INTERNATIONAL STANDARD

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Cardiovascular implants and extracorporeal systems — Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters

Implants cardiovasculaires et systèmes extracorporels — Circuit sanguin extracorporel pour les hémodialyseurs, les hémodiafiltres et les hémofiltres

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 8638 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This third edition cancels and replaces the second edition (ISO 8638:2004), which has been technically revised.

Introduction

This International Standard 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 International Standard for the extracorporeal blood circuit will help to ensure safety and satisfactory function.

It was not found practicable to specify materials of construction. This International Standard 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 specified to ensure compatibility with these devices, as specified in ISO 8637. 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 International Standard reflects the consensus of physicians, manufacturers and other interested parties for devices that are approved for clinical use. Conformance with this International Standard is voluntary and it is not intended to supersede any national regulation.

Cardiovascular implants and extracorporeal systems — Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters

1 Scope

This International Standard specifies requirements for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators (hereafter referred to as "the device") and (integral and non-integral) transducer protectors which are intended for use in haemodialysis, haemodiafiltration and haemofiltration.

This International Standard 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 Requirements for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators are specified in ISO 8637.

2 Normative references

The following referenced documents are indispensable for the application 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 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 7864, *Sterile hypodermic needles for single use*

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*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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 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

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

3.3
fluid pathway
internal surfaces of the extracorporeal blood circuit

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.

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.

4.2 Sterility

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

4.3 Non-pyrogenicity

The blood pathway of the device shall be non-pyrogenic. Compliance 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 × the manufacturer's recommended maximum 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. Compliance 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 594-2.

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 594-2). Connectors made of semi-rigid materials shall meet the performance requirements of ISO 594-2 taper lock fittings. Compliance 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 594-2 taper lock fittings. Compliance 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. Compliance with this requirement shall be verified in accordance with 5.5.5.

Dimensions in millimetres

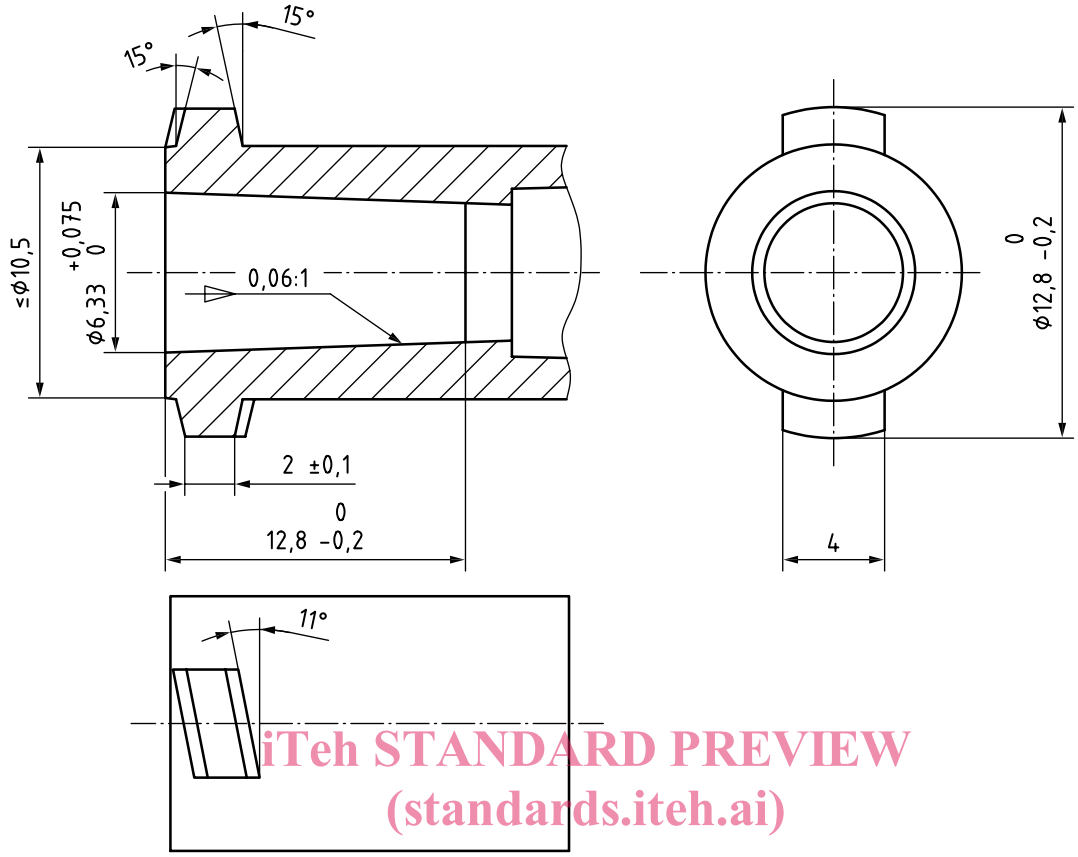

Figure 1 — Main fitting dimensions of extracorporeal blood circuit connector to blood ports of haemodialyser, haemodiafilter or haemofilter

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. Compliance with 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. Compliance with 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 × 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. Compliance with 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 × 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. Compliance with 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. Compliance with 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).

Compliance with this requirement shall be verified in accordance with 5.5.11.

4.5 Expiry date

If the expiry date is given, it shall be validated. Accelerated stability studies are acceptable if real time data are not available. Compliance with this requirement shall be verified in accordance with 5.6.

4.6 Tubing compliance

The blood tubing shall be capable of being occlusively clamped by the venous line clamp of the dialysis delivery system(s) with which the extracorporeal blood circuit is intended to be used, as indicated in the labelling for the blood tubing. Compliance with this requirement shall be verified in accordance with 5.7.

5 Test methods

5.1 General

The performance characteristics specified in Clause 4 shall be determined prior to marketing a new type of device and shall be re-evaluated after changes in the device that might alter its performance.

The sample of devices shall be drawn at random from the manufacturer's production and shall have passed all applicable quality control steps, as well as sterilization, if applicable. They shall be prepared according to the manufacturer's recommendations as though they are to be used for a clinical procedure.