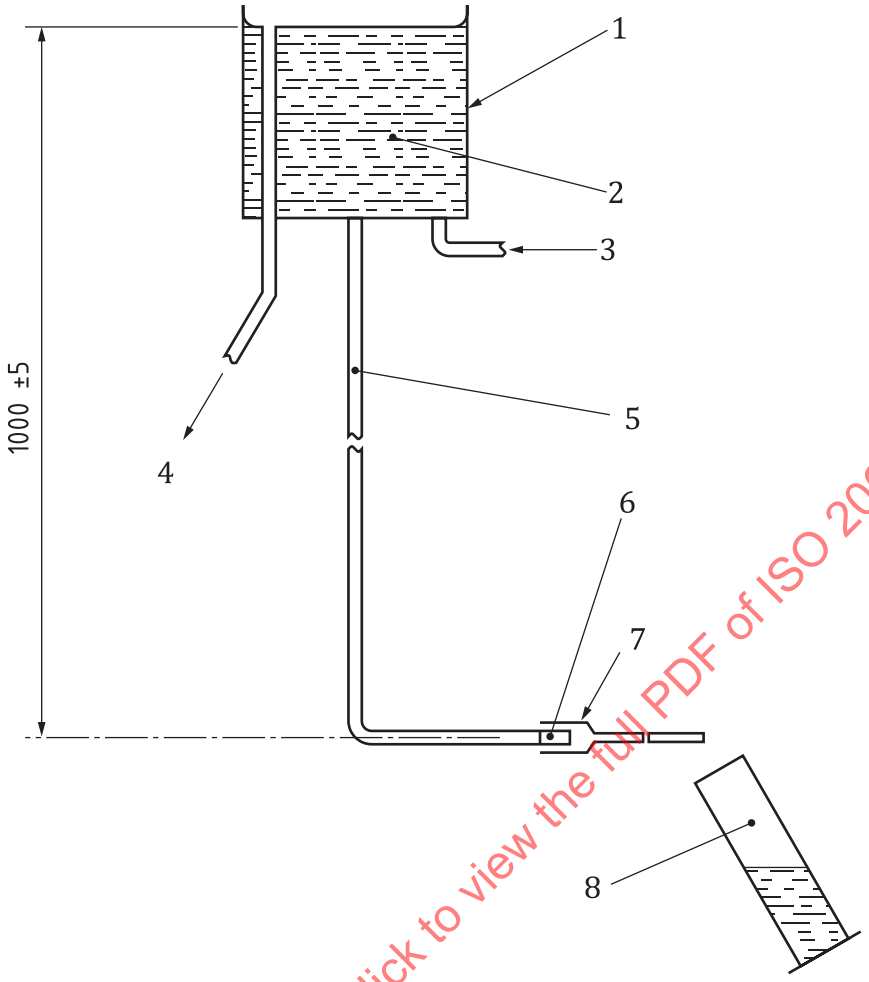
Potable degassed water for human consumption or normal 0,9 % saline solution may also be used.

B.3 Apparatus

B.3.1 Constant-level tank, fitted with a delivery tube and a connector capable, when no test catheter is attached, of providing a flow rate of (525 ± 25) ml/min, and having a hydrostatic head height of (1 000 ± 5) mm.

An example of a suitable apparatus is shown in Figure B.1.

Dimensions in millimetres



Key

1	constant-level tank	5	delivery tube
2	distilled or deionized water	6	connector
3	inlet	7	catheter system under test
4	overflow	8	collecting/measuring vessel

Figure B.1 — Example of apparatus for determination of flow rate of water

B.3.2 Equipment for collecting and determining the mass or volume of the catheter system efflux to an accuracy of ±1 % or other appropriate means of flow rate measurement.

NOTE Glassware complying with the following standards satisfy present accuracy requirement: ISO 4788 (class A for all sizes and class B for sizes of at least 100 ml) and ASTM E1272 (class A for all sizes and class B for sizes of at least 100 ml).

B.3.3 A way to measure the time test period, e.g. a timer.

B.4 Procedure

B.4.1 Supply the constant-level tank (B.3.1) with media at (22 ± 2) °C. Fit the catheter system to be tested to the connector.

B.4.2 Start the media flowing through the catheter system. Collect the efflux for a period of time (not less than 30 s) and determine its volume either by means of a measuring cylinder or by weighing, taking into account the density of the media or directly measure the flow rates.

B.4.3 Perform three determinations on each applicable catheter system.

