FINAL DRAFT
International Standard

ISO/FDIS 8637-3

Extracorporeal systems for blood purification —

Part 3: Plasmafilters

Systèmes extracorporels pour la purification du sang —

Partie 3: Filtres pour plasma

ISO/TC **150**/SC **2**

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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 document 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).

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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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see 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 second edition cancels and replaces the first edition (ISO 8637-3:2018), which has been technically revised.

The main changes are as follows:

— terms and definitions have been aligned with those defined in other parts of the ISO 8637 series;

— additional figures relating to a gauge to test dimensional compliance of connectors have been added;

— test methods for measurement of the sieving coefficient and haemolytic characteristics have been revised;

— requirements for accompanying documentation have been revised and extended to ensure that the risk of inadvertent use of a plasmafilter for haemofiltration is minimized.

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document is concerned with filters intended to perform plasma filtration in humans. If such a filter is used with an extracorporeal circuit, the dimensions of the blood compartment connectors and filtrate compartment connectors 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.

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.

Extracorporeal systems for blood purification —

Part 3: Plasmafilters

1 Scope

This document specifies requirements and test methods for plasmafilters, a device intended for the separation of plasma from blood in therapeutic plasmapheresis therapy. It specifies the requirements for sterile, single-use plasmafilters, intended for use on humans, hereinafter collectively referred to as "the device", for use in humans. This document does not apply to;

— extracorporeal blood circuits;

— haemodialysers, haemodiafilters, haemofilters, and haemoconcentrators;

— haemoperfusion devices;

— vascular access devices;

— blood pumps;

— systems or equipment intended to perform plasma separation

NOTE 1 Requirements for the extracorporeal blood circuit are specified in ISO 8637-2.

NOTE 2 Requirements for haemodialysers, haemodiafilters haemofilters and haemoconcentrators are specified in ISO 8637-1.

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 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

ISO 80369-20, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

ISO 20417, *Medical devices — Information to be supplied by the manufacturer*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
blood compartment
part of the *plasmafilter* (3.7) through which blood is intended to pass

3.2
blood compartment volume
volume which is needed to fill the *blood compartment* (3.1)

Note 1 to entry: For hollow fibre devices, the blood compartment volume includes the volume of the hollow fibres plus the headers.

3.3
plasma filtrate compartment
part of the *plasmafilter* (3.7) through which filtrate flows

3.4
plasma filtration rate
rate at which plasma is removed from the *blood compartment* (3.1) across the semipermeable membrane into the *plasma filtrate compartment* (3.3) of a *plasmafilter* (3.7)

3.5
labelling
written, printed, graphic or electronic matter that is affixed to the *plasmafilter* (3.7) or any of its containers or wrappers, or accompanies a plasmafilter and which is related to identification, technical description and use of that device, but excluding shipping documents

3.6
plasma separation
plasmapheresis
plasma filtration
separation of a portion of the whole plasma from formed elements of blood by means of a semipermeable membrane

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

3.7
plasmafilter
plasma separator
device intended to perform membrane *plasmapheresis* (3.6)

3.8
sieving coefficient
ratio of a solute concentration in the filtrate to the simultaneous concentration of the same solute on the feed side

3.9
transmembrane pressure
TMP
p_{TM}
mean pressure exerted across the semipermeable membrane contained in the *plasmafilter* (3.7)

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 the blood compartment inlet;

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

p_F is the pressure at the filtrate compartment outlet.

4 Requirements

4.1 Biological safety and haemocompatibility

Parts of the plasmafilter 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.

4.2 Sterility

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

4.3 Non-pyrogenicity

The blood and filtrate pathways of the plasmafilter shall be non-pyrogenic. Compliance shall be verified in accordance with 5.4.

4.4 Mechanical characteristics

4.4.1 Structural integrity

The plasmafilter external casing shall be capable of withstanding a positive pressure of 1,5 times of the manufacturer's recommended maximum pressure above atmospheric pressure and a negative pressure not exceeding 66,7 kPa (500 mmHg) below atmospheric pressure, when tested in accordance with 5.5.1.2 and 5.5.1.3.

4.4.2 Blood compartment integrity

When exposing the blood compartment of the plasmafilter to a validated test procedure performed at 1,5 times of 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 Connectors

4.4.3.1 Plasmafilter blood compartment connectors

Except where the plasmafilter and the extracorporeal blood circuit are designed as an integral system, the dimensions of the blood compartment connectors shall be as given in Figure 1 and Table 1.

