
**Cardiovascular implants and artificial
organs — Plasmafilters**

Implants cardio-vasculaires et organes artificiels — Filtres de plasma

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ISO 13960:2003

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 13960 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants*.

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Introduction

This International Standard contains requirements and acceptance criteria (including test methods) for safety-related parameters for plasmafilters. Only those requirements that are specific to plasmafilters have been included. Non-specific requirements are covered by references to other International Standards, listed in the Normative references clause. This International Standard does not address matters related to toxicity. Such issues are covered in the relevant part of ISO 10993. The reader is advised to review the normative references.

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Cardiovascular implants and artificial organs — Plasmafilters

1 Scope

This International Standard specifies requirements for sterile, single-use plasmafilters, intended for use on humans.

This International Standard is not applicable to the extracorporeal circuits used for plasmapheresis or other extracorporeal blood exchange devices, such as haemodialysers, haemodiafilters, haemofilters, haemoperfusion devices, vascular access devices, oxygenators or active medical devices.

This International Standard does not address the replacement fluid.

2 Normative references

The following referenced documents are indispensable for the application 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 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

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ISO 8637, *Cardiovascular implants and artificial organs — Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

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 11134, *Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization*

ISO 11135, *Medical devices — Validation and routine control of ethylene oxide sterilization*

ISO 11137, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization*

ISO 13485:2003, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 13488, *Quality systems — Medical devices — Particular requirements for the application of ISO 9002*

3 Terms and definitions

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

3.1

blood compartment

part of a plasmafilter through which blood is intended to pass

3.2

filtration rate

rate at which fluid is removed from the blood compartment across the semi-permeable membrane into the filtrate compartment of a plasmafilter

3.3

plasmapheresis

plasma separation

separation of a portion of the whole plasma from formed elements of blood by means of a semi-permeable membrane

NOTE Plasmapheresis can also be accomplished through the use of differential centrifugation, but this method is not addressed in this International Standard.

3.4

plasmafilter

device intended to perform membrane plasmapheresis

3.5

transmembrane pressure

p_{TM}

the mean pressure across the semipermeable membrane

$$p_{TM} = \frac{p_{inlet} + p_{outlet}}{2} - p_{filtrate}$$

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3.6

sieving coefficient

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

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4 Requirements

4.1 Biological characteristics

4.1.1 Biocompatibility

Parts of plasmafilters 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.

Compliance shall be verified in accordance with 5.2.1.

4.1.2 Sterility and non-pyrogenicity

Blood and filtrate compartments shall be sterile and non-pyrogenic.

Compliance shall be verified in accordance with 5.2.2.

4.2 Physical characteristics

4.2.1 Structural integrity

When tested in accordance with 5.3.1, plasmafilters shall not leak.

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

4.2.2 Blood compartment integrity

When tested in accordance with 5.3.2, plasmafilters shall not leak.

4.2.3 Connectors and ports

4.2.3.1 Connections to the blood compartment

Except when plasmafilters and the extracorporeal circuits are designed as an integral system, the dimensions of the blood inlet and outlet connectors of plasmafilters shall be in accordance with ISO 8637.

Compliance shall be verified by inspection.

4.2.3.2 Connection to the filtrate compartment

Except when plasmafilters and their extracorporeal circuits are designed as an integral system, the filtrate ports shall be male 6 % (Luer) taper lock fittings with dimensions in accordance with ISO 594-2 or dialysing fluid inlet and outlet ports in accordance with ISO 8637.

Compliance shall be verified by inspection.

4.2.3.3 Volume

When measured in accordance with 5.3.3, the volumes of the blood compartments of plasmafilters shall be within the range of values stated by the manufacturer [see 7.2.1 b)].

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4.2.3.4 Pressure drop

When measured in accordance with 5.3.4, the pressure drop across the blood compartment of the plasmafilter shall be within the range of values stated by the manufacturer [see 7.2.1 f)].

4.3 Performance characteristics

4.3.1 Filtration rate

When measured in accordance with 5.4.1, the filtration rate shall be within the range of values stated by the manufacturer [see 7.2.1 e) 1)].

4.3.2 Sieving coefficient

When measured in accordance with 5.4.2, the sieving coefficients for albumin, immunoglobulin (IgM) and beta-lipoprotein or equivalent indicators shall be within the range of values stated by the manufacturer [see 7.2.1 e) 2)].

4.3.3 Nonhaemolytic characteristics

The device shall not cause haemolysis that represents a safety hazard to patients when tested at the maximum specified operating conditions. Testing shall be in accordance with 5.4.3.