BRITISH STANDARD

BS EN
1283 : 1996

Haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and their extracorporeal circuits

The European Standard EN 1283 : 1996 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/23, Cardiovascular implants, dialysis systems and oxygenators, upon which the following bodies were represented:

Association of Anaesthetists of Great Britain and Ireland
Association of British Health-care Industries
Association of Renal Technicians
British Cardiac Society
British Textile Technology Group
Department of Health
Institute of Physics and Engineering in Medicine and Biology
Medical Sterile Products Association
National Heart and Lung Institute
Renal Association
Royal College of Nursing
Royal College of Physicians of London
Royal College of Surgeons of England
Scottish Office
Society of Cardiothoracic Surgeons of Great Britain and Ireland
Society of Perfusionists (of Great Britain and Ireland)
Vascular Surgical Society of Great Britain

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on
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Contents

National foreword

This British Standard has been prepared by Technical Committee CH/23, Cardiovascular implants, dialysis systems and oxygenators, and is the English language version of EN 1283 : 1996 *Haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and their extracorporeal circuits* published by the European Committee for Standardization (CEN). It supersedes BS 7297 : Part 1 : 1990 *Haemodialysers and related equipment — Part 1: Specification for haemodialysers, haemofilters and haemoconcentrators* and BS 7297 : Part 2 : 1990 *Haemodialysers and related equipment — Part 2: Specification for extracorporeal circuits for use with haemodiafilters, haemofilters and haemoconcentrators*, which are withdrawn.

Cross-references

Publication referred to	Corresponding British Standard
EN 556 : 1994	BS EN 556 : 1995 *Sterilization of medical devices — Requirements for terminally-sterilized devices to be labelled 'Sterile'*
prEN 980	BS EN 980 *Terminology, symbols and information provided with medical devices — Graphical symbols for use in the labelling of medical devices*[1)]
prEN 1041	BS EN 1041 *Terminology, symbols and information provided with medical devices — Information supplied by the manufacturer with medical devices*[1)]
EN 30993-1 : 1993	BS EN 30993 *Biological evaluation of medical devices* Part 1 : 1994 *Guidance on selection of tests*
prEN 30993-7 : 1995	BS EN ISO 10993 *Biological evaluation of medical devices* Part 7 : 1996 *Ethylene oxide sterilization residuals*
prEN 30993-11 : 1996	BS EN ISO 10993 *Biological evaluation of medical devices* Part 11 : 1996 *Test for systemic toxicity*
EN 46001 : 1993	BS EN 46001 : 1994 *Application of EN 29001 (BS 5750 : Part 1) to the manufacture of medical devices*
EN 46002 : 1993	BS EN 46002 : 1994 *Application of EN 29002 (BS 5750 : Part 2) to the manufacture of medical devices*
HD 395-2-16 : 1989	BS 5724 *Medical electrical equipment* Part 2 *Particular requirements for safety* Section 2.16 : 1989 *Specification for haemodialysis equipment*
ISO 594-2 : 1987	BS 3930 *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment* Part 2 : 1991 *Specification for lock fittings*
ISO 7864 : 1988	BS 5081 *Sterile hypodermic syringes and needles* Part 2 : 1993 *Specification for sterile hypodermic needles for single use*

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

[1)] In preparation.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1283

April 1996

ICS 11.040.20

Descriptors: Medical equipment, dialysis apparatus, haemodialysers, filters, disposable equipment, definition, specifications, performance evaluation, physical properties, tests, information

English version

Haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and their extracorporeal circuits

Hémodialyseurs, hémodiafiltres, hémofiltres, hémoconcentrateurs et leurs circuits extracorporels

Hämodialysatoren, Hämodiafilter, Hämofilter, Hämokonzentratoren und dazugehörige Blutschlauchsysteme

This European Standard was approved by CEN on 1996-03-14. 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.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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 1283 : 1996 E

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 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 1996, and conflicting national standards shall be withdrawn at the latest by October 1996.

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, United Kingdom.

0 Introduction

This European Standard contains requirements and acceptance criteria (including test methods) for safety-related parameters for haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and the extracorporeal circuits for these devices.

This European Standard contains only those requirements that are specific to the devices concerned. Non-specific requirements are covered by references to other European or International Standards, listed in the normative references section. Since non-toxicity is anticipated to be the subject of a future standard, this standard does not cover non-toxicity.

1 Scope

This European Standard specifies requirements for sterile, single use haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and the extracorporeal circuits for these devices (including any integral accessory lines, such as fluid and infusion lines and lines for connection to pressure monitors) intended for renal care and cardiovascular use on humans.

This European Standard does not apply to extracorporeal circuits for cardiovascular use or to other extracorporeal blood exchange devices, such as plasmafilters, haemoperfusion devices, vascular access devices, oxygenators, active medical devices or devices for peritoneal dialysis.

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	*Sterilization of medical devices — Requirements for medical devices to be labelled 'sterile'*
prEN 980	*Terminology, symbols and information provided with medical devices — 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 30993-1	*Biological evaluation of medical devices — Part 1: Guidance on selection of tests* (ISO 10993-1 : 1992 + Technical Corrigendum 1 : 1992)
prEN 30993-7	*Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals* (ISO/DIS 10993-7 : 1994)
prEN 30993-11	*Biological evaluation of medical devices — Part 11: Test for systemic toxicity* (ISO 10993-11 : 1993)
EN 46001	*Quality systems — Medical devices — Particular requirements for the application of EN 29001*
EN 46002	*Quality systems — Medical devices — Particular requirements for the application of EN 29002*
HD 395-2-16	*Medical electrical equipment — Part 2: Particular requirements for the safety of haemodialysis equipment* (IEC 601-2-16 : 1989)
ISO 594-2 : 1987	*Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*
ISO 7864 : 1988	*Sterile hypodermic needles for single use*

3 Definitions

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

3.1 blood compartment

Part of haemodialysers, haemodiafilters, haemofilters and haemoconcentrators through which blood is intended to pass.

