INTERNATIONAL STANDARD

ISO 10555-1

Third edition
2023-11

Intravascular catheters — Sterile and single-use catheters —

Part 1: General requirements

Cathéters intravasculaires — Cathéters stériles et non réutilisables —

Partie 1: Exigences générales

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

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

This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 10555-1:2013), which has been technically revised. It also incorporates the amendment ISO 10555-1:2013/Amd 1:2017.

The main changes are as follows:

— added definitions for “inside diameter”, “gauge length”, and “coating” in Clause 3;

— added clarification on requirements (Clause 4) related to:

  — peak tensile force (revised the NOTE in Table 1);

  — leakage during pressurization: option for air pressure test (Annex I);

  — power injection burst pressure.

— added new requirements (Clause 4) related to:

  — risk approach;

  — usability engineering;

  — shelf life;

  — packaging system;

  — simulated use, kink and torque;

- coating integrity, particulate;
- distal tip stiffness.

— removed the requirements on side holes and distal tip;

— added text on “Nominal inside diameter for some applications” (Clause 5);

— added test details in the instructions for use for power injection (Clause 6);

— added reporting of maximum, minimum, standard deviation for variable data analysis in test reports;

— clarified “conditioning time” and “gauge length” (Annex B);

— clarified “minimum outside pressure requirement” (Annex D);

— introduced alternative test method using constant flowrate source (Annex G);

— replaced Figure H.1 in previous version with the new Table H.1;

— added new Annex I for alternative leakage under pressurization using air pressure;

— added new Annex J for rationale.

A list of all parts in the ISO 10555 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Intravascular catheters — Sterile and single-use catheters —

Part 1: General requirements

1 Scope

This document specifies general requirements for intravascular catheters, supplied sterile and intended for single use, for any application.

This document does not apply to intravascular catheter accessories, e.g. those covered by ISO 11070.

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 7886-1, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

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

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

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

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

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

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

3 Terms and definitions

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

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

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

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

3.1
intravascular catheter
tubular device, single or multilumen, designed to be partially or totally inserted or implanted into the vascular system for diagnostic and/or therapeutic purposes

3.2
distal end
end of the catheter inserted furthest into the patient

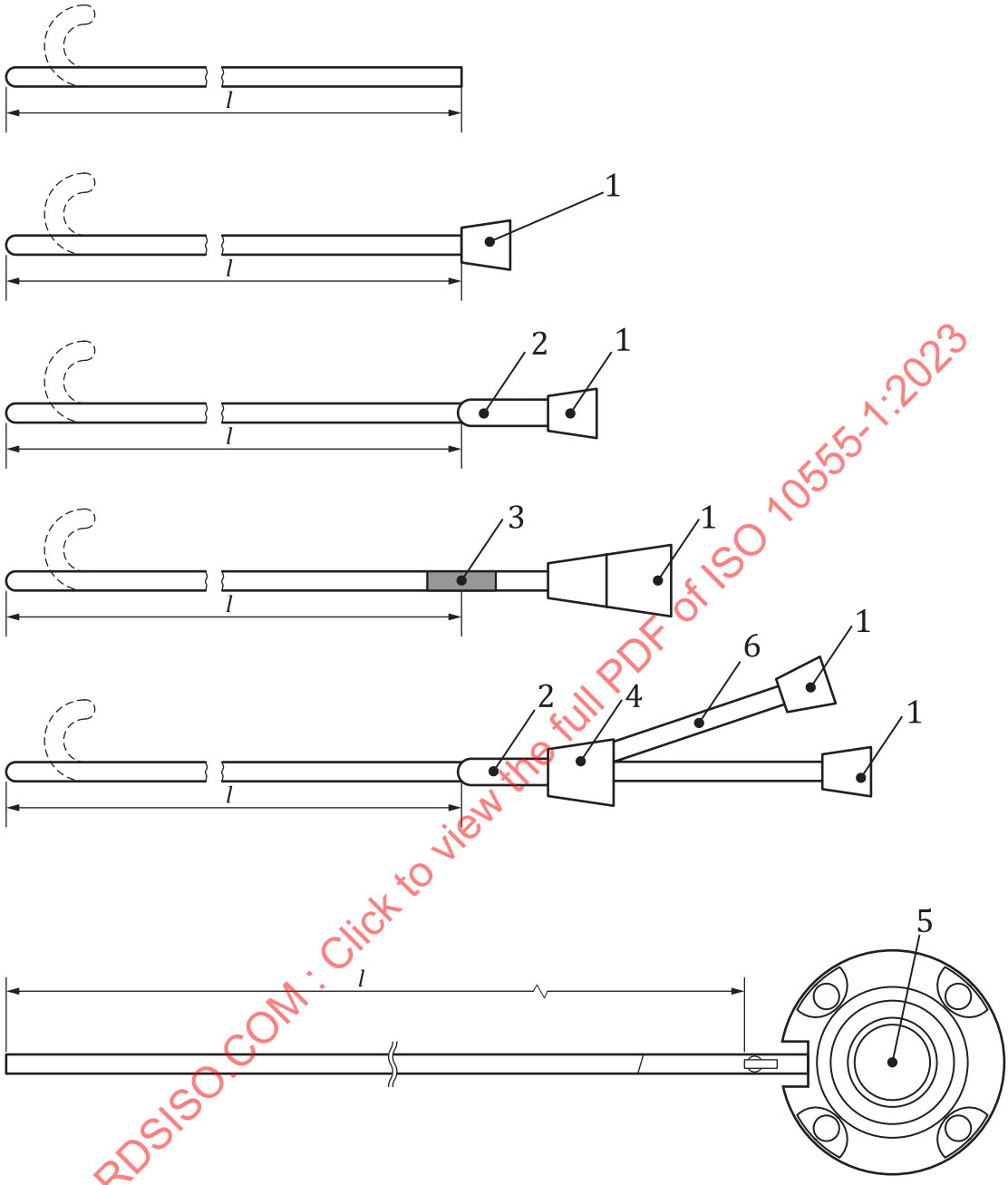
3.3
distal end configuration
shape of the catheter which is designed to facilitate its manual manipulation through the vascular system and the placement and anchoring of the distal tip in the chosen location

3.4
proximal end
access end
end of the catheter to which connection to another device can be made

3.5
hub
connector(s) at the *proximal end* (3.4) of the catheter which can either be integral with the catheter or be capable of being securely fitted to the *proximal end* (3.4) of the catheter

3.6
effective length
working length
usable length
length of the catheter, or pre- and *post-hydration* (3.11) lengths of hydratable catheters, that can be inserted into the body

Note 1 to entry: See Figure 1 where "*l*" is denoted as effective length.



Key

l effective length
1 catheter hub
2 catheter strain reinforcement
3 length mark
4 junction
5 pre-connected port
6 sidearm

Figure 1 — Examples of effective length of catheters

3.7
outside diameter
largest diameter of the catheter or pre- and *post-hydration* (3.11) largest diameters of hydratable catheters over the *effective length* (3.6)

3.8
inside diameter
largest diameter that can pass through a catheter lumen intended to deliver other devices

Note 1 to entry: See Annex J for additional information.

3.9
junction
joint
fixed connection
joining of one tube or more tubes with another tube or component where the assembly provides mechanical support in tension/compression during clinical use

3.10
hydratable intravascular catheter
intravascular catheter consisting of a material which, when subjected to an aqueous medium, results in an increase of more than 1 % of the effective length or 10 % or more of the *outside diameter* (3.7) of the effective length in *post-hydration* (3.11) state compared to pre-hydration

3.11
post-hydration
state of a *hydratable intravascular catheter* (3.10) after immersion in aqueous medium at (37 ± 2) °C for a minimum of 2 h or a shorter time upon appropriate clinical justification

3.12
power injection
injection of an imaging contrast agent with a constant-pressure source or constant-flowrate source capable of generating pressures greater than or equal to 689 kPa

3.13
primary packaging
packaging, which has direct contact with the device and/or maintains sterility

3.14
secondary packaging
packaging designed to contain one or more *primary packages* (3.13) and/or accessories

3.15
gauge length
length of the test piece between the grips of the tensile testing apparatus that elongates significantly during testing

Note 1 to entry: See Figure B.1.

