

Nederlandse norm

# NEN-ISO 8637-3

(en)

Extracorporele systemen voor bloedzuivering -  
Deel 3: Plasmafiltraats (ISO 8637-3:2018, IDT)

Extracorporeal systems for blood purification -  
Part 3: Plasmafilters (ISO 8637-3:2018, IDT)

Vervangt NEN-ISO 13960:2010

ICS 11.040.40  
september 2018

Als Nederlandse norm is aanvaard:

- ISO 8637-3:2018, IDT

Normcommissie 301060 'Chirurgische implantaten'



**THIS PUBLICATION IS COPYRIGHT/PROTECTED**

**DEZE PUBLICATIE IS AUTEURSRECHTELIJK BESCHERMD**

Apart from exceptions provided by the law, nothing from this publication may be duplicated and/or published by means of photocopy, microfilm, storage in computer files or otherwise, which also applies to full or partial processing, without the written consent of the Royal Netherlands Standardization Institute.

The Royal Netherlands Standardization Institute shall, with the exclusion of any other beneficiary, collect payments owed by third parties for duplication and/or act in and out of law, where this authority is not transferred or falls by right to the Reproduction Rights Foundation.

Auteursrecht voorbehouden. Behoudens uitzondering door de wet gesteld mag zonder schriftelijke toestemming van het Koninklijk Nederlands Normalisatie-instituut niets uit deze uitgave worden verveelvoudigd en/of openbaar gemaakt door middel van fotokopie, microfilm, opslag in computerbestanden of anderszins, hetgeen ook van toepassing is op gehele of gedeeltelijke bewerking.

Het Koninklijk Nederlands Normalisatie-instituut is met uitsluiting van ieder ander gerechtigd de door derden verschuldigde vergoedingen voor verveelvoudiging te innen en/of daartoe in en buiten rechte op te treden, voor zover deze bevoegdheid niet is overgedragen c.q. rechtens toekomt aan de Stichting Reprorecht.

Although the utmost care has been taken with this publication, errors and omissions cannot be entirely excluded. The Royal Netherlands Standardization Institute and/or the members of the committees therefore accept no liability, not even for direct or indirect damage, occurring due to or in relation with the application of publications issued by the Royal Netherlands Standardization Institute.

Hoewel bij deze uitgave de uiterste zorg is nagestreefd, kunnen fouten en onvolledigheden niet geheel worden uitgesloten. Het Koninklijk Nederlands Normalisatie-instituut en/of de leden van de commissies aanvaarden derhalve geen enkele aansprakelijkheid, ook niet voor directe of indirecte schade, ontstaan door of verband houdend met toepassing van door het Koninklijk Nederlands Normalisatie-instituut gepubliceerde uitgaven.

Preview

COORDELORE

---

---

**Extracorporeal systems for blood  
purification —**

**Part 3:  
Plasmafilters**

*Systèmes extracorporels pour la purification du sang —  
Partie 3. Filtres pour plasma*



Copyright  
Preview



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Fax: +41 22 749 09 47  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

Page

<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Requirements</b> .....	<b>2</b>
4.1 Biological safety.....	2
4.2 Sterility.....	3
4.3 Non-pyrogenicity.....	3
4.4 Mechanical characteristics.....	3
4.4.1 Structural integrity.....	3
4.4.2 Blood compartment integrity.....	3
4.4.3 Connectors and ports.....	3
4.4.4 Volume of the blood compartment.....	5
4.4.5 Pressure drop of the blood compartment.....	5
4.5 Performance characteristics.....	5
4.5.1 Filtration rate.....	5
4.5.2 Sieving coefficient.....	5
4.5.3 Haemolytic characteristics.....	6
4.6 Expiry date.....	6
<b>5 Test methods</b> .....	<b>6</b>
5.1 General.....	6
5.2 Biological safety.....	6
5.3 Sterility.....	6
5.4 Non-pyrogenicity.....	6
5.5 Mechanical characteristics.....	7
5.5.1 Structural integrity.....	7
5.5.2 Blood compartment integrity.....	7
5.5.3 Blood compartment ports.....	7
5.5.4 Blood compartment volume.....	7
5.6 Plasma filtrate port.....	7
5.7 Pressure drop.....	7
5.7.1 Test solution.....	7
5.7.2 Pressure drop test procedure.....	7
5.8 Performance characteristics.....	8
5.8.1 Filtration rate.....	8
5.8.2 Sieving coefficient.....	8
5.8.3 Haemolytic characteristics.....	10
5.9 Expiry date.....	10
<b>6 Labelling</b> .....	<b>10</b>
6.1 Labelling on the device.....	10
6.2 Labelling on unit containers.....	11
6.3 Labelling on the outer containers.....	11
6.4 Information to be given in the accompanying documentation.....	12
<b>Bibliography</b> .....	<b>14</b>

## 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 8637-3:2018 cancels and replaces the second edition of ISO 13960:2010, which has been technically revised. The following changes have been made:

- the Figures relating to connector dimensions have been revised.

A list of all the parts in the ISO 8637 series can be found on the ISO website.

## Introduction

It was not found practicable to specify materials of construction. Therefore, this document only requires that materials used have been tested, and that the testing methods and the 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.

If the plasmafilter is used with an extracorporeal circuit, the dimensions of the blood ports and 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 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.

Copyright  
Preview

Probleem  
Preview



# Extracorporeal systems for blood purification —

## Part 3: Plasmafilters

### 1 Scope

This document specifies requirements and acceptance criteria (including test methods) for safety related parameters for plasmafilters. Only those requirements that are specific to plasmafilters have been included.

It specifies requirements for sterile, single-use plasmafilters, intended for use on humans.

This document does not cover matters related to toxicity. Such issues are covered in relevant parts of ISO 10993.

It does not apply to the extracorporeal circuits that can be used for plasmapheresis vascular access devices, oxygenators or active medical devices. This document does not address the replacement fluid.

### 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 8637-1, *Extracorporeal systems for blood purification — Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators*

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 plasmafilter through which blood is intended to pass

# ALTIJD DE ACTUELE NORM IN UW BEZIT HEBBEN?

Nooit meer zoeken in de systemen en uzelf de vraag stellen:  
“Is NEN-ISO 8637-3:2018 en de laatste versie?”™

Via het digitale platform NEN Connect heeft u altijd toegang tot de meest actuele versie van deze norm. Vervallen versies blijven ook beschikbaar. **U en uw collega's** kunnen de norm via NEN Connect makkelijk raadplagen, online en offline.

Kies voor slimmer werken en bekijk onze mogelijkheden op [www.nenconnect.nl](http://www.nenconnect.nl).

## Heeft u vragen?

Onze Klantenservice is bereikbaar maandag tot en met vrijdag, van 8.30 tot 17.00 uur.

Telefoon: 015 2 690 391

E-mail: [klantenservice@nen.nl](mailto:klantenservice@nen.nl)

