BRITISH STANDARD

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1618 : 1997

Catheters other than intravascular catheters — Test methods for common properties

The European Standard EN 1618 : 1997 has the status of a British Standard

ICS 11.040.20

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/27, Medical plastics tubing, upon which the following bodies were represented:

Association of Anaesthetists of Great Britain and Ireland
Association of British Health-care Industries
British Dietetic Association (PENG)
British Surgical Trades Association
Department of Health
Disposable Hypodermic and Allied Equipment Manufacturers' Association (UK)
Guild of Hospital Pharmacists
Institution of Physics and Engineering in Medicine and Biology
Intensive Care Society
Medical Sterile Products Association
National Association of Theatre Nurses
Royal College of Paediatrics and Child Health
Royal Pharmaceutical Society of Great Britain

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Contents

National foreword

This British Standard has been prepared by Technical Committee CH/27 and is the English language version of EN 1618 : 1997 *Catheters other than intravascular catheters — Test methods for common properties*, published by the European Committee for Standardization (CEN).

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 8, an inside back cover and a back cover.

EUROPEAN STANDARD
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EUROPÄISCHE NORM

EN 1618

February 1997

ICS 11.040.20

Descriptors: Medical equipment, catheters, tests, characteristics, corrosion resistance, mechanical strength, leaktightness, flow rate

English version

Catheters other than intravascular catheters — Test methods for common properties

Cathéters autres que les cathéters intravasculaires — Méthodes d'essai des propriétés communes

Nicht-intravasale Katheter — Prüfverfahren für allgemeine Eigenschaften

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 205, Non-active medical devices, the secretariat of which is held by BSI.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of the EU Directive(s).

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 1997, and conflicting national standards shall be withdrawn at the latest by August 1997.

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this standard.

Annexes A, B, C, D, E and F form normative parts of this standard. Annex ZA is for information only.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Contents

1 Scope

This European Standard specifies test methods for common properties for catheters as they relate to the device ready for clinical use. The purpose of the standard is to ensure uniformity in the evaluation of catheter properties.

This European Standard is not applicable to intravascular catheters.

2 Test methods and results

The test methods are given in annexes A to F and results shall be expressed as, e.g.:

'Corrosion test according to EN 1618: No sign of corrosion'.

Unless otherwise specified, tolerances on all variables in the test methods shall be $\pm$ 10 %.

Annex A (normative)

Test method for corrosion resistance of metallic components

A.1 Principle

The catheter is immersed in the sodium chloride solution, then in boiling distilled water, and afterwards the metallic components are examined visually for evidence of corrosion.

A.2 Reagents

A.2.1 *Saline solution*, comprising 0,9 % *m/V* of analytical reagent grade sodium chloride in freshly prepared, distilled water.

A.2.2 *Distilled or deionized water.*

A.3 Apparatus

Borosilicate glass beakers.

A.4 Procedure

Immerse the catheter in the saline solution (**A.2.1**) in a glass beaker (**A.3**) at (23 ± 2) °C 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, and remain at, (23 ± 2) °C for 48 h. Remove the test specimen and allow it to dry at (23 ± 2) °C. Disassemble specimens that have two or more components which are intended to be separable in use. Do not strip away or cut open any opaque coatings on metallic components. Inspect the metallic components of the specimen visually for signs of corrosion.

A.5 Test report

The test report shall include the following information:

a) identity of catheter;

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

Annex B (normative)

Test method for tensile properties

B.1 Principle

Test pieces 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 or until a specified force is applied.

B.2 Apparatus

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

B.3 Procedure

B.3.1 Condition those parts of the catheter that are intended for insertion into the body in an atmosphere of 100 % relative humidity (RH), or water, and a temperature of (37 ± 2) °C for 2 h. Condition the remainder of the catheter at 40 % RH to 60 % RH and a temperature of (23 ± 2) °C. Test immediately after conditioning.

B.3.2 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 tip, if present. Exclude distal tips of lengths less than 3 mm from the test piece.

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/per millimetre of gauge length (see table B.1) until the test piece separates into two or more pieces, or until a specified force is applied. Note the value of the applied tensile force, in newtons.

Table B.1 Example of conditions for a 20 mm/min strain rate per millimetre of gauge length

Gauge length (mm)	**Testing speed** (mm/min)
10	200
20	400
25	500

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

B.3.7 If testing a catheter that has a side port or side ports:

a) repeat **B.3.2** to **B.3.5** on each side port;

b) repeat **B.3.2** to **B.3.5** on a test piece that includes the joint between a side port 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 each test piece.

