INTERNATIONAL STANDARD

ISO 20696

First edition
2018-06

Corrected version
2019-12

Sterile urethral catheters for single use

Sondes urinaires stériles non réutilisables

Reference number
ISO 20696:2018(E)

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Published in Switzerland

Contents

Page

Foreword

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

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

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

This document is based on EN 1616, *Sterile urethral catheters for single use*.

This corrected version of ISO 20696:2018 incorporates the following corrections:

— in Figure A.1, key items 1 and 2 were inverted.

Introduction

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

Sterile urethral catheters for single use

1 Scope

This document specifies requirements and test methods for sterile urethral catheters for single use, with or without a balloon.

This document does not include drainage catheters covered by ISO 20697, e.g. ureteral catheters, nephrostomy catheters, and suprapubic catheters. This document also excludes ureteral stents.

NOTE Ureteral stents are covered in ASTM F1828-97.

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 14971:—[1)], *Medical devices — Application of risk management to medical devices*

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

ISO 80369-1, *Small bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

3 Terms and definitions

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

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

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

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

3.1
balloon capacity
volume of liquid to be introduced into the catheter in order to fill the inflation channel and inflate the balloon

3.2
coating
substance applied to the surface of the catheter

3.3
compliant balloon
balloon that continues to expand in size as internal pressure increases

3.4
effective length
L_1
length of the catheter that can be inserted into the body

1) To be published (revises ISO 14971:2007). Stage at time of publication ISO/DIS 14971:2018.

3.5
effective shaft length
L_3
length of non-perforated portion of the catheter excluding the tip, balloon(s), *funnel(s)* (3.6), protective sleeves and/or access port(s)

3.6
funnel
proximal portion of the catheter, which may be connected to a drainage system

Note 1 to entry: See Figures J.1 and J.2.

3.7
intermittent
intended to be removed immediately after emptying the bladder

3.8
non-compliant balloon
balloon that expands to one specific size or size range, even as internal pressure increases

3.9
outer diameter
maximum dimension measured across the cylindrical portion of the shaft

3.10
overall length
L_2
total length from the tip of the catheter to the end of the *funnel* (3.6)

3.11
risk
combination of the probability of occurrence of harm and the severity of that harm

[SOURCE: ISO 14971:—, 3.18]

3.12
risk analysis
systematic use of available information to identify hazards and to estimate the *risk* (3.11)

[SOURCE: ISO 14971:—, 3.19]

3.13
risk assessment
overall process comprising a *risk analysis* (3.12) and a risk evaluation

[SOURCE: ISO 14971:—, 3.20]

3.14
risk management file
set of records and other documents that are produced by risk management

[SOURCE: ISO 14971:—, 3.25]

3.15
urethral catheter
tubular device intended for being introduced into the urinary bladder through the urethra in order to provide drainage, drug delivery and/or flushing of the bladder

4 Intended performance

The urethral catheter shall demonstrate the ability to accurately and safely access the intended location. The urethral catheter shall demonstrate the ability to drain urine.

5 General requirements

5.1 Risk management

An established risk management process shall be applied to the design of the device.

Compliance shall be checked by inspection of the risk management file verifying compliance to ISO 14971.

5.2 Biocompatibility

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

5.3 Detectability

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

NOTE Such as ASTM F640 or DIN 13273-7.

5.4 Surface finish

When examined by normal or corrected to normal vision, the external surface of the effective length of the catheter shall appear free from:

— extraneous matter;

— process and surface defects that may present an unacceptable risk of patient harm.

If deemed necessary based on risk assessment, inspection shall be conducted under a minimum 2,5× magnification.

5.5 Size designation

5.5.1 General

The nominal size of the catheter shall be designated as specified in 5.5.2.

5.5.2 Outer diameter

Unless otherwise specified in another clause of this document for a particular type of catheter, the outer diameter shall be expressed as the nominal dimension in millimetres, rounded upwards to the nearest 0,1 mm. Tolerances on this stated size shall be ±1 French.

NOTE Additional units can also be given. French size (Fr, Ch, FG) is a nominal dimensional identification of the outer size of urethral catheters; calculated as three times the diameter (in millimetres): Fr = 3 × D (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.

The balloon capacity shall be expressed in millilitres.

5.5.3 Effective shaft lengths

The minimum effective shaft lengths (L_3) shall be as given in Table 1 (see also Figure 1).

