BRITISH STANDARD

BS EN
1733:1998

Suction catheters for use in the respiratory tract

The European Standard EN 1733:1998 has the status of a British Standard

ICS 11.040.20

National foreword

This British Standard is the English language version of EN 1733:1998. It supersedes BS 7213:1989 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/45, Tracheal tubes and related equipment, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Summary of pages

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EUROPEAN STANDARD
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EN 1733

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Descriptors: Medical equipment, tracheal tubes, specifications, definitions, designation, dimensions, design, mechanical strength, tests, packing, marking, labelling

English version

Suction catheters for use in the respiratory tract

Sondes d'aspiration pour les voies respiratoires

Absaugkatheter zur Verwendung im Atemtrakt

This European Standard was approved by CEN on 5 July 1997.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. 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.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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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

Ref. No. EN 1733:1998 E

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 215, Respiratory and anaesthetic equipment, the secretariat of which is held by BSI.

This European Standard is based on ISO 8836:1988 *Suction catheters for use in the respiratory tract*, prepared by ISO/TC 121. However, it differs from ISO 8836 in that it introduces a table of colour identification for use with suction catheters. It no longer includes requirements for suction catheters made of rubber, and the size should be designated by outside diameter expressed in millimetres.

Annexes A, B and C are normative and form part of this European Standard. Annexes D and E are for information only.

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 1998, and conflicting national standards shall be withdrawn at the latest by August 1998.

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

Contents

Introduction

This European Standard specifies dimensions and requirements for suction catheters for use in the respiratory tract.

Size is designated by outside diameter which is important when selecting catheters, because of its relationship to the ease with which the catheter can be passed through a tracheal or tracheostomy tube (see prEN 1782 for details of tracheal tube standards and EN 1282-1 and EN 1282-2 for details of tracheostomy tube standards). Requirements for suction catheters made of rubber have been deleted because such catheters are no longer in general use.

Flammability of suction catheters, for example if flammable anaesthetics or lasers are used, is a well-recognized hazard that is addressed by appropriate clinical management, and is outside the scope of this standard.

1 Scope

This European Standard specifies requirements for suction catheters made of plastics materials and intended for use in suction of the respiratory tract. Specialized suction catheters are excluded from the scope of this standard. Angled tip suction catheters (e.g. Coudé catheters) are not considered to be specialized and are therefore included in the scope.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 556:1994, *Sterilization of medical devices — Requirements for medical devices to be labelled "STERILE".*

EN 868-1, *Packaging materials and systems for medical devices which are to be sterilized — Part 1: General requirements and test methods.*

EN 30993-1, *Biological evaluation of medical devices — Part 1: Guidance on selection of tests.* (ISO 10993-1:1992 + Technical Corrigendum 1:1992)

ISO 468, *Surface roughness — Parameters, their values and general rules for specifying requirements.*

3 Definitions

For the purposes of this European Standard, the following definitions apply.

3.1

adaptor

specialized connector to establish functional continuity between otherwise disparate or incompatible components

3.2

connector

fitting to join together two or more components [EN ISO 4135:1996]

3.3

effective shaft length

the main part of the catheter which is of uniform outside diameter

3.4

eye

lateral aperture near the patient end of the catheter [EN ISO 4135:1996]

3.5

machine end

that end of the catheter which is intended to be connected to a source of vacuum [EN ISO 4135:1996]

3.6

patient end

that end of the catheter which is intended to be inserted into the patient [EN ISO 4135:1996]

3.7

residual vacuum

the negative pressure at the patient end of the suction catheter when the vacuum control device is in the relief position

3.8

suction catheter

flexible tube designed for introduction into a respiratory tract to remove material by suction [EN ISO 4135:1996]

3.9

tip

extremity of the patient end of a catheter [EN ISO 4135:1996]

3.10

vacuum control device

means provided at the machine end of a catheter to control the flow of air and entrained material [EN ISO 4135:1996]

3.11

terminal orifice

central opening of the patient end of the suction catheter

4 Size designation and dimensions

4.1 Size designation

4.1.1 The size of suction catheters shall be designated by the following:

a) the outside diameter of the effective shaft length, expressed in millimetres;

NOTE It can additionally be expressed in French (Charrière) gauge size.

b) the nominal effective shaft length, expressed in millimetres.