3.2 clearance

Volume of a solution from which a solute is completely removed per unit time.

3.3 dialysing fluid; dialysate; dialysis fluid

Solution which is intended to exchange solutes and/or water with blood during haemodialysis or haemodiafiltration.

3.4 dialysing fluid compartment

Part of a haemodialyser or haemodiafilter through which dialysing fluid is intended to pass.

3.5 haemoconcentration

Process whereby excess fluid, and possibly electrolytes, are removed from diluted blood across a semipermeable membrane.

3.6 haemoconcentrator

Device intended to perform haemoconcentration.

3.7 haemodiafilter

Device intended to perform haemodiafiltration.

3.8 haemodiafiltration

Process whereby solute imbalances in a patient's blood are corrected by means of simultaneous filtration and diffusion across a semipermeable membrane and replacement with an appropriate physiological fluid.

NOTE. This process normally includes fluid removal.

3.9 haemodialyser

Device intended to perform haemodialysis.

3.10 haemodialysis

Process whereby solute imbalances in a patient's blood are corrected, mainly by diffusion across a semipermeable membrane.

NOTE. This process normally includes fluid removal.

3.11 haemofilter

Device intended to perform haemofiltration.

3.12 haemofiltration

Process whereby solute imbalances in a patient's blood are corrected, mainly by filtration across a semipermeable membrane and replacement with an appropriate physiological fluid.

NOTE. This process normally includes fluid removal.

3.13 transmembrane pressure

Hydrostatic pressure exerted across a semipermeable membrane.

NOTE. For practical reasons the mean transmembrane pressure is generally expressed as either:

a) the difference between the arithmetic means of inlet and outlet pressures of the blood and dialysing fluid compartments of a haemodialyser or a haemodiafilter; or

b) the difference between the arithmetic mean of the inlet and outlet pressures of the blood compartment and the filtrate pressure of a haemofilter or a haemoconcentrator.

3.14 access port

Component intended to provide access to the interior of the extracorporeal circuit.

NOTE. Access can be for sampling and/or injection purposes.

3.15 sieving coefficient

Ratio of a solute concentration in the filtrate to the simultaneous concentration of the same solute in the plasma.

4 Requirements

4.1 Biological characteristics

4.1.1 *Sterility and non-pyrogenicity*

Pathways for blood and other fluids shall be sterile and non-pyrogenic.

NOTE. The fact that it is common practice to make aseptic connections to blood compartments and/or pathways should be considered.

Compliance shall be verified in accordance with **5.2.1**.

4.1.2 *Biocompatibility*

Parts of haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and the extracorporeal circuit that will come into direct or indirect contact with blood during their intended clinical use shall be biocompatible with respect to their intended use.

Compliance shall be verified in accordance with **5.2.2**.

4.2 Physical characteristics

4.2.1 *Structural integrity*

When tested in accordance with **5.3.1**, haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and extracorporeal circuits shall not leak.

NOTE. This requirement refers to the external integrity of the device.

4.2.2 *Blood compartment integrity*

When tested in accordance with **5.3.2**, the blood compartments of haemodialysers, haemodiafilters, haemofilters and haemoconcentrators shall not show leakage under the transmembrane pressures stated by the manufacturer for their intended clinical use (see **7.2.11**).

4.2.3 *Connectors and ports*

4.2.3.1 *Connections to the blood compartment*

Except if haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and the extracorporeal circuit are designed as an integral system, the dimensions of the blood inlet and outlet connectors of haemodialysers, haemodiafilters, haemofilters and haemoconcentrators shall be as given in figures 1 and 3 and the dimensions of the connectors of the extracorporeal circuit shall be as given in figures 2 and 3.

Compliance shall be verified by inspection.

4.2.3.2 *Connections for dialysing fluid or filtrate*

Except if haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and the dialysing fluid and/or filtrate lines are designed as an integral system, the dimensions of the ports of haemodialysers, haemodiafilters, haemofilters and haemoconcentrators shall be as given in figure 4.

Compliance shall be verified by inspection.

4.2.3.3 *Connections to vascular access devices*

Except if the extracorporeal circuit and the vascular access device are designed as an integral part, the extracorporeal circuit shall terminate in a male 6 % (Luer) taper lock fitting in accordance with ISO 594-2.

Compliance shall be verified by inspection.

4.2.3.4 *Connections to ancillary components*

Except if the extracorporeal circuit and any ancillary components are designed as integral parts and except for connectors for substitution fluid containers, the extracorporeal circuits shall terminate in a female 6 % (Luer) taper lock fitting in accordance with ISO 594-2.

Compliance shall be verified by inspection.

4.2.3.5 *Access ports*

When tested in accordance with **5.3.3**, any access ports which incorporate a membrane intended to be pierced by a needle and which are incorporated in the extracorporeal circuit, shall not leak.

Any access ports shall be designed so as to minimize the risk of the needle piercing the extracorporeal circuit completely and/or causing potential leakage.

Access ports shall not be located downstream of the intended location for any air detection device.

4.2.4 ***Volume***

When tested in accordance with **5.3.4**, the volume of the blood compartments of haemodialysers, haemodiafilters, haemofilters, haemoconcentrators and the volume of the extracorporeal circuit shall be within the range of values stated by the manufacturer (see **7.2.2**).

4.2.5 ***Pressure drops***

When tested in accordance with **5.3.5**, the pressure drops across the blood compartments of haemodialysers, haemodiafilters, haemofilters and haemoconcentrators and the dialysing fluid compartments of haemodialysers and haemodiafilters shall be within the range of values stated by the manufacturer (see **7.2.7**).

