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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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# 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 third edition cancels and replaces the second edition (ISO 8637-2:2024), which has been technically revised.

The main changes are:

— introduction of a link to ISO 14971 for risk management procedures;

— addition of new terms to the definitions (recommended pressure and foreseeable misuse);

— detailing of the requirements for transducer protectors resistance;

— detailing of the procedures for expiration date;

— revision of the testing procedure for access port leakage;

— introduction of an Annex A to explain the changes and to describe the further development of the standard in the context of regulatory requirements.

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.

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# 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.

There is no intention to specify, or to set limits on, the performance characteristics of the extracorporeal blood and fluid circuits manufactured for single, nor to specify the materials acceptable for use. Such restrictions are unnecessary for the qualified user and would limit the alternatives available when selecting the extracorporeal blood and fluid circuits manufactured for single use for a specific application.

All materials used in the manufacture of the extracorporeal blood and fluid circuits meet the necessary mechanical strength requirements as well as those relating to biocompatibility thrombogenicity and pyrogenicity after sterilization and have been appropriately tested. The methods used and the test results are available on request.

To minimize the risk of accidental disconnection, the leakage of blood, and the ingress of air during use, the design and the dimensions of the connectors intended for connecting the extracorporeal blood and fluid circuits to devices, specified in ISO 8637-1 (haemodialysers, haemodiafilters or haemofilters) have been selected to ensure compatibility. Connectors with either fixed or loose locking shells are allowed.

This document reflects the consensus of physicians, manufacturers and other interested parties for extracorporeal blood and fluid circuits approved for clinical use.

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# 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 and haemofiltration.

This document does not apply to

— haemodialysers, haemodiafilters or haemofilters,

— plasmafilters,

— haemoperfusion devices, and

— vascular access devices.

NOTE 1 Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators are addressed in ISO 8637-1.

NOTE 2 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: Requirements and general principles for the evaluation of biological safety 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 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 14971, *Medical devices — Application of risk management to medical devices*

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

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

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ISO 80369-20:2024, *Small-bore connectors for liquids and gases in healthcare applications — Part 20: Common test methods*

IEC 60601-2-16:2025, *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**
**air capture chamber**
drip chamber
bubble trap
venous and arterial blood chamber
component intended to capture air, and which can also provide volume expandability 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.

**3.3**
**arterial pressure**
pressure measured in the blood withdrawal segment or line of the extracorporeal blood 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 blood circuit between the blood pump and the inlet to the dialyser.

**3.4**
**basic safety**
freedom from unacceptable risk caused directly by physical hazards when *haemodialysis system* (3.16) is used under normal condition and single fault condition

[SOURCE: IEC 60601-1:2020, 3.10[10]]

**3.5**
**blood leak**
movement of blood from the blood compartment to the *dialysis fluid* (3.7) compartment of the dialyzer or movement from the blood compartment to the environment

[SOURCE: IEC 60601-2-16:2025, 201.3.202]

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**3.6**
**blood pathway**
internal surfaces of the blood circuit

**3.7**
**dialysis fluid**
dialysing fluid
DEPRECATED: dialysate
DEPRECATED: dialysis solution
aqueous fluid made from *dialysis water* (3.9) containing electrolytes and, usually, buffer and glucose, which is intended to exchange solutes with blood during *haemodialysis* (3.14) or *haemodiafiltration* (3.17)

Note 1 to entry: The term "dialysis fluid" is used throughout this document to mean the fluid [made from *dialysis water* (3.9) 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* (3.17) and *haemofiltration* (3.18).

[SOURCE: ISO 23500-1:2024, 3.15]

**3.8**
**dialysis fluid concentrate**
mixture of chemicals and water or chemicals in a highly concentrated media which are mixed with *dialysis water* (3.9) to produce *dialysis fluid* (3.7)

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

**3.9**
**dialysis water**
water that has been treated and which is suitable for use in *haemodialysis* (3.14) applications, including the preparation of *dialysis fluid* (3.7), reprocessing of dialyzers, preparation of concentrates and preparation of *substitution fluid* (3.29) for online convective therapies

**3.10**
**essential performance**
performance of a clinical function, other than that related to *basic safety* (3.4), where loss or degradation beyond the limits specified by the *manufacturer* (3.20) 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, 3.27[10]]

**3.11**
**extracorporeal blood circuit**
**blood circuit**
disposable circuit with direct contact to blood or blood components, used to perform either *haemodialysis* (3.14), *haemodiafiltration* (3.17) or *haemofiltration* (3.18)

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* (3.16)

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

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**3.12**
**fluid circuit**
disposable circuit with indirect or no contact with blood or blood components, used to perform either *haemodialysis* (3.14), *haemodiafiltration* (3.17) or *haemofiltration* (3.18)

Note 1 to entry: to entry Fluid circuit can include circuits for *dialysis fluid* (3.7)*dialysis water* (3.9) and concentrates as well as for infusion or monitoring

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

**3.13**
**fluid pathway**
internal surfaces of the *fluid circuit* (3.12)

**3.14**
**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* (3.7)

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.

