DRAFT INTERNATIONAL STANDARD

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Cardiovascular implants and extracorporeal systems — Centrifugal blood pumps

Titre manque

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web 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.

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 18242 was prepared by Technical Committee ISO/TC 150, *TC Implants for surgery*, Subcommittee 2, *Cardiovascular implants and extracorporeal systems*.

Introduction

This International Standard 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 labeling the device.

This International Standard 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 International Standard 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 International Standard 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 International Standard. Such studies may be part of a manufacturer's quality system.

This International Standard contains only those requirements that are specific to centrifugal blood pumps. Nonspecific requirements are covered by references to other International Standards listed in the normative references section.

DRAFT INTERNATIONAL STANDARD **ISO/DIS 18242:xxxx**

Cardiovascular implants and extracorporeal systems — Centrifugal Blood Pumps

1 Scope

This International Standard 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 International Standard does not apply to:

- centrifugal pumps used as ventricular assist devices;
- other components of extracorporeal circuits (e.g., blood tubing, pump console/driver)~~;~~

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2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the most recent 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 10993-4, *Biological evaluation of medical devices-Part4: Selection of tests for interaction 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 11135-1, *Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for 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*

ASTM F1830, *Standard Practice for Selection of Blood for in vitro Evaluation of Blood Pumps*

3 Terms and definitions

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

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

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

3.8 blood analogue
test solution which simulates blood viscosity between 2 cP to 3,5 cP

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 volumes

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 (rpm) shall be within the range of values specified by the manufacturer (see 6.3).

4.3.2 Blood cell damage

4.3.2.1 Plasma-free hemoglobin

When determined in accordance with 5.4.2, the rate of generation of plasma-free hemoglobin shall be within the range of values specified by the manufacturer.

NOTE Testing performed at the maximum rated flow specified by the manufacturer and using an appropriate circuit blood volume, is one way to comply with this requirement.

4.3.2.2 Platelet reduction

When determined in accordance with 5.4.2, the percentage reduction of platelets shall be within the range of values specified by the manufacturer.

4.3.2.3 White blood cell reduction

When determined in accordance with 5.4.2, the percentage reduction of white blood cells shall be within the range of values specified by the manufacturer.

4.3.3 Bearing durability