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Extracorporeal systems for blood purification —

Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

Systèmes extracorporels pour la purification du sang —

Partie 1: Hémodialyseurs, hémodiafiltres, hémofiltres et hémoconcentrateurs

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Foreword

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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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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 version of this document (ISO 8637-1:2017), 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 gauges used to test dimensional compliance have been added;

— test methods have been revised and an example of a test method for endotoxin transfer measurement has been added;

— requirements for accompanying documentation have been revised.

A list of all 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 devices intended for haemodialysis, haemodiafiltration, haemofiltration and haemoconcentration in humans. If such a device 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.

The requirements specified in this document 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 which have been used have been tested and that the methods and 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. The performance characteristics together with their methods of measurement have been revised and updated to take into consideration developments in technology that have occurred since the publication of the previous edition of this document.

Extracorporeal systems for blood purification —

Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

1 Scope

This document specifies requirements and test methods for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators, hereinafter collectively referred to as "the device", for use in humans.

This document does not apply to:

— extracorporeal blood circuits;

— plasmafilters;

— haemoperfusion devices;

— vascular access devices;

— blood pumps;

— systems to prepare, maintain or monitor dialysis fluid;

— systems or equipment intended to perform haemodialysis, haemodiafiltration, haemofiltration or haemoconcentration;

— reprocessing procedures and equipment.

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

NOTE 2 Requirements for plasmafilters are specified in ISO 8637-3.

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 11737-2, *Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*

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 14971, *Medical devices — Application of risk management to medical devices*

ISO 17664-1, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

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

ISO 80369-7:2021, *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 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 a *haemodialyser* (3.16), *haemodiafilter* (3.14), *haemofilter* (3.18) or *haemoconcentrator* (3.13) through which blood is intended to pass

3.2
blood compartment volume
volume which is needed to fill the blood compartment

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

3.3
blood compartment connector
blood connector
cone type connector to permit the entry and exit of blood and to connect the device to blood tubing sets

Note 1 to entry: Historically the term blood port was used.

3.4
clearance
volume of a solution from which a solute is completely removed per unit time

3.5
convection
transport of a solvent across a semipermeable membrane resulting from a pressure differential across the membrane

Note 1 to entry: Convective solute transport supplements diffusive transport as a result of “solute drag” whereby solutes contained in the solvent are co-transported with the solvent.

3.6
convective therapy
form of renal replacement therapy that removes uremic toxins from blood either by convection solely or by a combination of diffusion and convection through a semipermeable membrane

Note 1 to entry: Convective therapies remove toxins from the blood by removing fluid from the device in excess of that required to achieve the patient’s target fluid balance, thereby requiring infusion of replacement fluid into the patient’s blood. In contrast, haemodialysis removes fluid from the device only to correct the patient’s fluid weight gain realized between dialysis treatments.

Note 2 to entry: Haemofiltration and haemodiafiltration are types of convective therapies.

Note 3 to entry: Haemoconcentrators are fluid removal devices used during cardiac surgery.

3.7
dialysis fluid
aqueous fluid containing electrolytes and, usually, buffer and glucose, which is intended to exchange solutes with blood during *haemodialysis* (3.17) or *haemodiafiltration* (3.15)

Note 1 to entry: The term "dialysis fluid" is used throughout this document to mean the fluid (made from dialysis water and concentrates) which is delivered to the haemodialyser or haemodiafilter by a dialysis fluid delivery system. Phrases such as "dialysate", "dialysis solution" or "dialysing fluid" can be used in place of dialysis fluid.

Note 2 to entry: The dialysis fluid entering the haemodialyser or haemodiafilter is referred to as "fresh dialysis fluid", while the fluid leaving the haemodialyser or haemodiafilter is referred to as "spent dialysis fluid" or "effluent".

Note 3 to entry: Dialysis fluid does not include pre-packaged fluids used in some renal replacement therapies.

3.8
dialysis fluid compartment
part of a *haemodialyser* (3.16) or *haemodiafilter* (3.14) through which *dialysis fluid* (3.7) is intended to pass

3.9
dialysis fluid connector
dialysate connector
connector forming part of the device to permit the passage of dialysis fluid through the device and to link the device to equipment producing the dialysis fluid

3.10
diffusion
transport of solutes across a semipermeable membrane, caused by a concentration gradient

3.11
filtrate
fluid removed from the blood across the semipermeable membrane contained in a *haemodialyser* (3.16), *haemodiafilter* (3.14), *haemofilter* (3.18) or *haemoconcentrator* (3.13), due to a pressure gradient (including the contributions of both hydrostatic and oncotic pressures) across the semipermeable membrane

Note 1 to entry: In a haemodialyser and haemodiafilter, the fluid removed is mixed with dialysis fluid flowing through the device.