Note 2 to entry: See Annex J for additional information.

3.16
coating
substance or material with any different property (e.g. antimicrobial, lubricity, antithrombogenicity) than the natural surface of the substrate that is intentionally added to cover the substrate

Note 1 to entry: The coating can partially or fully cover the substrate surface. Liquid lubricant is not considered as coating.

4 Requirements

4.1 Risk approach

Risk analysis, risk evaluation, risk control, evaluation of residual risk acceptability shall be performed in accordance with ISO 14971.

NOTE See Annex J for additional information.

4.2 Usability engineering

A usability engineering program shall be developed and implemented in accordance with IEC 62366-1, which shall include addressing use risks and tests and/or assessments as part of the design verification and validation.

NOTE See Annex J for additional information.

4.3 Sterilization

The devices shall be sterilized by a validated method.

The devices shall fulfil the requirements specified in 4.4 to 4.18 after being sterilized by a sterilization cycle representative of the final manufacturing process.

NOTE See applicable clause(s) of the ISO 17665 series, ISO 11135 and the ISO 11137 series for appropriate methods of sterilization.

4.4 Shelf life

The impact of aging on product performance shall be considered based on risk assessment in order to support the shelf life.

4.5 Detectability

Parts of the catheter shall be detectable by X-ray or by other means (e.g. ultra-sound, MRI, etc.) if required as determined by the risk assessment.

Detectability shall be demonstrated by an appropriate test method (see, e.g. ASTM F640-20 or DIN 13273-7).

4.6 Biocompatibility

The catheter shall be free from biological hazard in accordance with the appropriate testing in ISO 10993-1.

4.7 Surface

When examined by normal or corrected to normal vision and with a minimum x2,5 magnification the external surface of the catheter shall appear free from foreign matter.

The external surface of the effective length of the catheter, including the distal end, shall be free from surface defects which could cause embolic risks or trauma to vessels.

If the catheter is lubricated, the lubricant shall not be visible as drops of fluid on the external surface when the catheter is examined under normal or corrected to normal vision.

4.8 Corrosion resistance

Metallic components of the catheter intended for fluid path contact shall show no signs of corrosion when tested in accordance with the method given in Annex A.

4.9 Peak tensile force

Every section of the catheter shall be tested for peak tensile force in accordance with Annex B. Table 1 specifies the minimum peak tensile force for different sized tubular test pieces. Testing can be done on the complete device or different sections; however, minimum peak tensile force shall meet the requirements as specified in Table 1. See Figure 2 for examples of catheter sections and determination of effective outside diameter.

This document does not specify requirements for peak tensile force for tubing of less than 0,55 mm outside diameter (prehydration outside diameter for hydratable intravascular catheters). For those cases, the tensile test should be performed in accordance with Annex B and the peak tensile force shall be determined by the manufacturer based on risk assessment.

For a distal tip with a junction to the shaft tube, the peak tensile force shall be determined by the manufacturer based on risk assessment. For a distal tip of less than 3 mm with a junction for which a tensile test is not practical, the test method and requirements shall be determined by the manufacturer based on risk assessment.

For a distal tip of length less than 3 mm without a junction to the shaft tube, the tensile test is not required.

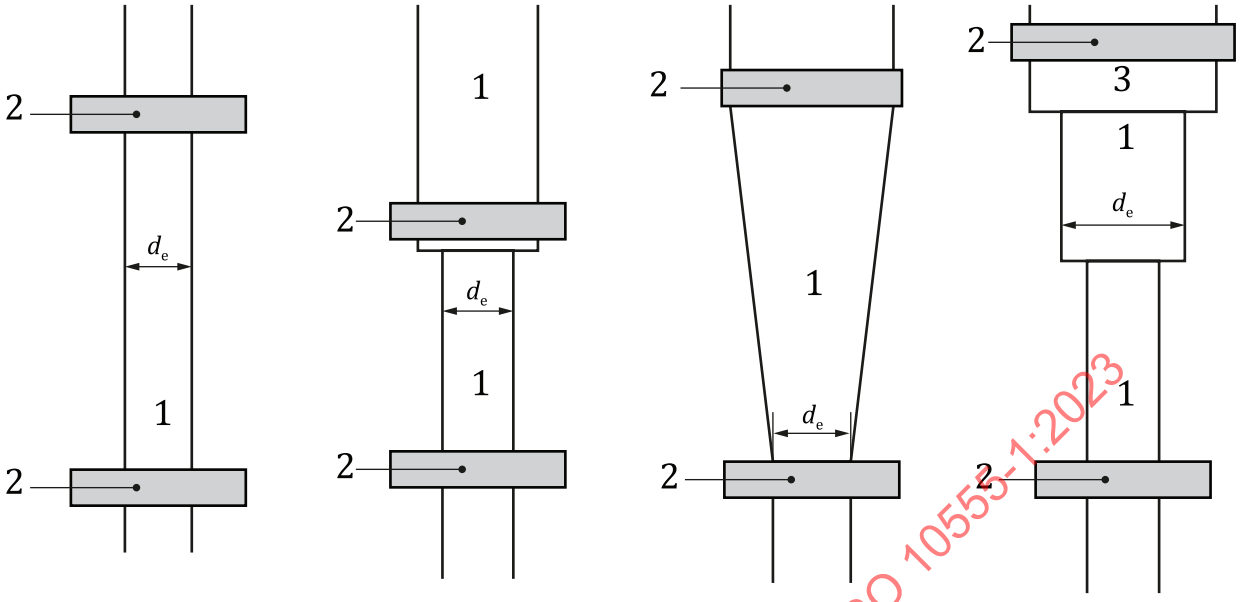
For a distal tip of length equal to or more than 3 mm without a junction to the shaft tube, the peak tensile force shall be determined by the manufacturer based on risk assessment.

The forces experienced during clinical use may be greater than the values listed in Table 1, e.g. the expected forces applied to a delivery system during clinical use to access the intended location, to deploy the device, or to withdraw the system. If the forces experienced during clinical use are determined by the manufacturer to be greater than the values listed in Table 1, the acceptance criteria for the peak tensile force of each test piece shall be as determined by the manufacturer based on risk assessment.

NOTE See Annex J for additional information.

Table 1 — Peak tensile force of catheter test pieces

Effective outside diameter range of tubular portion of test piece mm	Minimum peak tensile force *N*
≥ 0,55 < 0,75	3
≥ 0,75 < 1,15	5
≥ 1,15 < 1,85	10
≥ 1,85	15
NOTE 1 Values listed in Table 1 are not based on clinical data or forces that have been determined to be clinically-relevant. However, these values have been historically used to support functional performance and can be acceptable with appropriate rationale. NOTE 2 See Annex J for additional information.	



a) Straight tubing section **b) Junction between two sections of tubing** **c) Tapered tubing section** **d) Multiple junctions tested simultaneously**

Key

d_e effective outside diameter
1 tubing
2 grip
3 hub

Figure 2 — Illustration of effective outside diameter

NOTE See Annex J for additional information.

4.10 Freedom from leakage during pressurization

If subjected to liquid pressure during intended use, the hub or connection fitting assembly or any other part of the catheter shall not leak when tested using either liquid pressure as set out in Annex C or air pressure in accordance with Annex I. If a sample fails the air leakage under water test (see Annex I), it is acceptable to retest the sample using the method in Annex C.

