
British Standard

Haemodialysers and related equipment

Part 2. Specification for extracorporeal circuits for use with haemodialysers, haemofilters and haemoconcentrators

Contents	Page	Figures	Page
National foreword	Inside front cover	1 Main fitting dimensions of extracorporeal circuit connector to blood ports of haemodialyser, haemofilter or haemoconcentrator	3
Committees responsible	Back cover	2 Length of engagement of male and female cones of blood inlet and outlet connectors	3
Specification		3 Details of 6 % taper test fitting for connector to haemodialyser, haemofilter or haemoconcentrator blood port	4
1 Scope	1	4 Diagram for testing structural integrity of extracorporeal circuit	6
2 Normative references	1		
3 Definitions	1		
4 Requirements	1		
5 Test methods	5		
6 Packaging, marking and accompanying documentation	7		

National foreword

This Part of BS 7297 has been prepared under the direction of the Health Care Standards Policy Committee. It is identical with ISO 8638 : 1989 'Extracorporeal circuit for haemodialysers, haemofilters and haemoconcentrators', published by the International Organization for Standardization (ISO).

This Part of BS 7297 is concerned with the extracorporeal circuits intended for single use in conjunction with haemodialysers, haemofilters and haemoconcentrators for humans. The requirements will help to ensure the safety and satisfactory function of these circuits. It has not been found practicable, however, to specify materials of construction nor to give test methods for biocompatibility, validation of sterility, non-pyrogenicity and some performance characteristics of extracorporeal circuits. This standard therefore requires that materials used in the manufacture of these circuits will have been tested and that the methods and results are to be made available upon request.

The specifications for physical characteristics have been limited to those deemed necessary for safe and effective function of the extracorporeal circuits. The dimensions of the connectors to the blood ports of the haemodialyser, haemofilter or haemoconcentrator as well as to the blood access device have been specified to ensure compatibility of these circuits with the devices specified in BS 7297 : Part 1. The design and dimensions have been selected in order to minimize the risk of leakage of blood and the ingress of air. Connectors with either fixed or loose locking shells are permitted.

There are no internationally recognized standards for assessing the toxicity, biocompatibility and pyrogenicity of medical devices. Hence 4.2 and 4.4 require only that such assessments are to be carried out on samples of each device and that the details of the method(s) and the results are to be made available on request. However, in the UK, it is common practice to assess the biological hazards of medical devices by application of the principles and methods given in BS 5736 'Evaluation of medical devices for biological hazards'.

It has been assumed in the drafting of this British Standard that the procedures described should be carried out and applied only by appropriately qualified and experienced personnel.

This Part of BS 7297 is published simultaneously with Part 1 'Specification for haemodialysers, haemofilters and haemoconcentrators'. Other Parts of BS 7297 concerning plasma separators and the solutions to be used in haemodialysis are under consideration.

Cross-references

International standard	Corresponding British Standard
ISO 472 : 1979	BS 1755 Glossary of terms used in the plastics industry Part 1 : 1982 Polymer and plastics technology (Technically equivalent)
ISO 8637 : 1989	BS 7297 Haemodialysers and related equipment Part 1 : 1990 Specification for haemodialysers, haemofilters and haemoconcentrators (Identical)

ISO 594-2, to which reference is made in 4.6.3, 4.6.4 and 5.6.1.3.6, was still in preparation at the time of publication of this British Standard. The Technical Committee has reviewed the provisions of ISO/DIS 594-2 and has decided that they are acceptable for use in conjunction with this standard.

Additional information. Attention is especially drawn to BS 5724 : Section 2.16 : 1989, which specifies particular safety requirements for haemodialysis equipment.

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

Extracorporeal blood circuit for haemodialysers, haemofilters and haemoconcentrators

1 Scope

This International Standard specifies requirements for the extracorporeal blood circuit for single use which is to be used in conjunction with haemodialysers, haemofilters and haemoconcentrators.

Materials of construction and test methods for biocompatibility, validation of sterility, non-pyrogenicity and some performance characteristics are not specified; the rationale for these omissions is given in the Introduction.

This International Standard applies to the blood tubing and integral accessory tubing, including fluid and infusion tubings and tubing for attaching the extracorporeal blood circuit to pressure monitors.

This International Standard does not apply to haemodialysers, haemofilters, haemoconcentrators, vascular access devices, blood pumps, pressure monitors of the extracorporeal blood circuit, air detection devices, haemodialysis systems to prepare, maintain and monitor the dialysing fluid, and hardware used to perform haemofiltration or haemoconcentration.

NOTE — Requirements for haemodialysers, haemofilters and haemoconcentrators are specified in ISO 8637.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 472: 1979, *Plastics — Vocabulary*.

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

ISO 8637 : 1989, *Haemodialysers, haemofilters and haemoconcentrators*.

3 Definitions

For the purposes of this International Standard the following definitions apply.

3.1 arterial blood circuit: Portion of the extracorporeal blood pathway from the vascular access device of the patient to the blood inlet of the haemodialyser, haemofilter or haemoconcentrator.

