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Cardiovascular implants and artificial organs — Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags

Implants cardiovasculaires et organes artificiels — Systèmes réservoirs de cardiotomie/veineux à paroi dure (avec/sans filtre) et sacs réservoirs veineux mous

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Foreword

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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).

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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.

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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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This third edition cancels and replaces the second edition (ISO 15674:2009), which has been technically revised.

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Cardiovascular implants and artificial organs — Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags

1 Scope

This document specifies requirements for sterile, single-use, extracorporeal hard-shell cardiotomy/venous reservoir systems and soft venous reservoir bags intended for use as a blood reservoir during cardiopulmonary bypass (CPB) surgery.

This document applies only to the blood reservoir aspects for multifunctional systems which can have integral parts such as blood-gas exchangers (oxygenators), blood filters, defoamers, blood pumps, etc.

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.

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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*

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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 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

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:

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

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

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3.1
hard-shell cardiotomy reservoir
extracorporeal device consisting of rigid walls designed to collect, defoam and filter suctioned blood

3.2
hard-shell venous reservoir
extracorporeal device consisting of rigid walls designed to collect and defoam venous blood

3.3
soft-bag venous reservoir
extracorporeal device consisting of collapsible, pliable walls designed to collect venous blood

3.4
hard-shell cardiotomy/venous reservoir system
extracorporeal device designed to function simultaneously as both a venous reservoir and cardiotomy reservoir

3.5
blood-gas exchanger
oxygenator
extracorporeal device designed to supplement, or be a substitute for, the respiratory function of the lungs

3.6
integral part
part that is connected to the reservoir or is part of the reservoir system that cannot normally be separated by the user

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3.7
operating variable
setting of controls which affects the function of the device

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3.8
static volume
priming volume present in the device at zero flow

3.9
break-through volume
volume of fluid that, when added during the initial priming of the dry device (as received from the manufacturer), must be exceeded before fluid first exits the device

3.10
sealed hard-shell reservoir
hard-shell reservoir that may be operated at either positive or negative pressure

3.12
dynamic priming volume
amount of fluid volume that is contained inside the defoamer/filter compartment at a specified flow rate and, for soft bag reservoir, depending on the head pressure and the position of the compression mechanism

Note 1 to entry: The dynamic priming volume can be affected by negative pressure applied to a hard-shell reservoir.

3.13
platelet reduction
percentage reduction of platelets contained in a circuit as a function of time

3.14
plasma-free haemoglobin level
concentration of plasma-free haemoglobin in a circuit as a function of time

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3.14.1
normalized index of hemolysis
NIH
grams of plasma-free hemoglobin released after pumping 100 L of blood

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

where

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

V circuit volume (L);

Q flow rate (L/min);

Hct hematocrit (%);

T sampling time interval (min)

3.15
white blood cell reduction
percentage reduction of white blood cells contained in a circuit as a function of time

3.16
predicate reservoir
similar reservoir to the test reservoir that has previously been approved and used for the same intended clinical use

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3.17
filtration efficiency
ability of the filter to remove particles from the simulated blood suspension test fluid, expressed as a percentage

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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 General

When tested in accordance with 5.3.1 and 5.3.2, the blood pathway shall not leak.

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4.2.2 Blood volumes

The volume of the blood pathway shall be within the tolerances specified by the manufacturer [see 6.3 k)].

4.2.3 Connectors

Connectors for connection to the blood pathway shall, when tested in accordance with 5.3.4, allow a secure connection.

NOTE 1 Connectors of a type that allows 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 8637:2010, Figure 1 or a type that complies with ISO 594-2, have been used.

NOTE 2 Connectors corresponding to ISO 8637:2010, Figure 3 are considered as one way to comply with this requirement.

4.3 Performance characteristics

NOTE 1 Guidance for testing is given in Annex A.

NOTE 2 Some of these tests can be combined and performed at the same time.

4.3.1 Blood cell damage

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4.3.1.1 Plasma-free haemoglobin

When determined in accordance with 5.3.4, the increased concentration of plasma-free haemoglobin shall be within the range of values specified by the manufacturer.

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The hemolysis results shall be reported as mg/dL and NIH.

4.3.1.2 Platelet reduction and white blood cell reduction

When determined in accordance with 5.3.4, the percentage reduction of platelets and the percentage reduction of white blood cells shall be within the range of values specified by the manufacturer.

4.3.2 Air-handling capacity

Testing to demonstrate the air-handling characteristics shall be conducted at various flow rates and the results shall be recorded [see 6.3 p)]. The test shall be conducted according to the manufacturer's protocols.

4.3.3 Priming volume of the reservoirs in accordance with the manufacturer's quality control management system

The volume of the reservoir(s) shall be determined and the results presented in accordance with 6.3 o). Testing shall be conducted according to the manufacturer's protocols.

4.3.4 Defoaming characteristics

Where applicable, the defoaming characteristics shall be determined and the results shall be recorded [see 6.3 p)]. The testing shall be conducted according to the manufacturer's protocols.

4.3.5 Volume calibration

Where applicable, the accuracy of the volume markings shall be measured and tolerances shall be presented as required in 6.3 n). The testing shall be conducted according to the manufacturer's protocols.

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4.3.6 Filtration efficiency

The efficiency of the filter shall be determined by the manufacturer according to their protocol. The filter efficiency results shall be recorded [see 6.3 p)]. The testing shall be performed around the anticipated flow range of the filter.

4.3.7 Break-through volume

Where applicable, the break-through volume shall be measured and the results shall be recorded [see 6.3 p)]. The testing shall be performed according to the manufacturer's protocols.

4.3.8 Dynamic priming volume

Where applicable, the dynamic priming volume applies to hard-shell cardiotomy/venous reservoir systems (with/without filter) and shall be measured and reported as in 6.3 k). Results shall indicate the priming volume over the entire range of flows specified by the manufacturer and operational volume used for the test. Testing shall be performed according to the manufacturer's protocols.

4.3.9 Minimum and maximum volumes

The minimum and maximum volumes shall be specified by the manufacturers in the testing protocols.

4.3.10 Shelf life

When tested in accordance with 5.3.4, test results shall demonstrate the rated shelf life, as specified by the manufacturer.

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5 Tests and measurements to determine compliance with this document

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5.1 General

5.1.1 Tests and measurements shall be performed with the device under test prepared according to the manufacturer's instructions for intended clinical use.

5.1.2 Operating variables shall be those specified by the manufacturer for intended clinical use, unless otherwise specified.

5.1.3 Unless otherwise stated, the temperature of test liquids shall be (37 ± 1) °C.

5.1.4 If the relationship between variables is nonlinear, sufficient determinations shall be made to permit valid interpolation between data points.

5.1.5 The test or measurement procedures are to be regarded as reference procedures. Other procedures can be accepted provided that the alternative procedure has been shown to be of comparable precision.

5.2 Biological characteristics

5.2.1 Sterility and non-pyrogenicity

Compliance shall be verified by inspection of the manufacturer's documentation on sterilization and pyrogen testing, in accordance with ISO 17665-1, ISO 11135, ISO 11137-1, ISO 14937, or ISO 10993-11, as applicable.

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