SLOVENSKI STANDARD
oSIST prEN ISO 7199:2015

01-julij-2015

Vsadki (implantati) za srce in ožilje ter umetni organi - Izmenjevalniki krvnih plinov (oksigenatorji) (ISO/DIS 7199:2015)

Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators) (ISO/DIS 7199:2015)

Kardiovaskuläre Implantate und künstliche Organe - Blutgasaustauscher (Oxygenatoren) (ISO/DIS 7199:2015)

Implants cardiovasculaires et organes artificiels - Échangeurs gaz/sang extracorporels (oxygénateurs) (ISO/DIS 7199:2015)

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ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics

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Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators)

Implants cardiovasculaires et organes artificiels — Échangeurs gaz/sang extracorporels (oxygénateurs)

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.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

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.

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 meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

ISO 7199 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 7199:2009), which has been technically revised.

Introduction

This International Standard is intended to ensure that devices designed to affect the exchange of gases in support of, or as a substitution for, the normal respiratory function of the lungs have been adequately tested for both their safety and function, and that extracorporeal device characteristics are appropriately disclosed when labelling the device.

This International Standard therefore contains procedures to be used for evaluation of extracorporeal blood-gas exchangers (oxygenators). Type test procedures for determination of the gas transfer, blood cell damage and heat exchanger performance are described, although limits for these characteristics are not specified. Ready identification of the performance characteristics should, however, assist the user in the selection of an oxygenator that will suit the needs of the patient.

This International Standard also includes minimum reporting requirements, which will allow the user to compare performance characteristics of oxygenators of different designs in a standard way.

This International Standard makes reference to other International Standards in which methods for determination of characteristics common to medical devices can be found.

No provisions have been made for quantification of microbubble generation or for non-formed elements of bovine blood because there currently is no consensus regarding satisfactorily reproducible test methods.

Requirements for animal and clinical studies have not been included in this International Standard. Such studies may be parts of a manufacturer's quality system.

This International Standard contains only those requirements that are specific to oxygenators. Non-specific requirements are covered by references to other International Standards listed in the normative references section. Since non-toxicity is anticipated to be the subject of a future horizontal/level 1 standard, this International Standard does not cover non-toxicity.

Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators)

1 Scope

This International Standard specifies requirements for sterile, single-use, extracorporeal blood-gas exchangers (oxygenators) intended for supply of oxygen to, and removal of carbon dioxide from, the blood of humans.

This International Standard also applies to heat exchangers and arterials filters that are integral parts of the oxygenator.

This International Standard also applies to external equipment unique to the use of the device.

This International Standard does not apply to:

— implanted oxygenators;

— liquid oxygenators;

— extracorporeal circuits (blood tubing);

— separate heat exchangers;

— separate ancillary devices

— separate arterial line filter.

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

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 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

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 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

3 Terms and definitions

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

3.1
blood-gas exchanger
oxygenator
extracorporeal device designed to supplement, or be a substitute for, the respiratory function of the lungs

3.2
blood pathway
paths of the oxygenator containing blood during intended clinical use

3.3
gas pathway
parts of the oxygenator containing the ventilation gas during intended clinical use

3.4
heat exchanger
component that is intended to control the temperature of the circulating blood or priming solution

3.5
heat exchanger performance factor
R
ratio of the difference between the temperature of blood at the outlet of the oxygenator and the temperature of blood at the inlet of the oxygenator to the difference between the temperature of the water at the inlet of the heat exchanger and the temperature of blood at the inlet of the oxygenator

3.6
integral arterial filter
component that is intended to filter particles such as blood clots, debris, and gas emboli from the blood

3.7
filtration efficiency
ability of the filter to remove particles from the simulated blood suspension test fluid, expressed as a percentage

3.8
integral part
part that is connected to the oxygenator and cannot normally be separated by the user

3.9
operating variables
settings of controls that affect the function of the device

3.10
platelet reduction
percentage reduction of platelets contained in a circuit incorporating an oxygenator, less the percentage reduction in an identical control circuit without an oxygenator, as a function of time

3.11
plasma-free haemoglobin level
concentration of plasma-free haemoglobin in a circuit incorporating an oxygenator, less the concentration in an identical control circuit without an oxygenator, as a function of time

3.12
white blood cell reduction
percentage reduction of white blood cells contained in a circuit incorporating an oxygenator, less the percentage reduction in an identical control circuit without an oxygenator, as a function of time