B.4 Test report

The test report shall include the following information:

a) identity of the catheter;

b) the force at break, or the specified force applied, and outside diameter of each test piece.

Annex C (normative)
Test method for resistance to liquid leakage under pressure

C.1 Principle
The test piece is connected as intended by the manufacturer and filled with water. A connection is made to a pressure system with a measuring gauge. A hydraulic pressure is applied and the assembly is then inspected for leakage.

C.2 Reagent
De-aerated distilled or deionized water.

C.3 Apparatus
C.3.1 *A hydraulic pressure system*, with a measuring gauge.

C.3.2 *Means for occluding the test specimen*, e.g. a clamp.

C.3.3 *Connector*, capable of making a leak proof coupling between the hydraulic system and the device.

C.4 Procedure
C.4.1 Connect the connector to the hydraulic pressure system (**C.3.1**).

C.4.2 Fill the system with water (**C.2**) at (23 ± 2) °C and expel the air. Occlude the test specimen (**C.3.2**).

C.4.3 Apply the test pressure and maintain it for not less than 30 s. Examine the total assembly for any liquid leakage (i.e. the formation of one or more falling drops of water) and record whether or not leakage occurs.

NOTE. The test pressure is specified in the relevant product standard.

C.5 Test report
The test report shall include the following information:

a) identity of the catheter;

b) test pressure;

c) statement as to whether and where leakage occurred from the assembly.

Annex D (normative)
Test method for resistance to leakage during aspiration or vacuum

D.1 Principle
The catheter is connected as intended by the manufacturer and filled with water. A connection is made to a source of negative pressure with a measuring gauge. A negative pressure is applied and the assembly is allowed to stabilize. The assembly is then inspected for leakage.

D.2 Reagent
De-aerated distilled or deionized water.

D.3 Apparatus
D.3.1 *A differential pressure system*, with a measuring gauge.

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

D.3.3 *Means of detecting air ingress*, if the test specimen is not transparent.

D.3.4 *Leak-proof connector*.

D.3.5 *Hydraulic pressure system*, as specified in **C.3.1**.

D.4 Procedure
D.4.1 Connect the connector to the hydraulic pressure system (**D.3.5**).

D.4.2 Fill the system with water (**D.2**) at (23 ± 2) °C and expel the air. Occlude the test specimen (**D.3.2**).

D.4.3 Apply a negative pressure and allow the system to stabilize for 120 s. Leave the system under negative pressure for another 120 s. During this period examine the assembly for leakage (i.e. the formation of one or more bubbles of air) and record whether or not leakage occurs.

NOTE. The test pressure is specified in the relevant product standard.

D.5 Test report
The test report shall include the following information:

a) identity of the catheter;

b) test negative pressure;

c) statement as to whether and where leakage occurred from the assembly.

Annex E (normative)
Test method for determining the flow rate of water through the catheter

E.1 Principle
Water is allowed to flow through the catheter and the amount of flow is measured either volumetrically or gravimetrically.

