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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 et fluide pour les Hémodialyseurs, hémodiafiltres, hémofiltres et hémoconcentrateurs

Second edition

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Contents

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 ~~documents~~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,* 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~~.~~;

— ~~the standard has been revised to permit the integration of~~ 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 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 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 13485 *Medical devices-Quality management systems- Requirements for regulatory purposes*~~

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*

~~ANSI/AAMI ST72:2019 *Bacterial Endotoxins – Test Methods, Routine Monitoring, And Alternatives To Batch Testing*~~

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~~, the operation of which depends~~ 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 ~~devices,~~device without an integral power source~~.~~

~~In the context of this standard~~ EXAMPLE A non-active medical device ~~is the~~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 ~~by~~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 ~~ISO23500~~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 ~~with responsibility~~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
~~**maximum recommended pressure**~~
~~pressure the disposable is able to withstand without damage or functional impairment~~

~~**3.9**~~
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* (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.~~10~~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* (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.~~11~~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~~haemodialysis and ~~HF~~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.~~12~~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.~~13~~12
protective measure
constructional feature, specifically designed to protect the patient or user against hazardous situations

3.~~14~~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

~~[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.

~~3.15~~
[SOURCE: IEC 60601-1:2020, 4.3]

3.14
fluid pathway
internal surfaces of the *fluid circuit* (3.~~16~~5)

3.15
blood pathway
internal surfaces of the blood circuit

3.~~17~~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 ~~may~~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 ~~may~~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.~~18~~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 ~~may~~can be referred to as the venous or blood return side.

3.~~19~~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.~~20~~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 are also known as drip chambers, bubble traps or venous and arterial blood chambers.~~

~~Note 2 to entry~~: Air capture chambers can be equipped with a filter that captures blood thrombi.

3.~~21~~20
transducer protector
pressure-transmitting sterile barrier
~~TP~~
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.~~22~~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