3.12
haemoconcentration
convective process with the purpose of removing excess plasma water from the patient's blood volume, that has been expanded by physiologic fluid, as typically required during cardiac surgery

3.13
haemoconcentrator
device intended to perform *haemoconcentration* (3.12)

3.14
haemodiafilter
device intended to perform *haemodiafiltration* (3.15)

3.15
haemodiafiltration
HDF
process whereby concentrations of water-soluble substances in a patient's blood and an excess of fluid of a patient are corrected by a simultaneous combination of *haemodialysis* (3.17) and *haemofiltration* (3.19)

Note 1 to entry: Diffusive solute removal is achieved using a dialysis fluid stream as in haemodialysis. Enhanced convective solute removal is achieved by adding ultrafiltration in excess of that needed to achieve the desired weight loss; fluid balance is maintained by the infusion of a replacement solution into the blood circuit either before (pre-dilution haemodiafiltration) or after (post-dilution haemodiafiltration) or a combination of the two (mixed dilution haemodiafiltration).

[SOURCE: IEC 60601-2-16:2018, 201.3.209, modified — Note 1 to entry has been added.]

3.16
haemodialyser
device intended to perform *haemodialysis* (3.17)

3.17
haemodialysis
HD
process whereby concentrations of water-soluble substances in a patient's blood and an excess of fluid of a patient are corrected by bidirectional diffusive transport and ultrafiltration across a semipermeable membrane separating the blood from the dialysis fluid

Note 1 to entry: This process typically includes fluid removal by filtration. This process is usually also accompanied by diffusion of substances from the dialysis fluid into the blood.

[SOURCE: IEC 60601-2-16:2018, 201.3.209]

3.18
haemofilter
device intended to perform *haemofiltration* (3.19)

3.19
haemofiltration
HF
process whereby concentrations of water-soluble substances in a patient's blood and an excess of fluid of a patient are corrected by convective transport via ultrafiltration and partial replacement by a substitution fluid resulting in the required net fluid removal

[SOURCE: IEC 60601-2-16:2018, 201.3.211]

Note 1 to entry: In haemofiltration, there is no dialysis fluid stream.

3.20
labelling
written, printed, graphic or electronic matter that is affixed to a device (haemodialyser, haemodiafilter, haemofilter or haemoconcentrator) or any of its containers or wrappers, or accompanies a device and which is related to identification, technical description and use of that device, but excluding shipping documents

3.21
sieving coefficient
ratio of a solute concentration in the filtrate to the simultaneous concentration of the same solute in the plasma

3.22
transmembrane pressure
TMP
p_{TM}
mean pressure exerted across a semipermeable membrane

Note 1 to entry: For practical reasons, the mean TMP is generally expressed as either:

— the difference between arithmetic means of inlet and outlet pressures of the blood and dialysis fluid compartments of a haemodialyser or a haemodiafilter; or

— the difference between the arithmetic mean of the inlet and outlet pressures of the blood compartment and the filtrate pressure of a haemofilter or a haemoconcentrator.

3.23
ultrafiltration
UF
pressure driven process employing a hydraulic pressure gradient applied to a semipermeable membrane

Note 1 to entry: In haemodialysis treatment, ultrafiltration generally refers to the removal process used to remove excess fluid from the patient.

3.24
ultrafiltration coefficient
permeability of the device to plasma water

Note 1 to entry: The ultrafiltration coefficient is generally expressed in millilitres per hour per millimetre of mercury.

3.25
ultrafiltration rate
UFR
filtrate flow rate from the blood compartment to the dialysis fluid compartment caused by a pressure gradient or pressure differential across the membrane measured as volume per time

Note 1 to entry: Ultrafiltration rate is expressed in ml/min or l/h.

4 Requirements

4.1 Biological safety and haemocompatibility

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. If the device is labelled for reuse, testing shall be performed after reprocessing following the manufacturer's instructions for use.

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 pathway of the device shall be sterile and the state of sterility of the device shall comply with the manufacturer's statement [see 7.2 h)].

Compliance shall be verified in accordance with 5.3.

4.3 Non-pyrogenicity

The blood pathway of the device shall be non-pyrogenic and the state of non-pyrogenicity of the device shall comply with the manufacturer's statement [see 7.2 h)].

Compliance shall be verified in accordance with 5.4.