SLOVENSKI STANDARD
oSIST prEN ISO 8637-2:2016

01-junij-2016

Zunajtelesni pretočni sistemi za čiščenje krvi - 2. del: Zunajtelesni krvni obtok za hemodializatorje, hemodiafiltre in hemofiltre (ISO/DIS 8637-2:2016)

Extracorporeal systems for blood purification - Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters (ISO/DIS 8637-2:2016)

Kardiovaskuläre Implantate und extrakorporale Système - Teil 2: Extrakorporaler Blutkreislauf bei Hämodialysatoren, Hämodiafiltern und Hämofiltern (ISO/DIS 8637-2:2016)

Systèmes extracorporels pour la purification du sang - Partie 2: Hémodialyseurs, hémodiafiltres, hémofiltres et hémoconcentrateurs (ISO/DIS 8637-2:2016)

Ta slovenski standard je istoveten z: **prEN ISO 8637-2**

ICS:

11.040.20	Transfuzijska, infuzijska in injekcijska oprema	Transfusion, infusion and injection equipment
11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics

oSIST prEN ISO 8637-2:2016 **en**

DRAFT INTERNATIONAL STANDARD

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Extracorporeal systems for blood purification —

Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters

Systèmes extracorporels pour la purification du sang

ICS: 11.040.40

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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

This fourth edition cancels and replaces the third edition (ISO 8638:2010), which has been technically revised. Users should note that Figure 1, Figure 2, and Figure 3 have been revised.

ISO 8637 consists of the following parts, under the general title *Extracorporeal systems for blood purification*:

Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators (previously ISO 8637)

Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters (previously ISO 8638)

Part 3: Plasmafilters (previously ISO 13960)

Introduction

This International Standard is concerned with the extracorporeal blood circuit manufactured for single use and intended for use in conjunction with haemodialysers, haemodiafilters and haemofilters. The requirements specified in this International Standard for the extracorporeal blood circuit 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.

The dimensions of the connectors intended for connecting the extracorporeal blood circuit to a haemodialyser, haemodiafilter or haemofilter have been revised and specified to ensure compatibility with these devices, as specified in ISO 8637-1. The design and dimensions have been selected in order to minimize the risk of leakage of blood and ingress of air. Connectors with either fixed or loose locking shells are permitted.

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 is not intended to supersede any national regulation.

Extracorporeal systems for blood purification — Part 2: Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters

1 Scope

This International Standard specifies requirements for the blood circuit for devices used in extracorporeal blood filtration therapies such as, but not limited to, haemodialysis, haemodiafiltration, haemofiltration and transducer protectors (integral and non-integral) intended for use in such circuits.

This International Standard does not apply to:

— haemodialysers, haemodiafilters or haemofilters;

— 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.

NOTE Requirements for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators are specified in ISO 8637-1, and requirements for plasmafilters are specified in ISO 8637-3

NOTE Extracoproreal blood tubing sets may also be used for other extracorporeal therapies such as haemoperfusion, plasmafiltration and plasma adsorption.

2 Normative references

The following referenced documents are indispensable for the application of this document.

ISO 594-2:1998, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 7864:1993, *Sterile hypodermic needles for single use*

ISO 10993-1:2009, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-4:2002, *Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood*

ISO 10993-7:2008, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 10993-11:2006, *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
air capture chamber
component intended to capture air and which can 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.

3.2
extracorporeal blood circuit
blood tubing and integral accessory tubing, including fluid and infusion tubing, for attaching the extracorporeal blood circuit to pressure monitors and integral components

EXAMPLES (Of integral components.) Air-capture chambers and transducer protectors.

3.3
fluid pathway
internal surfaces of the extracorporeal blood circuit

3.4
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.

3.5
pump segment
portion of the extracorporeal blood circuit (3.2) that is acted upon by the blood pump

3.6
transducer protector
pressure-transmitting sterile barrier
component of the extracorporeal blood circuit (3.2) that is intended to provide an interconnection between the extracorporeal blood circuit and the haemodialysis machine while allowing the pressure within the extracorporeal blood circuit to be measured by the machine

