INTERNATIONAL STANDARD

**ISO 10555-1**

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# Intravascular catheters — Sterile and single-use catheters —

## Part 1: General requirements

*Cathéters intravasculaires — Cathéters stériles et non réutilisables —*

*Partie 1: Exigences générales*

Reference number
ISO 10555-1:2014(E)

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 10555-1 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

This second edition cancels and replaces the first edition (ISO 10555-1:1995), which has been technically revised. It also incorporates the amendments ISO 10555-1:1995/Amd 1:1999 and ISO 10555-1:1995/Amd 2:2004.

ISO 10555 consists of the following parts, under the general title *Intravascular catheters — Sterile and single-use catheters*:

— *Part 1: General requirements*

— *Part 3: Central venous catheters*

— *Part 4: Balloon dilatation catheters*

— *Part 5: Over-needle peripheral catheters*

The following part is under preparation:

— *Part 6: Subcutaneous implanted ports*

The following part has been withdrawn and the content has been included in ISO 10555-1:

— *Part 2: Angiographic catheters*

Attention is drawn to ISO 11070, which specifies requirements for accessory devices for use with intravascular catheters.

This corrected version of ISO 10555-1:2013 incorporates an editorial correction in H.3.

# Intravascular catheters — Sterile and single-use catheters —

# Part 1: General requirements

## 1 Scope

This part of ISO 10555 specifies general requirements for intravascular catheters, supplied in the sterile condition and intended for single use, for any application.

lt is not applicable to intravascular catheter accessories, e.g. those covered by ISO 11070.

## 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for 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*[1)]

ISO 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*[1)]

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

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

## 3 Terms and definitions

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

**3.1**
**intravascular catheter**
tubular device, single or multilumen, designed to be partially or totally inserted or implanted into the cardiovascular 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 cardiovascular system and the placement and anchoring of the distal tip in the chosen location

1) Upon its publication, ISO 80369-7 will replace ISO 594-1 and ISO 594-2.

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

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

**3.6**
**effective length**
*l*
length of the catheter, or pre- and post-hydration lengths of hydratable catheters that can be inserted into the body

SEE: Figure 1.

**3.7**
**outside diameter**
largest diameter of the catheter or pre- and post-hydration largest diameters of hydratable catheters that can be inserted into the vessel

**3.8**
**junction**
the joining of one tube or more tubes, where the assembly of the tubes provide mechanical support in tension/compression during clinical use

**3.9**
**hydratable intravascular catheter**
intravascular catheter consisting of a material that manifests clinically significant hydration when subjected to an aqueous medium