4.3 Performance characteristics

4.3.1 ***Clearance of haemodialysers and haemodiafilters***

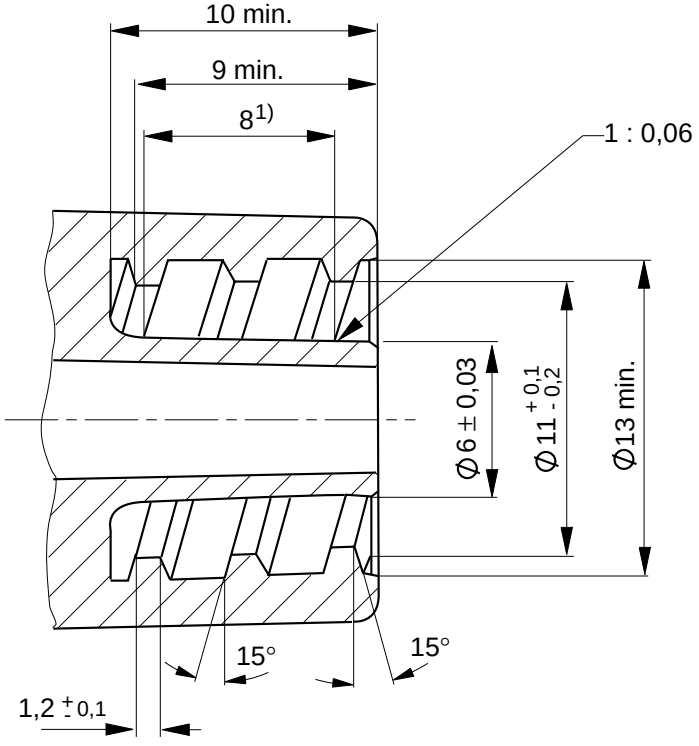
When measured in accordance with **5.4.1**, the clearance rates of urea, creatinine, phosphate, cyanocobalamin and, for haemodiafilters, inulin shall be within the range of values stated by the manufacturer (see **7.2.6**a).

4.3.2 ***Sieving coefficient for haemodiafilters, haemofilters and haemoconcentrators***

When measured in accordance with **5.4.2**, the sieving coefficients for albumin, inulin, myoglobin and cyanocobalamin shall be within the range of values stated by the manufacturer (see **7.2.6**).

4.3.3 ***Ultrafiltration rate***

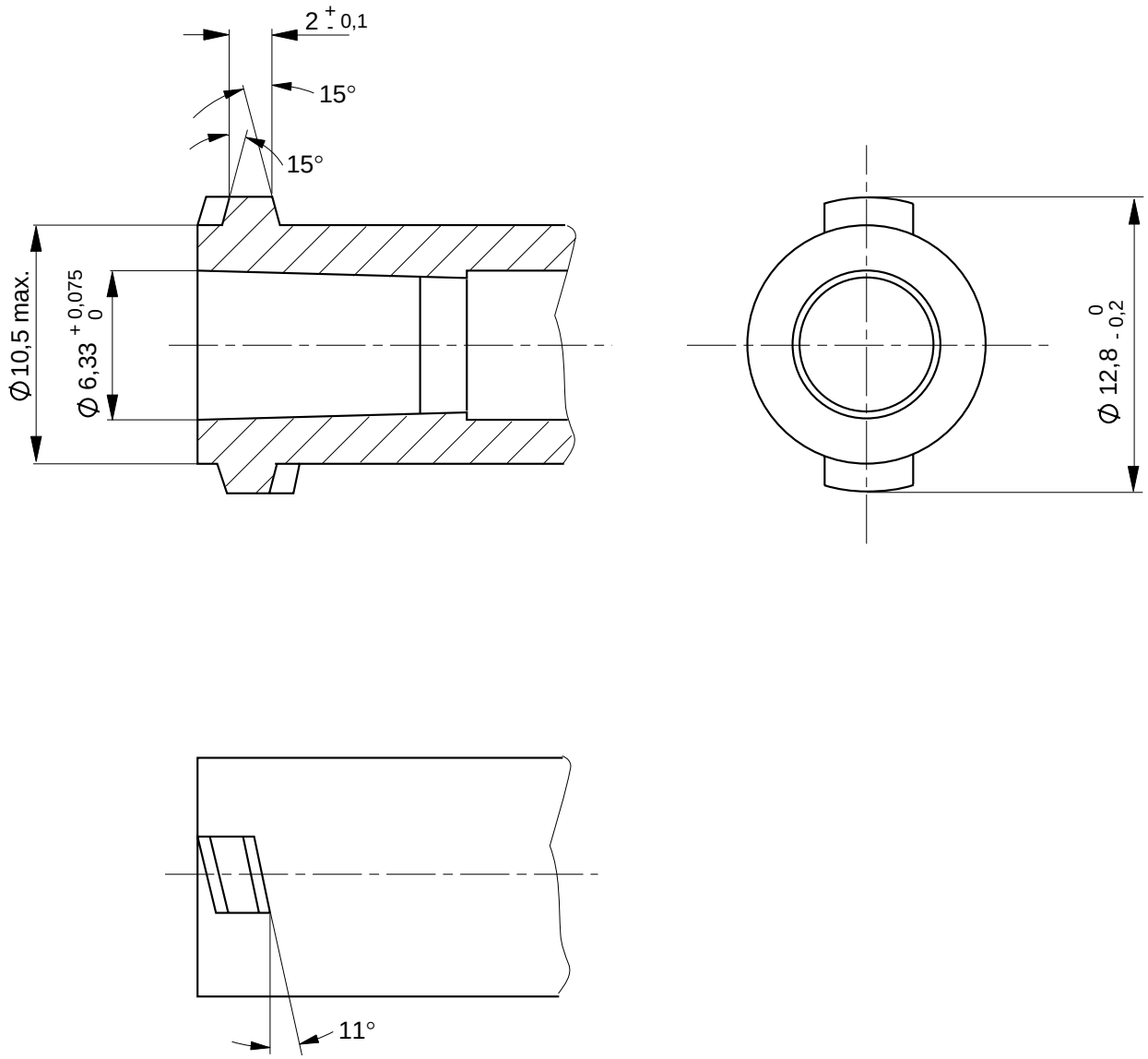
When measured in accordance with **5.4.3**, the ultrafiltration rate shall be within the range of values stated by the manufacturer (see **7.2.6**).