4.1.2 The size of the catheter can additionally be designated by the use of colour identification at the machine end. If a colour code is used it shall be in accordance with Table 1.

4.2 Dimensions

4.2.1 The outside diameter and the minimum inside diameter of suction catheters excluding at the tip shall be in accordance with Table 2 or Table 3.

NOTE For the purposes of this European Standard, the French (Charrière) gauge system of size is based on the outside diameter of the shaft gauged in steps of thirds of a millimetre (1 millimetre corresponds to 3F); the French gauge size is not an SI unit. Size designation in millimetres facilitates matching suction catheter outside diameter to the inside diameter of the tracheal or tracheostomy tube.

4.2.2 The minimum inside diameter at the tip shall be not less than 90 % of the minimum inside diameter specified in Tables 2 and 3.

4.2.3 The actual effective shaft length shall be the marked effective length subject to a tolerance of ±5 %.

Table 1 — Colour identification for designated size of suction catheter

Designated size		Colour identification
Nominal outside diameter (mm)	French (Charrière) size equivalent	
1,67	5	grey
2,0	6	light green
2,5	7,5	pink
2,67	8	light blue
3,0	9	turquoise
3,33	10	black
4,0	12	white
4,67	14	green
5,0	15	brown
5,33	16	orange
6,0	18	red
6,67	20	yellow

Table 2 — Basic dimensions of suction catheters — Metric sizes

Designated size		Outside diameter tolerance mm	Minimum inside diameter mm
Nominal outside diameter mm	French (Charrière) size equivalent[1)]		
1,5	4,5 F	±0,1	0,8
2	6 F	±0,1	1,05
2,5	7,5 F	±0,1	1,45
3	9 F	±0,15	1,75
4	12 F	±0,15	2,45
5	15 F	±0,2	3,2
6	18 F	±0,2	3,9

[1)] The letters "Ch" can replace the letter "F" in the size designation (see **4.1.1**); 1 F or 1 Ch corresponds to one-third of a millimetre for the outside diameter [see also **9.3**b) and **9.4**b)].

Table 3 — Basic dimensions of suction catheters — French (Charrière) sizes

Designated size		Outside diameter tolerance (mm)	Minimum inside diameter (mm)
French size[1)]	Outside diameter equivalent[1)] (mm)		
4 F	1,33	±0,1	0,55
5 F	1,67	±0,1	0,8
6 F	2	±0,1	1,05
8 F	2,67	±0,1	1,5
10 F	3,33	±0,15	2
12 F	4	±0,15	2,45
14 F	4,67	±0,2	2,95
16 F	5,33	±0,2	3,4
18 F	6	±0,2	3,9
20 F	6,67	±0,2	4,3

[1)] The letters "Ch" can replace the letter "F" in the size designation (see **4.1.1**); 1 F or 1 Ch corresponds to one-third of a millimetre for the outside diameter [see also **9.3**b) and **9.4**b)].

5 Materials

Suction catheters for use in the respiratory tract, in their ready-for-use state after any preparation for use recommended by the manufacturer, shall satisfy appropriate biological safety testing, as indicated in EN 30993-1.

NOTE It is recommended that the shaft be colourless and either transparent or translucent

6 Design

6.1 Lumen

The inside diameter of the shaft at any point between the machine end and the eye nearest to the machine end shall be not less than the inside diameter of the shaft at that eye.

6.2 Patient end

6.2.1 The catheter shall have a terminal orifice.

NOTE 1 The catheter can have one or more eyes.

NOTE 2 The use of a catheter with eye(s) can reduce the likelihood of trauma during suctioning.

NOTE 3 The dimensions of the eye(s) should be such that they do not cause the suction catheter to kink or collapse in use.

6.2.2 The axis of the patient end can be at an angle to the long axis of the shaft (see Coudé catheter tip in Figure 1).

6.3 Machine end

6.3.1 The machine end of the suction catheter shall be either:

a) female — designed to receive a male-to-male adaptor suitable for connection to a vacuum source that terminates in a female end; or

b) male — designed for connection to a vacuum source that terminates in a female end; or

c) a permanently attached vacuum control device that terminates in either a male or female end.