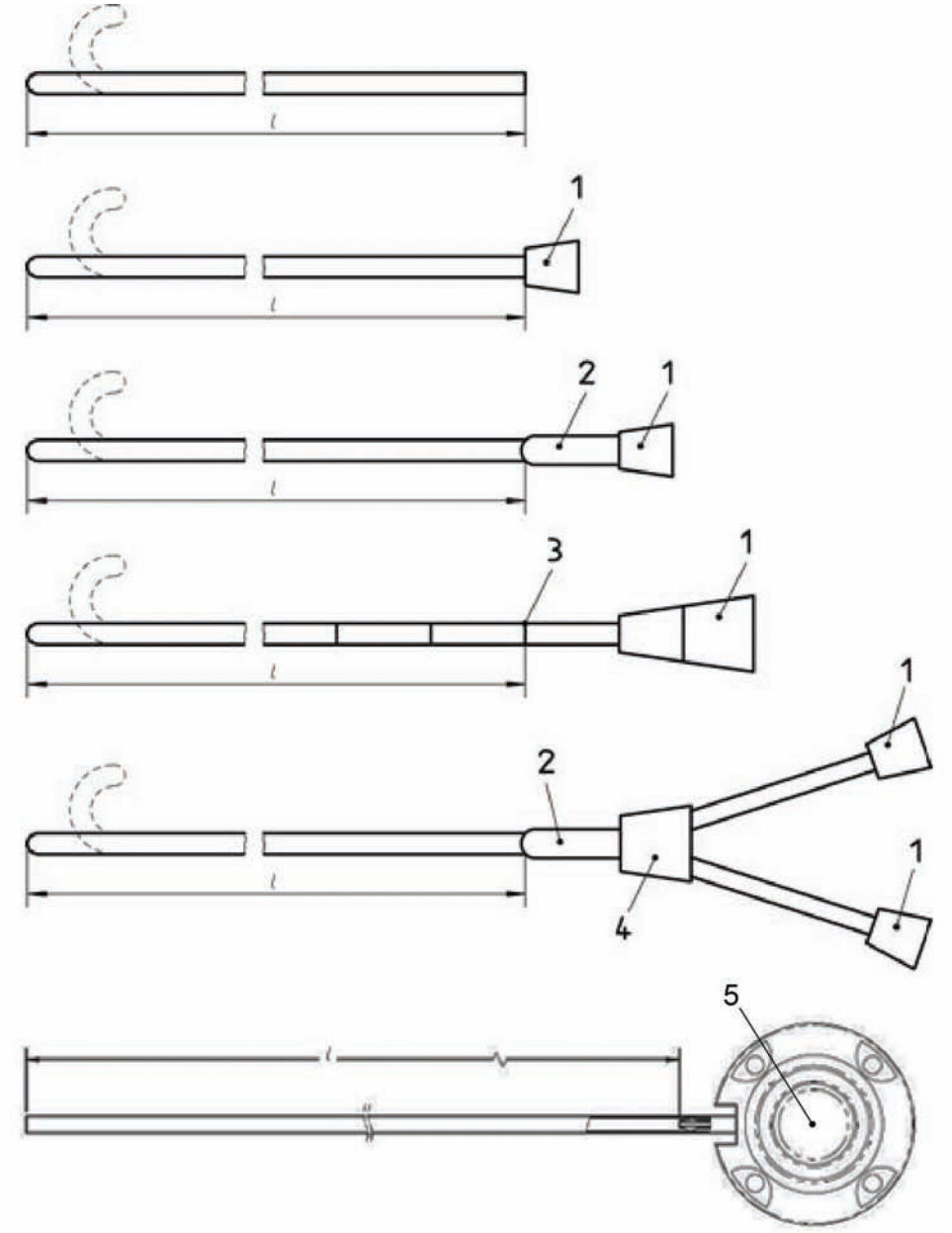
**3.10**
**post-hydration**
state of a hydratable intravascular catheter after immersion in aqueous medium at (37 ± 2) °C for a clinically appropriate period of time

**3.11**
**clinically significant hydration**
hydrated state in which either the post-hydration effective length is greater than the pre-hydration effective length by more than 1 % of the effective length, or the post-hydration outside diameter is greater than the pre-hydration outside diameter by 10 % or more

**3.12**
**power injection**
rapid injection of fluid at high pressure

**3.13**
**primary packaging**
packaging which has direct contact with the device and/or maintains the sterility of the product

**3.14**
**secondary packaging**
packaging designed to contain one or more primary packages




**Key**

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

**Figure 1 — Examples of effective length of catheters**

**3.15**
**angiographic catheter**
intravascular catheter used for the injection of contrast media and/or fluids and which may be used for pressure measurements and to obtain blood samples or insertion of coaxial inner catheter, occlusion coils or other devices

# 4 Requirements

## 4.1 General

The catheter shall have been sterilized by an appropriate validated method, and shall comply with 4.2 to 4.8 in the sterile condition.

## 4.2 Radio-detectability

Parts of the catheter shall be radio-detectable if required as determined by the risk assessment.

Compliance should be demonstrated by an appropriate test method, such as ASTM F640-12 or DIN 13273-7.

## 4.3 Biocompatibility

The catheter shall be free from biological hazard.