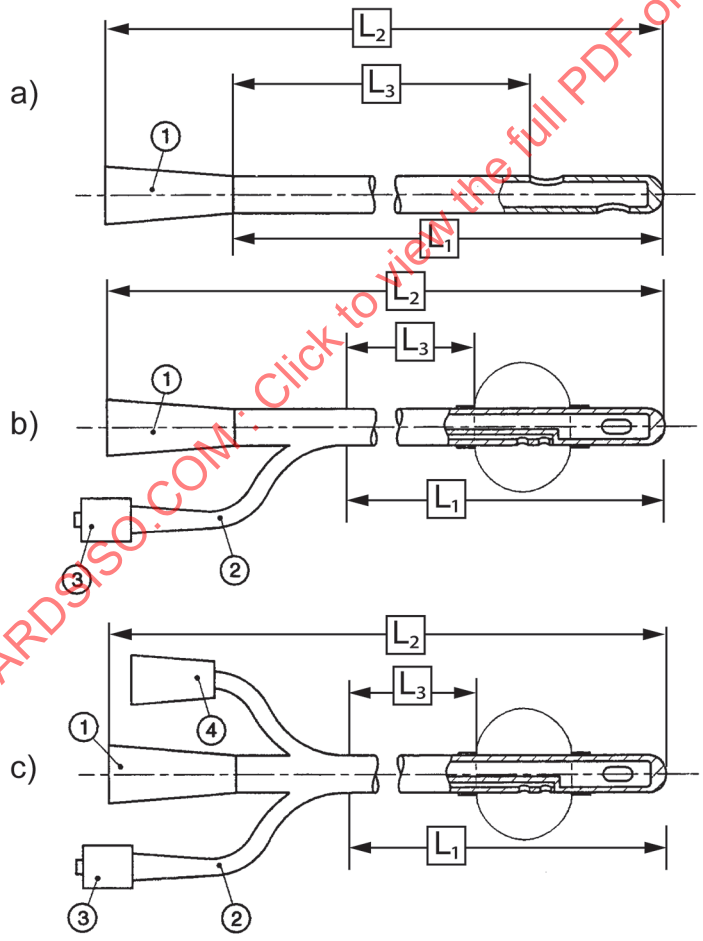
The nominal effective shaft length (L_3) shall be expressed in millimetres, rounded to the nearest millimetre.

NOTE 1 Additional units can also be given.

NOTE 2 Tolerances to the effective length are not specified.

Table 1 — Effective shaft length

Catheter type	L_3 (minimum) mm
Paediatric male	150
Paediatric female	45
Female	60
Male	275
NOTE Shaft dimensions: Shorter sizes can be produced using appropriate risk based clinical justification.	



Key

1 drainage funnel
2 inflation access port
3 valve
4 irrigation access port
L_1 effective length
L_2 overall length
L_3 effective shaft length

Figure 1 — Typical urethral catheters with and without balloon

5.6 MRI compatibility

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

NOTE Such as ASTM F2052, F2213, F2182, and F2119.

5.7 Connector

There is no standardized connector. However, risk of misconnection shall be avoided. This shall be determined by the manufacturer based on risk assessment according to the general requirements of ISO 80369-1.

NOTE 1 A future part of ISO 80369 will address connectors for urethral and urinary applications.

NOTE 2 The funnel is a connecting part, but does not comply with the requirements of ISO 80369-1.

5.8 Sterilization

Urethral catheters and accessories that are sterile shall comply with international, national or regional standards and shall have a sterility assurance level (SAL) of 10^{-6}.

NOTE See applicable parts of ISO 17665, ISO 11135 and ISO 11137 (all parts) for appropriate methods of sterilization.

6 Specific requirements

6.1 Strength

When tested the tip/shaft union and lateral drainage holes shall not show any sign of breaking and neither the tip nor the funnel shall become detached from the shaft.

Compliance shall be checked by the test method in Annex A.

6.2 Connector security

When tested the drainage funnel shall not part from the test connector.

Compliance shall be checked by the test method in Annex B.

6.3 Balloon safety

If present, the balloon shall not leak and shall not occlude the lateral drainage holes.

Compliance shall be checked by the test method in Annex C.

The change in profile at each end of the uninflated balloon should have a smooth transition to the shaft. The balloon should be capable of approximately symmetrical expansion when filled with water at ambient temperature to its specified balloon capacity.

6.4 Catheter inflation lumen integrity and volume maintenance

6.4.1 General

If a balloon is present, choose the appropriate requirement from 6.4.2 and 6.4.3.

6.4.2 Compliant balloon

When deflating the balloon, the percentage of water recovered shall not be lower than the value given in Table 2.

Table 2 — Balloon test volume percentage recovery

Balloon capacity ml	Minimum percentage of volume recovered %
5	55
10	75
20	80
30	80
This document does not specify requirements for balloon capacity of less than 5 ml. These values should be determined by the manufacturer based on risk assessment. Intermediate cases are recommended to comply with the next higher value.	

Compliance shall be checked by using the test method in Annex D.

6.4.3 Non-compliant balloon

For 4,0 mm (12 French) and larger catheters, the balloon shall pass through a French size scale no greater than four (4) French larger than the label French size.

This document does not specify requirements for catheter sizes less than 4,0 mm (12 French). These values should be determined by the manufacturer based on risk assessment.

Compliance shall be checked by using the test method in Annex I.

6.5 Flow rate

The minimum average flow rates shall be as given in Table 3.

Table 3 — Average flow rates

Designated size		Average flow rate (minimum)	
Outer diameter mm	**Charrière equivalent**[a] FG/Ch/Fr	**Drainage lumen** ml/min	**Irrigation lumen** ml/min
2,0	6	10	n.a.[b]
2,7	8	15	n.a.
3,3	10	30	n.a.
4,0	12	50	n.a.
4,7	14	70	25
5,3	16	100	25
6,0	18	100	25
6,7	20	100	25
7,3	22	100	30
8,0	24	100	30
8,7	26	100	30
9,3	28	100	n.a.

NOTE The listed flow rate values are a minimum requirement; clinical flow rate values may be higher.

[a] The Charrière equivalent is given for information.

[b] n.a. = not applicable

Table 3 *(continued)*

Designated size		Average flow rate (minimum)	
Outer diameter mm	**Charrière equivalent**[a] FG/Ch/Fr	**Drainage lumen** ml/min	**Irrigation lumen** ml/min
10,0	30	100	n.a.
NOTE The listed flow rate values are a minimum requirement; clinical flow rate values may be higher.			
[a] The Charrière equivalent is given for information.			
[b] n.a. = not applicable			

Compliance shall be checked using the flow rate test method in Annex E.