6.3.2 Female ends shall be semi-rigid or elastomeric and shall be either conical or cylindrical (see Figure 1) over a length of not less than 20 mm for suction catheters with outside diameters of up to and including 3 mm and not less than 25 mm for suction catheters of outside diameters greater than 3 mm.

NOTE Where a suction catheter with a female machine end is provided for use with a vacuum source with a female end, a male-to-male adaptor is needed (see Figure 1). The minimum inside diameter of the adaptor should be not less than the minimum inside diameter of the suction catheter with which it is provided. The adaptor should fit inside elastomeric tubing having an inside diameter of 6 mm.

6.3.3 Male ends (see Figure 1) shall be rigid or semi-rigid and shall fit inside semi-rigid or elastomeric tubing having an inside diameter of 6 mm.

NOTE It is advantageous if the male end fits inside semi-rigid or elastomeric tubing with a larger inside diameter which can be used in emergency to clear the airway.

6.3.4 The machine end of a suction catheter having an angled patient end shall, by a mark or other means, indicate the direction in which the tip points.

7 Performance requirements

7.1 Security of fit of female ends

When tested in accordance with annex A, the female end shall not separate from the test connector.

7.2 Security of construction

When tested in accordance with annex B, the force required to detach any component permanently attached to the shaft shall be not less than that specified in Table 4.

Table 4 — Minimum force needed to detach any component permanently attached to shaft

Designated size (outside diameter) mm	Minimum force N
1,33 to 2,67	5
3 to 4,67	15
5 and greater	20

7.3 Shaft

When the machine end of the suction catheter is connected to a vacuum source at 40 kPa (300 mmHg) below ambient pressure for 15 s at a temperature of (23 ± 2) °C with the patient end occluded and, if present, the vacuum control device occluded, the shaft shall not collapse.

7.4 Residual vacuum

When a suction catheter fitted with a permanently attached vacuum device is tested in accordance with annex C, the residual vacuum shall not exceed 0,33 kPa.

8 Requirements for suction catheters supplied sterile

8.1 Sterility assurance

Suction catheters supplied and marked as "STERILE" shall satisfy the requirements of **4.1** of EN 556:1994 for the assurance of sterility needed to make the claim of being sterile.

8.2 Packaging of suction catheters supplied sterile

8.2.1 Each suction catheter supplied and marked as "STERILE" shall be contained in an individual pack.

8.2.2 The pack shall serve as an effective barrier to the penetration of micro-organisms and particulate material, in accordance with the relevant sections of EN 868-1.

8.2.3 The pack shall permit the aseptic extraction of the contents and shall not be capable of re-closure without clearly revealing that it has been opened.

8.2.4 Individual packs shall be contained within a shelf or multi-unit pack.

9 Marking

NOTE Marking of suction catheters, packages and inserts, and information to be supplied by the manufacturer should comply with prEN 1041.

9.1 Marking

9.1.1 Suction catheters that are not individually packaged shall be marked with the nominal outside diameter in accordance with **4.1**.

9.1.2 Suction catheters that are individually packaged can be marked with the nominal outside diameter, expressed in millimetres or French (Charrière) gauge (see **4.1**).

NOTE 1 Manufacturers of the smaller sizes of suction catheters for paediatric use should also mark the distance in centimetres or parts thereof, from the patient end.

NOTE 2 Suction catheters can be colour-coded in accordance with Table 1.

9.2 Use of graphical symbols

NOTE The requirements of **9.3** and **9.4** can be met by use of appropriate graphical symbols as given in EN 980.

9.3 Labelling of unit packs

The labelling of unit packs shall include the following:

a) a description of contents;

b) the designated size in accordance with **4.1.1**;

The size shall be expressed in accordance with one or both of the following examples:

6 mm (18 F) × 500 mm, or

6 mm (18 Ch) × 500 mm

c) the name and/or trademark of the manufacturer and/or supplier;

d) the batch number;

NOTE It is strongly recommended that the "use by" date be given.

e) the word "STERILE" or "NON-STERILE" as appropriate;

f) for suction catheters not intended for re-use, the words "single use" or equivalent.