Dimensions in mm

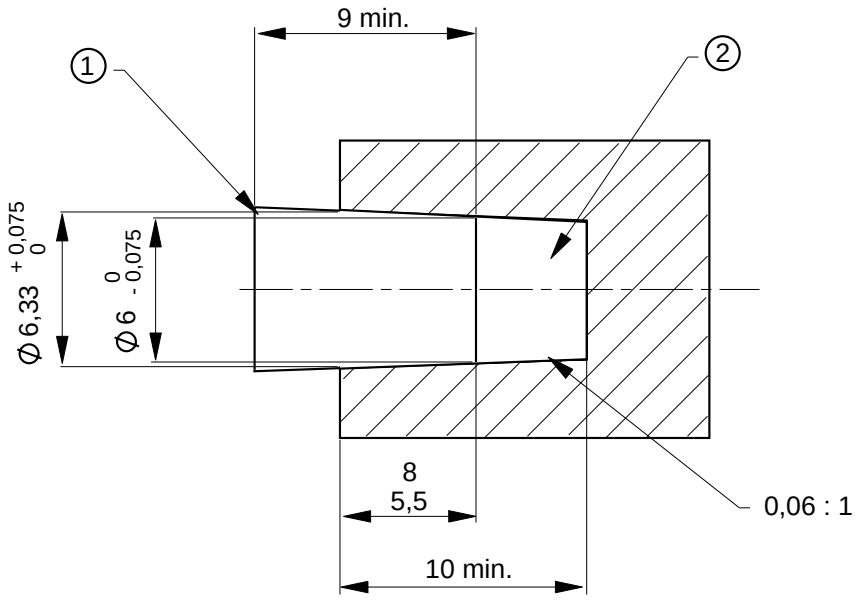
1) Double thread

Figure 1. Main fitting dimensions of blood inlet and outlet connections



Dimensions in mm

Figure 2. Main fitting dimensions of extracorporeal circuit connector to blood ports of haemodialyser, haemofilter or haemoconcentrator

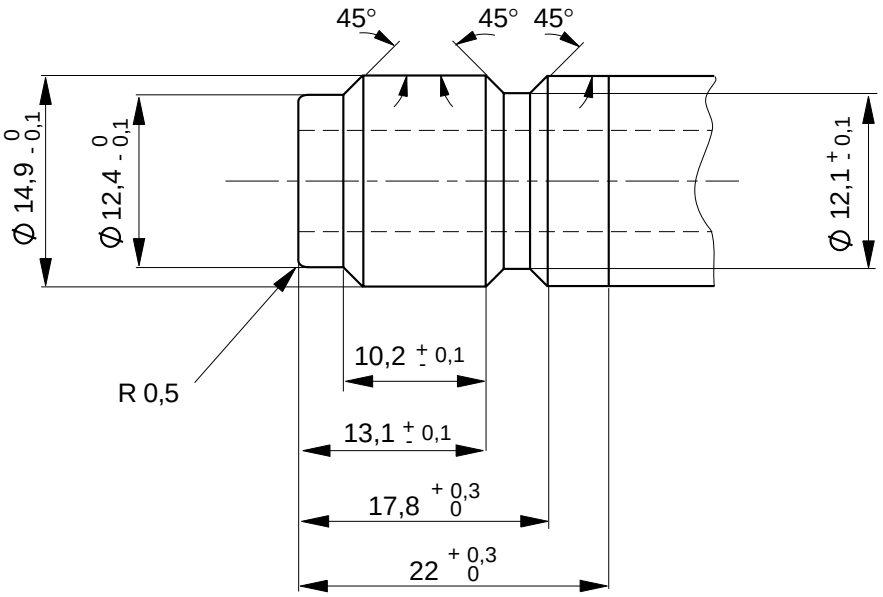


Dimensions in mm

1 Outer cone

2 Inner cone

Figure 3. Length of engagement of male and female cones of blood inlet and outlet connectors



Dimensions in mm

Figure 4. Main fitting dimensions of dialysing fluid inlet and outlet port

5 Test methods

5.1 General

Carry out tests and measurements with the device under test prepared in accordance with the manufacturer's instructions for the intended clinical use.

Unless otherwise stated in clause **5**, use the pressures and flow rates stated by the manufacturer for the intended clinical use and conduct tests with the test liquids at (37 ± 1) °C. If the relationship between variables is non-linear, make sufficient determinations to permit valid interpolation between data points.

The test methods in clause **5** are reference methods. Other test methods may be used provided that they have been shown to be of comparable precision and reproducibility.

5.2 Test methods for assessment of biological characteristics

5.2.1 *Sterility and non pyrogenicity*

Verify compliance in accordance with EN 556 and prEN 30993-11.

NOTE. EN 550, EN 552 and EN 554 contain suitable test methods for validation.

5.2.2 *Biocompatibility*

Verify compliance, as relevant, by the test methods for the finished device in accordance with EN 30993-1 and/or prEN 30993-7.

5.3 Test methods for physical characteristics

5.3.1 *Structural integrity*

Fill the device under test with water and pressurize the water to a pressure 1,5 times the maximum stated by the manufacturer (see **7.3.1**). Maintain this pressure for approximately 60 s, and visually inspect the device for the emergence of water.

5.3.2 *Blood compartment integrity*

5.3.2.1 *Test liquids*

a) **Anticoagulated bovine or human blood**, with a haematocrit value of (32 ± 2) % and a protein content of (60 ± 5) g/l.

b) **Dialysing fluid**.

