INTERNATIONAL STANDARD

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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

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 15674 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants*.

Annex A of this International Standard is for information only.

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

1 Scope

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

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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 — Requirements for validation and routine control — Radiation sterilization*.

ISO 11607, *Packaging for terminally sterilized medical devices*.

ISO 13485, *Quality systems — Medical devices — Particular requirements for the application of ISO 9001*.

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

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*.

3 Terms and definitions

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

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 lung

3.6
blood
⟨referring to a fluid used in testing⟩ heparinized human or bovine blood, whole or diluted with physiological saline solution

3.7
integral part
part that is connected to the reservoir or is part of the reservoir system and that cannot normally be separated by the user

3.8
operating variable
setting of controls which affects the function of the device

3.9
hold-up volume
volume present in the device during passage of fluid through the device

NOTE This volume may vary with the flow rate and other factors.

3.10
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

3.11
sealed hard-shell reservoir
hard-shell reservoir that may be operated at either positive or negative pressure

3.12
priming volume
volume of fluid required to fill the filter

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

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.

4.2.2 Blood volumes

The volume of the blood pathway shall be within the tolerance 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 inside diameter of 4,8 mm, 6,3 mm, 9,5 mm 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 have been used.

NOTE 2 Connectors corresponding to Figure 3 of ISO 8637:1989 are considered as one way to comply with this requirement.

4.3 Performance characteristics

4.3.1 Cell damage

Testing to determine the amount of cell damage generated during use of the device shall be conducted at maximum flowrates and the results presented in accordance with item 6.3 p). Testing shall be over the specified time of operation or 6 h. The testing shall be conducted according to the manufacturer's protocols.

4.3.2 Air-handling capacity

Testing to demonstrate the air-handling characteristics shall be conducted at various flowrates and the results presented as in 6.3 p). The test shall be conducted according to the manufacturer's protocols.

4.3.3 Priming volume of the filters (where applicable)

The volume of the filter(s) shall be determined and the results presented as in 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 reported as in 6.3 p). The testing shall be conducted according to the manufacturer's protocols.

4.3.5 Volume calibration

The accuracy of the volume markings shall be measured and tolerances shall be presented as required in 6.3 n).

4.3.6 Filtration efficiency

The efficiency of the filter shall be determined by the manufacturer according to their protocol. The filter efficiency shall be reported as in 6.3 p). The testing shall be performed around the anticipated flow range of the filter.

4.3.7 Break-through volume

The break-through volume shall be measured and reported as in 6.3 p). The testing shall be performed according to the manufacturer's protocol.

4.3.8 Dynamic priming volume

The dynamic priming volume 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. Testing shall be performed according to the manufacturer's protocol.

NOTE 1 Guidance for testing is given in annex A.

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

5 Tests and measurements to determine compliance with this International Standard

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 $(37 \pm 1)^{\circ}$ C.

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

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

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 11134, ISO 11135, ISO 11137, ISO 14937 or ISO 10993-11, as applicable.

5.2.2 Biocompatibility

Compliance shall be verified by inspection of the manufacturer's documentation on biocompatibility for the finished device in accordance with ISO 10993-1 and ISO 10993-7.

5.3 Physical characteristics

5.3.1 Determination of blood pathway integrity for soft venous reservoir bags

Subject the blood pathway of the device, filled with water, to a negative or positive pressure of 1,5 times the manufacturer's rated pressure, or, if none is given, to a pressure of 152 kPa (22 psi) gauge and maintain this pressure for 6 h or for the intended use time specified by the manufacturer. Visually inspect the device for evidence of water leakage.

5.3.2 Determination of blood pathway integrity for sealed hard-shell reservoirs

5.3.2.1 Perform the test with air or water at the appropriate pressures.

5.3.2.2 Subject the blood pathway of the device to a negative or positive pressure of 1,5 times the manufacturer's rated pressure and maintain this pressure for 6 h or for the intended time of use specified by the manufacturer. Using air pressure decay or visual inspection, check for leakage.

NOTE Some hard-shell reservoirs are normally operated at atmospheric pressure. No test for blood pathway integrity needs to be performed on these units.

5.3.3 Test liquid

The test liquid shall be heparinized human or bovine blood or water.

5.3.4 Connectors

The connection shall be made in accordance with the manufacturer's instructions for use. The connection shall withstand a pull force of 15 N for 15 s without separating.

6 Information supplied by the manufacturer

6.1 Information to be given on the reservoir (labelling)

The following shall be provided on the reservoir:

a) the manufacturer's identity;

b) batch, lot or serial number designation;

c) model designation;

d) the direction of blood flow, if necessary;

e) the minimum and maximum operating reservoir levels, where appropriate.

6.2 Information to be given on the packaging

6.2.1 Information to be given on the unit container

The following shall be given on the unit container:

a) the manufacturer's name and address;

b) description of contents;

c) model designation;

d) statement on sterility and non-pyrogenicity;

e) batch, lot or serial number designation;

f) the statement “read instructions before use”;

g) special handling or storage conditions;

h) statement on single-use;

i) expiry date.

6.2.2 Information to be given on the shipping container

The following shall be provided on the shipping container:

a) the manufacturer's name and address;

b) description of contents, including number of units;

c) model designation;

d) statement on sterility and non-pyrogenicity;

e) special handling, storage or unpacking instructions;

f) lot number or serial number.

6.3 Information to be given in the accompanying documents

Each shipping container shall contain an “Instructions for Use” leaflet with the following information:

a) the manufacturer's address, and telephone and fax numbers;

b) model designation;

c) required ancillary equipment;

d) instructions on necessary, special or unique procedures applicable;

e) placement, type and securing of tubing connections;

f) location and purpose of additional entry or exit ports;

g) direction of blood flow;

h) general operating procedures for normal use;

i) a recommended procedure for intraoperative replacement of a reservoir system;

j) maximum and minimum recommended blood flowrates;

k) maximum and minimum operating volumes of the blood pathway, including any integral reservoir and dynamic priming volume;

l) pressure limitations for blood pathways;

m) the hold-up volume and summary of the protocol used;

n) tolerance of scales used for blood measurements;

o) the priming volume of the filter (if applicable);

p) a statement that the following are available upon request:

   1) sterilization method;

   2) a list of the materials comprising the blood pathway;

   3) data related to blood cell damage and a summary of the protocol used;

   4) relevant tolerances for data presented;

   5) air-handling capability and summary of the protocols used;

   6) antifoam characteristics and a summary of the protocols used;

   7) break-through volume;

   8) filtration efficiency.

6.4 Information to be given in the accompanying documents in a prominent form

The following information shall be provided in a prominent form in the accompanying documents:

a) pressure limitations;

b) flowrate limitations;

c) blood level limitation;

d) other device limitations, e.g. material incompatibility with known volatile anaesthetic agents, solvents or disinfectants.

7 Packaging

Packaging shall comply with the appropriate requirements of ISO 13485 or ISO 13488 and with ISO 11607.