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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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Contents

Page

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 (see 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 (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on 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 the following URL: 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*.

This first edition of ISO 8637-1:2017 cancels and replaces the third edition of ISO 8637:2010 and ISO 8637:2010/Amd1:2013, which has been technically revised. The following changes have been done:

— Figure 1, Figure 2, and Figure 3 have been revised.

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

Introduction

This document is concerned with devices intended for haemodialysis, haemodiafiltration, haemofiltration and haemoconcentration in humans. 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 dimensions of the blood ports and the dialysis fluid or 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 in order to minimize the risk of leakage of blood and the ingress of air.

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 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

1 Scope

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

This document specifies requirements 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;

— pressure monitors for the extracorporeal blood circuit;

— air detection devices;

— systems to prepare, maintain or monitor dialysis fluid;

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

— reprocessing procedures and equipment.

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

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 80369-7, *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 terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

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

3.1
blood compartment
part of a *haemodialyser* (3.12), *haemodiafilter* (3.10), *haemofilter* (3.14) or *haemoconcentrator* (3.9) through which blood is intended to pass

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

3.2
clearance
volume of a solution from which a solute is completely removed per unit time

3.3
convection
transport of solutes across a semipermeable membrane, along with filtered fluid, caused by a pressure gradient or pressure differential across the membrane

3.4
dialysis fluid
aqueous fluid containing electrolytes and, usually, buffer and glucose, which is intended to exchange solutes with blood during *haemodialysis* (3.13) or *haemodiafiltration* (3.11)

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".

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

3.5
dialysis fluid compartment
part of a *haemodialyser* (3.12) or *haemodiafilter* (3.10) through which *dialysis fluid* (3.4) is intended to pass

3.6
diffusion
transport of solutes across a semipermeable membrane, caused by a concentration gradient

3.7
filtrate
fluid removed from the blood across the semipermeable membrane into the dialysis fluid or filtrate compartment of a *haemodialyser* (3.12), *haemodiafilter* (3.10), *haemofilter* (3.14) or *haemoconcentrator* (3.9), due to a pressure gradient (including the contributions of both hydrostatic and oncotic pressures) across the semipermeable membrane

3.8
haemoconcentration
process whereby plasma water and electrolytes are removed from diluted blood across a semipermeable membrane

3.9
haemoconcentrator
device intended to perform *haemoconcentration* (3.8)

3.10
haemodiafilter
device intended to perform *haemodiafiltration* (3.11)

3.11
haemodiafiltration
form of renal replacement therapy in which the waste solutes are removed from blood by a combination of diffusion and enhanced convection through a high flux or high permeability membrane

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).

3.12
haemodialyser
device intended to perform *haemodialysis* (3.13)

3.13
haemodialysis
form of renal replacement therapy in which waste solutes from the blood are removed primarily by diffusion across a semi-permeable membrane contained in a haemodialyser in which the blood flows on one side of the membrane and dialysis fluid flowing on the other

Note 1 to entry: Fluid removal that is sufficient to achieve the desired weight loss is achieved by a hydrostatic pressure gradient across the membrane. This fluid removal provides some additional solute removal particularly for higher molecular weight compounds.

3.14
haemofilter
device intended to perform *haemofiltration* (3.15)

3.15
haemofiltration
a form of renal replacement therapy in which waste solutes are removed from the blood by convection

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.

3.16
labelling
written, printed, graphic or electronic matter that is affixed to a medical device or any of its containers or wrappers, or accompanies a medical device and which is related to identification, technical description and use of that medical device, but excluding shipping documents

3.17
sieving coefficient
ratio of a solute concentration in the filtrate to the simultaneous concentration of the same solute in the plasma

3.18
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

3.19
ultrafiltration coefficient
permeability of membrane to water, generally expressed in millilitres per hour per millimetre of mercury

4 Requirements

4.1 Biological safety

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. Compliance shall be verified in accordance with 5.3.

4.3 Non-pyrogenicity

The blood pathway of the device shall be non-pyrogenic. Compliance shall be verified in accordance with 5.4.

4.4 Mechanical characteristics

4.4.1 Structural integrity

The device shall be capable of withstanding a positive pressure of 1,5 times the manufacturer's recommended maximum pressure above atmospheric pressure and a negative pressure not exceeding 700 mmHg (93,3 kPa) below atmospheric pressure, when tested according to 5.5.1.

NOTE This requirement refers to the external case integrity of the device.

4.4.2 Blood compartment integrity

When exposing the blood compartment to a validated test procedure performed at 1,5 times the manufacturer's maximum recommended transmembrane pressure, the blood compartment shall not leak. Compliance with this requirement shall be verified in accordance with 5.5.2.

4.4.3 Haemodialyser, haemodiafilter and haemofilter blood compartment ports

Except where the haemodialyser, haemodiafilter or haemofilter and the extracorporeal blood circuit are designed as an integral system, the dimensions of the blood ports shall be as given in Figure 1. Compliance with this requirement shall be verified in accordance with 5.5.3.