INTERNATIONAL STANDARD

ISO 8637-3

First edition
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Extracorporeal systems for blood purification —

Part 3: Plasmafilters

Systèmes extracorporels pour la purification du sang —

Partie 3: Filtres pour plasma

Reference number
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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
Website: 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.

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).

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).

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.

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.

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

3.2
filtrate compartment
part of plasmafilter through which filtrate flows

3.3
filtration rate
rate at which fluid is removed from the *blood compartment* (3.1) across the semipermeable membrane into the *filtrate compartment* (3.2) of a plasmafilter

3.4
plasmapheresis
plasma separation
separation of a portion of the whole plasma from formed elements of blood by means of a semipermeable membrane

Note 1 to entry: Plasmapheresis can also be accomplished through the use of differential centrifugation but this method is not covered by this document.

3.5
plasmafilter
device intended to perform membrane *plasmapheresis* (3.4)

3.6
sieving coefficient
ratio of a solute concentration in the filtrate to the simultaneous concentration of the same solute in blood

3.7
transmembrane pressure
TMP
p_{TM}
mean pressure exerted across the semipermeable membrane

Note 1 to entry: The transmembrane pressure is given by Formula (1):

$$p_{TM} = \frac{p_{BI} + p_{BO}}{2} - p_F \quad (1)$$

where

p_{BI} is the pressure at blood compartment inlet;

p_{BO} is the pressure at blood compartment outlet;

p_F is the pressure at filtrate compartment outlet.

4 Requirements

4.1 Biological safety

Parts of the device that will come into direct or indirect contact with blood during their intended clinical use shall be biocompatible with respect to their intended clinical use.

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.

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.

Conformity shall be verified in accordance with 5.2.

4.2 Sterility

The blood and filtrate pathways of the device shall be sterile. Conformity shall be verified in accordance with 5.3.

4.3 Non-pyrogenicity

The blood and filtrate pathways of the device shall be non-pyrogenic. Conformity 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, plasmafilters shall not leak.