3.2 non-pyrogenic: Free of pyrogenic materials within the limit of error of test methods for such determinations, as defined by the national regulatory agency of the country in which the device is to be marketed or, where available, an International Standard, and maintained in that state by suitable protection.

3.3 pump segment: Portion of the extracorporeal blood circuit that is acted upon by the blood pump.

3.4 sterile: Free from all living organisms within the limits of validation tests for sterility and maintained in that state by suitable protection.

3.5 venous blood circuit: Extracorporeal blood circuit from the outlet of the haemodialyser, haemofilter or haemoconcentrator, returning blood to the vascular access device of the patient.

4 Requirements

4.1 Good manufacturing practice

The extracorporeal circuit shall be manufactured in a clean environment and the fluid pathways shall be free of visible foreign material.

NOTE — Attention is drawn to the need to establish whether codes for good manufacturing practice exist in the country in which the device is produced and, if applicable, in the countries in which the device is to be marketed.

Testing shall be carried out in accordance with 5.1.

4.2 Toxicology and biological compatibility

Samples of the device shall be tested for freedom from toxicity using, if available, the method specified in the relevant national standard and the results of such tests shall indicate freedom from biological hazard. If requested, details of the test method

1) To be published.

and the results shall be made available by the manufacturer of the device.

NOTE — Attention is drawn to the need to establish whether national regulations or national standards governing toxicology and biocompatibility testing exist in the country in which the device is produced and, if applicable, in the countries in which the device is to be marketed.

Testing shall be carried out in accordance with 5.2.

4.3 Sterility

The fluid pathways of the device shall be supplied sterile.

NOTE — Attention is drawn to the need to establish whether national regulations or national standards governing sterility testing exist in the country in which the device is produced and, if applicable, in the countries in which the device is to be marketed.

Testing shall be carried out in accordance with 5.3.

4.4 Pyrogenicity

The blood pathway(s) of the device shall be non-pyrogenic. If requested, details of the test method(s) and the results shall be made available by the manufacturer of the device.

NOTE — Attention is drawn to the need to establish whether national regulations or national standards governing pyrogen testing exist in the country in which the device is produced and, if applicable, in the countries in which the device is to be marketed.

Testing shall be carried out in accordance with 5.4.

4.5 Residues from sterilization

After sterilization by the procedure recommended by the manufacturer, the device shall be tested for freedom from toxic residues that have adverse chemical, physical or biological effects on the blood or that result in release of clinically significant amounts of potentially toxic substances into the blood. If requested, details of the test methods and the results shall be made available by the manufacturer of the device.

NOTE — Attention is drawn to the need to establish whether national regulations or national standards governing testing for residues from sterilization exist in the country in which the device is produced and, if applicable, in the countries in which the device is to be marketed.

Testing shall be carried out in accordance with 5.5.

4.6 Mechanical characteristics

4.6.1 Structural integrity

Samples of the extracorporeal circuit shall be capable of withstanding

- a pressure above atmospheric pressure at sea level that is 1,5 times the manufacturer's specified maximum pressure, and
- a pressure 200 mmHg below atmospheric pressure (at sea level).

The pump segment shall be capable of withstanding a minimum of 24 h of use under worst-case conditions.

Testing shall be carried out in accordance with 5.6.1.

4.6.2 Connectors to haemodialyser, haemofilter or haemoconcentrator

The dimensions of the fitting for connection to the haemodialyser, haemofilter or haemoconcentrator shall be as given in figures 1 to 3.

The dimensions shall be checked in accordance with 5.6.2.

4.6.3 Connector to vascular access device

The fitting for connecting the extracorporeal circuit to a vascular access device shall be a male 6 % (Luer) taper lock fitting; this fitting shall be in accordance with ISO 594-2. *

The fitting shall be checked in accordance with 5.6.3.

4.6.4 Connectors to ancillary components

All parts of the extracorporeal circuit intended for use with ancillary components, such as heparin lines and pressure transducer lines, shall terminate in a female 6 % (Luer) taper lock fitting; this fitting shall be in accordance with ISO 594-2. *

The fittings shall be checked in accordance with 5.6.4.

4.6.5 Access ports

Where injection ports are incorporated into the extracorporeal circuit, they shall be capable of withstanding, without leakage, puncture by needle having at least an internal diameter of 0,8 mm (21 gauge). The injection ports shall be designed so as to minimize the risk of the needle piercing the tube completely and causing injury.

Testing shall be carried out in accordance with 5.6.5.

4.6.6 Colour coding

If the arterial extracorporeal blood circuit differs from the venous extracorporeal blood circuit, the arterial circuit shall be colour-coded **red** and the venous circuit shall be colour-coded **blue**. The coding shall be prominently displayed within 100 mm of the end of the tubing.

The colour coding shall be checked in accordance with 5.6.6.

4.7 Physical characteristics

4.7.1 Volume

The volume of the blood pathway of the venous and arterial extracorporeal circuits shall be equal to the manufacturer's stated values ± 20 %.

Testing shall be in accordance with 5.7.1.

4.7.2 Pump segment

The length and internal diameter of the pump segment shall be equal to the manufacturer's stated values ± 5 %.

The dimensions shall be checked in accordance with 5.7.2.

*See national foreword.