9.4 Labelling of shelf or multi-unit packs

The labelling of shelf or multi-unit packs shall include the following:

a) a description of contents;

b) the designated size in accordance with **4.1.1**;

The size shall be expressed in accordance with one or both of the following examples:

6 mm (18 F) × 500 mm, or

6 mm (18 Ch) × 500 mm

c) the name and/or trademark and address of the manufacturer and/or supplier;

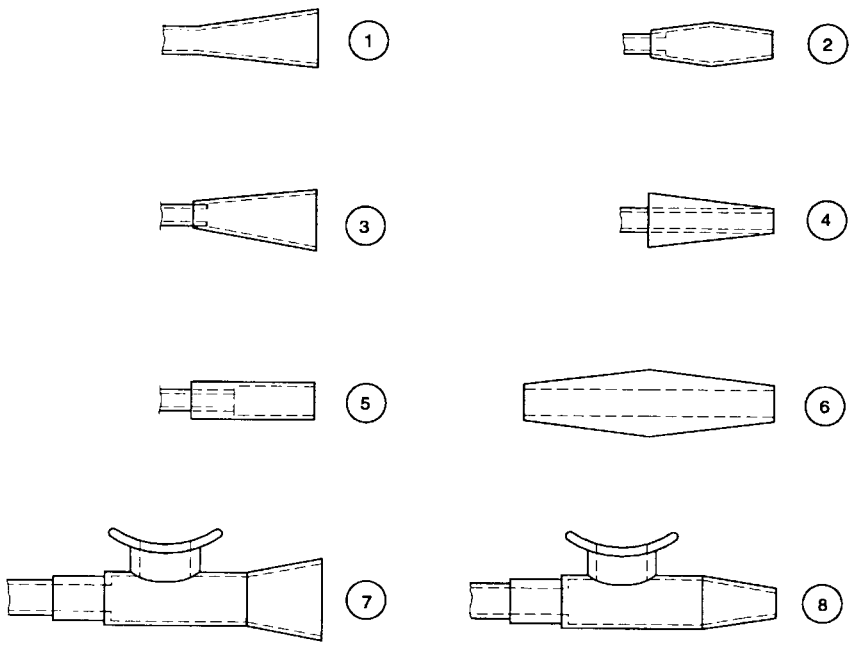
d) the batch number;

NOTE It is strongly recommended that the "use by" date be given.

e) the word "STERILE" or "NON-STERILE" as appropriate;

f) for suction catheters intended for re-use, instructions for cleaning and disinfection or sterilization shall be given. For suction catheters supplied non-sterile, instructions on preparation for use shall be provided;

g) for suction catheters not intended for re-use, the words "single use" or equivalent.



a) Machine ends

b) Patient ends

1 Female conical
2 Male
3 Female conical
4 Male
5 Female cylindrical
6 Male/male adaptor
7 Female connector with vacuum control device
8 Male connector with vacuum control device
9 Catheter tip with eyes
10 Coudé catheter tip with eyes

Figure 1 — Examples of different designs for a) the machine ends and b) patient ends of suction catheters for use in the respiratory tract

Annex A (normative)

Test method for security of fit of female ends

A.1 Principle

The security of fit of female ends is tested by fitting a specified test connector into the female end and then applying an axial separation force to the suction catheter relative to the test connector.

A.2 Apparatus

A.2.1 *Test connector*, made of metal, with the dimensions as shown in Figure A.1 and having a surface roughness (R_a) of of 0,8 μm according to ISO 468. For testing suction catheters with outside diameters of up to and including 3 mm, diameter *A* shall be either 4 mm ± 0,1 mm or 6 mm ± 0,1 mm. For testing suction catheters with outside diameters greater than 3 mm, diameter *A* shall be 6 mm ± 0,1 mm.

A.2.2 *Clamp*, for suspending the suction catheter.

A.2.3 *Device for attaching a weight to the test connector and a weight*, the combined mass of connector, device and weight being 0,5 kg for testing catheters with outside diameters of up to and including 3 mm and 1 kg for testing those with outside diameters greater than 3 mm.

A.2.4 *Stopwatch.*

A.2.5 *Means of conditioning the suction catheter and test connector*, at (23 ± 2) °C and at (50 ± 20) % relative humidity and carrying out the test under the same conditions.

A.3 Test procedure

A.3.1 Condition the suction catheter and the test connector at (23 ± 2) °C and at (50 ± 20) % relative humidity for 1 h and carry out the test under the same conditions.

A.3.2 Ensure that the female end of the catheter and the test connector are clean and dry.