NOTE See ISO 10993-1 for the selection of appropriate test methods.

## 4.4 Surface

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

The external surface of the effective length of the catheter, including the distal end, shall be free from process and surface defects which could cause trauma to vessels during use.

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.

## 4.5 Corrosion resistance

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

## 4.6 Peak tensile force

When tested in accordance with the method given in Annex B, the peak tensile force of each test piece shall be as given in Table 1.

**Table 1 — Peak tensile force of catheter test pieces**

| Smallest outside diameter of tubular portion of test piece<br>mm | Minimum peak tensile force<br>*N* |
|---|---|
| ≥ 0,55 < 0,75 | 3 |
| ≥ 0,75 < 1,15 | 5 |
| ≥ 1,15 < 1,85 | 10 |
| ≥ 1,85 | 15 |
| NOTE This part of ISO 10555 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) or for a distal tip and its junction to the shaft tube. These values should be determined by the manufacturer based on risk assessment. | |

### 4.7 Freedom from leakage

**4.7.1** 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.

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

**4.7.2** 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.

### 4.8 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 594-1 and ISO 594-2.

### 4.9 Flowrate

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

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

### 4.10 Power injection

If the catheter is indicated for power injection, the catheter burst pressure shall exceed the peak pressure present in the catheter at maximum flow conditions as determined by Annexes F and G.

### 4.11 Side holes

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

### 4.12 Distal tip

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

## 5 Designation of nominal size

The nominal size of the catheter shall be designated as specified in 5.1 and 5.2.

### 5.1 Outside diameter

Unless otherwise specified in one other part of this International Standard for a particular type of catheter, the outside diameter 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 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.

NOTE Tolerances to the effective length are not specified.

## 6 Information to be supplied by the manufacturer

### 6.1 General

Each device shall be accompanied by the information needed to use it safely and properly. All dimensions given shall be expressed in SI units of measurement.

Units of measurement systems other than those specified may additionally be used.

Where appropriate, ISO 15223-1 should be used.

### 6.2 Marking on the device and/or primary packaging

NOTE 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 are to be considered.

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

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

b) the 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) the method of sterilization;

e) the 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 special storage and/or handling conditions;

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 angiographic catheters, 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 details referred to in 6.2 with the exception of d) 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;

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

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

   — description of the additive or coating material,

   — duration of effectiveness in use,

   — 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:

   — recommended power injector pressure limit setting(s);

   — maximum flow rates for a range of clinically applicable viscocities and/or specific injectates.

## 6.4 Marking on the secondary packaging

Where devices are provided in secondary packaging, the marking on the secondary packaging shall include the details referred to in 6.2, if appropriate.

# Annex A
(normative)

# Test method for corrosion resistance

## A.1 Principle

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

**A.3.1 Borosilicate glass beakers**.

## A.4 Procedure

Immerse the catheter in the saline solution (A.2.1) in a glass beaker (A.3.1) at room temperature for 5 h. Remove the test specimen and immerse it in boiling distilled water (A.2.2) for 30 min. Allow the water and the test specimen to cool to 37° C, and maintain them at this temperature for 48 h. Remove the test specimen and allow it to dry at room temperature. 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.

## A.5 Test report

The test report shall include the following information:

a) identity of the catheter;

b) statement as to whether corrosion occurred during 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 at a minimum.

## B.2 Apparatus

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

## B.3 Procedure

**B.3.1** Assemble the catheter in accordance with the manufacturer's instructions. Select a test piece from 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. Exclude distal tips of lengths less than 3 mm from the test piece.

For hydratable catheters, prepare identical test pieces from two catheters. Condition one test piece in accordance with B.3.2. Do not condition the other test piece; test it immediately in accordance with B.3.3 to B.3.8.

**B.3.2** Place the test pieces to be conditioned (see B.3.1) in appropriate aqueous medium at (37 ± 2) °C for a clinically appropriate period of time. Test in accordance with B.3.3 to B.3.8 immediately after conditioning.