For hydratable intravascular catheters, this requirement shall be met in both the pre- and post-hydration states.

NOTE See Annex J for additional information.

4.11 Freedom from leakage during aspiration

If subjected to aspiration during intended use, air shall not leak into the hub assembly during aspiration when tested in accordance with the method given in Annex D.

For hydratable intravascular catheters, this requirement shall be met in both the pre- and post-hydration states.

4.12 Hubs

If the catheter is supplied with either an integral or a separate hub, it shall be a female hub in accordance with ISO 80369-7.

4.13 Flowrate

For devices for which flow rate is specified, when tested in accordance with Annex E for all catheter lumen indicated for gravity delivery of fluid, the flow rate for each lumen shall be a minimum of 80 % of that stated in the information supplied by the manufacturer for catheters of nominal outside diameter less than 1,0 mm or a minimum of 90 % of that stated in the information supplied by the manufacturer for catheters of nominal outside diameter equal to or greater than 1,0 mm.

If the flowrate through hydratable catheters is determined, it shall be determined in post-hydration states.

4.14 Power injection burst pressure

If a catheter lumen is indicated for power injection, it shall be tested in accordance with Annexes F and G. In Annex G, either test A or B may be used. The lumen burst pressure (in accordance with Annex F) shall exceed the peak pressure present in that lumen (in accordance with Annex G) when flowing at the maximum flowrate stated in the information supplied by the manufacturer.

If desired, each fluid path may be divided into zones along its length and different pressure specifications can be assigned for each zone. A rationale shall be provided supporting why the pressure specification for each zone is sufficient. For example, analysis and/or empirical testing can be an appropriate justification for lower pressures (than that used in accordance with Annex G) in distal zones.

NOTE See Annex J for additional information.

4.15 Packaging system

Design of sterile barrier systems and packaging systems for the catheter shall be in accordance with the requirements of ISO 11607-1.

NOTE ISO 11607-2 describes the process development and validation requirements for forming, sealing and assembly processes and addresses controls during normal operations.

4.16 Simulated use, kink and/or torque testing to consider depending on device design, intended use, and risk analysis

Simulated use testing, kink testing, and torque strength testing shall be considered (if applicable) for devices that are intended to traverse anatomy that might expose it to multiple modes of mechanical loading in sufficiently challenging clinical setting (e.g. guide catheters intended to reach neurovasculature, PTA balloons intended to be used in a contralateral antegrade approach) based on risk assessment.

— For simulated use testing, the device shall perform as intended in a sufficiently challenging simulated clinical setting without damage that could affect functionality or safety of the device.

— For kink testing, the device shall resist kinking when used in a sufficiently challenging radius of curvature.

— For torque testing, the device shall resist damage that can affect functionality or safety of the device when subjected to sufficiently challenging torque.

Clinical use conditions or scientific justification shall be used to establish methods and criteria depending on device design, intended use, and risk analysis.

4.17 Coating integrity and/or particulate testing to consider depending on device design, intended use, and risk analysis

Coating integrity and/or particulate testing shall be considered, if applicable, for devices that include a coating which might pose a safety risk if inadvertently removed from the device.

— For coating integrity testing, representative sections of the coated device surface shall be examined under magnification (e.g. light microscopy, scanning electron microscopy) before and after simulated use to evaluate the amount of material that is removed during simulated use. Non-disruptive visualization enhancements (e.g. liquid dyes) may be used where appropriate.

— For particulate testing, particulate generated after simulated use shall be quantitatively characterized using appropriate means (e.g. light obscuration counting, scanning electron microscopy), across a range of equivalent spherical diameters determined by the manufacturer based on intended use and risk assessment.

Clinical use conditions or scientific justification shall be used to establish methods and criteria depending on device design, intended use, and risk analysis. Either test may be sufficient for lower risk application, while both tests may be applicable for high-risk applications.

NOTE AAMI TIR42 lists several examples of acceptable particulate generation measurement methods.

4.18 Distal tip stiffness testing to consider for neurovascular applications

Distal tip stiffness testing shall be considered for devices that are intended to be used in the neurovasculature, based on risk assessment.

Clinical use conditions or scientific justification shall be used to establish methods and criteria depending on device design, intended use, and risk analysis.

NOTE See Annex K for additional information.

5 Designation of nominal size

5.1 Nominal outside diameter

Unless otherwise specified in this document for a particular type of catheter, the outside diameter of the effective length shall be expressed as the nominal dimension in millimetres, rounded upwards to the nearest 0,01 mm or 0,1 mm.

For devices which 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.

5.2 Nominal inside diameter

For a neurovascular or coronary device intended to deliver other devices (not included with it), the inside diameter shall be expressed as the nominal dimension in mm, rounded downwards to the nearest 0,01 mm or 0,1 mm.

NOTE See Annex J for additional information.

5.3 Nominal effective length

The nominal effective length shall be expressed in millimetres for effective lengths of less than 100 mm.

The nominal effective length shall be expressed in millimetres or centimetres for effective lengths of 100 mm or more.

The tolerances to the effective length shall be determined by the manufacturer based on the intended use and risk assessment.

6 Information to be supplied with the catheter

6.1 General

The catheter shall be accompanied by information, including instruction for use, that is sufficient for its safe use, considering the training and knowledge of intended users and the intended use environment. All dimensions given shall be expressed in SI units of measurement. Units of measurement systems other than those specified should additionally be given if clinically relevant. See Annex H.

For neurovascular devices, additional units of measurement should be given as specified:

— For outside diameter: inches, and French;

— For inside diameter: inches;

— For sheath inside diameter: inches, and French.

Any markings needed for the safe use of the catheter shall be visible and legible. If required, this shall be assessed by the manufacturer based on the risk assessment.

Where appropriate, specific information to be supplied by the manufacturer should be selected from ISO 20417, and symbols should be selected from ISO 15223-1.

NOTE Labelling requirements specific to any country or region in which the device is intended to be sold can apply.

6.2 Marking on the device and/or primary packaging

The primary packaging is often transparent. Therefore, for the purposes of this subclause, the combination of marking of the device which is visible through the package and the primary packaging itself shall be considered.

The following information shall be specified on the first practical level in the following order: device, primary packaging, instructions for use:

a) name or trade name and address of the manufacturer and/or his authorized representative;

b) details strictly necessary to identify the device, including the nominal size as designated in Clause 5, and the contents of the packaging and, if applicable, the guidewire that is intended by the manufacturer for use with the catheter;

c) the word “STERILE” or the appropriate symbol in ISO 15223-1;

d) method of sterilization;

e) batch code, preceded by the word 'LOT', or the serial number or the appropriate symbol in ISO 15223-1;

f) an indication of the date by which the device should be used, in safety, expressed as, at a minimum, the year and month (e.g. as YYYY-MM);

g) an indication that the device is for single use;

h) any specific storage and/or handling requirements;

i) if the intended purpose of the device is not obvious to the user, the manufacturer shall clearly state it. Where a device is provided with separate instructions for use, this requirement may be omitted from the primary packaging;

j) where appropriate, an indication to consult the instructions for use;

k) for catheters without axial symmetry in their distal tips, or for catheters with atypical distal tip shapes, a depiction or description of the distal end configuration, if not identifiable through the package.