**3.15**
**haemodialysis equipment**
*active medical device* (3.1) used to perform either *haemodialysis* (3.14), *haemodiafiltration* (3.17) or *haemofiltration* (3.18)

**3.16**
**haemodialysis system**
extracorporeal blood and *fluid circuits* (3.12), in combination with *haemodialysis equipment* (3.15), haemodialysers, haemodiafilters or haemofilters,

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

**3.17**
**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

Note 1 to entry: Diffusive solute removal is achieved using a *dialysis fluid* (3.7) stream as in *haemodialysis* (3.14). 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 60601-2-16:2025, 201.3.209, modified — Note 1 to entry has been added.]

**3.18**
**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* (3.29) resulting in the required *net fluid removal* (3.22)

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 stream.

[SOURCE: IEC 60601-2-16:2025, 201.3.211, modified — Notes 1 and 2 to entry have been added.]

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**3.19**
**labelling**
written, printed, graphic or electronic matter that is affixed to the extracorporeal blood or *fluid circuit* (3.12) packaging and container which is related to identification, technical description and use of the circuit but excluding shipping documentation

**3.20**
**manufacturer**
natural or legal person responsible for the design, manufacture, packaging or *labelling* (3.19) of the extracorporeal circuit or the *fluid circuit* (3.12), 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.

**3.21**
**maximum recommended pressure**
pressure that the disposable can withstand without damage or functional impairment

**3.22**
**net fluid removal**
DEPRECATED: weight loss
fluid loss from the patient

[SOURCE: IEC 60601-2-16:2025, 201.3.212]

**3.23**
**non-active medical device**
medical device without an integral power source

EXAMPLE A non-active medical device can be a disposable *extracorporeal bloodcircuit* (3.11) or *fluid circuit* (3.12).

**3.24**
**protective measure**
constructional feature, specifically designed to protect the patient or user against hazardous situations

**3.25**
**pump system**
portion of either the *extracorporeal blood circuit* (3.11) or the *fluid circuit* (3.12) that is acted upon by the pumping mechanism forming part of the *haemodialysisequipment* (3.15)

**3.26**
**reasonably foreseeable misuse**
use of a product or system in a way not intended by the *manufacturer* (3.20), but which can result from readily predictable human behaviour

Note 1 to entry: Readily predictable human behaviour includes the behaviour of all types of users, e.g. lay and professional users.

Note 2 to entry: Reasonably foreseeable misuse can be intentional or unintentional.

[SOURCE: ISO/IEC Guide 63:2019, 3.8]

**3.27**
**rigid material**
material with a modulus of elasticity either in flexure or in tension greater than 3 433 MPa

EXAMPLE Metal, glass, some fibre-reinforced polymers and high-performance polymers.

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**3.28**
**semi-rigid material**
material with a modulus of elasticity either in flexure or in tension between 700 and 3 433 MPa

EXAMPLE Thermoplastics.

**3.29**
**substitution fluid**
fluid used in *haemofiltration* (3.18) and *haemodiafiltration* (3.17) treatments which is infused directly infused into the patients' blood as a replacement for the fluid that is removed from the blood by ultrafiltration

Note 1 to entry: Substitution fluid can also be used for administering a bolus, priming an extracorporeal blood circuit and returning blood to the patient at the end of a treatment.

[SOURCE: ISO 23500-1:2024, 3.40]

**3.30**
**transducer protector**
pressure-transmitting sterile barrier
component of either the *extracorporeal blood circuit* (3.11) or the *fluid circuit* (3.12) that provides a sterile interconnection between the extracorporeal circuits and *haemodialysis equipment* (3.15) while allowing the pressure within the extracorporeal circuits to be measured by the haemodialysis equipment

**3.31**
**venous pressure**
pressure measured in the blood return segment or line of the extracorporeal blood circuit between the dialyzer connection and patient connection

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

# 4 Requirements

## 4.1 General

This clause gives the requirements for an extracorporeal blood and fluid circuit.

The evaluation of requirements of this conform shall form part of a structured evaluation plan within a risk management process in accordance with ISO 14971.

## 4.2 Biological safety and haemocompatibility

Parts of the disposable circuit intended to come into direct or indirect contact with blood shall be evaluated within a documented biological and haemocompatibility plan in accordance with ISO 10993-1 and ISO 10993-4. The plan shall identify the contact type and duration and select appropriate blood interaction endpoints proportionate to clinical risk. The key endpoints for blood-material interactions include thrombosis, coagulation, platelets, hematology (including hemolysis), and complement activation. Haemocompatibility shall be verified as specified in 5.2.

## 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.

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