

SÜDAME-VERESOOKONKONNA IMPLANTAADID JA  
KEHAVÄLISED SÜSTEEMID. OSA 1:  
HEMODIALÜSAATORID, VERELAHUTUSFILTRID,  
VEREFILTRID JA VEREKONTSENTEERIJAD

Extracorporeal systems for blood purification - Part 1:  
Haemodialysers, haemodiafilters, haemofilters and  
haemoconcentrators (ISO 8637-1:2017)

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 8637-1:2020 sisaldab Euroopa standardi EN ISO 8637-1:2020 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 8637-1:2020 consists of the English text of the European standard EN ISO 8637-1:2020.
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English Version

Extracorporeal systems for blood purification - Part 1:  
Haemodialysers, haemodiafilters, haemofilters and  
haemoconcentrators (ISO 8637-1:2017)

Systèmes extracorporels pour la purification du sang -  
Partie 1: Hémodialyseurs, hémodiafiltres, hémofiltres  
et hémoco concentrateurs (ISO 8637-1:2017)

Kardiovaskuläre Implantate und extrakorporale  
Systeme - Teil 1: Hämodialysatoren, Hämodiafilter,  
Hämo filter und Hämo konzentratoren (ISO 8637-  
1:2017)

This European Standard was approved by CEN on 8 April 2020.

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COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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## European foreword

This document (EN ISO 8637-1:2020) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN/TC 205 "Non-active medical devices" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2020, and conflicting national standards shall be withdrawn at the latest by April 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 8637:2014.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

## Endorsement notice

The text of ISO 8637-1:2017 has been approved by CEN as EN ISO 8637-1:2020 without any modification.

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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.

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 (see [www.iso.org/directives](http://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 (see [www.iso.org/patents](http://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 on 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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

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 8637-1:2017 cancels and replaces the third edition of ISO 8637:2010 and ISO 8637:2010/Amd1:2013, which has been technically revised. The following changes have been done:

— [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 devices intended for haemodialysis, haemodiafiltration, haemofiltration and haemoconcentration in humans. The requirements specified in this document 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 which have been used 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 dialysis fluid or filtrate ports have been specified to ensure compatibility of the device with the extracorporeal blood circuit specified in ISO 8637-2. The design and dimensions have been selected in order to minimize the risk of leakage of blood and the ingress of air.

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

# Extracorporeal systems for blood purification —

## Part 1:

## Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

### 1 Scope

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

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

This document does not apply 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 dialysis fluid;
- systems or equipment intended 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 8637-2.

### 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 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 <http://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

#### 3.1 blood compartment

part of a *haemodialyser* (3.12), *haemodiafilter* (3.10), *haemofilter* (3.14) or *haemoconcentrator* (3.9) through which blood is intended to pass

Note 1 to entry: 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 dialysis fluid

aqueous fluid containing electrolytes and, usually, buffer and glucose, which is intended to exchange solutes with blood during *haemodialysis* (3.13) or *haemodiafiltration* (3.11)

Note 1 to entry: The term “dialysis fluid” is used throughout this document to mean the fluid (made from dialysis water and concentrates) which is delivered to the haemodialyser or haemodiafilter by a dialysis fluid delivery system. Phrases such as “dialysate”, “dialysis solution” or “dialysing fluid” can be used in place of dialysis fluid.

Note 2 to entry: The dialysis fluid entering the haemodialyser or haemodiafilter is referred to as “fresh dialysis fluid”, while the fluid leaving the haemodialyser or haemodiafilter is referred to as “spent dialysis fluid”.

Note 3 to entry: Dialysis fluid does not include pre-packaged parenteral fluids used in some renal replacement therapies, such as haemodiafiltration and haemofiltration.

#### 3.5 dialysis fluid compartment

part of a *haemodialyser* (3.12) or *haemodiafilter* (3.10) through which *dialysis fluid* (3.4) 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 dialysis fluid or filtrate compartment of a *haemodialyser* (3.12), *haemodiafilter* (3.10), *haemofilter* (3.14) or *haemoconcentrator* (3.9), due to a pressure gradient (including the contributions of both hydrostatic and oncotic pressures) across the semipermeable membrane