5.3.2.2 *Procedure*

a) Fill the blood compartment of the device with blood (**5.3.2.1**a) and circulate it through the blood compartment, while gradually increasing the transmembrane pressure to 1,5 times the maximum stated by the manufacturer (see **7.2.1**) over a period not exceeding 10 min;

b) If testing haemodialysers and haemofilters, simultaneously circulate dialysing fluid (**5.3.2.1**b) through the dialysing fluid compartment;

c) Continue circulating the test liquid(s) for 30 min. During this time either:

1) pass the dialysing fluid leaving the device through a blood leak detector, according to HD 395-2-16; or

2) inspect the filtrate visually for evidence of the presence of blood.

NOTE. The composition of the blood (**5.3.2.1**a) should be monitored and, if necessary, corrected.

5.3.3 *Access ports*

5.3.3.1 *Equipment*

Hypodermic needle, as stated by the manufacturer (see **7.3.5**) or, if the manufacturer gives no details, of outside diameter 0,8 mm and in accordance with ISO 7864.

5.3.3.2 *Procedure*

Fill the portion of the extracorporeal circuit that contains the access port with water and apply a pressure 1,5 times the maximum stated by the manufacturer (see **7.3.1**). Puncture the access port with the needle, and insert and withdraw the needle a further five times through the puncture. Maintain the pressure for 6 h, and visually inspect the device for the emergence of water.

NOTE. The water may be circulated through the device.

5.3.4 *Volume*

5.3.4.1 *Test liquids*

a) **A non-ultrafilterable liquid**.

b) **Any aqueous solution**.

5.3.4.2 *Procedure*

5.3.4.2.1 *Blood compartment*

Fill the dialysing fluid/filtrate compartment with an aqueous solution (**5.3.4.1**b). Do not circulate the aqueous solution. Fill the blood compartment gradually with a non-ultrafilterable liquid (**5.3.4.1**a). Measure the volume of non-ultrafilterable liquid necessary to fill the blood compartment. Make measurements over the range of transmembrane pressures stated by the manufacturer (see **7.2.1**).

5.3.4.2.2 *Extracorporeal circuit*

Attach the extracorporeal circuit to an appropriate machine to support the circuit.

Fill with an aqueous solution (**5.3.4.1**b) those portions of the extracorporeal circuit, including drip and expansion chambers, which may be filled with blood during their intended clinical use. Measure the volume of aqueous solution necessary to fill the circuit.

NOTE. The volumes of any drip and expansion chambers may be measured separately.

5.3.5 *Pressure drops*

5.3.5.1 *Test liquids*

a) **Anticoagulated bovine or human blood**, with a haematocrit value of (32 ± 2) % and a protein content of (60 ± 5) g/l.

b) **Dialysing fluid**.

5.3.5.2 *Procedure*

Measure the pressure drop over the manufacturer's stated range of blood and dialysing fluid flow rates and transmembrane pressures (see **7.2.1**). Use blood (**5.3.5.1**a) for testing the pressure drop across the blood compartment and use dialysing fluid (**5.3.5.1**b) for testing the pressure drop across the dialysing fluid compartment.

5.4 Performance characteristics

5.4.1 *Clearance of haemodialysers and haemodiafilters*

5.4.1.1 *Test liquids and equipment*

a) **Dialysing fluid** (adjusted to pH ($7{,}4 \pm 0{,}1$) if phosphate is used as a solute (see **5.4.1.1**b 4)).

b) **Test liquid** comprising dialysing fluid (**5.4.1.1**a) in which one or more of the following substances have been dissolved:

1) urea;
2) creatinine;
3) cyanocobalamin (vitamin B_{12});
4) phosphate (solution adjusted to pH ($7{,}4 \pm 0{,}1$));
5) inulin.

c) **Test equipment** as shown in figure 5.

5.4.1.2 *Procedure*

Set up the test circuit as shown in figure 5. Collect test samples after steady state has been reached for the test liquid (**5.4.1.1**b) and the dialysing fluid (**5.4.1.1**a) at each flow rate of blood and dialysing fluid stated by the manufacturer (see **7.2.1**).

Calculate the clearance (C) by means of the expression (which takes ultrafiltration into account):

$$C = \frac{C_{Bin} - C_{Bout}}{C_{Bin}} Q_{Bin} + \frac{C_{Bout}}{C_{Bin}} Q_F$$

where

C_{Bin} is the concentration of a solute at the blood inlet side of the device under test;

C_{Bout} is the concentration of a solute at the blood outlet side of the device under test;

Q_{Bin} is the blood flow rate at the blood inlet of the device under test;

Q_F is the ultrafiltration flow rate.

NOTE. A practical method of confirming the reliability of the measurement is to monitor the mass balance error (MBE), estimated by means of the expression:

$$MBE = \frac{Mass_{in} - Mass_{out}}{Mass_{in}}$$

where

$Mass_{in} = Q_{Bin}\, C_{Bin} - Q_{Bout}\, C_{Bout}$

$Mass_{in} = Q_{Dout}\, C_{Dout} - Q_{Din}\, C_{Din}$

where

Q_{Bout} is the blood flow rate at the blood outlet of the device under test;

Q_{Dout} is the dialysing fluid flow rate at the dialysing fluid outlet of the device under test;

Q_{Din} is the dialysing fluid flow rate at the dialysing fluid inlet of the device under test;

C_{Din} is the concentration of a solute at the dialysing fluid inlet side of the device under test;

C_{Dout} is the concentration of a solute at the dialysing fluid outlet side of the device under test.