B.5 Expression of results

Calculate the arithmetic average of the three determinations and express it as average flow rate through the catheter, in millilitres per minute. Round the calculated average flow rate to the nearest whole number of millilitres per minute for values over one millilitre per minute and to one decimal point for values less than one millilitre per minute.

B.6 Test report

The test report shall include the following information:

a) a reference to this document, i.e. ISO 20698:2018;

b) identity of the catheter system and the length of the catheter tested;

c) the average flow rate, expressed in millilitres per minute (see B.5);

d) if applicable, the identity of the components used to connect the apparatus with the catheter system;

e) any deviations from the procedure;

f) any unusual features observed;

g) the date of the test.

Annex C
(normative)

Test method for liquid leakage under pressure

C.1 Principle

The catheter system is connected, via a leak-proof connection, to a syringe or pressure apparatus. A hydraulic pressure is applied to the catheter system and to the hub assembly, if present, and the catheter tube inspected for leakage.

C.2 Reagents

C.2.1 **Distilled or deionized water** or **potable water for human consumption**.

C.3 Apparatus

C.3.1 **Leak proof connector**, to connect catheter system to syringe or a pressure apparatus (C.3.3) fitted with a gauge capable of measuring at least 300 kPa pressure and having a small internal volume.

C.3.2 **Connector**, to make leak proof connection between syringe or a pressure apparatus (C.3.3) and catheters that do not have hubs.

C.3.3 **Syringe** or **pressure apparatus**, which can supply a pressure at least of 300 kPa for at least 30 s to the device under test (e.g. a syringe checked for absence of leakage past the piston and nozzle in conformance with ISO 7886-1).

C.3.4 **Means for occluding a test specimen**, e.g. a clamp.

C.4 Procedure

C.4.1 When testing catheters that have a hub or hubs, if necessary assemble detachable hubs in accordance with the manufacturer's instructions. Connect the hub to the leak proof connector (C.3.1) to form a leak proof connection.

C.4.2 When testing catheters that do not have hubs, connect the catheter to the syringe or pressure apparatus (C.3.3) by means of a connector (C.3.2).

C.4.3 Fill the syringe or a pressure apparatus (C.3.3) with water (C.2.1) at (22 ± 5) °C and expel the air from the whole assembly under test. Occlude (C.3.4) the test specimen as near to the distal end as possible.

C.4.4 Apply a pressure of 300 kPa minimum. Maintain the pressure for 30 s. Examine the catheter/hub assembly, if present, and the catheter tube for liquid leakage, i.e. the formation of one or more falling drops of water, and record whether or not leakage occurs.

NOTE A colorant can be added to the reagent to aid identification of leakage (e.g. Patent blue V or Methylene blue).

C.5 Test report

The test report shall include the following information:

a) a reference to this document, i.e. ISO 20698:2018;

b) identity of the catheter system;

c) statement as to whether leakage occurred from the hub assembly, if present, or catheter tube;

d) any deviations from the procedure;

e) any unusual features observed;

f) the date of the test.

Annex D
(normative)

Method for determining peak tensile force

D.1 Principle

Test pieces or the total length of a catheter are chosen so that each tubular portion, each junction between hub or connector and tubing, and each junction between tubular portions is tested. A tensile force is applied to each test piece until the tubing or the junction breaks or separates.

D.2 Apparatus

D.2.1 **Tensile testing apparatus**, capable of exerting a force of greater than 15 N.

D.3 Procedure

D.3.1 Assemble the catheter system in accordance with the manufacturer's instructions. Select a test piece from the catheter system to be tested. Include in the test piece the hub or connector, as applicable, and the junction between segments, e.g. between the tubing and the distal tip.

D.3.2 Precondition the test pieces according to the intended use. The duration of the preconditioning shall represent the clinically stable phase. Test in accordance with D.3.3 to D.3.6 immediately after conditioning.

D.3.3 Fix the test piece in the tensile testing apparatus. If a hub or connector is present, use an appropriate fixture to avoid deforming the hub or connector.

D.3.4 Measure the gauge length of the test piece, i.e. the distance between the jaws of the tensile testing apparatus or the distance between the hub or connector and the jaw holding the other end of the test piece, as appropriate.

D.3.5 Apply a tensile strain at a unit strain rate of 20 mm/min/mm of gauge length (see Table D.1) until the test piece separates into two or more pieces. Note the peak tensile force in Newtons reached by the tensile testing of a catheter test piece before or at the point of separation into two pieces.

D.3.6 Do not perform more than one test on any test piece.

Table D.1 — Examples of conditions for 20 mm/min/mm strain rate

Gauge length mm	Test speed mm/min
10	200
20	400
25	500