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Cardiovascular implants and extracorporeal systems — Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

Implants cardiovasculaires et systèmes extracorporels — Hémodialyseurs, hémodiafiltres, hémofiltres et 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 8637 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This third edition cancels and replaces the second edition (ISO 8637:2004), which has been technically revised.

Introduction

This International Standard is concerned with devices intended for haemodialysis, haemodiafiltration, haemofiltration and haemoconcentration in humans. The requirements specified in this International Standard will help to ensure safety and satisfactory function.

It was not found practicable to specify materials of construction. This International Standard therefore requires only that materials 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 8638. The design and dimensions have been selected in order to minimize the risk of leakage of blood and the ingress of air.

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

Cardiovascular implants and extracorporeal systems — Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

1 Scope

This International Standard specifies requirements for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators, hereinafter collectively referred to as “the device”, for use in humans.

This International Standard is not applicable 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 used 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 8638.

2 Normative references

The following referenced documents are indispensable for the application 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 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

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*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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 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 The term “dialysis fluid” is used throughout this International Standard to mean the fluid (made from dialysis water and concentrates) which is delivered to the haemodialyser or haemodiafilter by the dialysis fluid delivery system. Such phrases as “dialysate”, “dialysis solution” or “dialysing fluid” can be used in place of dialysis fluid.

NOTE 2 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 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
process whereby solute imbalances in a patient's blood are corrected by means of simultaneous convection and diffusion across a semipermeable membrane, and by replacement with an appropriate physiological fluid

NOTE Normally, the process also includes a net fluid removal.

3.12
haemodialyser
device intended to perform haemodialysis (3.13)

3.13
haemodialysis
process whereby solute imbalances in a patient's blood are corrected, mainly by diffusion across a semipermeable membrane

NOTE Normally, the process also includes a net fluid removal.

3.14
haemofilter
device intended to perform haemofiltration (3.15)

3.15
haemofiltration
process whereby solute imbalances in a patient's blood are corrected, mainly by convection across a semipermeable membrane and replacement with an appropriate physiological fluid

NOTE Normally, the process also includes a net fluid removal.

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
TPM
p_{TM}
mean pressure exerted across a semipermeable membrane

NOTE 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 × the manufacturer's recommended maximum pressure and a negative pressure not exceeding 700 mmHg (93,3 kPa below atmospheric pressure) or the highest obtainable negative pressure if at high elevation, when tested according to 5.5.1.

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

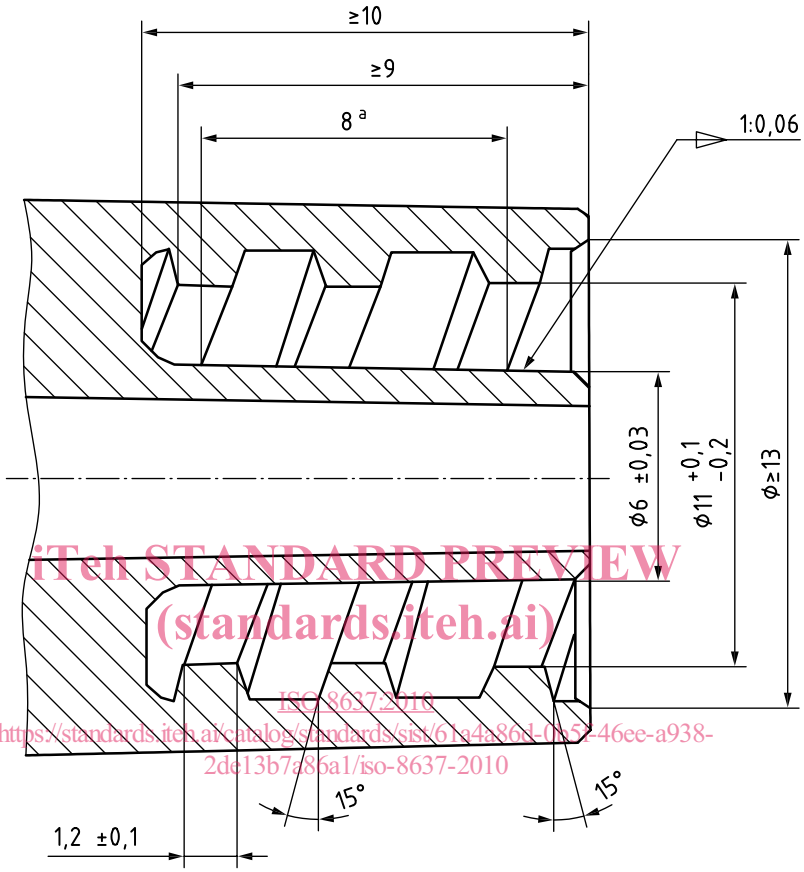
4.4.2 Blood compartment integrity

When exposing the blood compartment to a validated test procedure performed at 1,5 × 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.

Dimensions in millimetres



[a] Double thread.

Figure 1 — Main fitting dimensions of blood inlet and outlet ports

4.4.4 Haemodialyser and haemodiafilter dialysis fluid compartment ports

Except where the haemodialyser or haemodiafilter and the dialysis fluid circuit are designed as an integral system, the dimensions of the dialysis fluid compartment ports shall be as given in Figure 2. Compliance with this requirement shall be verified in accordance with 5.5.4.

4.4.5 Haemofilter filtrate ports

Except where the haemofilter and the filtrate circuit are designed as an integral system, the filtrate ports of haemofilters shall comply either with Figure 2 or with the requirements of the Luer lock fitting of ISO 594-2. Compliance with this requirement shall be verified in accordance with 5.5.5.

4.4.6 Haemoconcentrator blood and filtrate ports

The blood and filtrate ports of haemoconcentrators shall allow for a secure connection to the tubing which is to be used with the device. Compliance with this requirement shall be verified in accordance with 5.5.6.