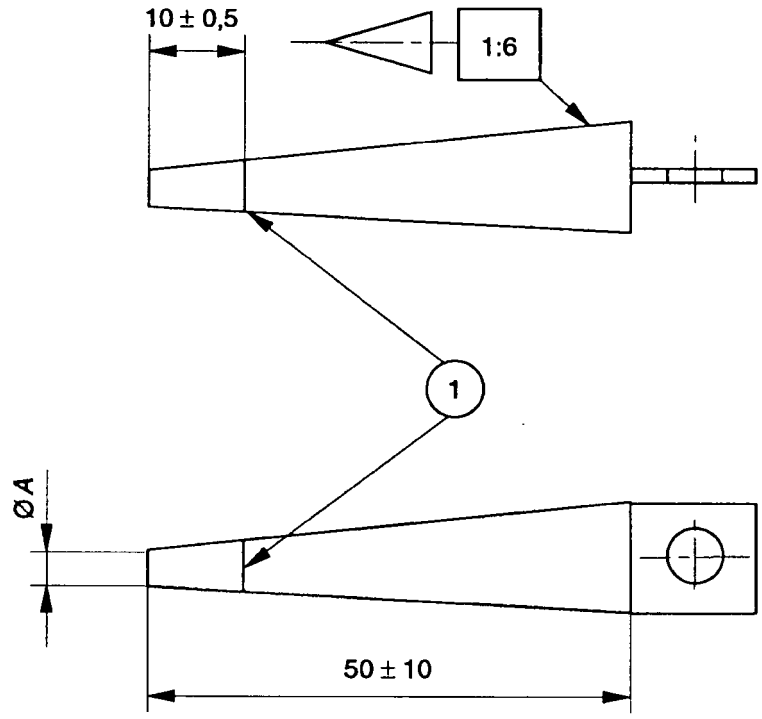
A.3.3 Fit the appropriate test connector (**A.2.1**) into the female end to a depth of engagement up to, or beyond, the mark circumscribed on the connector.

A.3.4 Suspend the catheter by clamping it at a point between 30 mm and 60 mm from the female end.

A.3.5 Manually support the weight. 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 1 min, and observe.

A.4 Expression of results

Record whether the test connector becomes detached from the female end of the suction catheter.



1 Circumscribed mark

Dimensions in millimetres

Figure A.1 — Test connector for testing security of fit of female ends

Annex B (normative)
Test method for security of construction

B.1 Principle

The security of attachment of any component permanently attached to the shaft is tested by applying an axial separation force to the component relative to the shaft of the suction catheter.

B.2 Apparatus

B.2.1 *Means of conditioning the suction catheter*, at (23 ± 2) °C at (50 ± 20) % relative humidity and carrying out the test under the same conditions.

B.2.2 *Means of separately securing the component under test and the shaft of the suction catheter*, and separating the two at a rate of (200 ± 20) mm/min and measuring and recording the axial separation force applied.

B.3 *Procedure*

B.3.1 Condition the suction catheter at (23 ± 2) °C and at (50 ± 20) % relative humidity for 1 h and carry out the test under the same conditions.

B.3.2 Separate the component under test and the shaft of the catheter at a rate of (200 ± 20) mm/min and observe whether the component becomes detached from the shaft before the appropriate minimum force given in Table 4 has been reached.

B.4 Expression of results

Record whether the component becomes detached from the shaft before the appropriate minimum force given in Table 4 has been reached.

Annex C (normative)
Test method for residual vacuum

C.1 Principle

The effectiveness of the vacuum control device as a means of relieving vacuum at the patient end is tested by measuring the residual vacuum at the tip of the catheter with the vacuum control device in the relief position, and with suction being applied to the machine end of the catheter.

C.2 Apparatus

Flowmeter, capable of measuring a flow rate of 30 l/min with a limit of error of 5 %, and a resistance to flow of less than 0,1 kPa at 30 l/min.

C.2.1 *Adjustable vacuum pump.*

C.2.2 *Manometer*, with a limit of error of ±0,01 kPa (0,1 cmH_2O).