6.3 Instructions for use

When a separate instruction for use is provided, it shall at least contain information on the following:

a) the requirements in 6.2 with the exception of d), e), f), j) and k);

b) precautions to be taken and any warnings, e.g. to cleaning agents, if relevant;

c) if the device is intended to be connected to other devices or accessories in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices in order to obtain a safe combination;

d) description of additives or coatings, as well as any specific preparation, handling and/or disposal requirements due to the additives or coatings;

e) any unique requirements for disposal of device, taking into account item d) above;

f) if applicable, specific claims made because of the presence of an additive or coating, and as applicable:

   1) description of the additive or coating material,

   2) duration of effectiveness in use,

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

g) if applicable, known reactions between the catheter and magnetic resonance imaging (MRI);

h) date of issue or the latest revision of the instructions for use;

i) for devices indicated for power injection, the following information shall be included:

   1) recommended power injector pressure limit setting(s) based upon risk assessment;

   2) maximum recommended flow rates for clinically applicable viscosities and/or specific injectates;

   3) power injection flowrate test details including, at a minimum;

      i) extension tube length and internal diameter, if used;

      ii) any accessories that may limit flowrate;

      iii) injectate dynamic viscosity (mPa s);

      iv) injectate temperature expressed in °C.

6.4 Marking on the secondary packaging

Where devices are provided in secondary packaging, the marking on the secondary packaging shall be in accordance with 6.2, if appropriate.

Annex A
(normative)

Test method for corrosion resistance

A.1 Principles

The catheter is immersed in sodium chloride solution, then in boiling distilled 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 water [c(NaCl) = 0,15 mol/l].

A.2.2 Distilled or deionized water.

A.3 Apparatus

Corrosion resistant and temperature insensitive containers, e.g. borosilicate glass beakers.

A.4 Procedure

Immerse the catheter in the saline solution (A.2.1) in a container (A.3) at room temperature for 5 h. Remove the catheter and immerse it in boiling distilled water (A.2.2) for 30 min. Allow the water and the catheter to cool to 37 °C and maintain them at this temperature for 48 h. Remove the catheter and allow it to dry at room temperature. Disassemble catheters that have two or more components that are intended to be separable in use. Do not strip away or cut open any coatings on metallic components. Inspect the catheter visually for signs of corrosion.

A.5 Test report

The test report shall include at least the following information:

a) identity of the catheters;

b) a reference to this document (including its year of publication) and annex;

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

d) any deviations from the procedure;

e) the date of the test.

Annex B
(normative)

Method for determining peak tensile force

B.1 Principle

Test pieces or the entire 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 breaks or the junction separates. When testing hydratable catheters, both the pre- and post-hydration states shall be considered; a worst-case scenario shall be documented.

NOTE See Annex J for additional information.

B.2 Reagents

Aqueous medium, e.g. saline solution, water, etc.

B.3 Apparatus

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

B.4 Procedure

B.4.1 Where applicable, prepare the catheter in accordance with the instructions for use. Select a test piece or the entire length of the catheter to be tested. Include in the test piece the hub or connector, if present, and the junction between segments, e.g. between the tubing and the distal tip.

For hydratable catheters, prepare identical test pieces from two catheters. Condition one test piece in accordance with B.4.2 and test this piece immediately in accordance with B.4.3 to B.4.7. Do not condition the other test piece and test this piece immediately in accordance with B.4.3 to B.4.7.

For non-hydratable catheters, condition in accordance with B.4.2 and test the sample immediately in accordance with B.4.3 to B.4.7.

B.4.2 When the tested portion is intended to be inserted into the body, place the test pieces to be conditioned (see B.4.1) in an appropriate aqueous medium at (37 ± 2) °C for a minimum of 2 h or a shorter time upon appropriate clinical justification. Test in accordance with B.4.3 to B.4.7 immediately after conditioning to minimize temperature change.

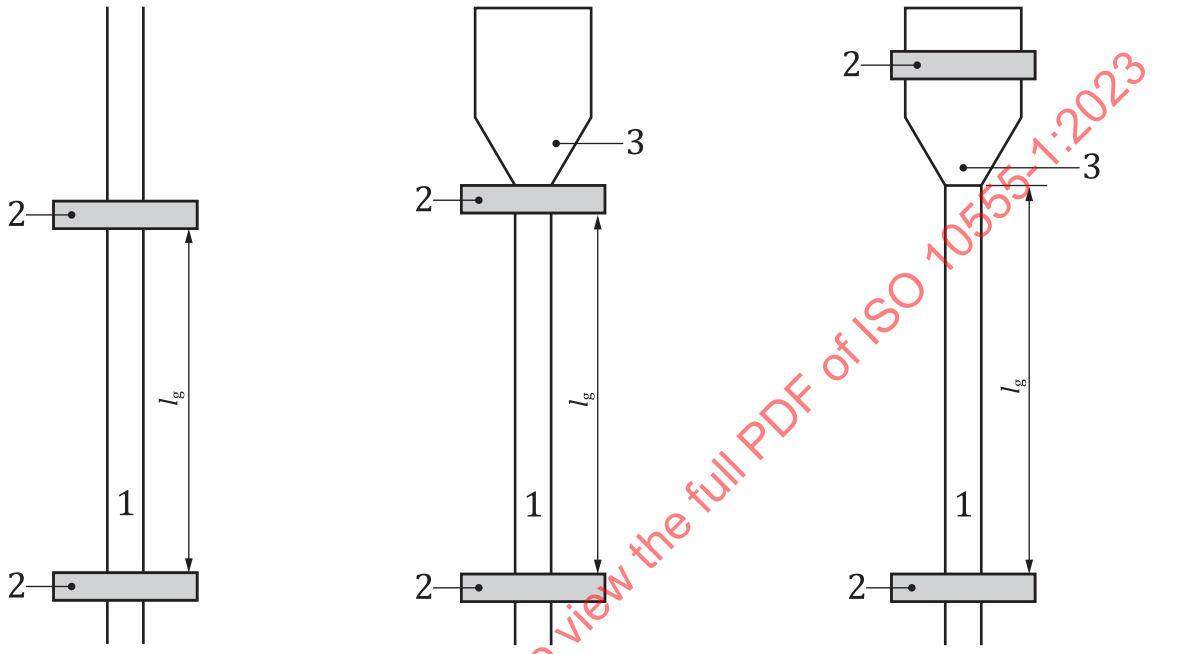
Junctions or extension tubing that are not intended to be inserted into the body do not need to be conditioned in aqueous medium. If the entire device is tested as one sample, only the portion of the sample meant to be inserted into the body shall be conditioned in aqueous medium.

B.4.3 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.

B.4.4 Measure the gauge length of the test piece. See Figure B.1.

If the test piece consists of two or more segments of significantly different tensile stiffness, the gauge length should be specified as the length of the material with the lowest stiffness, and the length of the stiffer segment between the grips should be minimized to the extent practicable.

For example, if the test piece consists of a low-stiffness polymer segment and one or more high-stiffness metal or rigid plastic segments, the gauge length would be the length of the low-stiffness polymer segment between the grips. See Figure B.1, c).



a) Tubing only **b) Clamp section contains only tubing** **c) Clamp section includes both hub and tubing**

Key

l_g gauge length
1 tubing
2 grip
3 hub/rigid material

Figure B.1 — Illustration of gauge length

B.4.5 Apply a tensile strain at a unit strain rate of 20 (mm/min)/mm of gauge length (see Table B.1) until the test piece separates into two or more pieces. Record 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.

If testing a catheter that consists of a single tubular portion having regions of different outside diameter, the test piece should include the smallest diameter.

B.4.6 If testing a catheter that has a sidearm or sidearms,

a) repeat B.4.3 to B.4.5 on each sidearm;

b) repeat B.4.3 to B.4.5 on a test piece that includes the junction between a sidearm and the adjacent part of that portion of the catheter intended to be introduced into the body;

c) repeat B.4.6 b) for each junction.

B.4.7 Do not perform more than one test on any test piece.

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

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

B.5 Test report

The test report shall include at least the following information:

a) identity of the catheters;

b) a reference to this document (including its year of publication) and annex;

c) the peak tensile force in newtons of each test piece;

d) the location(s) and type(s) of the failure of each test piece;

e) for variable data analysis, the maximum, minimum, mean and standard deviation of the peak tensile force, in newtons, of all tested samples;

f) any deviations from the procedure;

g) the date of the test.