6.6 Corrosion resistance

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

6.7 Kink stability

During placement, the urethral catheter shall demonstrate the ability to safely access the intended location. This document does not specify requirements for kink stability testing. Clinically relevant placement value is determined by the manufacturer based on intended use and risk assessment.

NOTE Such as kink stability test method in Annex G.

6.8 Peak tensile force

The minimum peak tensile force of the urethral catheter tubular portion, each junction between catheter component and tubing, and each junction between tubular portions shall be as given in Table 4.

Table 4 — Peak tensile force of urethral catheters

Smallest outer diameter of tubular portion of test piece mm	Minimum peak tensile force N
≥2 and ≤4	10
>4	20
This document does not specify requirements for peak tensile force for tubing of less than 2 mm outer diameter. These values should be determined by the manufacturer based on risk assessment.	

Compliance shall be checked using the test method in Annex H.

6.9 Inflated balloon resistance to traction

For 4,66 mm to 8,66 mm (14 French to 26 French) urethral catheters, the balloon shall not pass into or through a funnel-like apparatus, with a size 28 French lumen, representing the bladder outlet and urethra.

This document does not specify requirements for catheter sizes less than 14 French. These values should be determined by the manufacturer based on risk assessment.

Compliance shall be checked using the test method in Annex J.

7 Information to be supplied by the manufacturer

7.1 General

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

Marking on all devices shall be durable and legible. Compliance shall be checked by inspection of markings and durability assessed by use of suitable test method.

NOTE Such as ASTM F1842-09 or ASTM F2252-13.

Where appropriate, ISO 11607 (all parts) and EN 1041 should be used and symbols should be made according to ISO 15223-1.

7.2 Marking on the device and/or 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.

If not practicable on the device itself then marking shall be displayed on the primary (individual) packaging, secondary (case) packaging or in the instructions for use (IFU).

The primary and/or secondary packaging shall be labelled with the following information at a minimum.

a) Any special storage or handling conditions.

b) An indication that the device is for single use or single patient use. A manufacturer's indication of single use shall be consistent across its range, where appropriate.

c) Where appropriate, detectability.

d) Where appropriate, the manufacturer’s stated nominal balloon inflation volume.

e) The manufacturer’s stated effective length.

7.3 Instructions for use

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

a) 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.

b) 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.

c) Any warnings or precautions to take.

d) Date of issue or the revision level of the instructions for use.

e) Where appropriate, an indication that the device is for single use or single patient use. A manufacturer's indication of single use shall be consistent across its range.

f) Where appropriate, the method of cleaning, disinfecting or sterilization necessary prior to use.

g) Where appropriate, known reactions between the catheter and magnetic resonance imaging (MRI) environment.

h) Where appropriate, description of additives or coatings:

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

Annex A
(normative)

Test method for determining the strength of the catheter

A.1 Principle

Catheters fitted with balloons may be in position for prolonged periods. Such catheters are therefore immersed for 14 d in simulated urine prior to testing. This step is omitted for catheters without balloons and intermittent catheters. A tensile force is applied to the union of the tip and shaft of the catheter. For catheters with lateral drainage holes, the tensile force is to be applied to the lateral drainage holes. For catheters with no lateral drainage holes, the tensile force is applied between the shaft of the catheter and the drainage funnel. On removal of this force, the catheter is examined for signs of failure.

A.2 Reagents

Simulated urine, pH approximately 6,6, of the following composition, the reagents being of recognized analytical grade:

— Urea 25,0 g;

— Sodium chloride 9,0 g;

— Disodium hydrogen orthophosphate anhydrous 2,5 g;

— Potassium dihydrogen orthophosphate 2,5 g;

— Ammonium chloride 3,0 g;

— Creatinine 2,0 g;

— Sodium sulfite, hydrated 3,0 g;

— Distilled water to 1,0 l.

WARNING — This solution can support microbial growth. There is a strong possibility that large numbers of microorganisms will be present in the solution at the end of the tests described in A.4 and C.4. These procedures should be carried out by trained personnel taking appropriate precautions in the handling of the immersed catheter and the disposal of the contaminated solution.

A.3 Apparatus

A.3.1 Device for suspending catheter with lateral drainage holes, comprising a pin which passes through a lateral drainage hole of the catheter, the pin having a diameter of minimum 50 % of that of the drainage lumen of the catheter to be tested. An example of a suitable device is shown in Figure A.1. For catheters without lateral drainage holes, the shaft of the catheter is suspended in a suitable clamp.

A.3.2 Device for attaching a weight to the drainage funnel and weight, their combined minimum mass being given in Table A.1.

Table A.1 — Drainage funnel weights

Outer diameter mm	Charrière equivalent[a] FG/Ch/Fr	Mass kg
≤2,0	≤6	0,5
2,0 < outer diameter ≤ 3,3	6 < outer diameter ≤10	0,75
>3,3	>10	1,0
[a] The Charrière equivalent is given for information.		

A.3.3 Water bath or other device, capable of being controlled at (37 ± 2) °C.

A.3.4 Stopwatch.

A.4 Procedure

A.4.1 Immerse the catheter in the freshly prepared simulated urine (A.2) in the water bath (A.3.3), controlled at (37 ± 2) °C, so that the balloon and shaft are completely submerged.

A.4.2 Allow the catheter to remain in the simulated urine for 14 d (when required) and then remove the catheter, rinse it with tap water and dry it.

A.4.3 Allow the catheter to come to a temperature of (22 ± 5) °C.