Plasmafilter blood compartment functional requirements, such as acceptable leakage rate, minimum separation force, minimum separation and maximum connection torque shall be defined in accordance with the manufacturer's risk management process. The boundary parameters used in tests such as the torques, the connection and disconnection forces as well as holding times, and ambient temperatures must be considered and defined as part of the manufacturer's risk assessment on the use of the product.

Functional testing shall be performed subject to the manufacturer's risk assessment.

Compliance with this requirement shall be verified in accordance with 5.5.3.2.

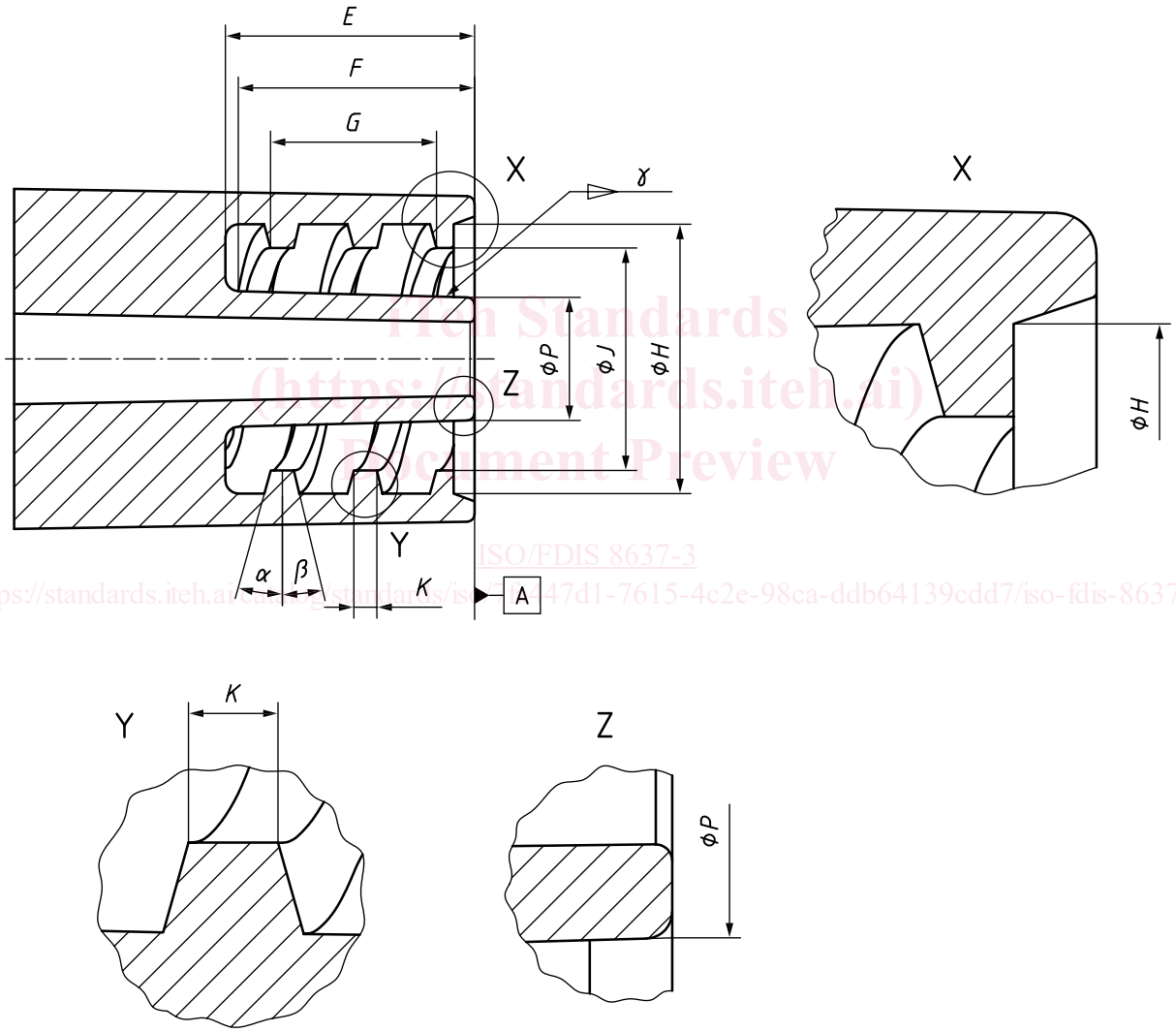

Figure 1 — Cone blood inlet and outlet blood compartment connectors of the plasmafilter