Annex C
(normative)

Test method for liquid leakage under pressure

C.1 Principle

The catheter is connected, via a leakproof connection, to a pressure generating device. A hydraulic pressure is applied to the catheter and to the hub assembly, if present, and the catheter inspected for leakage. When testing hydratable catheters, both the pre- and post-hydration states shall be considered; a worst-case scenario shall be documented. For multi-lumen devices, each lumen subjected to liquid pressure during intended use shall be tested separately.

NOTE See Annex I for alternative test method.

C.2 Reagents

Distilled or deionized water.

C.3 Apparatus

C.3.1 Leak proof connector, to connect a catheter to a pressure generating device (C.3.3) and capable of at least 300 kPa.

C.3.2 Connector, to make leak proof connection between a pressure generating device (C.3.3) and catheters which do not have hubs.

C.3.3 Pressure generating device, e.g. a syringe, fitted with a gauge and capable of providing at least 300 kPa.

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

C.3.5 Timer, for measuring time with specified accuracy of at least ±1 s.

C.4 Procedure

C.4.1 When testing catheters which have a hub or hubs, if necessary, assemble detachable hubs in accordance with the instructions for use. Connect the hub to the pressure generating device (C.3.3) by means of a leak proof connector (C.3.1)

C.4.2 When testing catheters which do not have hubs, connect the catheter to the pressure generating device (C.3.3) by means of a connector (C.3.2).

C.4.3 Fill the pressure generating device (C.3.3) with water (C.2) at (22 ± 5) °C and expel the air. When testing multi-lumen catheters fill all lumen with water and leave open the hubs/connectors of the lumens not under test. Finally, occlude (C.3.4) the test specimen as near the distal end as possible.

C.4.4 Apply a minimum pressure of 300 kPa. Maintain the pressure for a minimum of 30 s while examining the hub/connection fitting assembly and any other part of the catheter for liquid leakage, i.e. the formation of one or more falling drops of water, and record whether or not leakage occurs.

C.4.5 For hydratable intravascular catheters, carry out the steps in C.4.1 to C.4.4, considering both pre- and post-hydration states.

C.5 Test report

The test report shall include at least the following information:

a) identity of the catheters;

b) a reference to this document (including its year of publication) and annex;

c) statement as to whether leakage occurred from the hub assemblies, if present, or catheter tubes and in the case of failures the locations of the leaks if they can be determined;

d) any deviations from the procedure;

e) the date of the test.

Annex D
(normative)

Test method for air leakage into hub assembly during aspiration

D.1 Principle

The hub(s) of the catheter is (are) connected to a partially filled syringe. A reduced pressure is applied to the interface of the hub and the syringe by withdrawing the syringe plunger, and visual inspection made for the ingress of air bubbles to the syringe. When testing hydratable catheters, both the pre- and post- hydration states shall be considered; a worst-case scenario shall be documented. The test shall be performed in elevation less than 570 metres or in a setting where pressure outside of the catheter is greater than 95 kPa.

NOTE See Annex J for additional information.

D.2 Reagents

De-aerated distilled water or de-aerated deionized water.

D.3 Apparatus

D.3.1 10 ml syringe, which has passed the tests for leakage past the piston and nozzle as specified in ISO 7886-1 or equivalent equipment.

D.3.2 Means for occluding test specimen, e.g. a clamp.

D.3.3 Timer, for measuring time with specified accuracy of at least ±1 s.

D.4 Procedure

D.4.1 Assemble detachable hubs in accordance with the instructions for use. Connect the hub to be tested to the syringe (D.3.1) to form a leak proof connection. Seal all valves that are intended to open during aspiration.

D.4.2 Draw into the syringe, through the test specimen, a volume of water (D.3.1) at (22 ± 5) °C exceeding 25 % of the graduated capacity of the syringe. Avoid wetting the hub/syringe union.

D.4.3 Expel the air from the apparatus except for a small air bubble. Adjust the volume of the water in the syringe to 25 % of the graduated capacity. Occlude (D.3.2) the test specimen as close as practicable to the hub.

D.4.4 With the nozzle of the syringe downward, withdraw the plunger to the maximum graduated capacity mark. Hold and maintain under vacuum until steady state is achieved with respect to bubble formation. Examine the syringe for a minimum of 10 s to ensure the catheter is not leaking by way of air ingress. Repeat, if needed, to ensure the catheter is not leaking.

D.4.5 For hydratable intravascular catheters, carry out the steps in D.4.1 to D.4.4 considering both pre- and post-hydration states.

NOTE Other means of creating the aspiration pressure could be used. In such case, set the aspiration pressure to a maximum of 2,67 kPa absolute.

D.5 Test report

The test report shall include at least the following information:

a) identity of the catheters;

b) a reference to this document (including its year of publication) and annex;

c) statement as to whether the samples passed or failed and in the case of failures the locations of the leaks if they can be determined;

d) any deviations from the procedure;

e) the date of the test.

Annex E
(normative)

Determination of flowrate through catheter

E.1 Principle

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

E.2 Reagents

Distilled or deionized water or other clinically relevant media.

E.3 Apparatus

E.3.1 **Constant-level tank**, fitted with a delivery tube and a leak-proof male 6 % (Luer) taper fitting, capable, when no test catheter is attached, of providing a flowrate 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 E.1.

E.3.2 **Equipment for collecting and determining the mass or volume of the catheter efflux** to an accuracy of ±1 %.

E.3.3 **Timer**, for measuring collection time with specified accuracy of at least ±1 s.

E.3.4 **A flowrate sensor** to an accuracy of ±5 % (alternative to the apparatus in E.3.2 and E.3.3).

E.4 Procedure

E.4.1 Supply the constant-level tank (E.3.1) with media (E.2) at (22 ± 5) °C. Fit the catheter to be tested to the male 6 % (Luer) taper fitting.

E.4.2 Start the media flowing through the catheter. Collect the efflux for a measured period of time (not less than 30 s) in a suitable vessel and determine its volume by means of a measuring cylinder or by weighing, taking into account the density of the media.

In case of using the flowrate sensor, measure the flowrate after a steady state is achieved.

E.4.3 Perform three determinations on each applicable catheter lumen.

E.5 Expression of results

Calculate the arithmetic average of the three determinations and express it as media flowrate through the catheter, in millilitres per minute. Round the calculated average media flowrate to the nearest whole number of millilitres per minute.

E.6 Test report

The test report shall include at least the following information:

a) identity of the catheters;

b) a reference to this document (including its year of publication) and annex;

