SLOVENSKI STANDARD
oSIST prEN ISO 8637-2:2023

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Zunajtelesni pretočni sistemi za čiščenje krvi - 2. del: Zunajtelesni krvni in tekočinski obtok za hemodializatorje, hemodiafiltre, hemofiltre in hemokoncentratorje (ISO/DIS 8637-2:2022)

Extracorporeal systems for blood purification - Part 2: Extracorporeal blood and fluid circuits for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators (ISO/DIS 8637-2:2022)

Extrakorporale Systeme zur Blutreinigung - Teil 2: Extrakorporaler Blutkreislauf bei Hämodialysatoren, Hämodiafiltern und Hämofiltern (ISO/DIS 8637-2:2022)

Systèmes extracorporels pour la purification du sang - Partie 2: Circuits sanguins extracorporels et liquidiens pour les hémodialyseurs, les hémodiafiltres, les hémofiltres et les hémoconcentrateurs (ISO/DIS 8637-2:2022)

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Extracorporeal systems for blood purification —

Part 2: Extracorporeal blood and fluid circuits for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

Systèmes extracorporels pour la purification du sang —

Partie 2: Circuit sanguin extracorporel pour les hémodialyseurs, les hémodiafiltres et les hémofiltres

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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. 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. www.iso.org/patents

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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 WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword - Supplementary information

This document was prepared by Technical committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This second edition of ISO 8637-2:2021 replaces the first version of this document (ISO8637-2:2017). It cancels and replaces the earlier versions of this document (third edition of ISO 8638:2010) The standard has been revised to permit the integration of blood and fluid circuits with haemodialysis equipment The following changes have been made:

— Alignment in the terms and definitions with those used in other parts of ISO 8637 and IEC 60601-2-16

— Introduction of a risk based approach to structural integrity testing

— Widening the scope of haemocompatibility testing

— Widening the scope of the standard to include Basic Safety and Essential performance

— Integration of the standard with those for haemodialysis equipment with which the blood and fluid circuits are intended

— Extension of the scope of the standard to include disposable fluid circuits

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

Introduction

This document is concerned with the extracorporeal blood and fluid circuits manufactured for single use and intended for use in conjunction with haemodialysers, haemodiafilters, haemofilters and heamodialysis equipment. The requirements specified in this document for the extracorporeal blood and fluid circuits 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. This document therefore requires only that materials have been tested and that the methods and results are made available upon request.

The dimensions of the connectors intended for connecting the extracorporeal blood and fluid circuits to a haemodialyser, haemodiafilter or haemofilter have been specified to ensure compatibility with these devices, as specified in ISO 8637-1. The design and dimensions selected are intended to minimize the risk of leakage of blood and ingress of air. Connectors with either fixed or loose locking shells are permitted.

This document reflects the consensus of physicians, manufacturers and other interested parties for devices that are approved for clinical use. Conformance with this document is voluntary and it does not supersede any national regulation.

Extracorporeal systems for blood purification —

Part 2:
Extracorporeal blood and fluid circuits for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

1 Scope

This document specifies requirements for disposable extracorporeal blood and fluid circuits and accessories used in combination with haemodialysis equipment intended for extracorporeal blood treatment therapies such as, but not limited to, haemodialysis, haemodiafiltration, haemofiltration.

This document does not apply to:

— haemodialysers, haemodiafilters or haemofilters;

— plasmafilters;

— haemoperfusion devices;

— vascular access devices;

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

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 7864, *Sterile hypodermic needles for single use — Requirements and test methods*

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*

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

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 23500-3, *Preparation and quality management of fluids for haemodialysis and related therapies — Part 3: Water for haemodialysis and related therapies*

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

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

ISO 23500-4, *Preparation and quality management of fluids for haemodialysis and related therapies — Part 4: Concentrates for haemodialysis and related therapies*

ISO 23500-5, *Preparation and quality management of fluids for haemodialysis and related therapies — Part 5: Quality of dialysis fluid for haemodialysis and related therapies*

IEC 60601-2-16, *Medical electrical equipment – Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment*

IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

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

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

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

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 https://www.electropedia.org/

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

3.1
active medical device
any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices. Software shall also be deemed to be an active device.

3.2
non-active medical device
medical devices, without an integral power source. In the context of this standard the non-active medical device is referred to as the disposable.

3.3
haemodialysis system
extracorporeal blood and fluid circuits, in combination with its haemodialysis equipment, haemodialysers, haemodiafilters or haemofilters and other additional accessory.

Note 1 to entry: Haemodialysers, haemodiafilters or haemofilters are covered by ISO 8637-1

3.4
extracorporeal blood circuit
disposable circuit with direct contact to blood or blood components, used to perform haemodialysis, heamodiafiltration and/or haemofiltration

Note 1 to entry: The extracorporeal blood circuit can also contain accessory tubing for attaching the extracorporeal blood circuit to monitors forming part of the haemodialysis system

Note 2 to entry: Extracorporeal blood circuits can also be used for other extracorporeal therapies such as haemoperfusion, plasmafiltration and plasma adsorption.

Note 3 to entry: System components regarding fluid circuit can include dialysis fluid, dialysis water and concentrates that are covered by ISO 23500 series of standards

3.5
fluid circuit
Disposable circuit with indirect or no contact to the blood or blood components, used to perform haemodialysis, haemodiafiltration and/or haemofiltration.

Note 1 to entry: Fluid circuits can also be used for other extracorporeal therapies such as haemoperfusion, plasmafiltration and plasma adsorption.

3.6
haemodialysis equipment
active medical device used to perform haemodialysis, haemodiafiltration and/or haemofiltration.

3.7
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging, or labelling of the extracorporeal circuit or the fluid circuit, assembling an extracorporeal circuit or a fluid circuit, or adapting an extracorporeal circuit or a fluid circuit, regardless of whether these operations are performed by that person or on that person's behalf by a third party.

Note 1 to entry: “Adapting” includes making substantial modifications to a disposable or a haemodialysis system already in use.

Note 2 to entry: In some jurisdictions, the responsible organization can be considered a manufacturer when involved in the activities described.

3.8
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 semi-permeable 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]

3.9
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: Convective transport is achieved by ultrafiltration across a high flux membrane. Fluid balance is maintained by the infusion of a replacement solution into the blood either before the haemofilter (predilution haemofiltration) or after the haemofilter (post-dilution haemofiltration) or a combination of the two (mixed dilution haemofiltration).

Note 2 to entry: In haemofiltration there is no dialysis fluid stream.

3.10
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 HD and HF

[SOURCE: IEC 60601-2-16:2018, 201.3.208]

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 (predilution haemodiafiltration) or after (post-dilution haemodiafiltration) or a combination of the two (mixed dilution haemodiafiltration).

3.11
basic safety
freedom from unacceptable risk caused directly by physical hazards when haemodialysis system is used under normal condition and single fault condition

[SOURCE: IEC 60601-1]

3.12
protective measure
a constructional feature, specifically designed to protect the patient or user against hazardous situations

3.13
essential performance
performance of a clinical function, other than that related to basic safety, where loss or degradation beyond the limits specified by the manufacturer results in an unacceptable risk

[SOURCE: IEC 60601-1]

Note 1 to entry: Essential Performance is most easily understood by considering whether its absence or degradation would result in an unacceptable risk.

3.14
fluid pathway
internal surfaces of the fluid circuit

3.15
blood pathway
internal surfaces of the blood circuit