
**Cardiovascular implants and artificial
organs — Extracorporeal blood circuit for
haemodialysers, haemodiafilters and
haemofilters**

*Implants cardiovasculaires et organes artificiels — Circuit sanguin
extracorporel pour les hémodialyseurs, les hémodiafiltres et les
hémoiltres*

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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*.

This second edition cancels and replaces the first edition (ISO 8638:1989), which has been technically revised.

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Introduction

This International Standard is concerned with extracorporeal blood circuits manufactured for single use and intended for use in conjunction with haemodialysers, haemodiafilters and haemofilters. The requirements specified in this International Standard for extracorporeal blood circuits will help to ensure their 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.

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Cardiovascular implants and artificial organs — Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters

1 Scope

This International Standard specifies requirements for single-use extracorporeal blood circuits (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 is not applicable 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 dialysing fluid,
- systems 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*

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 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

NOTE Examples of integral components are: air-capture chambers, transducer protectors.

3.2 fluid pathway
internal surfaces of the extracorporeal blood circuit

3.3 labelling
written, printed, graphic or electronic matter which is:

- affixed to a medical device or any of its containers or wrappers, or
- accompanying a medical device, and is related to identification, technical description and use of the medical device, but excluding shipping documents

3.4 pump segment
portion of the extracorporeal blood circuit that is acted upon by the blood pump

**3.5 transducer protector
pressure-transmitting sterile barrier**
component of the extracorporeal blood circuit 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

**3.6 air-capture chamber
drip chamber
bubble trap
venous and arterial blood chamber**
component intended to capture air and which may provide compliance to the blood circuit or allow pressure to be monitored

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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. If the device is labelled for reuse, testing shall be performed after reprocessing following the manufacturer's instructions for use.

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

The blood pathway of the device shall be sterile. Compliance shall be verified in accordance with 5.3.

4.3 Nonpyrogenicity

The blood pathway of the device shall be nonpyrogenic. 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 times the recommended pressure and a negative pressure not exceeding 700 mmHg (or 93,3 kPa below atmospheric pressure), or the highest obtainable sub-atmospheric pressure if at high elevation, when tested according to 5.5.1.

4.4.2 Connection 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.

Dimensions in millimetres

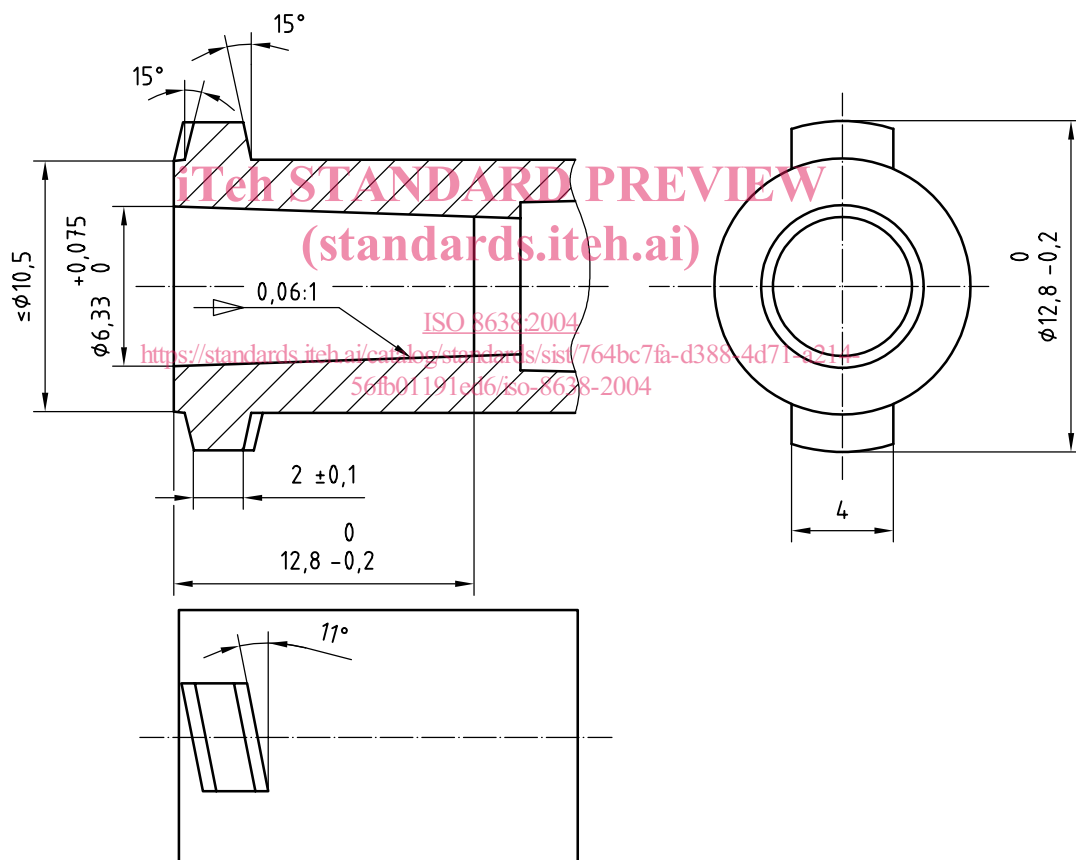


Figure 1 — Main fitting dimensions of extracorporeal blood circuit connector to blood ports of haemodialyser, haemodiafilter or haemofilter

4.4.3 Connection to vascular access device

Except where the extracorporeal blood circuit and the vascular access device are an integral system, the connector intended for connection to vascular access devices shall be a male 6 % (Luer) taper lock fitting in accordance with ISO 594-2.

Compliance shall be verified in accordance with 5.5.3.

4.4.4 Connection 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 which 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.

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.

4.4.6.3 Access port location

Access ports shall not be located downstream of the location intended for the air detector.

4.4.7 Blood pathway volume

The range of the volume of blood pathway in 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 shall be marked as applicable on the air-capture chamber. 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 secure and leak-free connection to the haemodialysis machine when subjected to pressures of 1,5 times the manufacturer's recommended pressure for the device. The machine side of the transducer protector shall be transparent (clear) to allow visual inspection of blood for contamination during use. Compliance with this requirement shall be verified 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 secure and leak-free connection to the haemodialysis machine when subjected to pressures of 1,5 times the manufacturer's recommended pressure for the device. The machine side of the transducer protector shall be transparent (clear) to allow visual inspection of blood for contamination during use. Compliance with this requirement shall be verified 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 intended inlet pressures (normally 0 mmHg to –250 mmHg).

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

4.5 Expiration date

If the expiration 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 tubing shall be capable of being occlusively clamped by the dialysis delivery system(s) for which the extracorporeal blood circuit is labelled. 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 may alter its performance.

Sample devices for testing 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.

Measurements shall be made *in vitro* at $(37 \pm 1) ^\circ\text{C}$. If the relationship between variables is non-linear, sufficient determinations shall be made to permit interpolation between the data points. The techniques of measurement are reference tests. Other test methods may be used, provided it can be shown that they are of comparable precision and reproducibility.

The test systems shown do not indicate all the necessary details of practicable test apparatus. The design and construction of actual test systems and their establishment shall also address the many factors contributing to measurement error, including, but not limited to, pressure measurement errors due to static head effects and dynamic pressure drops; parameter stabilization time; uncontrolled temperature variations at non-constant flow rates; pH; degradation of test substances due to heat, light and time; degassing of test fluids; trapped air; and system contamination by foreign material, algae and bacteria.