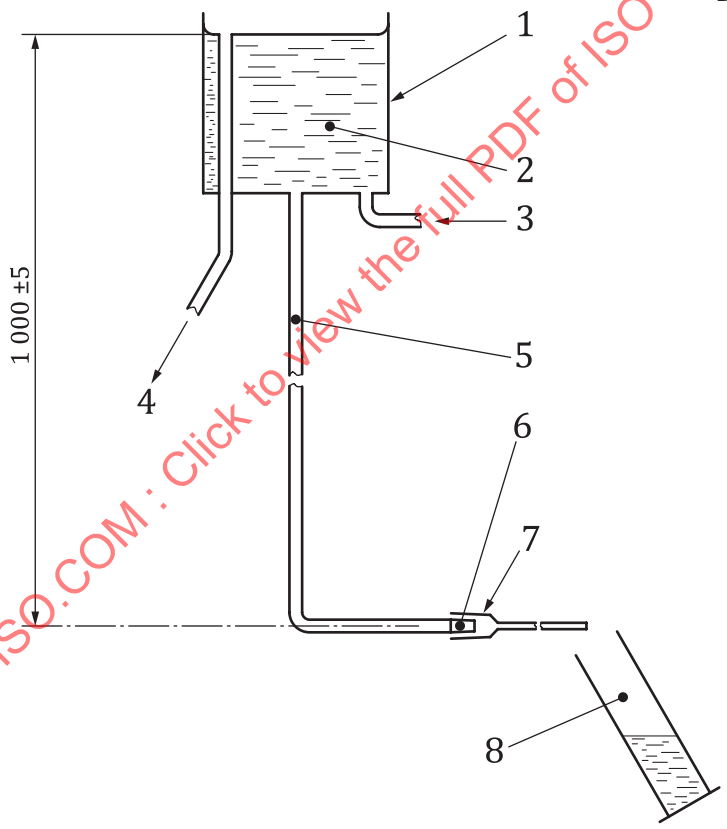
c) average flowrate of three determinations, expressed in millilitres per minute, for each applicable catheter lumen;

d) for variable data analysis, the maximum, minimum, mean and standard deviation of the average flow rate expressed in millilitres per minute, for each applicable catheter lumen, of all tested samples;

e) any deviations from the procedure;

f) the date of the test.

Dimensions in millimetres



Key

1 constant-level tank
2 distilled or deionized water
3 inlet
4 overflow
5 delivery tube
6 male 6 % (Luer) taper fitting
7 catheter under test
8 collecting/measuring vessel

Figure E.1 — Example of apparatus for determination of flowrate of water through catheter

Annex F
(normative)

Test for burst pressure under static conditions

F.1 Principle

The catheter is connected via its hub or proximal end to a pressure generating device. Fluid is applied at a constant rate until the catheter leaks or bursts while pressure is monitored. Maximum pressure achieved is recorded.

F.2 Apparatus

F.2.1 **Pressure generating device**, which supplies a liquid working fluid.

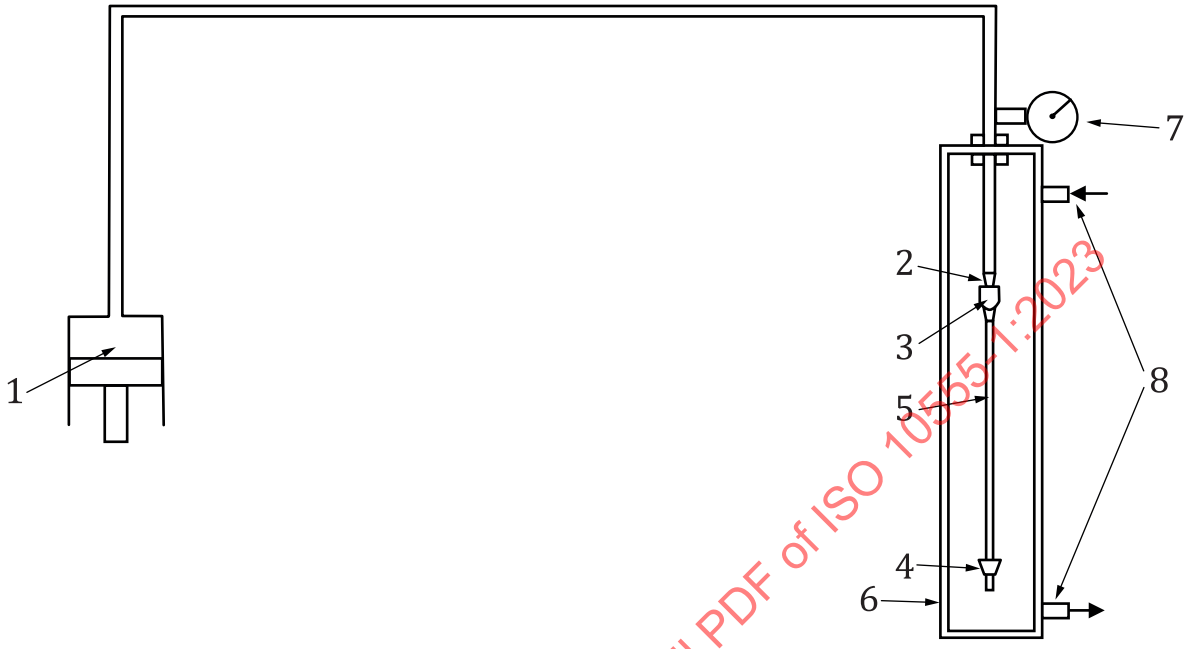
F.2.2 **Pressure gauge** (if not included in the pressure generating device, see F.2.1)

F.2.3 **Leak-proof connector**.

F.2.4 **Locking device**, for securing the connection between the catheter and the connector (F.2.3).

F.2.5 **Means of occluding the catheter**, for example a clamp.

F.2.6 Fluid-filled, temperature-controlled test chamber. The general arrangement of the apparatus is shown in Figure F.1. The apparatus for generating and controlling the fluid volume input is not shown in detail, as it can vary in design, complexity, and degree of automation.



Key

1 pressure generating device (F.2.1)
2 connector (F.2.3)
3 locking device (F.2.4)
4 clamp or plug (F.2.5) (positions may vary when zones are used)
5 catheter under test
6 example of fluid-filled temperature-controlled test chamber (F.2.6)
7 pressure gauge (F.2.2)
8 inlet and outlet ports for test chamber fluid circulation, if applicable

Figure F.1 — General arrangement of test apparatus for assessing high-pressure capability

F.3 Procedure

WARNING — It is essential that precautions and safeguards be taken to protect the test operator from the consequences of failure of the pressurized system and the resulting escape of liquid under high pressure.

F.3.1 Apply clinically relevant preconditions to the catheters under test. For example, saline pre-soak, exposure to common infusates, and/or transluminal delivery of any other devices.

F.3.2 Bring the test chamber fluid (F.2.6) to a temperature of (37 ± 2) °C and maintain this temperature throughout the test.

F.3.3 Attach the hub of the catheter to the connector (F.2.3), securing it with the locking device (F.2.4), if applicable.

F.3.4 Ensure all air is displaced from the catheter by the liquid, then occlude the catheter using the clamp (F.2.5). When testing the entire device, the clamp shall be placed at the distal end. When testing using zones, the clamp shall be placed at the distal end of the zone under test.

F.3.5 Examine the hydraulic circuit for integrity and freedom from leaks.

F.3.6 Immerse the catheter parts that are intended to be inserted into the body into the test chamber fluid for a minimum of 1 min prior to testing to allow thermal equilibrium.

F.3.7 The pressure generating device shall apply fluid to the catheter under test at a rate of 1 ml/s, or at the maximum intended power injection flowrate, whichever is smaller. The pressure generating device shall produce sufficient pressure to cause the catheter to leak or burst.

For alternative equipment, a pressure ramp rate shall be selected to control the testing apparatus that will allow to accurately detect a static burst pressure.

F.3.8 Inject fluid into the occluded catheter until the catheter leaks or bursts.

F.3.9 While the system is being pressurized, record at least the maximum pressure achieved.

F.3.10 Perform F.3.1 to F.3.9 for each applicable catheter lumen separately.

F.4 Test report

The test report shall include at least the following information:

a) identity of the tested catheters;

b) a reference to this document (including its year of publication) and annex;

c) description of pre-conditioning;

d) maximum pressure achieved of each catheter lumen tested, including zones as applicable;

e) location of leakage or burst of each catheter lumen tested;

f) for variable data analysis, the maximum, minimum, mean and standard deviation of the maximum pressure achieved, for each applicable catheter lumen, of all tested samples;

g) any deviations from the procedure;

h) the date of the test.