C.3 Procedure

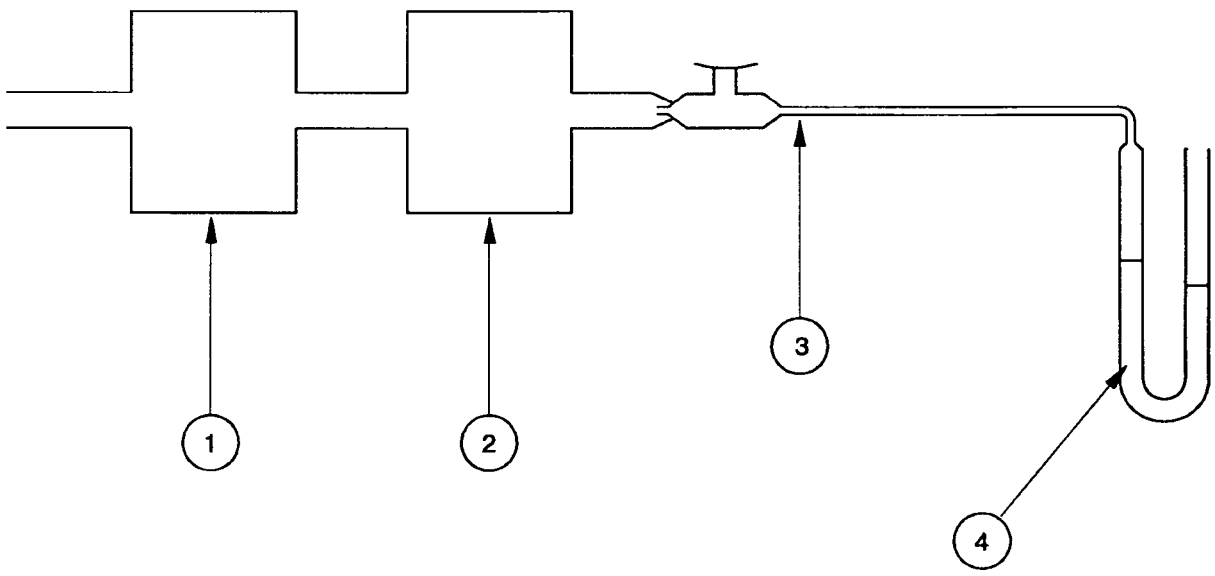
C.3.1 Assemble the apparatus, as shown in Figure C.1, with the flowmeter fitted to the exit of the vacuum pump, ensuring an airtight fit between the catheter and the manometer.

C.3.2 Open the catheter vacuum control device to the relief position.

C.3.3 Switch on the vacuum pump and adjust the applied vacuum until a flow rate of 30 l/min is indicated on the flow meter.

C.4 Expression of results

Express the value of the residual vacuum in kPa as indicated by the reading on the manometer.



1 Flowmeter
2 Vacuum pump
3 Suction catheter with vacuum control device
4 Manometer

Figure C.1 — Apparatus for residual vacuum test

Annex D (informative)
Guidance on design and materials

D.1 The inside surface of the suction catheter should be smooth and free from irregularities.

D.2 The outside surface of the suction catheter should be free from characteristics which would hinder easy insertion through all types of plastics, rubber and metal oro- and naso-tracheal tubes, tracheostomy tubes and appropriate connectors.

The outside surface of the shaft should be finished so as to reduce surface drag.

D.3 The tip at the patient end of the suction catheter should be well-rounded.

D.4 The edges of eye(s) and the terminal orifice of the suction catheter should be smooth and free from sharp edges.

D.5 The materials used for the manufacture of suction catheters should allow construction of a suction catheter with the thinnest possible wall, which at the same time maintains resistance to collapse and kinking.

D.6 Suction catheters under normal conditions of use should be reasonably resistant to deterioration by anaesthetic vapours and gases.

Annex E (informative)
Bibliography

EN 980, *Graphical symbols for use in the labelling of medical devices.*

prEN 1041, *Terminology, symbols and information provided with medical devices — Information supplied by the manufacturer with medical devices.*

EN 1282-1, *Anaesthetic and respiratory equipment — Tracheostomy tubes — Part 1: Tubes for use in adults.*

EN 1282-2, *Tracheostomy tubes — Part 2: Paediatric tubes.*

prEN 1782, *Tracheal tubes and connectors.*

EN ISO 4135, *Anaesthesiology — Vocabulary.* (ISO 4135:1995)

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