A.4.4 Suspend the catheter from the suspension device (A.3.1) by passing the pin into the lateral drainage hole nearest the tip of the catheter (see Figure A.1). For catheters without lateral drainage holes, use a suitable clamp.

A.4.5 Manually support the weight (A.3.2). Attach the weight to the drainage funnel of the catheter. Gently lower the weight until it is freely suspended from the catheter. Allow it to remain in this position for minimum 1 min. Remove the weight.

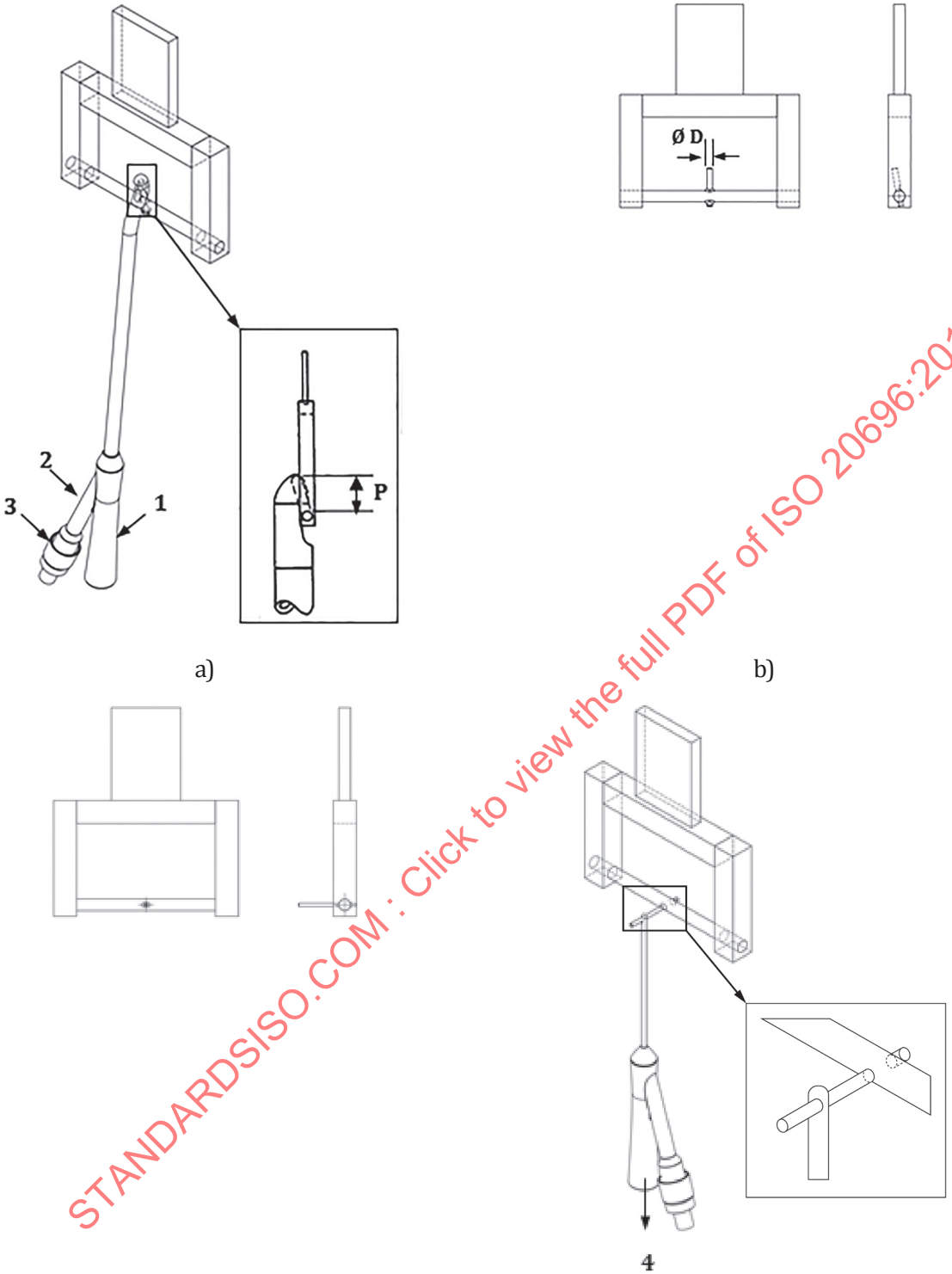
A.4.6 Visually examine all unions of the catheter for detachment or failure of bonds and any lateral drainage holes for signs of splitting.

A.5 Test report

The test report shall contain the following information:

a) the identity of the catheter;

b) the condition of the tip/shaft union and lateral drainage holes after testing.



a) b)

c) d)

Key

1 drainage funnel
2 inflation funnel
3 valve
4 direction of test force

[a] Arrangement for testing with close-up of pin introduced through the lateral drainage hole of the catheter for catheters outer diameters greater than 2 mm.

b Example of support frame and pin for catheters outer diameters greater than 2 mm.

c Example of support frame and pin for catheters outer diameters less than or equal to 2 mm.

d Arrangement for testing with close-up of pin introduced through the lateral drainage holes of the catheter for catheters outer diameters less than or equal to 2 mm.

NOTE 1 Dimension D is minimum 50 % of the diameter of the catheter lumen.

NOTE 2 Dimension P is sufficient to allow the tip of the pin to engage the tip of the catheter and not permit the supporting member to engage the rim of the eye when the catheter is loaded.

