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**Cardiovascular implants and artificial  
organs — Haemodialysers,  
haemodiafilters, haemofilters and  
haemoconcentrators**

*Implants cardiovasculaires et organes artificiels — Hémodialyseurs,  
hémodiafiltres, hémofiltres et hémococoncentrateurs*

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Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

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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 8637 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 8637:1989), which has been technically revised.

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## Introduction

This International Standard is concerned with devices intended for haemodialysis, haemofiltration, haemodiafiltration and haemoconcentration in humans. The requirements specified in this International Standard 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. There is no intention to specify, or to set limits on, the performance characteristics of the devices because such restrictions are unnecessary for the qualified user and would limit the alternatives available when choosing a device for a specific application.

The dimensions of the blood ports and the dialysate or filtrate ports have been specified to ensure compatibility of the device with the extracorporeal blood circuit specified in ISO 8638. The design and dimensions have been selected in order to minimize the risk of leakage of blood and the ingress of air.

This International Standard reflects the consensus of physicians, manufacturers and other interested parties for devices that are approved for clinical use. Conformance with the standard is voluntary and it does not supersede any national regulation.

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# Cardiovascular implants and artificial organs — Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

## 1 Scope

This International Standard specifies requirements for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators, hereinafter collectively referred to as “the device”, for use for humans.

This International Standard is not applicable to

- extracorporeal blood circuits,
- plasmafilters,
- haemoperfusion devices,
- vascular access devices,
- blood pumps,
- pressure monitors for the extracorporeal blood circuit,
- air detection devices,
- systems to prepare, maintain or monitor dialysate,
- systems used to perform haemodialysis, haemodiafiltration, haemofiltration or haemoconcentration,
- reprocessing procedures and equipment.

NOTE Requirements for the extracorporeal blood circuit for haemodialysers, haemodiafilters, and haemofilters are specified in ISO 8638.

## 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 8638, *Cardiovascular implants and artificial organs — Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters*

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 blood compartment**  
part of a haemodialyser, haemodiafilter, haemofilter or haemoconcentrator through which blood is intended to pass

NOTE For hollow-fibre devices, the blood compartment includes the volume of the hollow fibres plus the headers.

**3.2 clearance**  
volume of a solution from which a solute is completely removed per unit time

**3.3 convection**  
transport of solutes across a semipermeable membrane, along with filtered fluid, caused by a pressure gradient or pressure differential across the membrane

**3.4 dialysate dialysing fluid**  
solution which is intended to exchange solutes and/or water in blood during haemodialysis or haemodiafiltration

**3.5 dialysate compartment**  
part of a haemodialyser or haemodiafilter through which dialysate is intended to pass

**3.6 diffusion**  
transport of solutes across a semipermeable membrane, caused by a concentration gradient

**3.7 filtrate**  
fluid removed from the blood across the semipermeable membrane into the dialysate or filtrate compartment of a haemodialyser, haemodiafilter, haemofilter or haemoconcentrator, due to a pressure gradient across the semipermeable membrane

**3.8 haemoconcentration**  
process whereby plasma water and electrolytes are removed from diluted blood across a semipermeable membrane

**3.9 haemoconcentrator**  
device intended to perform haemoconcentration

**3.10 haemodiafilter**  
device intended to perform haemodiafiltration

**3.11 haemodiafiltration**  
process whereby solute imbalances in a patient's blood are corrected by means of simultaneous convection and diffusion across a semipermeable membrane and replacement with an appropriate physiological fluid

NOTE Normally the process also includes a net fluid removal.



**3.12****haemodialyser**

device intended to perform haemodialysis

**3.13****haemodialysis**

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

NOTE Normally the process also includes a net fluid removal.

**3.14****haemofilter**

device intended to perform haemofiltration

**3.15****haemofiltration**

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

NOTE Normally the process also includes a net fluid removal.

**3.16****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

**3.17****sieving coefficient**

ratio of a solute concentration in the filtrate to the simultaneous concentration of the same solute in the plasma

**3.18****transmembrane pressure****TMP**

Differential pressure exerted across a semipermeable membrane

NOTE For practical reasons, the mean TMP is generally expressed as either

- the difference between arithmetic means of inlet and outlet pressures of the blood and dialysate compartments of a haemodialyser or a haemodiafilter, or
- 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.

**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 in accordance with 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

When tested in accordance with 5.5.1, haemodialysers, haemodiafilters, haemofilters and haemoconcentrators shall not leak. The device shall be evaluated at

- a) 1,5 times the maximum pressure specified, and
- b) 1,5 times the recommended sub-atmospheric pressure specified by the manufacturer, not to exceed 700 mmHg or the maximum obtainable sub-atmospheric pressure.