**B.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.

**B.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.

**B.3.5** 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. 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.

**B.3.6** 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.3.7** If testing a catheter that has a sidearm or sidearms,

a) repeat B.3.2 to B.3.5 on each sidearm;

b) repeat B.3.2 to B.3.5 on a test piece that includes the joint between a sidearm and the adjacent part of that portion of the catheter intended to be introduced into the body;

c) repeat B.3.7 b) for each joint.

**B.3.8** 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<br>mm | Test speed<br>mm/min |
|---|---|
| 10 | 200 |
| 20 | 400 |
| 25 | 500 |

## B.4 Test report

The test report shall include the following information:

a) identity of the catheter;

b) the peak tensile force, in newtons;

c) the location of the failure.

# Annex C
(normative)

# Test method for liquid leakage under pressure

## C.1 Principle

The catheter is connected, via a leakproof connection, to a syringe or pressure apparatus. A hydraulic pressure is applied to the catheter and to the hub assembly, if present, and the catheter tube inspected for leakage. When testing hydratable catheters, both the pre- and post-hydration states shall be considered; a worst case scenario shall be documented at a minimum.

## C.2 Reagent

**C.2.1 Distilled or deionized water**.

## C.3 Apparatus

**C.3.1 Leak proof connector**, to connect catheter 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 which do not have hubs.

**C.3.3 Syringe** of suitable size, which has passed the tests for leakage past the piston and nozzle as specified in ISO 7886-1 or equivalent equipment.

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

## C.4 Procedure

**C.4.1** When testing catheters which 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.3.2) to form a leak proof connection.

**C.4.2** When testing catheters which 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) at (22 ± 5) °C and expel the air. Adjust the volume of water in the syringe to the nominal graduated capacity. Occlude (C.3.4) the test specimen as near 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 catheter tube 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 the following information:

a) identity of the catheter;

b) statement as to whether leakage occurred from the hub assembly, if present, or catheter tube (considering both pre- and post-hydration states for hydratable intravascular catheters).

# 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 reference fitting 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 at a minimum.

## D.2 Reagent

**D.2.1** **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.4 Procedure

**D.4.1** Assemble detachable hubs in accordance with the manufacturer's instructions. 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 and reference fitting, a volume of water (D.2) at (22 ± 5) °C exceeding 25 % of the graduated capacity of the syringe. Avoid wetting the hub/reference fitting 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 for sufficient time that no bubbles are forming and wait an additional 10 s to ensure the sample 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 the aspiration pressure is set to 2,67 kPa absolute.

## D.5 Test report

The test report shall include the following information:

a) identity of the catheter;

b) statement as to whether the sample passed or failed and in the case of failure the location of the leakage if it can be determined (considering both pre- and post-hydration states for hydratable intravascular catheters).

# 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 Reagent

**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 male 6 % (Luer) taper fitting complying with ISO 594-1, 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.

## E.4 Procedure

**E.4.1** Supply the constant-level tank (E.3.1) with media at (22 ± 2) °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.

