



BSI Standards Publication

Extracorporeal systems for blood purification

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

National foreword

This British Standard is the UK implementation of EN ISO 8637-2:2018. It is identical to [ISO 8637-2:2018](#). It supersedes [BS EN ISO 8638:2014](#), which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/150/2, Cardiovascular implants.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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English Version

Extracorporeal systems for blood purification - Part
2: Extracorporeal blood circuit for haemodialysers,
haemodiafilters and haemofilters (ISO 8637-2:2018)

Systèmes extracorporels pour la purification du
sang - Partie 2: Circuit sanguin extracorporel
pour les hémodialyseurs, les hémodiafiltres
et les hémofiltres (ISO 8637-2:2018)

Kardiovaskuläre Implantate und extrakorporale
Systeme - Teil 2: Extrakorporaler Blutkreislauf
bei Hämodialysatoren, Hämodiafiltern
und Hämofiltern (ISO 8637-2:2018)

This European Standard was approved by CEN on 17 June 2018.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 8637-2:2018) 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of an identical text or by endorsement, at the latest by February 2019, and conflicting national standards shall be withdrawn at the latest by August 2021.

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 8638:2014.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZA, which is an integral part of this document.

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Endorsement notice

The text of [ISO 8637-2:2018](#) has been approved by CEN as EN ISO 8637-2:2018 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. www.iso.org/directives

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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.

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