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Cardiovascular implants and extracorporeal systems — Centrifugal blood pumps

Implants cardiovasculaires et systèmes extracorporels — Pompes sanguines centrifuges

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: 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*.

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Introduction

This document is intended to ensure that devices designed to provide continuous flow of blood in support of, or as a substitution for, the normal pumping function of the heart 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 centrifugal blood pumps. Test procedures for determination of the hydraulic performance, blood cell damage and other performance characteristics 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 a centrifugal blood pump 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 centrifugal blood pumps 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.

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

This document contains only those requirements that are specific to centrifugal blood pumps. Non-specific requirements are covered by references to other International Standards listed in Clause 2.

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Cardiovascular implants and extracorporeal systems — Centrifugal blood pumps

1 Scope

This document specifies requirements for sterile, single-use, extracorporeal centrifugal blood pumps, whether coated, non-surface modified, or surface-modified, intended for producing blood flow during extracorporeal circulation. Such blood flow is most commonly used to provide systemic perfusion during cardiopulmonary bypass, but also has applications for veno-venous bypass, kinetic-assisted venous drainage, or extracorporeal membrane oxygenation.

This document does not apply to

— centrifugal pumps used as ventricular assist devices, and

— other components of extracorporeal circuits (e.g. blood tubing, pump console/driver).

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 — Part4: 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 11658, *Cardiovascular implants and extracorporeal systems — Blood/tissue contact surface modifications for extracorporeal perfusion systems*

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.

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

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

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

3.1
centrifugal blood pump
extracorporeal device designed to produce rotational flow by means of radial force

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

3.3
operating variables
settings of controls that affect the function of the device

3.4
blood cell damage
loss or destruction of cellular components of the blood

3.5
platelet reduction
percentage reduction of platelets contained in a circuit incorporating a centrifugal pump as a function of time

3.6
plasma-free hemoglobin level
concentration of plasma-free hemoglobin in a circuit incorporating a pump, as a function of time

3.6.1
normalized index of hemolysis
NIH
grams of plasma-free hemoglobin released after pumping 100 L of blood

$$NIH\left\{g\ /\ 100L\right\} = \Delta fHb \times V \times \frac{100 - Hct}{100} \times \frac{100}{Q \times T} \quad (1)$$

where

ΔfHb is the increase of plasma free hemoglobin concentration (g/L) over the sampling time interval;

V is circuit volume (L);

Q is flow rate (L/min);

Hct is hematocrit (%);

T is sampling time interval (min).

3.7
white blood cell reduction
percentage reduction of white blood cells contained in a circuit incorporating a centrifugal pump as a function of time

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3.8
blood analogue
test solution which simulates blood viscosity between $2,0 \times 10^{-3}$ Pa·s (2,0 cP), to $3,5 \times 10^{-3}$ Pa·s (3,5 cP) or defined by the manufacturer based on appropriate haematocrit and temperature of the circulating blood during intended clinical use (i.e. hypothermic conditions)

3.9
predicate pump
similar pump to the test pump that has previously been approved and used for the same intended clinical use

4 Requirements

4.1 Biological characteristics

4.1.1 Sterility and non-pyrogenicity

The blood pathway shall be sterile and non-pyrogenic. Compliance shall be verified in accordance with 5.2.1.

4.1.2 Biocompatibility

All parts of the blood pathway shall be biocompatible with respect to their intended use. Compliance shall be verified in accordance with 5.2.2.

4.2 Physical characteristics

4.2.1 Blood pathway integrity

When determined in accordance with 5.3.1, the blood pathway shall not leak.

4.2.2 Prime volume

When determined in accordance with 5.3.2, the volume of the blood pathway shall be within the tolerances specified by the manufacturer (see 6.3).

4.2.3 Connector integrity

When determined in accordance with 5.3.3, the inlet and outlet ports shall allow a secure connection.

NOTE Connectors of a type that allow connection of tubes with an inner diameter of 4,8 mm, 6,3 mm, 9,5 mm, or 12,7 mm, or a type that complies with ISO 7199.

4.3 Performance characteristics

4.3.1 Hydraulic performance

When determined in accordance with 5.4.1, the flow rates, pressure, and revolutions per minute (r/min) shall be within the range of values specified by the manufacturer (see 6.3).

4.3.2 Blood cell damage

NOTE Testing performed at the maximum rated flow specified by the manufacturer and using appropriate circuit blood volume, backpressure, pump r/min, and temperature is one way to comply with this requirement.

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