5.4.2 *Sieving coefficient for haemodiafilters, haemofilters and haemoconcentrators*

5.4.2.1 *Test liquid and equipment*

a) **Bovine or human plasma**, with a protein content of not less than 60 g/l and containing one or more of the following substances:

1) albumin (present as plasma albumin);
2) inulin;
3) myoglobin;
4) cyanocobalamin (vitamin B_{12}).

b) **Test equipment** as shown in figure 6.

5.4.2.2 *Procedure*

NOTE. Any adsorption effects should be monitored and taken into consideration.

a) Set up the test circuit as shown in figure 6. Set the test liquid flow rate to the maximum blood flow rate stated by the manufacturer (see **7.2.1**) and the filtration rate to 20 % of the test liquid flow rate;

b) Collect test samples after steady state has been reached;

c) Calculate the sieving coefficient, S, by means of the expression:

$$S = \frac{2C_F}{C_{Bin} + C_{Bout}}$$

where

C_F is the concentration of a solute in the ultrafiltrate;

C_{Bin} is the concentration of a solute at the blood inlet side of the device under test;

C_{Bout} is the concentration of a solute at the blood outlet side of the device under test.

5.4.3 *Ultrafiltration rate*

5.4.3.1 *Test liquid and equipment*

a) **Anticoagulated bovine or human blood**, with a haematocrit value of (32 ± 2) % and a protein content of not less than 60 g/l;

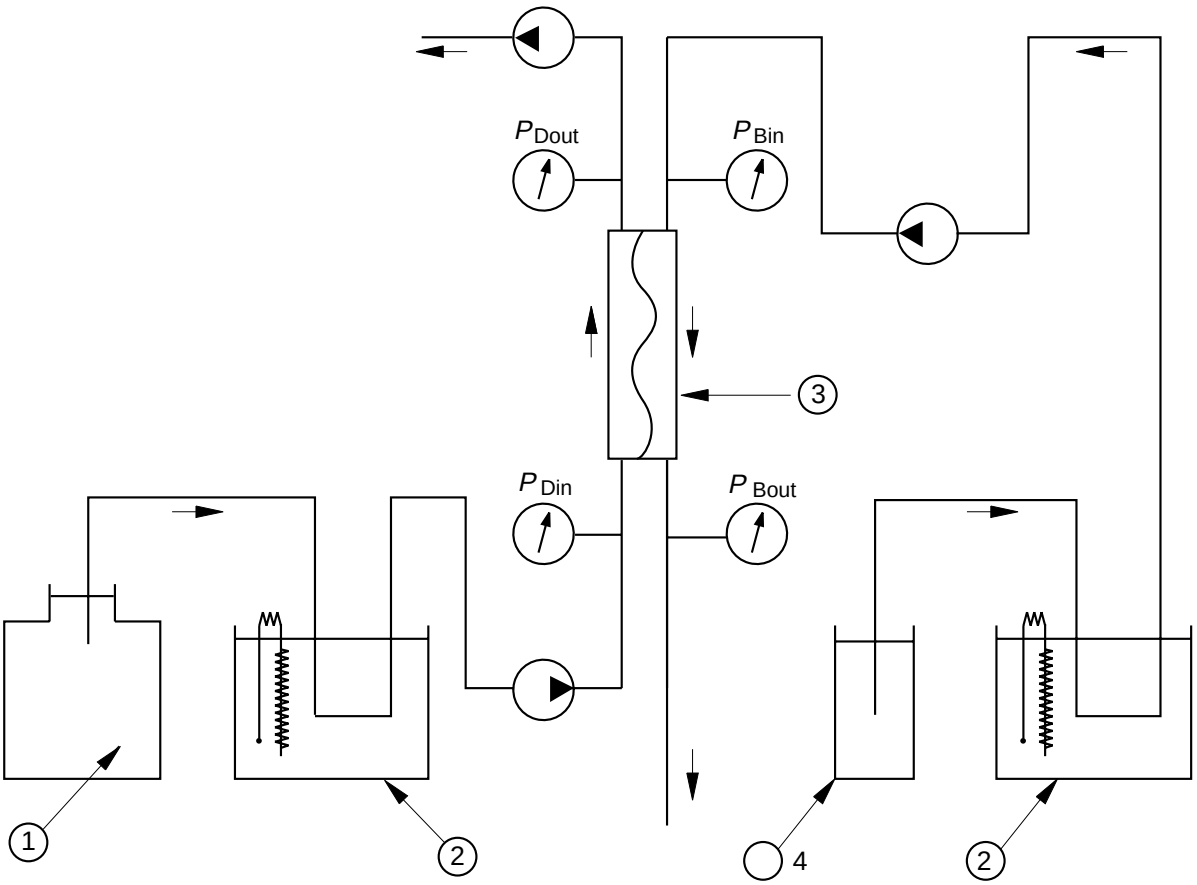
b) **Test equipment** as shown in figure 7.

5.4.3.2 *Procedure*

Set up the test circuit as shown in figure 7. Make measurements with the test liquid (**5.4.3.1**a) circulating through the blood compartment of the device while there is no fluid circulating through the other compartment, and in a sequence of measurement from minimum to maximum transmembrane pressure at each blood flow rate stated by the manufacturer (see **7.2.1**). Do not allow the priming pressure to exceed the maximum transmembrane pressure stated by the manufacturer (see **7.2.1**).

NOTE 1. Attention is drawn to the importance of maintaining a correct composition of the test fluid throughout the measurement.

NOTE 2. If the device design is such that the measurement cannot be performed without the presence of dialysing fluid, the measurement may be performed with circulating dialysing fluid.