Figure A.1 — Apparatus and general arrangement for testing catheters

Annex B
(normative)

Test method for determining the security of fit of the drainage funnel

B.1 Principle

A specified test connector is fitted to the drainage funnel of the catheter, and an axial extensional force is applied to test the security of the connection.

B.2 Apparatus

B.2.1 **Test connector**, of rigid material, having the dimensions shown in Figure B.1.

NOTE If the test connector is not clinically relevant, an alternative clinically relevant connector can be used. Clinical relevance is determined by the manufacturer based on intended use and risk assessment.

B.2.2 **Clamp or similar device**, for suspending the catheter.

B.2.3 **Device for attaching a weight to the test connector and a weight**, the combined mass of connector, device and weight being 0,75 kg for testing catheters up to size 3,3 mm and 1 kg for testing all larger outer diameters.

B.2.4 **Stopwatch**.

B.3 Procedure

B.3.1 Carry out the test at (22 ± 5) °C. Ensure that the drainage funnel of the catheter and the test connector (B.2.1) are clean and dry.

B.3.2 Fit the test connector into the drainage funnel to a depth of engagement of, or exceeding, 10 mm (i.e. up to, or beyond, the mark on the connector).

B.3.3 Suspend the catheter by clamping (B.2.2) it at a point near the junction of the funnels and the shaft (see Figure B.1).

B.3.4 Manually support the weight (B.2.3). Attach the weight to the test connector and gently lower the weight until it is freely suspended from the connector. Allow it to remain in this position for a minimum of 1 min and observe the connector.

B.3.5 Record whether the test connector parts from the drainage funnel.

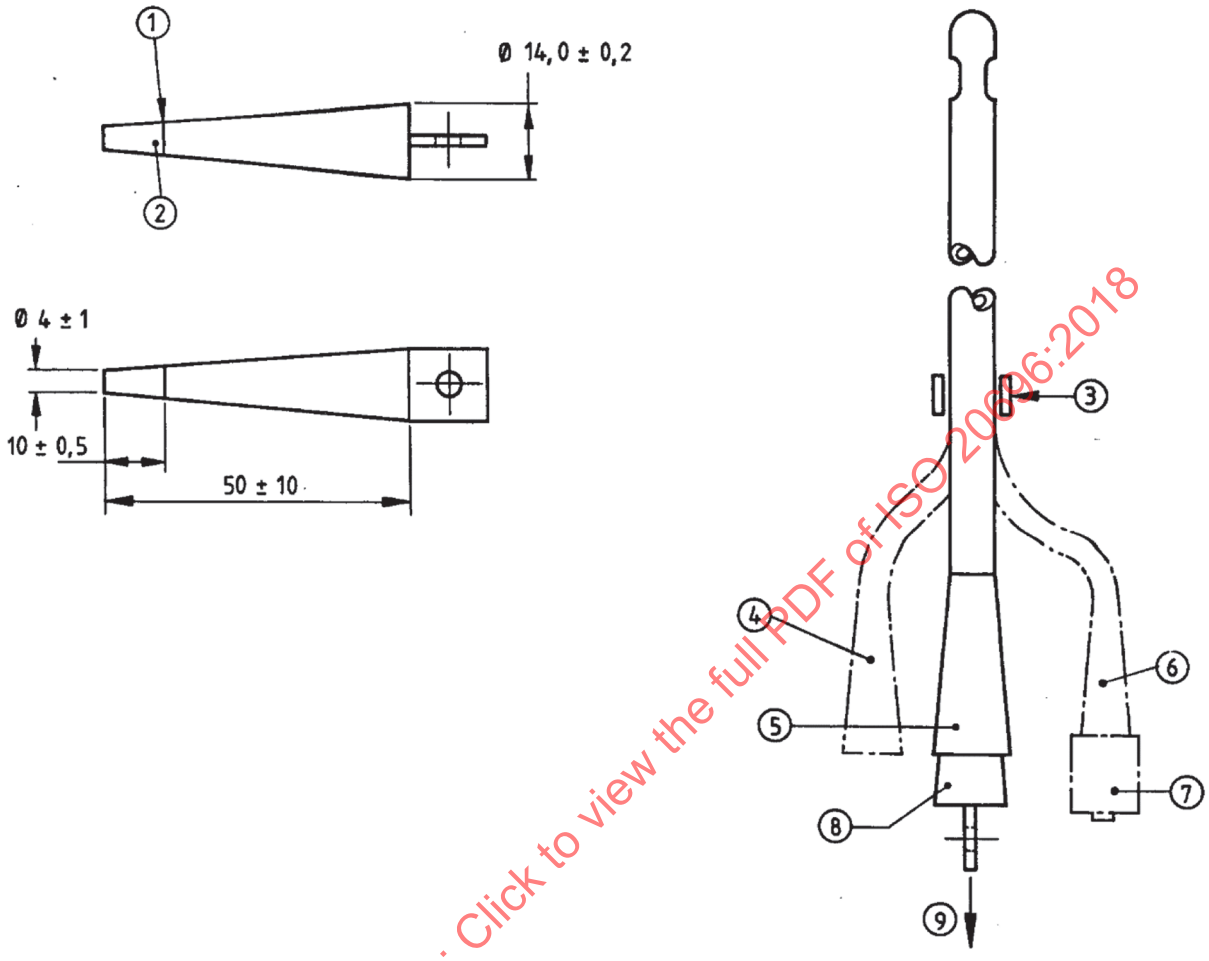
B.4 Test report

The test report shall contain the following information:

a) the identity of the catheter;

b) whether the test connector remained in the funnel during the test.

