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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: Circuits sanguins extracorporels et liquidiens pour les hémodialyseurs, les hémodiafiltres, les hémofiltres et les hémoconcentrateurs

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
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 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,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 8637-2:2018), which has been technically revised.

The main changes are:

— dimensional details of reference connectors for the testing blood port connectors have been included together with an illustration of a conical gauge suitable for the testing the blood connector socket;

— blood and fluid circuits with haemodialysis equipment have been integrated throughout this document;

— the terms and definitions have been aligned with those used in other parts of the ISO 8637 series and IEC 60601-2-16;

— a risk-based approach to structural integrity testing has been introduced;

— haemocompatibility testing has been updated;

— the scope has been widened to include disposable fluid circuits.

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 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 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 reviewed 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.

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 10993-11, *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 80369-20:2015, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

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

IEC 60601-2-16:2018, *Medical electrical equipment – Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment*

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
active medical device
medical device that relies 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 that energy or converting that energy

Note 1 to entry: 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 device without an integral power source

EXAMPLE A non-active medical device can be a disposable extracorporeal blood and *fluid circuits* (3.5).

3.3
haemodialysis system
extracorporeal blood and *fluid circuits* (3.5), in combination with its *haemodialysis equipment* (3.6), haemodialysers, haemodiafilters or haemofilters, and other additional accessory

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

3.4
extracorporeal blood circuit
disposable circuit with direct contact to blood or blood components, used to perform *haemodialysis* (3.8), heamodiafiltration and/or *haemofiltration* (3.9)

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* (3.3).

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

3.5
fluid circuit
disposable circuit with indirect or no contact to the blood or blood components, used to perform *haemodialysis* (3.8), haemodiafiltration and/or *haemofiltration* (3.9)

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

Note 2 to entry: System components regarding fluid circuit can include *dialysis fluid* (3.23), *dialysis water* (3.21) and concentrates and are covered by the ISO 23500 series.

Note 3 to entry: Dialysis water is defined as water that has been treated to meet the requirements of ISO 23500-3 and which is suitable for use in haemodialysis applications, including the preparation of dialysis fluid, reprocessing of dialysers, preparation of concentrates and preparation of *substitution fluid* (3.24) for online convective therapies (see ISO 23500-1:2019, 3.17).

3.6
haemodialysis equipment
active medical device (3.1) used to perform *haemodialysis* (3.8), haemodiafiltration and/or *haemofiltration* (3.9)

3.7
manufacturer
natural or legal person responsible for the design, manufacture, packaging or *labelling* (3.27) of the extracorporeal circuit or the *fluid circuit* (3.5), 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: In some jurisdictions, the responsible organization can be considered as a manufacturer when involved in the activities described.

3.8
haemodialysis
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* (3.23)

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
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* (3.24) resulting in the required *net fluid removal* (3.25)

[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 (pre-dilution 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* (3.23) stream.

3.10
haemodiafiltration
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 and haemofiltration

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

Note 1 to entry: Diffusive solute removal is achieved using a *dialysis fluid* (3.23) stream as in *haemodialysis* (3.8). 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).

3.11
basic safety
freedom from unacceptable risk caused directly by physical hazards when *haemodialysis system* (3.3) is used under normal condition and single fault condition

[SOURCE: IEC 60601-1:2023, 3.10]

3.12
protective measure
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* (3.11), where loss or degradation beyond the limits specified by the *manufacturer* (3.7) results in an unacceptable risk

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

[SOURCE: IEC 60601-1:2020, 4.3]

3.14
fluid pathway
internal surfaces of the *fluid circuit* (3.5)

3.15
blood pathway
internal surfaces of the blood circuit

3.16
arterial pressure
pressure measured in the blood withdrawal segment or line of the extracorporeal circuit between the patient connection and dialyzer connection

Note 1 to entry: The withdrawal segment of the extracorporeal circuit can be referred to as the arterial or blood access side.

Note 2 to entry: Pressure in the segment of the extracorporeal circuit taking the blood from the patient can be further differentiated as the pre-pump pressure, which relates to the extracorporeal circuit before the blood pump, and post-pump pressure, which relates to the segment of the extracorporeal circuit between the blood pump and the inlet to the dialyser.

3.17
venous pressure
pressure measured in the blood return segment or line of the extracorporeal circuit between the dialyzer connection and patient connection

Note 1 to entry: The return segment of the extracorporeal circuit between the dialyser connection and the patient connection can be referred to as the venous or blood return side.