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

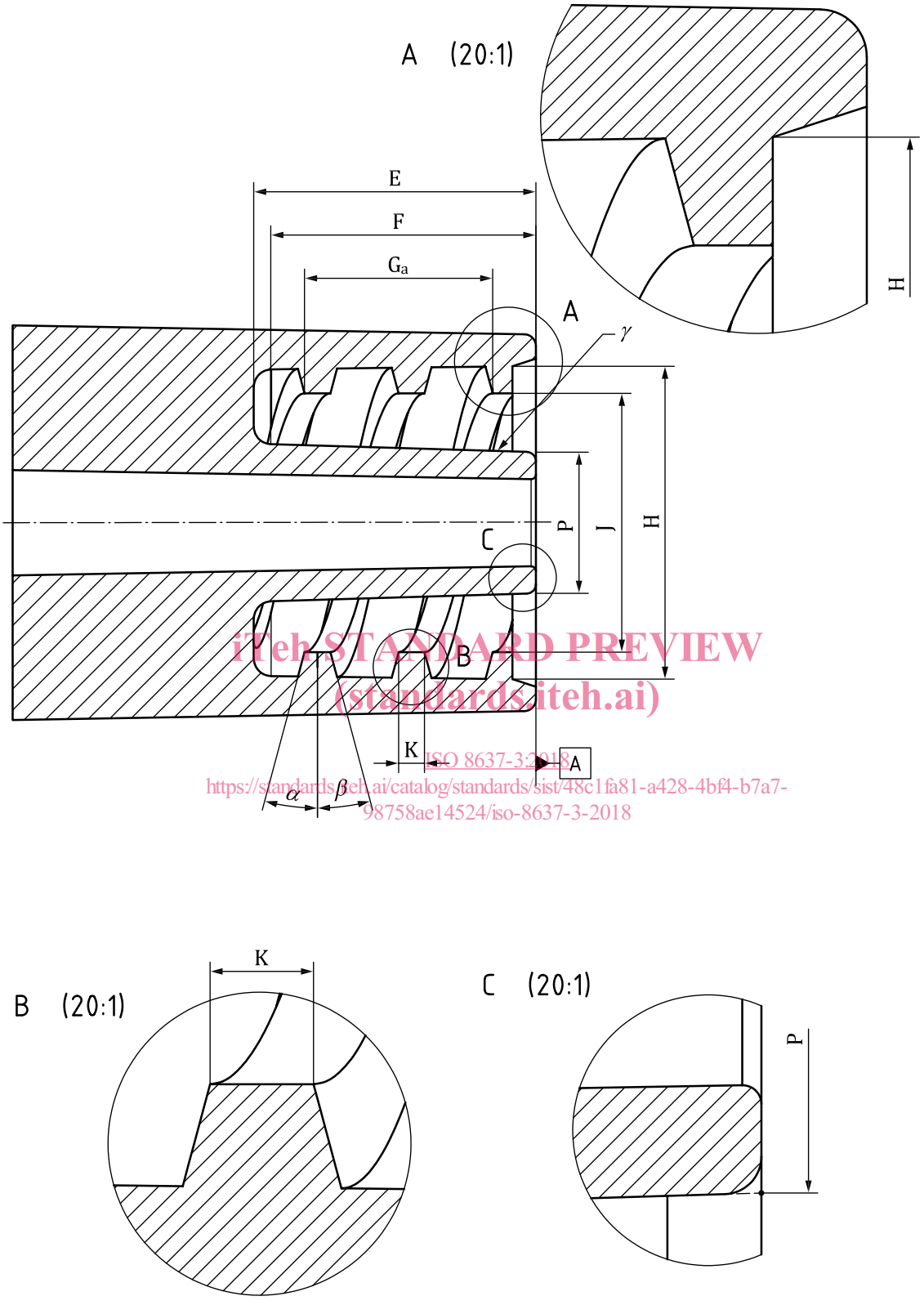
4.4.2 Blood compartment integrity

When tested in accordance with 5.5.2, the blood compartment shall not leak.

4.4.3 Connectors and ports

4.4.3.1 Blood Compartment Ports

Except where the plasmafilter and the extracorporeal blood circuit are designed as an integral system, the dimensions of the blood ports shall be as given in Figure 1. Conformity to this requirement shall be verified in accordance with 5.5.3.



Key

Symbol	Designation	Dimension in mm	Comments
α	Angle of thread	15°	—
β	Angle of thread	15°	—
γ	Dimension taper rate	6:100	—
E	Length of thread	10 or more	—

Symbol	Designation	Dimension in mm	Comments
F	Length of tapered region	9 or more	—
G[a]	Thread pitch	8	The superscript "a" of G[a] means double thread.
H	Root diameter	13 or more	—
J	Crest diameter	11 +0,3 -0,2	Altered upper tolerance to accommodate different components and materials.
K	Thread crest width	1,1 ±0,25	Revised dimension and tolerances based on existing manufacturing practice.
P	cone diameter male plane of reference"A square"	6 ±0,03	This dimension to be measured as a projection on the front face. See Figure 1 (C).

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

4.4.3.2 Connection to the plasma filtrate compartment

The filtrate ports of plasmafilters shall allow for a secure connection to the tubing which is to be used with the device, except when plasmafilters and their extracorporeal circuits are designed as an integral system.

The dimensions of the filtrate ports shall be a male 6 % (Luer) taper lock fitting in accordance with ISO 80369-7 or dialysis fluid inlet and outlet ports in accordance with ISO 8637-1.

Conformity to this requirement shall be verified in accordance with 5.6.

Connectors made of semi-rigid materials shall not separate under an axial force of 15 N for 15 s.

4.4.4 Volume of the blood compartment

When measured in accordance with 5.5.4, the volume of the blood compartment of the plasmafilters shall be within the range of values stated by the manufacturer [see 6.2 h)].

4.4.5 Pressure drop of the blood compartment

When measured in accordance with 5.7.2, the pressure drop across the blood compartment of the plasma filter shall be within the range of values stated by the manufacturer [see 6.2 h)].

4.5 Performance characteristics

4.5.1 Filtration rate

When measured in accordance with 5.8.1.2, the filtration rate shall be within the range of values stated by the manufacturer [see 6.4 i)].

4.5.2 Sieving coefficient

When measured in accordance with 5.8.2.2, the sieving coefficients for albumin, immunoglobulin M (IgM) and beta lipoprotein or equivalent indicators shall be within the range of values stated by the manufacturer [see 6.4 i)].