Dimensions in millimetres



a) b)

Key

1	circumscribed mark	7	valve
2	nominal taper 20 %	8	test connector
3	clamp to suspend catheter	9	direction of test force
4	irrigation funnel	a	Test connector.
5	drainage funnel	b	General arrangement for testing.
6	inflation funnel		

Figure B.1 — Test connector and general arrangement for testing security of fit of the drainage funnel

Annex C
(normative)

Test method for determining balloon safety

C.1 Principle

The catheter balloon is inflated with water to the manufacturer's maximum stated capacity and immersed for 14 d in simulated urine. A tensile force is applied to the catheter and the catheter examined visually for occlusion of the lateral drainage holes, if present, by the balloon and leakage from the balloon.

C.2 Reagents

C.2.1 Distilled water.

C.2.2 Simulated urine, of composition given in A.2.

C.3 Apparatus

C.3.1 Device for suspending the catheter, consisting of a plate of rigid material, having the following constructional features:

a) a hole of diameter of 1 mm greater than that of the nominal size of the catheter under test, with a countersink on the upper surface of the plate;

b) a countersink of 90° included angle of sufficient size to support the base of the balloon of the catheter under test;

c) no sharp edges at the junction of the hole and the countersink.

NOTE To facilitate placement of the catheter under test, the plate can comprise two halves, symmetrical about the centreline of the hole.

C.3.2 Water bath, or other device capable of being controlled at (37 ± 2) °C.

C.3.3 Device for attaching a weight to the drainage funnel or shaft of the catheter, and a series of weights, the combined masses of the attachment device and each mass being as given in Table C.1.

C.3.4 Stopwatch.

Table C.1 — Requirements for load test

Designated size		Minimum mass
Outer diameter mm	**Charrière equivalent**[a] FG/Ch/Fr	kg
2,7 or less	8 or less	0,3
3,3	10	0,45
4,0	12	0,6
4,7	14	0,7
5,3 to 10,0	16 to 30	1,0
Intermediate cases are recommended to comply with the next higher value.		
[a] The Charrière equivalent is given for information.		

C.4 Procedure

C.4.1 Inflate the catheter balloon with distilled water to the manufacturer's maximum stated balloon capacity.

C.4.2 Immerse the catheter in the freshly prepared simulated urine (C.2.2) in the water bath (C.3.2) controlled at (37 ± 2) °C, so that the tip and the balloon are completely submerged.

C.4.3 Allow the catheter to remain in the simulated urine for 14 d, then remove the catheter, rinse it with tap water, and dry it. Allow the catheter and contents to come to a temperature of (22 ± 5) °C. Inspect the catheter for balloon leakage or burst.

C.4.4 Place the catheter in the suspension device (C.3.1), with the tip uppermost, the balloon resting in the countersink and the shaft protruding from the hole.

NOTE To facilitate placement of the catheter in a single piece suspension device, it can be necessary to either remove the funnels, having first ligatured the catheter shaft, or to drain the balloon, introduce the catheter and then re-inflate the balloon.

C.4.5 Select the weight (C.3.3) appropriate to the catheter under test, as given in Table C.1.

C.4.6 Manually support the weight. Attach the weight to the shaft or drainage funnel of the catheter and gently lower the weight until it is freely suspended from the catheter. Allow it to remain in this position for a minimum of 1 min.

C.4.7 With the weight in position, visually examine the catheter at the end of a 1 min period for:

a) occlusion of the lateral drainage holes, if present, by the balloon;

b) leakage of water from the balloon.

C.5 Test report

The test report shall contain the following information:

a) the identity of the catheter;

b) whether the lateral drainage holes were occluded by the balloon;

c) whether leakage or burst from the balloon was observed.

Annex D
(normative)

Test method for determining inflation lumen leakage and/or function and/or balloon deflation (catheter with compliant balloon)

D.1 Principle

The catheter balloon and inflation lumen are inflated with water and immersed in simulated urine for 14 d. This step is omitted for intermittent catheters. The balloon is allowed to drain under gravity, and the volume of liquid recovered is measured.

D.2 Apparatus and reagents

D.2.1 **Clamp or similar device**, for suspending the catheter by the tip.

D.2.2 **Appropriate connector**, to connect to the inflation lumen of the device.

D.2.3 **Water bath**, or other device capable of being controlled at (37 ± 2) °C.

D.2.4 **Measuring cylinder**, with accuracy ±1 %, size appropriate to the balloon under test.

D.2.5 **Distilled water**.

D.2.6 **Simulated urine**, of composition given in A.2.

D.3 Procedure

D.3.1 Introduce into the catheter balloon, through the valve of the inflation funnel, the volume of distilled water (D.2.5) given in Table D.1.

D.3.2 Completely submerge the catheter in freshly prepared simulated urine (D.2.6) in the water bath (D.2.3), controlled at (37 ± 2) °C for 14 d.

D.3.3 Remove the catheter from the simulated urine, rinse it with tap water and dry it.

D.3.4 Suspend the catheter by the tip using the clamp (D.2.1). Insert the appropriate connector (D.2.2) into the valve of the inflation funnel and allow the contents of the balloon to drain gravimetrically into a measuring cylinder until the flow of liquid stops, or for 15 min, whichever is the shorter period.

D.3.5 If desired, allow the temperature of the liquid in the measuring cylinder (D.2.4) to come to (22 ± 5) °C.

D.3.6 Measure the volume removed from the balloon and calculate the percentage recovered.