3.18
pump system
portion of the *extracorporeal blood circuit* (3.4) and/or the *fluid circuit* (3.5) that is acted upon by the pumping mechanisms forming part of the *haemodialysis* (3.8) machine

3.19
air capture chamber
drip chamber
bubble trap
venous and arterial blood chamber
component intended to capture air, and which can also provide compliance to the blood circuit or allow pressure to be monitored

Note 1 to entry: Air capture chambers can be equipped with a filter that captures blood thrombi.

3.20
transducer protector
pressure-transmitting sterile barrier
component of the *extracorporeal blood circuit* (3.4) and/or the *fluid circuit* (3.5) that is intended to provide a sterile interconnection between the extracorporeal circuits and *haemodialysis equipment* (3.6) while allowing the pressure within the extracorporeal circuits to be measured by the haemodialysis equipment

3.21
dialysis water
water that has been treated to meet the requirements of ISO 23500-3 and which is suitable for use in *haemodialysis* (3.8) applications, including the preparation of *dialysis fluid* (3.23), reprocessing of dialyzers, preparation of concentrates and preparation of *substitution fluid* (3.24) for online convective therapies

Note 1 to entry: Ultrapure dialysis water is highly purified dialysis water (<0,1 CFU/ml and < 0,03 EU/ml) that is produced by some integrated validated systems, such as two stage RO systems with endotoxin filters. Other alternative design systems can also produce such water prior to mixing with concentrates to produce ultrapure dialysis fluid.

[SOURCE: ISO 23500-1:2019, 3.17, modified — Note 1 to entry has been deleted.]

3.22

dialysis fluid concentrate
mixture of chemicals and water or chemicals in a highly concentrated media which are mixed with *dialysis water* (3.21) to produce *dialysis fluid* (3.23)

Note 1 to entry: Chemicals can also be in the form of a dry powder.

3.23
dialysis fluid
dialysing fluid
DEPRECATED: dialysate
DEPRECATED: dialysis solution
aqueous fluid containing electrolytes and, usually, buffer and glucose, which is intended to exchange solutes with blood during *haemodialysis* (3.8) or *haemodiafiltration* (3.10)

Note 1 to entry: The term “dialysis fluid” is used throughout this document to mean the fluid [made from *dialysis water* (3.21) and concentrates] which is delivered to the haemodialyser or haemodiafilter by a dialysis fluid delivery system.

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”.

Note 3 to entry: Dialysis fluid does not include pre-packaged parenteral fluids used in some renal replacement therapies, such as haemodiafiltration and *haemofiltration* (3.9).

[SOURCE: ISO 23500-1:2019, 3.15, modified — Note 1 to entry has been shortened and Note 2 to entry has been deleted.]

3.24
substitution fluid
fluid used in haemofiltration and haemodiafiltration treatments which is directly infused into the extracorporeal circuit as a replacement for the fluid that is removed from the blood by filtration

[SOURCE: ISO 23500-1:2019, 3.40, modified — the words “patient's blood” and ”ultrafiltration” have been respectively replaced by “extracorporeal circuit” and “filtration” in the definition, and Notes 1 and 2 to entry have been deleted.]

3.25
net fluid removal
DEPRECATED: weight loss
fluid loss from the patient

[SOURCE: IEC 60601-2-16:2018, 201.3.212]

3.26
blood leak
movement of blood from the blood compartment to the *dialysis fluid* (3.23) compartment of the dialyzer or movement from the blood compartment to the environment

[SOURCE: IEC 60601-2-16:2018, 201.3.1-2]

3.27
labelling
written, printed, graphic or electronic matter that is affixed to the extracorporeal blood and/or *fluid circuit* (3.5) packaging and container which is related to identification, technical description and use of the circuit but excluding shipping documents

3.28
rigid material
material with a modulus of elasticity either in flexure or in tension greater than 3 433 MPa e.g. metal, glass, some fibre-reinforced polymers and high-performance polymers

3.29
semi-rigid material
material with a modulus of elasticity either in flexure or in tension between 700 and 3 433 MPa e.g. thermoplastics

4 Requirements

4.1 General

Clause 4 gives the blood purification requirements for an extracorporeal circuit.

4.2 Biological safety and haemocompatibility

Parts of the disposable circuit 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 standards governing toxicology and biocompatibility testing exist in the country in which the circuit is produced or to be marketed.

4.3 Sterility

The blood and fluid pathways of the circuit and the internal mating surfaces of all connectors in contact (directly or indirectly) with blood during use shall be sterile. Conformity shall be verified in accordance with 5.3. Elements of the blood and fluid circuits can have sections that are never in direct or indirect contact to the blood. Such elements do not require to be sterile.