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

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

[Revision of first edition (ISO 7199:1996)]

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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 3.

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 International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 7199 was prepared by Technical Committee ISO/TC 150, *TC Implants for surgery*, Subcommittee 2, *Cardiovascular implants and extracorporeal systems*.

This second edition cancels and replaces the first edition (ISO 7199:1996), 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 labeling the device.

This International Standard therefore contains recommended 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 nor for nonformed 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. Nonspecific requirements are covered by references to other International Standards listed in the normative references section. Since nontoxicity is anticipated to be the subject of a future horizontal/level 1 standard, this International Standard does not cover nontoxicity.

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 that are integral parts of oxygenators and 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.

2 Normative references

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

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 11134, *Sterilization of health care products—Requirements for validation and routine control—Industrial moist heat sterilization*

ISO 11135, *Medical devices—Validation and routine control of ethylene oxide sterilization*

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

ISO 13485, *Medical devices—Quality management systems—Requirements for regulatory purposes*

ISO 13488:1996, *Quality systems—Medical devices—Particular requirements for the application of ISO 9002*

ISO 14971, *Medical devices—Application of risk management to medical devices*

ISO 23810, *Cardiovascular implants and artificial organs—Checklist for preoperative extracorporeal circulation equipment setup*

3 Terms and definitions

For the purposes of this International Standard, 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 lung

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

3.3
bovine blood
heparinized bovine blood, whole or diluted with physiological saline solution

3.4
gas pathway
parts of the oxygenator containing the ventilation gas during intended clinical use

3.5
heat exchanger
component that is intended to control the temperature of the circulating blood or priming solution

3.6
heat exchanger performance factor, R
ratio R of the difference between the temperature of blood at the outlet and inlet of the oxygenator, to the difference between the temperature of the water at the inlet of the heat exchanger and the temperature at the inlet of the oxygenator, expressed by the following equation:

$$R = \frac{B_{To} - B_{Ti}}{W_{Ti} - B_{Ti}}$$

where

B_{To} is the temperature of the blood at the outlet of the oxygenator, in degrees Celsius;

B_{Ti} is the temperature of the blood at the inlet of the oxygenator, in degrees Celsius;

W_{Ti} is the temperature of the water at the inlet of the heat exchanger, in degrees Celsius.

3.7
integral part
part that is connected to the oxygenator and cannot normally be separated by the user

3.8
operating variables
settings of controls that affect the function of the device

3.9
platelet percentage 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

3.10
plasma–free haemoglobin generation
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

3.11
white blood cell percentage 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

3.12
residual blood volume
difference between the priming volume of the unit and the blood volume that can be extracted by the unit by holding it in its most advantageous drainage position for 20 seconds past the time that air first appears at the port being used for drainage until no remaining volume is noted in the device

4 Requirements

4.1 Biological characteristics

4.1.1 Sterility and nonpyrogenicity

The blood pathway shall be sterile and nonpyrogenic.

Compliance shall be verified in accordance with 5.1.1.

4.1.2 Biocompatibility

Parts of the blood pathway shall be biocompatible with respect to their intended use.

Compliance shall be verified in accordance with 5.1.2.

4.2 Physical characteristics

4.2.1 Blood pathway integrity

When tested in accordance with 5.2.1, the blood pathway shall not leak.

4.2.2 Heat exchanger fluid pathway integrity

When tested in accordance with 5.2.2, the heat exchanger fluid pathway shall not leak.

4.2.3 Blood volumes

When tested in accordance with 5.2.3, the volume of the blood pathway shall be within the tolerance specified by the manufacturer (see 6.3).

4.2.4 Connectors

Connectors for connection to the blood pathway shall, when tested in accordance with 5.2.4, allow a secure connection.

NOTE Connectors of a type that allows connection of tubes with an inner diameter of 4,8, 6,3, 9,5, or 12,7 mm, or a type that complies with figure 1 of ISO 8637:1989, or a type that complies with ISO 594-2:1991, have been found satisfactory.

When tested in accordance with 5.2.4, the gas inlet connection to the gas pathway shall not separate.