Table D.1 — Balloon test capacities

Designated size		Test capacity
Outer diameter mm	**Charrière equivalent**[a] FG/Ch/Fr	
2,7 to 3,3	8 to 10	Nominal balloon capacity
4,0 to 4,7	12 to 14	1,2 × balloon capacity
5,3 to 10,0	16 to 30	1,5 × balloon capacity
This document does not specify requirements for balloon test capacities for balloons of less than 2,7 mm outer diameter. These values should be determined by the manufacturer based on risk assessment.		
NOTE For diameter values falling between two lines, the greater test capacity value applies.		
[a] The Charrière equivalent is given for information.		

D.4 Test report

The test report shall contain the following information:

a) the identity of the catheter, including the designated size and balloon capacity;

b) the volume of liquid recovered through the valve, expressed as a percentage of the volume introduced.

Annex E
(normative)

Test method for determination of flow rate 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

E.2.1 **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 connector when no test catheter is attached, of providing a flow rate of not less than 500 ml/min, and having a hydrostatic head height of (1 000 ± 5) mm.

NOTE 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 ± 5) °C. Fit the catheter to be tested to the appropriate connector. If the catheter has a balloon, then the balloon should be inflated to the rated nominal volume prior to testing. Ensure that the catheter outlet is maintained at a hydrostatic head height of (1 000 ± 5) mm.

E.4.2 Flush air from the system by allowing water flow briefly through the catheter.

E.4.3 Start the media flowing through the catheter. Collect the efflux for a measured period of time (not less than 30 s) and determine its volume by means of a measuring cylinder or by weighing, taking into account the density of the media.

E.4.4 Perform three determinations on each applicable catheter lumen.

E.4.5 Expression of results.

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

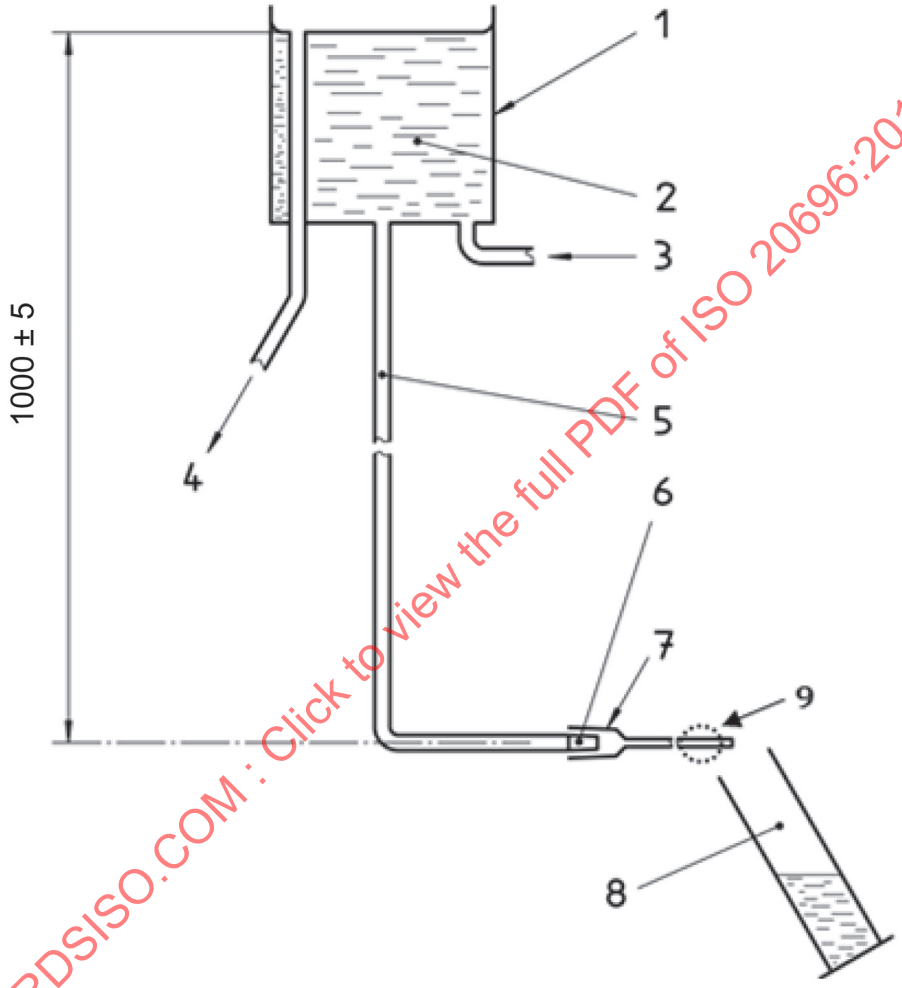
E.5 Test report

The test report shall include the following information:

a) identity of the catheter and the media used for flow rate testing;

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

Dimensions in millimetres



Key

1 constant-level tank
2 distilled or deionized water, or other clinically relevant media
3 inlet
4 overflow
5 delivery tube
6 connector fitting
7 catheter under test
8 collecting/measuring vessel
9 inflated balloon, where appropriate

NOTE If desired, the catheter can be turned around and the flow can go through the lateral drainage holes first.

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

Annex F
(normative)

Test method for corrosion resistance

F.1 Principle

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

F.2 Reagents

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

F.2.2 **Distilled or deionized water**.

F.3 Apparatus

F.3.1 **Borosilicate glass beakers**.

