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Vsadki (implantati) za srce in ožilje ter umetni organi - Izmenjevalniki krvnih plinov (oksigenatorji) (ISO/DIS 7199:2023)

Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators) (ISO/DIS 7199:2023)

Kardiovaskuläre Implantate und künstliche Organe - Blut-Gas-Austauscher (Oxygenatoren) (ISO/DIS 7199:2023)

Implants cardiovasculaires et organes artificiels - Échangeurs gaz/sang (oxygénateurs) (ISO/DIS 7199:2023)

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

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

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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. 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. 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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see the following URL: https://www.iso.org/iso/foreword.html

The committee responsible for this document is 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.

It also incorporates the Amendment ISO 7199:2009/Amd.1:2012.

Introduction

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

This document 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 necessary for regulatory submissions and/or be part of a manufacturer's quality system.

This document 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 clause. Since non-toxicity is anticipated to be the subject of a future horizontal/level 1 standard, this document does not cover non-toxicity.

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

1 Scope

This document specifies requirements for sterile, single-use, extracorporeal blood-gas exchangers (oxygenators) intended for supply of oxygen to, and removal of carbon dioxide from, human blood, during cardiopulmonary bypass (CPB) up to 6 h, extracorporeal lung assist (ECLA with VV, VAV, or AV cannulation strategies), cardiopulmonary support (CPS), extracorporeal life support (ECLS with VA cannulation strategy), extracorporeal carbon dioxide removal ($ECCO_2R$), and other extracorporeal circulation techniques requiring blood-gas exchange.

This document also applies to heat exchangers and arterial filters that are integral parts of the oxygenator.

This document also applies to external equipment unique to the use of the oxygenator.

This document does not apply to

— implanted oxygenators,

— liquid oxygenators,

— extracorporeal circuits (blood tubing),

— separate heat exchangers,

— separate ancillary devices, and

— separate arterial line filters.

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 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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

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

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

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
portions of the oxygenator containing blood during intended clinical use

3.3
gas pathway
portions 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, as a function of time

3.11
plasma-free haemoglobin level
concentration of plasma-free haemoglobin in a circuit incorporating an oxygenator, as a function of time

3.11.1
normalized index of hemolysis
NIH
grams of plasma-free hemoglobin released after pumping 100 l of blood

$$\mathrm{NIH}\,(\mathrm{g}\,/\,100\ \mathrm{l}) = \Delta f_{\mathrm{Hb}} \cdot V \cdot \frac{100 - \mathrm{Hct}}{100} \cdot \frac{100}{Q \cdot t} \quad (1)$$

where

Δf_{Hb} is the increase of plasma free hemoglobin concentration (g/l) over the sampling time interval;

V is the circuit volume (l);

Q is the flow rate (l/min);

Hct is the hematocrit (%);

t is the sampling time interval (min)

3.12
white blood cell reduction
percentage reduction of white blood cells contained in a circuit incorporating an oxygenator, as a function of time

3.13
residual blood volume
difference between the priming volume of the unit and the blood volume that can be extracted

3.14
blood analogue
test solution which simulates certain blood characteristics relevant for testing, such as viscosity and salinity

3.15
subject device
the device under test

3.16
comparator device
similar device to the subject device that is a legally marketed device, recognized-to-be-safe and is used for the same intended clinical use

3.17
worst-case conditions
operating variables within those specified by the manufacturer for intended clinical use which represent the supposed worst-case device operation for the respective test