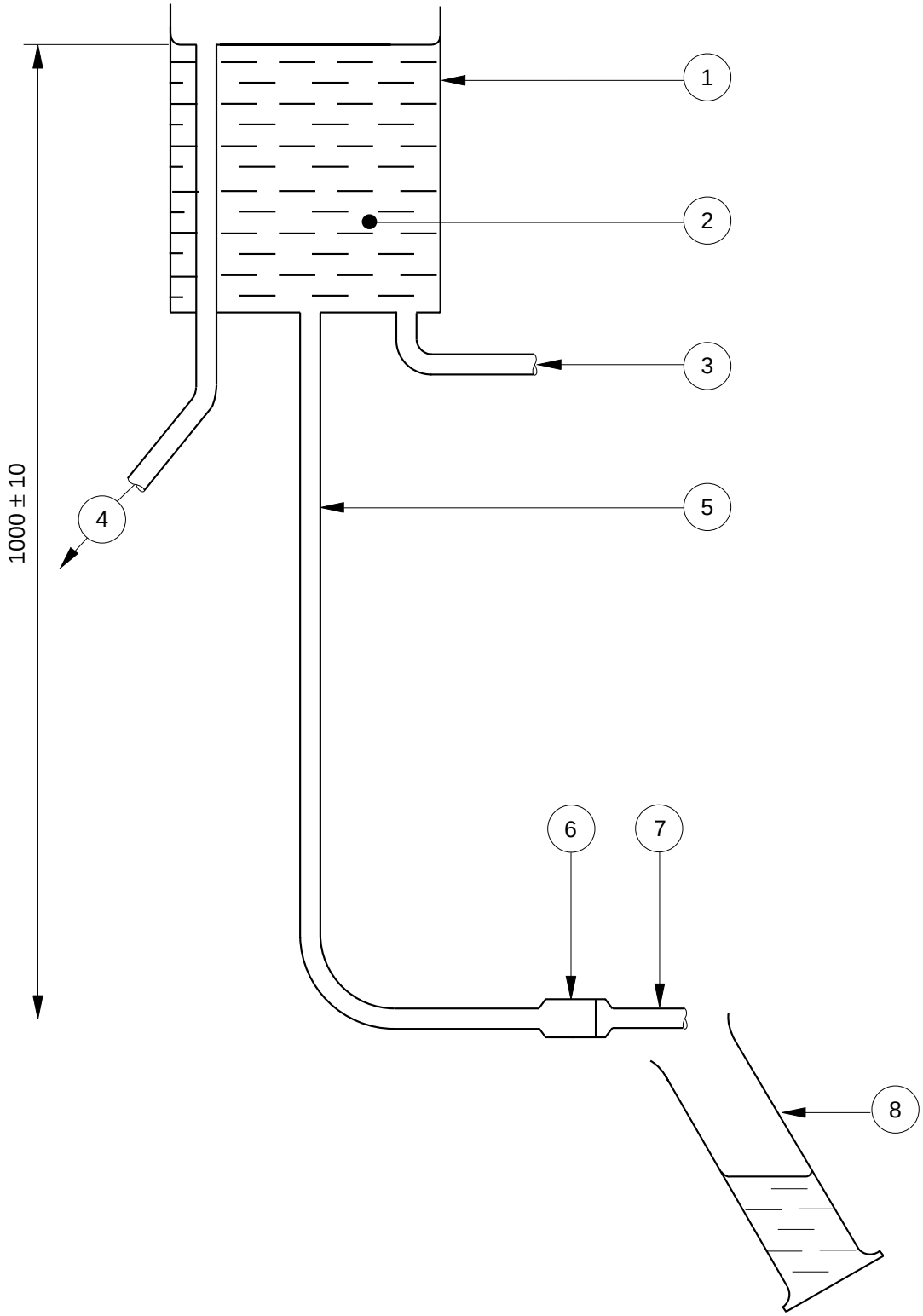
E.2 Apparatus
E.2.1 *A constant level tank*, fitted with a delivery tube and a male (or female) taper fitting capable, when no test catheter is attached, of providing a flow rate of not less than 500 ml/min. The constant level tank should have a hydrostatic head of height (1000 ± 10) mm, unless otherwise specified in the relevant product standard. An example of suitable apparatus is shown in figure E.1.

E.2.2 *Measuring cylinders*, or collecting vessel with balance of accuracy ± 1 %.

E.3 Procedure
E.3.1 Supply the constant level tank with water at (22 ± 2) °C. Fit the catheter to be tested to the appropriate connector.

E.3.2 Flush air from the system by allowing water to flow briefly through the catheter.

E.3.3 Start the water flowing through the catheter. Collect the efflux for a period of not less than 30 s in a suitable vessel and determine its volume by means of a measuring cylinder or by weighing using the assumption that the density of water equals 1000 kg/m^3. Perform three determinations on each catheter.



Dimensions in millimetres

1. Constant level tank
2. Water
3. Inlet
4. Overflow
5. Tube, 10 mm internal diameter, length 1000 mm min.
6. Appropriate connector
7. Catheter
8. Collecting/measuring vessel

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

E.4 Expression of results

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

E.5 Test report

The test report shall include the following information:

a) identity of the catheter;

b) average water flow rate expressed in millilitres per minute;

c) specification for connector used.

Annex F (normative)

Test method for security of connectors

F.1 Test for separation

The connector(s) are assembled in accordance with the manufacturer's instructions. A tensile force is applied and the assembled connection inspected for separation.

F.2 Apparatus

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

F.3 Procedure

Assemble the connectors in accordance with the manufacturer's instructions.

Fix the assembled connectors in the tensile test apparatus (using an appropriate fixture to avoid deforming the connector, if necessary).

Apply a tensile force, as specified in the product standard, at a testing speed of 500 mm/min. Inspect the assembled connectors for separation.

F.4 Test report

The test report shall include the following information:

a) identity of the catheter;

b) identity of the connector(s);

c) force applied, in newtons and whether the connectors separated.

Annex ZA (informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive 93/42/EEC.

WARNING. Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The clauses of this standard are likely to support essential requirements of Directive 93/42/EEC.

Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA requirements.

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