P_{Bin} is the pressure of test liquid at the blood inlet side of the device under test

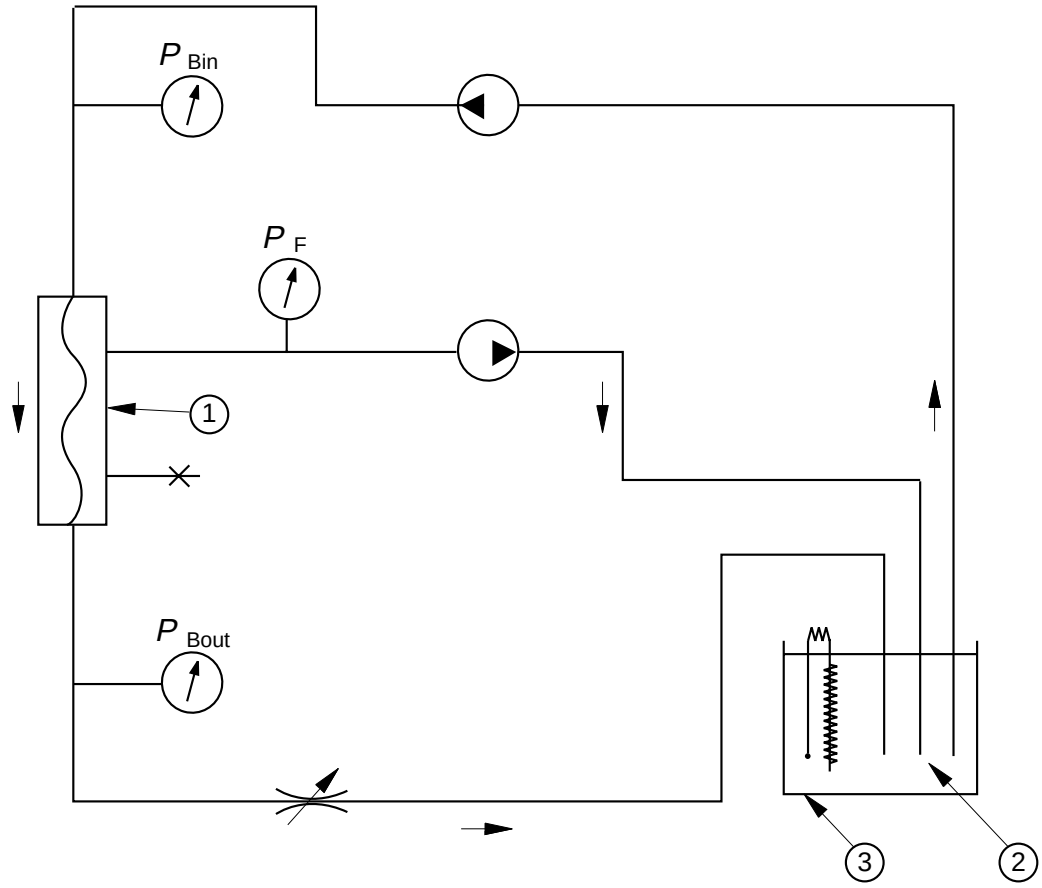
P_{Bout} is the pressure of test liquid at the blood outlet side of the device under test

P_{Din} is the pressure of dialysing fluid at the dialysing fluid inlet side of the device under test

P_{Dout} is the pressure of dialysing fluid at the dialysing fluid outlet side of the device under test

1 Dialysing fluid
2 Temperature-regulated bath
3 Device under test
4 Test liquid

Figure 5. Schematic test circuit for determination of the clearances of haemodialysers and haemodiafilters



P_{Bin} is the pressure of test liquid at the blood inlet side of the device under test

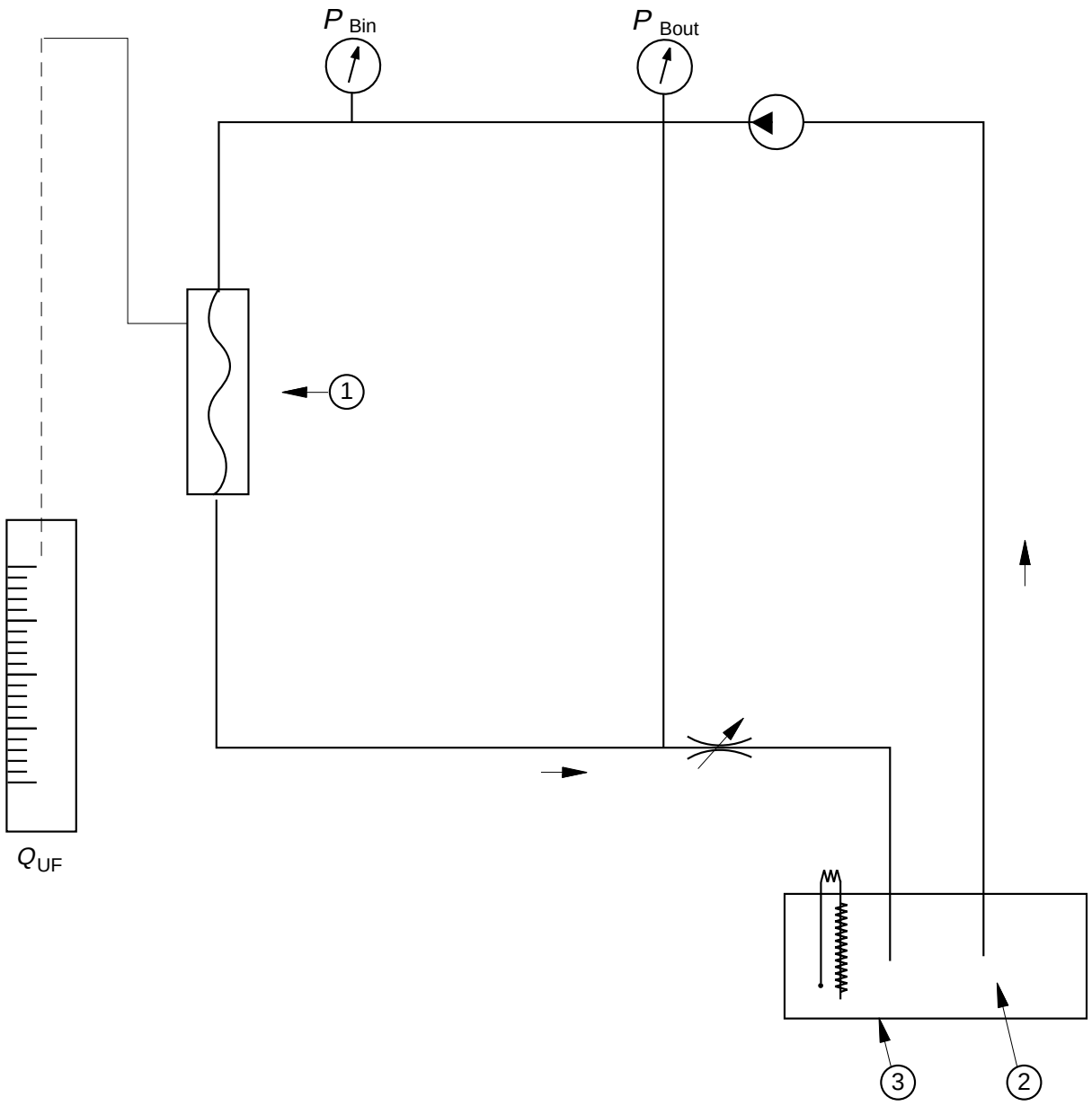
P_{Bout} is the pressure of test liquid at the blood outlet side of the device under test