**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.

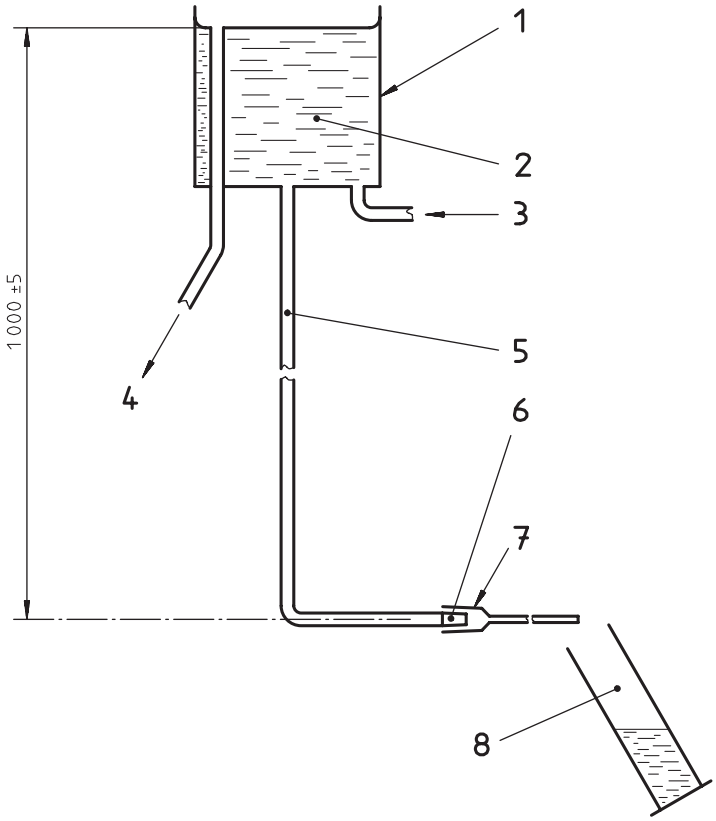
## E.6 Test report

The test report shall include the following information:

a) identity of the catheter;

b) average flowrate, expressed in millilitres per minute, for each applicable catheter lumen.

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 product leak or burst while device pressure is monitored. Peak pressure is recorded.

## F.2 Apparatus

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

**F.2.2** **Leak-proof connector**.

**F.2.3** **Locking device**, for securing the catheter to the connector (F.2.2).

**F.2.4** **Means of occluding the catheter**, for example a clamp.

**F.2.5** **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 may vary in design, complexity and degree of automation.

## 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, or sterilization cycles.

**F.3.2** Bring the test chamber fluid (F.2.5) 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.2.2), securing it with the locking device (F.2.3) if applicable.

**F.3.4** Ensure all air is displaced from the catheter by the liquid, then occlude the catheter using the clamp (F.2.4).

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

**F.3.6** Immerse the catheter in the circulating test chamber fluid for a minimum of 1 min prior to testing to allow thermal equilibrium.

**F.3.7** Adjust the hydraulic volume source to apply fluid to the catheter under test at a rate of 1 ml/s, producing sufficient pressure to cause the catheter to leak or rupture.

For alternative equipment the manufacturer should select a pressure ramp rate to control the testing apparatus that will allow them to accurately detect a static burst pressure.

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

**F.3.9** While the system is being pressurized, record pressure at the hub of the device, noting the maximum pressure achieved.

## F.4 Test report

The test report shall include the following information:

a) identity of the tested catheters;

b) burst pressure values;

c) location of leakage or rupture of each catheter tested.


**Key**

1 pressure generating device source
2 connector (F.2.2)
3 locking device (F.2.3)
4 clamp or plug (F.2.4)
5 catheter under test
6 example of fluid-filled temperature-controlled test chamber
7 pressure sensor and logger
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**

# Annex G
(normative)

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

## G.1 Principle

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.

## G.2 Apparatus

**G.2.1 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.2.2 Injectate or simulated injectate** (e.g. glycerine water mix or other) mixed to reproduce the dynamic viscosity (kinematic viscosity/fluid density) of the target injectate ± 5 % (see ISO 3104 and ISO 3105).

**G.2.3 Real or simulated connector tube** of clinically relevant internal diameter and length.

**G.2.4 Inline pressure transducer and data logger** inserted between the distal end of the simulated connector tube, and the hub of the catheter.

**G.2.5 Means of measuring system flowrate** with an accuracy of ± 2 %, such as a mass balance 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.

## G.3 Test procedure

**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.3.1** Fill the pressure source reservoir and bring the fluid to the desired temperature.

