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Extracorporeal systems for blood purification —

Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters

Systèmes extracorporels pour la purification du sang —
Partie 2: Circuit sanguin extracorporel pour les hémodialyseurs, les hémodiafiltres et les hémofiltres

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Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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. 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. www.iso.org/patents

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of 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 WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword - Supplementary information

This document was prepared by Technical committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This first edition of ISO 8637-2:2018 cancels and replaces the third edition (ISO 8638:2010), which has been technically revised. The following changes have been made:

— Figure 1, Figure 2, and Figure 3 have been revised.

A list of all the parts in the ISO 8637 series can be found on the ISO website.

Introduction

This document is concerned with the extracorporeal blood circuit manufactured for single use and intended for use in conjunction with haemodialysers, haemodiafilters and haemofilters. The requirements specified in this document for the extracorporeal blood circuit will help to ensure safety and satisfactory function.

It was not found practicable to specify materials of construction. This document therefore requires only that materials have been tested and that the methods and results are made available upon request.

The dimensions of the connectors intended for connecting the extracorporeal blood circuit to a haemodialyser, haemodiafilter or haemofilter have been revised and specified to ensure compatibility with these devices, as specified in ISO 8637-1. The design and dimensions have been selected in order to minimize the risk of leakage of blood and ingress of air. Connectors with either fixed or loose locking shells are permitted.

This document reflects the consensus of physicians, manufacturers and other interested parties for devices that are approved for clinical use.

Extracorporeal systems for blood purification —

Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters

1 Scope

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

This document specifies requirements for the blood circuit for devices used in extracorporeal blood filtration therapies such as, but not limited to, haemodialysis, haemodiafiltration, haemofiltration and transducer protectors (integral and non-integral) intended for use in such circuits.

This document does not apply to:

— haemodialysers, haemodiafilters or haemofilters;

— plasmafilters;

— haemoperfusion devices;

— vascular access devices;

— blood pumps;

— pressure monitors for the extracorporeal blood circuit;

— air detection devices;

— systems to prepare, maintain or monitor dialysis fluid;

— systems or equipment intended to perform haemodialysis, haemodiafiltration, haemofiltration or haemoconcentration.

NOTE 1 Requirements for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators are specified in ISO 8637-1, and requirements for plasmafilters are specified in ISO 8637-3.

NOTE 2 Extracorporeal blood tubing sets can also be used for other extracorporeal therapies such as haemoperfusion, plasmafiltration and plasma adsorption.

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 7864, *Sterile hypodermic needles for single use — Requirements and test methods*

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

ISO 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

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:

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

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

3.1
air capture chamber
component intended to capture air and which can provide compliance to the blood circuit or allow pressure to be monitored

Note 1 to entry: Air capture chambers are also known as drip chambers, bubble traps or venous and arterial blood chambers.

3.2
extracorporeal blood circuit
blood tubing and integral accessory tubing, including fluid and infusion tubing, for attaching the extracorporeal blood circuit to pressure monitors and integral components

EXAMPLE (Of integral components.) Air capture chambers and transducer protectors.

3.3
fluid pathway
internal surfaces of the *extracorporeal blood circuit* (3.2)

3.4
labelling
written, printed, graphic or electronic matter that is affixed to a medical device or any of its containers or wrappers, or accompanies a medical device and which is related to identification, technical description and use of that medical device, but excluding shipping documents

3.5
pump segment
portion of the *extracorporeal blood circuit* (3.2) that is acted upon by the blood pump

3.6
transducer protector
pressure-transmitting sterile barrier
component of the *extracorporeal blood circuit* (3.2) that is intended to provide an interconnection between the extracorporeal blood circuit and the haemodialysis machine while allowing the pressure within the extracorporeal blood circuit to be measured by the machine

4 Requirements

4.1 Biological safety

Parts of the device that are intended to come into direct or indirect contact with blood shall be evaluated for freedom from biological hazards, in accordance with 5.2. 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.

4.2 Sterility

All fluid contacting surfaces of the device, and the mating surfaces of all connectors integral to the device, shall be sterile. Conformity shall be verified in accordance with 5.3.