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

### 4.4.2 Blood compartment integrity

When exposing the blood compartment to a validated test procedure performed at 1,5 times the manufacturer's maximum recommended transmembrane pressure, the blood compartment shall not leak. Compliance with this requirement shall be verified in accordance with 5.5.2.

### 4.4.3 Haemodialyser, haemodiafilter and haemofilter blood compartment ports

Except where the haemodialyser, haemodiafilter or haemofilter and the extracorporeal blood circuit are designed as an integral system, the dimensions of the blood ports shall be as given in Figure 1. Compliance with this requirement shall be verified in accordance with 5.5.3.

### 4.4.4 Haemodialyser and haemodiafilter dialysate compartment ports

The dimensions of the dialysate compartment ports shall be as given in Figure 2. Compliance with this requirement shall be verified according to 5.5.4.

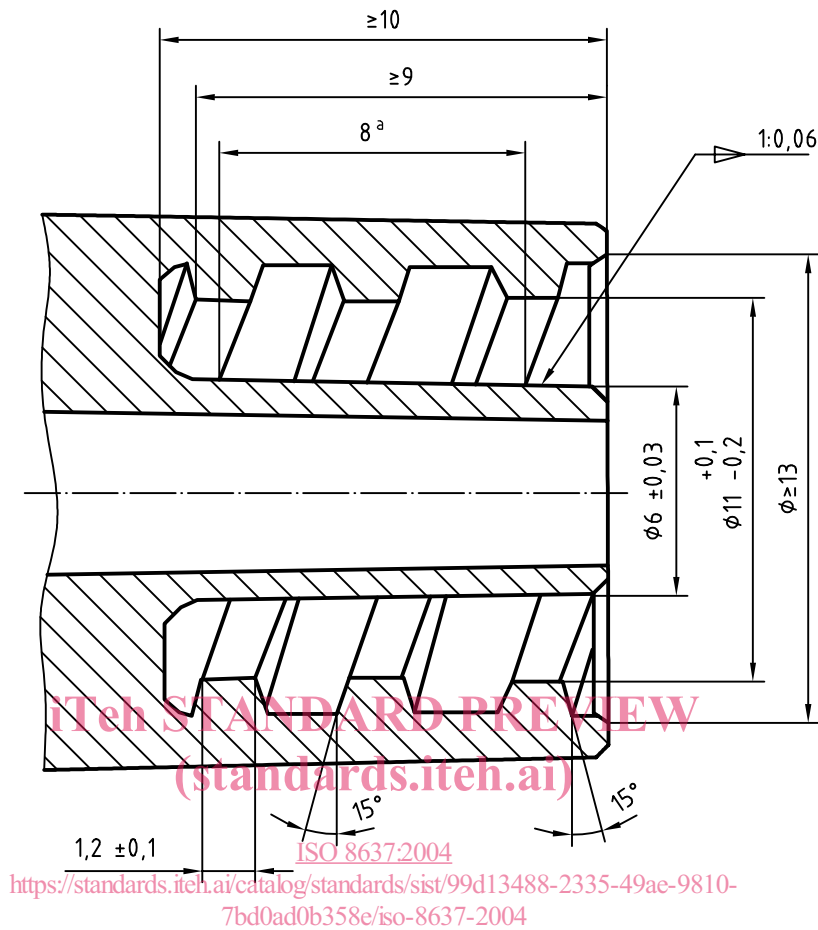
### 4.4.5 Haemofilter filtrate ports

The filtrate ports of haemofilters shall either comply with Figure 2 or comply with the requirements of the Luer taper lock fitting of ISO 594-2. Compliance with this requirement shall be verified in accordance with 5.5.5.

### 4.4.6 Haemoconcentrator blood and filtrate ports

The blood and filtrate ports of haemoconcentrators shall allow for a secure connection to the tubing which is to be used with the device. Compliance with this requirement shall be verified in accordance with 5.5.6.

Dimensions in millimetres



<sup>a</sup> Double thread.

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

## 4.5 Performance characteristics

### 4.5.1 Clearance of haemodialysers and haemodiafilters

The clearance of urea, creatinine, phosphate and vitamin B<sub>12</sub> shall be determined in accordance with 5.6.1. Blood and dialysate flowrates shall cover the manufacturer's recommended range.

NOTE As a supplement,  $K_0A$  results can be included.

### 4.5.2 Sieving coefficient of haemodiafilters, haemofilters and haemoconcentrators

The sieving coefficient for albumin, inulin and myoglobin shall be determined in accordance with 5.6.2. Test conditions shall be as presented by the manufacturer in the labelling.

### 4.5.3 Filtration rate

The ultrafiltration rate shall be determined in accordance with 5.6.3. Testing shall be conducted over the manufacturer's specified range of transmembrane pressures and blood flowrates.