**G.3.2** Attach the connector tube to the pressure source.

**G.3.3** Attach the inline pressure transducer to the distal end of the simulated connector tube.

**G.3.4** Prepare the catheter as indicated in instructions for use.

**G.3.5** Attach the catheter hub to the inline pressure transducer.

**G.3.6** Constrain the distal end of the catheter as needed to allow safe collection of the injectate.

**G.3.7** Purge the system of all air.

**G.3.8** Bring the pressure in the source to desired level.

**G.3.9** Initiate flow through the system, allowing sufficient time for pressure and flow to reach a steady-state.

**G.3.10** During injection, record the steady-state pressure achieved at the catheter inlet.

**G.3.11** During injection, record the flowrate achieved:

a) If using continuous monitoring flowrate measurement methods, record the steady-state flowrate.

b) If using mass balance, collect the injectate over a period of time not less than 15 s, and determine its volume by means of a measuring cylinder or by weighing, using the density measured in G.2.2 in the calculations.

## G.4 Test report

The test report shall include the following information:

a) identity of the tested catheters;

b) description of injectate, and measured injectate dynamic viscosity (mPa s) and density ($kg/m^3$);

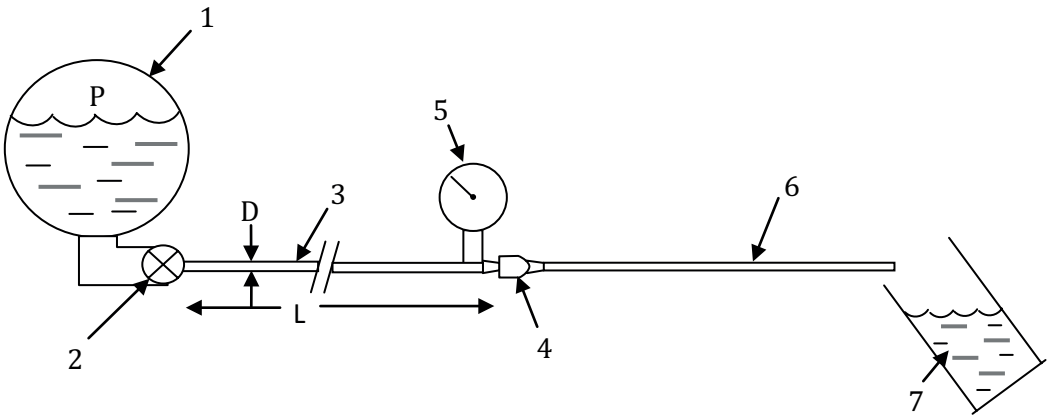
c) temperature of the test fluid in °C;

d) source pressure (Pa);

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

f) steady-state flowrate achieved through the system (ml/s);

g) pressure achieved at the catheter inlet (Pa).




**Key**

1 example of a constant-pressure source of pressure P (G.2.1) filled with injectate (G.2.2)
2 valve for initiating and terminating flow
3 connector tube of length L and internal diameter D (G.2.3)
4 locking device for securing the proximal end of the catheter if applicable
5 inline pressure transducer and data logger (G.2.4)
6 catheter under test
7 example of flowrate measurement means (G.2.5)

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

# Annex H
(informative)

# Units of measurement systems other than those specified in this part of ISO 10555, which may additionally be used

## 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 French

A nominal dimensional identification of the outer size of diameter of a catheter; calculated as three times the outer size of diameter (in millimeters): Fr = 3 × $D$(mm). French may be abbreviated as F, FR, Fr, Fg, CH, or Ch.