F.4 Procedure

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

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

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

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

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

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

F.5 Test report

The test report shall include the following information:

a) identity of the device;

b) statement as to whether corrosion occurred during the test.

Annex G
(informative)

Test method for determining kink stability

G.1 Principle

The device is wrapped around incrementally smaller mandrels until a kink is formed.

G.2 Apparatus

G.2.1 **Kink fixture**, mandrel with incrementally smaller diameters.

NOTE Typical apparatus can be found in Figure G.1.

G.2.2 **Calipers**.

G.3 Procedure

G.3.1 Identify and separate test pieces. Each tubular portion and each junction between a tubular portion shall be tested individually.

G.3.2 Pre-condition test pieces in a water bath at (37 ± 2) °C for a minimum of 2 h. This step is omitted for intermittent catheters. Test in accordance with G.3.3 to G.3.5 immediately after conditioning.

G.3.3 Hold the tubing in both hands, wrap it 180° around a large diameter mandrel to avoid kinking the catheter prematurely.

G.3.4 Continue to wrap the tubing around smaller diameters incrementally until a kink is observed in the tubing.

G.3.5 Once the tubing has kinked, measure the diameter of the mandrel with a caliper or record the mandrel diameter.

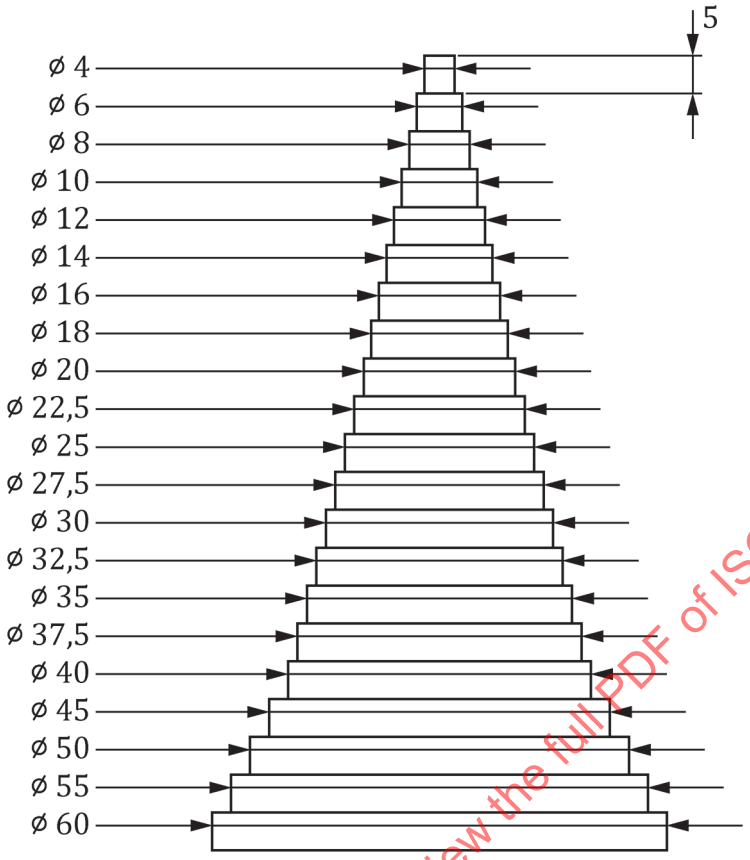
G.4 Test report

The test report shall include the following information:

a) identity of the catheter;

b) the diameter of the mandrel, expressed in millimetres.

Dimensions in millimetres



NOTE The apparatus in the figure is an example that has been found to be suitable, but is not intended to preclude other designs or sizes of apparatus from being used.

Figure G.1 — Apparatus for testing tubing until kinking

Annex H
(normative)

Test method for determining peak tensile force of urethral catheter

H.1 Principle

Test pieces or the entire length of a catheter are chosen so that each tubular portion, each junction between catheter component 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 or until a specified force is applied.

H.2 Apparatus

H.2.1 **Water bath**, at (37 ± 2) °C.

H.2.2 **Tensile testing apparatus**, capable of exerting a force of greater than 20 N.

H.3 Procedure

H.3.1 Select a test piece from the catheter to be tested. Include in the test piece the connector, if present, and the junction between segments, e.g. between the tubing and the tip, if present. Exclude distal tips of lengths less than 3 mm from the test piece.

H.3.2 Condition those parts of the urethral catheter that are intended for insertion into the body in an atmosphere of 100 % RH or water at a temperature of (37 ± 2) °C (H.2.1) for not less than 2 h. Condition other components at a minimum of 40 % RH and a temperature of (22 ± 5) °C for not less than 2 h. Test immediately after conditioning.

This step is omitted for catheters without balloons and intermittent catheters.

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

H.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 connector and the jaw holding the other end of the test piece, as appropriate.

H.3.5 Apply a tensile strain at a unit strain rate of 20 mm/min/mm of gauge length (see Table H.1) until the test piece separates into two or more pieces, or until a specified force is applied.

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

Gauge length mm	Testing speed mm/min
10	200
20	400

Table H.1 *(continued)*

Gauge length mm	Testing speed mm/min
25	500

H.3.6 If testing a catheter that consists of a single tubular portion having regions of different outside diameter, repeat H.3.2 to H.3.5 on test pieces of each different diameter.

H.3.7 Do not perform more than one test on each test piece.

H.4 Test report

The test report shall include the following information:

a) identity of the catheter;

b) the peak tensile force, or the specified force applied, in newtons;

c) outer diameter of each test piece;

d) and if appropriate, the location of the failure.