4.3 Non-pyrogenicity

The blood pathway of the device shall be non-pyrogenic. Conformity shall be verified in accordance with 5.4.

4.4 Mechanical characteristics

4.4.1 Structural integrity

The device shall be capable of withstanding a positive pressure of 1,5 times the manufacturer's recommended maximum pressure above atmospheric pressure and a negative pressure not exceeding 700 mmHg (93,3 kPa below atmospheric pressure) or the highest obtainable negative pressure if at high elevation, when tested in accordance with 5.5.1.

4.4.2 Connectors to haemodialyser, haemodiafilter or haemofilter

4.4.2.1 Except where the haemodialyser, haemodiafilter or haemofilter and the extracorporeal blood circuit are designed as an integral system, the dimensions of the connectors for the haemodialyser, haemodiafilter or haemofilter shall be as given in Figure 1. Conformity shall be verified in accordance with 5.5.2.

4.4.2.2 Connectors made of semi-rigid materials shall meet the performance requirements of ISO 80369-7.

4.4.3 Connectors to vascular access device

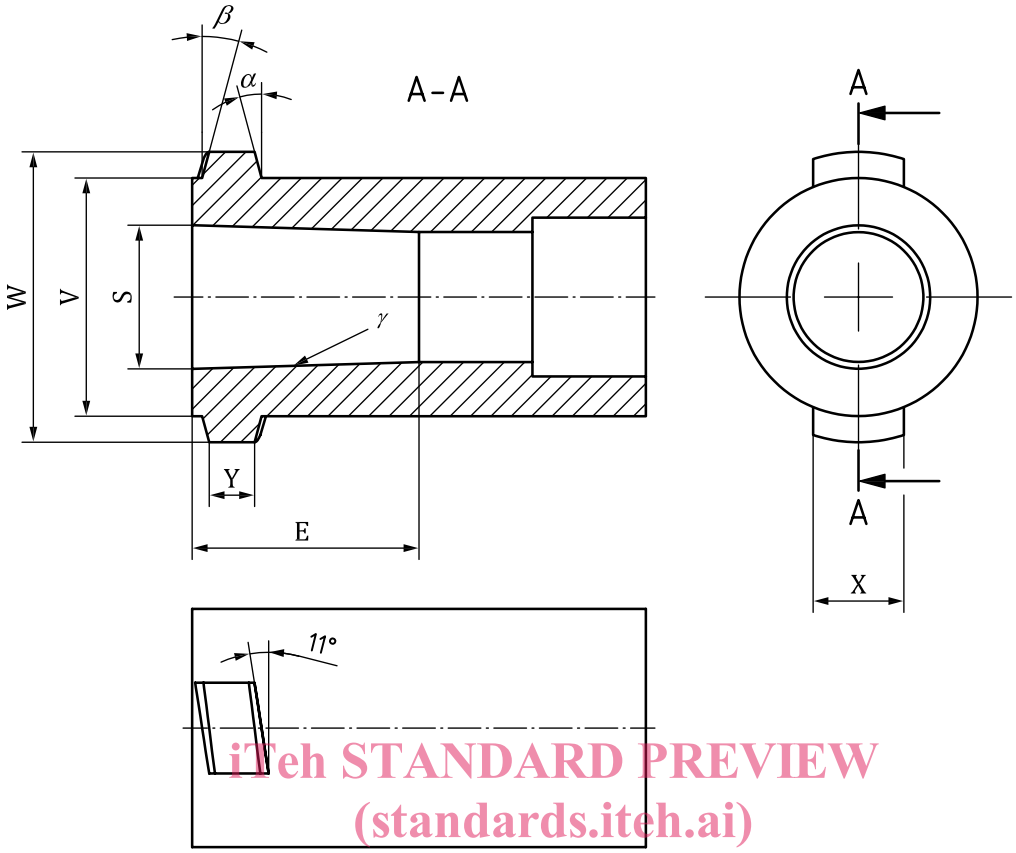
Except where the extracorporeal blood circuit and the vascular access device are an integral system, the dimensions of the connectors intended for connection to vascular access devices shall be a male 6 % (Luer) taper lock fitting (see ISO 80369-7). Connectors made of semi-rigid materials shall meet the performance requirements of ISO 80369-7. Conformity shall be verified in accordance with 5.5.3.