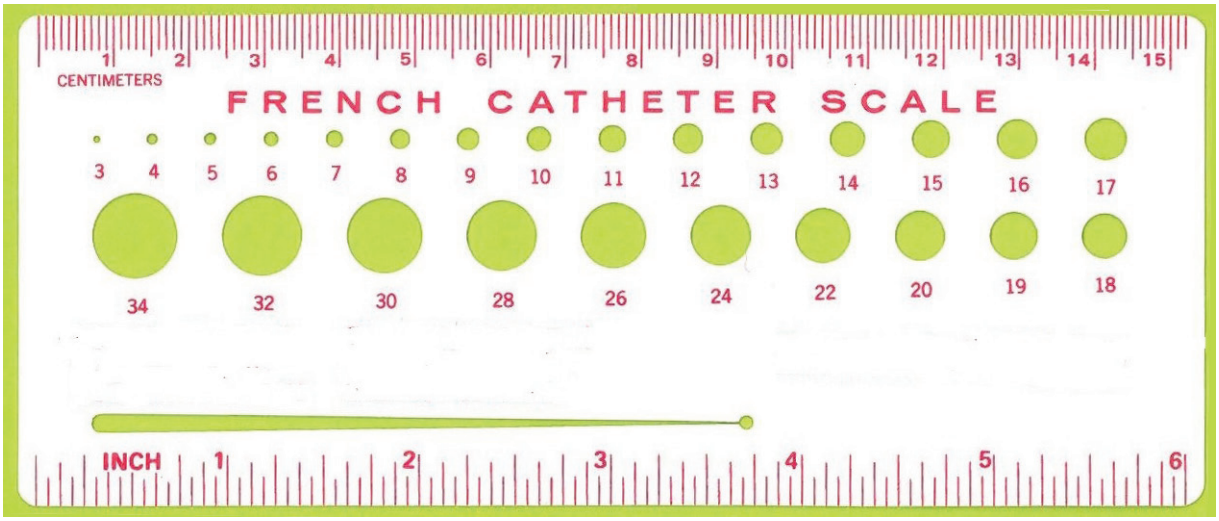
## H.3 Thousandths of an inch

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

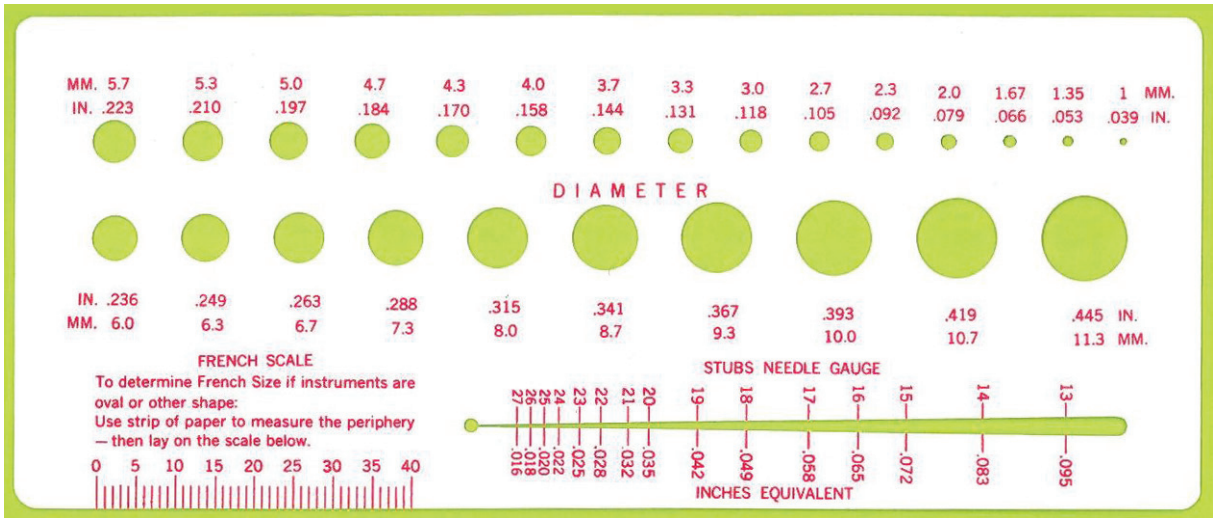
## H.4 Needle gauge

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

## H.5 Example of a French scale




**a) French scale front (not to scale)**




**b) French scale back**

**Figure H.1 — French scale**

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2) Under preparation.

3) Under preparation.

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