Annex G
(normative)

Power injection tests for flowrate and device pressure (only for products indicated for power injection)

G.1 General

This annex contains two test methods. Test A is covered by G.2 to G.5 and Test B is covered by G.6 to G.9.

G.2 Principle for Test A

The catheter is connected via its hub or proximal end to a real or simulated connector tube, which is in turn connected to a constant-pressure source, filled with an injectate, or simulated injectate. The source pressure is set to the product's recommended injector pressure limit, and the flowrate through the system is measured via mass balance or other suitable method. Peak pressure at the catheter inlet is also recorded via an inline pressure transducer.

NOTE See Annex J for additional information.

G.3 Apparatus for Test A

G.3.1 Constant-pressure source, which supplies a simulated injectate to the catheter and connector assembly while maintaining a clinically relevant pressure ±5 % and desired temperature ±2 °C throughout the measurement period.

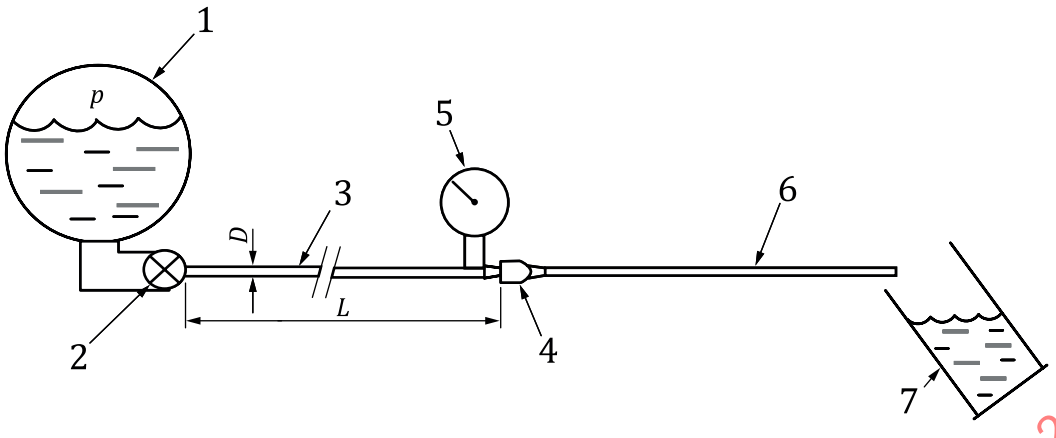
G.3.2 Injectate or simulated injectate (e.g. glycerine water mix or other), mixed to reproduce the dynamic viscosity (kinematic viscosity multiplied by fluid density) of the target injectate ±5 % (see ISO 3104 and ISO 3105).

G.3.3 Real or simulated connector tube, of clinically relevant internal diameter and length.

G.3.4 Inline pressure transducer and data logger, inserted between the distal end of the simulated connector tube and the hub of the catheter.

G.3.5 Means of measuring system flowrate with an accuracy of ±5 %, such as a mass balance and timer, a graduated cylinder and timer, or an inline flowmeter.

NOTE The general arrangement of the apparatus is shown in Figure G.1. The apparatus is not shown in detail, as it can vary in design, complexity, and degree of automation.



Key

1 example of a constant-pressure source of pressure p (G.3.1) filled with injectate (G.3.2)
2 valve for initiating and terminating flow
3 connector tube of length L and internal diameter D (G.3.3)
4 locking device for securing the proximal end of the catheter if applicable
5 inline pressure transducer and data logger (G.3.4)
6 catheter under test
7 example of flowrate measurement means (G.3.5)

Figure G.1 — General arrangement of test apparatus for Test A for assessing power-injection flowrate and device pressure

G.4 Test procedure for Test A

WARNING — It is essential that precautions and safeguards be taken to protect the test operator from the consequences of potential failure of the pressurized system and the resulting escape of fluid under high pressure.

G.4.1 Fill the pressure source reservoir and bring the fluid to the desired temperature.

G.4.2 Attach the connector tube and any infusion accessories to the pressure source.

G.4.3 Attach the inline pressure transducer to the distal end of the simulated connector tube.

G.4.4 Prepare the catheter as indicated in the instructions for use.

G.4.5 Attach the catheter hub to the inline pressure transducer.

G.4.6 Constrain the distal end of the catheter as needed to allow safe collection of the injectate.

G.4.7 Purge the system of all air.

G.4.8 Bring the pressure in the source to desired level.

G.4.9 Initiate flow through the system, allowing sufficient time for pressure and flow to reach a steady- state.

G.4.10 During injection, record the steady-state pressure achieved at the catheter inlet.

G.4.11 During injection, record the flowrate achieved:

a) if using a continuous flowrate measurement method, such as an inline flowmeter, record the steady-state flowrate;

b) if using a mass balance, collect the injectate over a period of time not less than 15 s, and determine its volume by means of weighing, using the density determined in G.3.2 in the calculations;

c) if using a graduated cylinder, collect the injectate over a period of time not less than 15 s, and measure the volume directly using the cylinder graduations.

G.4.12 Perform G.4.1 to G.4.11 for each applicable catheter lumen separately.

G.5 Test report for Test A

The test report shall include at least the following information:

a) identity of the tested catheter lumens;

b) a reference to this document (including its year of publication) and annex;

c) a reference to method chosen within Annex G (Test A);

d) description of injectate, including injectate dynamic viscosity (mPa s) and density (kg/m^3);

e) temperature of the test fluid in °C;

f) source pressure (Pa);

g) length (m) and internal diameter (mm) of the connector tubing, if used;

h) steady-state flowrate achieved through the system (ml/s) on each tested catheter lumen;

i) for variable data analysis, the maximum, minimum, mean and standard deviation of the pressure achieved at the catheter inlet (Pa);

j) any deviations from the procedure;

k) the date of the test.

G.6 Principle for Test B

The desired catheter lumen is connected via its hub or proximal end to a real or simulated connector tube, which is in turn connected to a constant-flowrate source, filled with an injectate, or simulated injectate. The source flowrate is set to the catheter lumen's recommended maximum power injection flowrate, and pressure is measured via pressure gauge at the catheter inlet. Trial runs and/or interpolation schemes may be used to arrive at the recommended maximum power injection flowrate prior to executing this test. A second pressure gauge at the source outlet may be used to aid in creating power injection maximum pressure recommendations, or source internal pressure-monitoring functions may be used for this same purpose.

NOTE See Annex J for additional information.

G.7 Apparatus for Test B

G.7.1 Constant-flowrate source, which supplies a simulated injectate to the catheter and connector-tube assembly while maintaining the desired flowrate ±10 % and desired temperature ±2 °C throughout the measurement period.

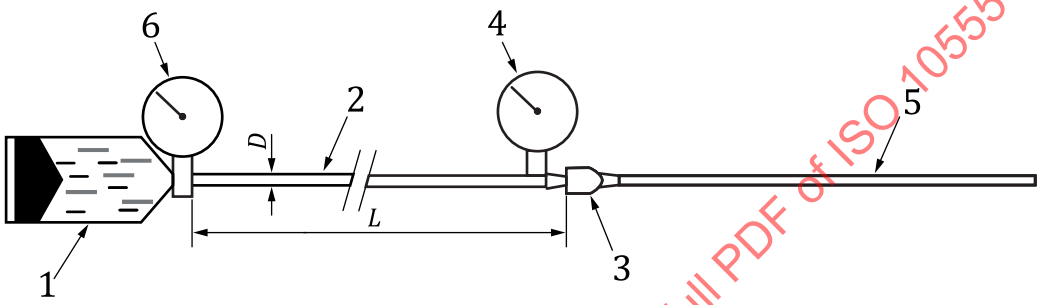
G.7.2 Injectate or simulated injectate (e.g. glycerine water mix or other) mixed to reproduce the dynamic viscosity (kinematic viscosity multiplied by fluid density) of the target injectate ±5 % (see ISO 3104, ISO 3105).