4.4.4 Connectors to ancillary components

All parts of the extracorporeal blood circuit intended for use with non-integral ancillary components, such as heparin lines, pressure-transducer lines, medication-administration lines and level-adjustment lines, shall terminate in fittings that meet the performance requirements of ISO 80369-7. Conformity shall be verified in accordance with 5.5.4.

4.4.5 Colour coding

The arterial patient-connection end shall be colour-coded red, and the venous patient-connection end shall be colour-coded blue. The coding shall be prominently displayed within 100 mm of the end of the tubing. Conformity to this requirement shall be verified in accordance with 5.5.5.



Symbol	Designation	Dimensions	Tolerances	Comments
α	angle of thread	15°		
β	angle of thread	15°		
γ	dimension taper rate	6:100		
δ	thread			Double thread pitch 8 mm
E	length of tapered region	10 mm or more		
S	cone diameter female	6,33 mm	+0,075 −0,0	Female connectors manufactured from soft or semi-rigid materials are not required to fulfill dimensional requirements but to comply with functional requirements.
V	core diameter	10,5 mm or less		
W	root diameter	12,8 mm	−0,20	
X	thread length	4 mm or more		
Y	thread width	2,0 mm	±0,10	

Figure 1 — Main fitting dimensions of extracorporeal blood circuit connector to blood ports of haemodialyser, haemodiafilter or haemofilter

4.4.6 Access ports

4.4.6.1 Needle access ports

Needle access ports shall not leak when tested in accordance with 5.5.6.1. The access ports shall be designed so as to minimize the risk of the needle piercing the tube completely and causing injury.

4.4.6.2 Needleless access ports

Needleless access ports shall not leak when tested in accordance with 5.5.6.2.

4.4.7 Blood pathway volume

The range of the blood pathway volume of the extracorporeal blood circuits shall be specified by the manufacturer. Conformity to this requirement shall be verified in accordance with 5.5.7.

NOTE The blood pathway volume is also known as the priming volume.

4.4.8 Air capture chamber fill level

The recommended fill level of the air capture chamber should be marked on the air capture chamber if that level is required for proper operation of some monitoring system. Conformity to this requirement shall be verified in accordance with 5.5.8.

4.4.9 Transducer protectors

4.4.9.1 Integral transducer protectors

Extracorporeal blood circuits supplied with integral transducer protectors shall be capable of preventing cross-contamination. The transducer protector shall be capable of maintaining a secure and leak-free connection to the haemodialysis machine when subjected to pressures of 1,5 times the manufacturer's recommended maximum pressure for the device. The machine side of the transducer protector shall be transparent (clear) to allow for visual inspection of blood contamination during use. Conformity to this requirement shall be in accordance with 5.5.9.

4.4.9.2 Non-integral transducer protectors

If not supplied as an integral component of the extracorporeal blood circuit, connectors shall be provided to allow the use of a transducer protector to prevent cross contamination. The transducer protector shall be capable of maintaining a secure and leak-free connection to the haemodialysis machine when subjected to pressures of 1,5 times the manufacturer's recommended maximum pressure for the device. The machine side of the transducer protector shall be transparent (clear) to allow for visual inspection of blood contamination during use. Conformity to this requirement shall be in accordance with 5.5.9.

4.4.10 Blood pathway flow dynamics

Extracorporeal blood pathways shall be designed to minimize harmful effects to the blood components. Conformity to this requirement shall be verified in accordance with 5.5.10.

4.4.11 Pump segment performance

The performance characteristics of the pump segment shall be evaluated over the range of inlet pressures (normally 0 mmHg to −250 mmHg).

Conformity to this requirement shall be verified in accordance with 5.5.11.