



BSI Standards Publication

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

National foreword

This British Standard is the UK implementation of ISO 15674:2016+A1:2020. It supersedes BS ISO 15674:2016, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/150/2, Cardiovascular implants.

A list of organizations represented on this committee can be obtained on request to its secretary.

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

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



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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

Contents

Page

1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Requirements	3
4.1	Biological characteristics	3
4.1.1	Sterility and non-pyrogenicity	3
4.1.2	Biocompatibility	3
4.2	Physical characteristics	4
4.2.1	General	4
4.2.2	Blood volumes	4
4.2.3	Connectors	4
4.3	Performance characteristics	4
4.3.1	Blood cell damage	4
4.3.2	Air-handling capacity	4
4.3.3	Priming volume of the reservoirs in accordance with the manufacturer's quality control management system	4
4.3.4	Defoaming characteristics	5
4.3.5	Volume calibration	5
4.3.6	Filtration efficiency	5
4.3.7	Break-through volume	5
4.3.8	Dynamic priming volume	5
4.3.9	Minimum and maximum volumes	5
4.3.10	Shelf life	5
5	Tests and measurements to determine compliance with this document	5
5.1	General	5
5.2	Biological characteristics	6
5.2.1	Sterility and non-pyrogenicity	6
5.2.2	Biocompatibility	6
5.3	Physical characteristics	6
5.3.1	Blood pathway integrity for soft venous reservoir bags	6
5.3.2	Blood pathway integrity for sealed hard-shell reservoirs	6
5.3.3	Connectors	6
5.3.4	Blood cell damage	6
5.3.5	Filtration efficiency	7
5.3.6	Shelf life	7
6	Information supplied by the manufacturer	7
6.1	Information on the reservoir (labelling)	7
6.2	Information on the packaging	8
6.2.1	Information on the unit container	8
6.2.2	Information on the shipping container	8
6.3	Information in the accompanying documents	8
6.4	Information in the accompanying documents in a prominent form	9
7	Packaging	9
Annex A (normative) Factors to be considered in evaluating performance characteristics		10
Annex B (informative) Examples of connectors and reference fittings		11
Bibliography		20

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.

[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*

[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*

[ISO 80369-7](#), *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications* 

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/>

3.1

hard-shell cardiectomy 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 cardiectomy/venous reservoir system

extracorporeal device designed to function simultaneously as both a venous reservoir and cardiectomy 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

3.7

operating variable

setting of controls which affects the function of the device

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

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

3.17

filtration efficiency

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

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](#).