P_F is the pressure of filtrate at the dialysing fluid outlet side of the device under test

1 Device under test 3 Temperature-regulated bath

2 Test liquid

Figure 6. Schematic test circuit for determination of sieving coefficients of haemodiafilters, haemofilters and haemoconcentrators



P_{Bin} is the pressure of test liquid at the blood inlet side of the device under test

P_{Bout} is the pressure of test liquid at the blood outlet side of the device under test

Q_{UF} is the ultrafiltrate volume

1 Device under test 3 Temperature-regulated bath

2 Test liquid

Figure 7. Schematic test circuit for the determination of the ultrafiltration rate

6 Packaging

Packaging shall comply with the appropriate requirements of EN 46001 and/or EN 46002.

7 Information provided by the manufacturer

The information provided by the manufacturer shall comply with the appropriate requirements of prEN 980 and prEN 1041. In addition, the following information shall be provided.

7.1 Information to be given on the device, as applicable

7.1.1 The arterial portion of the extracorporeal circuit shall be colour coded red and the venous portion blue. The colour coding shall be prominently displayed within 0,1 m of that end of the circuit which is intended for connection to the patient.

7.1.2 The maximum transmembrane pressure.

7.1.3 The direction of blood and/or dialysing fluid flows, if necessary.

NOTE. Colour coding may be used.

7.2 Information to be given in the instruction leaflet, as applicable

Each transport container shall contain an instruction leaflet. Data shall be given with relevant tolerances.

7.2.1 The specified ranges for blood and dialysing fluid flow rates and pressures (including transmembrane pressure).

7.2.2 The volumes of blood compartments and extracorporeal circuits.

NOTE. The volumes of any drip and expansion chambers may be presented separately.

7.2.3 The membrane surface area of haemodialysers, haemodiafilters, haemofilters and haemoconcentrators.

7.2.4 The length, inner diameter, wall thickness and material of any pump segment.

7.2.5 The generic names of materials of construction intended for direct or indirect contact with blood.

7.2.6 Performance characteristics, i.e.:

a) clearance rates for haemodialysers and haemodiafilters of urea, creatinine, phosphate, cyanacobalamin and, for haemodiafilters, inulin;

b) sieving coefficients for haemodiafilters, haemofilters and haemoconcentrators of albumin, inulin, myoglobin and cyanocobalamin;

c) ultrafiltration rates for the stated range of blood flows and transmembrane pressures.

7.2.7 The pressure drops at the specified flow rates across the blood compartments of haemodialysers, haemodiafilters, haemofilters and haemoconcentrators and across the dialysing fluid compartments of haemodialysers and haemodiafilters.

7.2.8 If integral pressure transducer lines are provided, an instruction that devices to prevent cross-contamination shall be used.

7.2.9 A list of disinfectants for external application (e.g. when taking blood samples) that are compatible with the relevant parts of the extracoporeal circuit.

7.2.10 A statement that the following information is available from the manufacturer upon request:

a) information about test methods used to obtain performance characteristics;

b) in vivo performance characteristics;

c) the volume of residual blood.

7.2.11 Directions for setting the device, including the maximum transmembrane pressure and the recommended priming and rinsing procedures for the device.

7.2.12 The recommended procedures for termination of a treatment session.

7.2.13 A typical circuit diagram, including the direction of fluid flows.

7.2.14 Recommendations on anticoagulation.

7.2.15 Relevant data on such parts that function as interfaces to active medical devices.

7.2.16 Method of sterilization.

7.3 Information to be given, as applicable, in the instruction leaflet in a prominent form

7.3.1 Pressure limitations.

7.3.2 Blood and dialysing fluid flow rate limitations.

7.3.3 A statement that, due to obligatory ultrafiltration, a zero ultrafiltration rate cannot be achieved without a risk of infusing dialysing fluid into the bloodstream and/or the risk of obstructing the blood pathway.

7.3.4 The importance of adhering to the manufacturer's instructions for rinsing.

7.3.5 Any need for special equipment.

NOTE. Details of the needle for testing access ports may be given.

7.3.6 A list of significant adverse reactions.

7.3.7 A list of general and specific contraindications.

Annex A (informative)
Bibliography

EN 550 *Sterilization of medical devices — Validation and routine control of ethylene oxide sterilization*

EN 552 *Sterilization of medical devices — Validation and routine control of sterilization by irradiation*

EN 554 *Sterilization of medical devices — Validation and routine control of steam sterilization*

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