G.7.3 Real or simulated connector tube of clinically relevant internal diameter and length.

G.7.4 An inline pressure transducer and data logger inserted between the distal end of the simulated connector tube, and the hub of the catheter.

G.7.5 An optional inline pressure transducer and data logger inserted between the distal end of the constant-flowrate source and the simulated connector tube.

NOTE The general arrangement of the apparatus is shown in Figure G.2. The apparatus is not shown in detail, as it can vary in design, complexity, and degree of automation.



Key

1 example of a constant-flowrate source (G.7.1) filled with injectate (G.7.2)
2 connector tube of length *L* and internal diameter *D* (G.7.3)
3 locking device for securing the proximal end of the catheter if applicable
4 inline pressure transducer and data logger (G.7.4)
5 catheter under test
6 optional inline pressure transducer and data logger (G.7.5)

Figure G.2 — General arrangement of test apparatus for Test B for assessing power-injection flowrate and device pressure

G.8 Test procedure for Test B

WARNING — It is essential that precautions and safeguards be taken to protect the test operator from the consequences of potential failure of the pressurized system and the resulting escape of fluid under high pressure.

G.8.1 Fill the constant-flowrate source and bring the fluid to the desired temperature.

G.8.2 Attach the connector tube and any infusion accessories to the constant-flowrate source.

G.8.3 Attach the inline pressure transducer to the distal end of the simulated connector tube.

G.8.4 Prepare the catheter as indicated in the instructions for use.

G.8.5 Attach the hub of the desired catheter lumen to the inline pressure transducer.

G.8.6 Constrain the distal end of the catheter as needed.

G.8.7 Set the system flowrate to the recommended maximum power injection flowrate for the lumen under test.

G.8.8 Purge the system of all air.

G.8.9 Initiate flow through the system, allowing sufficient time for catheter inlet pressure to reach its maximum pressure.

G.8.10 During injection, record the maximum pressure achieved at the catheter inlet.

G.8.11 During injection, the maximum pressure at the constant-flowrate source outlet may be recorded and used to aid in creating power injector maximum pressure recommendations.

G.9 Test report for Test B

The test report shall include at least the following information:

a) identity of the tested catheter lumens;

b) reference to this document (including its year of publication) and annex;

c) a reference to test method chosen within Annex G (Test B);

d) tested flowrate (ml/s);

e) description of injectate, including injectate dynamic viscosity (mPa s);

f) temperature of the injectate (°C);

g) length (m) and internal diameter (mm) of the connector tubing;

h) maximum pressure measured at the inlet of each catheter lumen tested (Pa);

i) for variable data analysis, the maximum, minimum, mean and standard deviation of the pressure achieved at the catheter inlet (Pa);

j) the maximum pressure measured at the constant-flowrate source outlet, if desired;

k) any deviations from the procedure;

l) the date of the test.

Annex H
(informative)

Units of measurement systems other than those specified in this document

H.1 General

The Seldinger technique is a method of percutaneous insertion of a catheter into a blood vessel or space, such as an abscess cavity. A needle is used to puncture the structure and a guidewire is threaded through the needle. When the needle is withdrawn, a catheter is threaded over the guidewire and the guidewire is then withdrawn, leaving the catheter inserted.

The following units of measure are used to designate the nominal size of needles, guidewires and catheters.

H.2 Conversion between French, inches and millimetres

A nominal dimensional identification of the outer size of diameter of a catheter; calculated as three times the outer size of diameter (in millimetres): Fr = 3 × *D* (mm). French can be abbreviated as F, FR, Fr, FG (French gauge), Fg (French gauge), CH (Charrière), or Ch (Charrière). See Table H.1.

Table H.1 — French size conversion table

French	Diameter mm	Diameter in
1	0,33	0,013
2	0,67	0,026
3	1,00	0,039
4	1,33	0,052
5	1,67	0,066
6	2,00	0,079
7	2,33	0,092
8	2,67	0,105
9	3,00	0,118
10	3,33	0,131
11	3,67	0,144
12	4,00	0,157
13	4,33	0,171
14	4,67	0,184
15	5,00	0,197
16	5,33	0,210
17	5,67	0,223
18	6,00	0,236
19	6,33	0,249
20	6,67	0,262
21	7,00	0,276

Table H.1 *(continued)*

French	Diameter mm	Diameter in
22	7,33	0,289
23	7,67	0,302
24	8,00	0,315
25	8,33	0,328
26	8,67	0,341
27	9,00	0,354
28	9,33	0,367
29	9,67	0,381
30	10,00	0,394
31	10,33	0,407
32	10,67	0,420
33	11,00	0,433
34	11,33	0,446

H.3 Thousandths of an inch

The nominal size of a guidewire with which a catheter is compatible is often expressed in thousandths of an inch.

H.4 Needle gauge

It represents the outer diameter of needles. Larger gauge numbers refer to smaller diameter needle.

NOTE See ISO 9626:2016, Table 1 for needle gauge dimensions.

Annex I
(normative)

Test method for air leakage under water

I.1 Principle

The catheter is connected, via a leakproof connection, to a pressure generating device. Air pressure is applied to the catheter and to the hub assembly, if present, and the catheter is inspected for leakage under water. No air bubbles shall be released from the catheter.

When testing hydratable catheters, both the pre- and post- hydration states shall be considered, a worse- case scenario shall be documented. For multi-lumen devices, each lumen subjected to liquid pressure during intended use shall be tested separately.

NOTE See Annex J for additional information.

I.2 Reagents

I.2.1 Compressed air.

I.2.2 Distilled or deionized water.

I.3 Apparatus

I.3.1 Leak proof connector, to connect a catheter to a pressure generating device (I.3.3) and capable of at least 300 kPa.

I.3.2 Connector, to make a leak proof connection between a pressure generating device (I.3.3) and catheters which do not have hubs.

I.3.3 Pressure generating device, e.g. syringe or compressed air test system with a pressure regulator (capable of measuring the desired pressure, with a min. accuracy: ±2,5 %).

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

I.3.5 Water bath, filled with distilled or deionized water (water temperature 22 °C ± 5 °C).

I.3.6 Timer, for measuring time with specified accuracy of at least ±1 s.

I.4 Procedure

I.4.1 When testing catheters which have a hub or hubs, if necessary, assemble detachable hubs in accordance with the instructions for use. Connect the hub to the pressure generating device (I.3.3) by means of a leak proof connector (I.3.1). When testing multi-lumen devices, leave open the lumens not under test.

I.4.2 When testing catheters which do not have hubs, connect the catheter to the pressure generating device (I.3.3) by means of a connector (I.3.2).

I.4.3 Prepare the water bath (I.3.5).

I.4.4 Occlude (I.3.4) the test specimen as near the distal end as possible.

I.4.5 Immerse the test specimen completely under water to a maximum depth of 20 cm.

I.4.6 Apply a minimum air pressure of 300 kPa. Maintain the pressure for a minimum of 30 s while examining the hub/connection fitting assembly and any other part of the catheter for air leakage, i.e. release of air bubbles from the test specimen. Record whether or not leakage occurs.

I.4.7 For hydratable intravascular catheters, carry out the steps in I.4.1 to I.4.7 considering both pre- and post-hydration states.

I.5 Test report

The test report shall include at least the following information:

a) identity of the catheters;

b) a reference to this document (including its year of publication) and annex;

c) statement as to whether leakage occurred from the hub assembly, if present, or catheter tube and in the case of failures the location of the leakage if it can be determined (considering both pre- and post-hydration states for hydratable intravascular catheters);

d) any deviations from the procedure;

e) the date of the test.

Annex J
(informative)

Rationale and guidance

This annex provides a rationale for some requirements of this document.