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Cardiovascular implants and extracorporeal systems — Cardiopulmonary bypass systems — Venous bubble traps

Titre manque

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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. 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 WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

Introduction

This International Standard is intended to ensure that devices designed to remove air entering the venous line during surgical procedures requiring extracorporeal circulatory support have been adequately tested for both their safety and function, and that extracorporeal device characteristics are appropriately disclosed when labelling the device.

This International Standard therefore contains procedures to be used for evaluation of extracorporeal venous bubble traps. Test procedures for determination of the air removal efficiency, 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 venous bubble trap 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 venous bubble traps 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 venous bubble traps. Nonspecific requirements are covered by references to other International Standards listed in the normative references section."

Cardiovascular implants and extracorporeal systems — Cardiopulmonary bypass systems — Venous bubble traps

1 Scope

This International Standard specifies requirements for sterile, single-use, venous bubble traps intended to remove air entering the venous line during surgical procedures requiring extracorporeal circulatory support, which may include cardiopulmonary bypass (CPB), extracorporeal membrane oxygenation (ECMO), or venovenous bypass for liver transplantation.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

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 11135-1, *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 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:

3.1
venous bubble trap
a device for removing air from the venous line of an extracorporeal circuit

3.2
blood pathway
blood-contacting surfaces of the venous bubble trap during its intended clinical use

3.3
blood cell damage
loss or destruction of cellular components of the blood

3.4
platelet reduction
percentage reduction of platelets contained in a circuit incorporating a venous bubble trap, less the percentage reduction in an identical control circuit without a venous bubble trap, as a function of time

3.5
plasma-free haemoglobin level
difference between the concentration of plasma-free haemoglobin in a circuit incorporating a venous bubble trap and the concentration in an identical control circuit without a venous bubble trap, as a function of time

3.6
white blood cell reduction
percentage reduction of white blood cells contained in a circuit incorporating a venous bubble trap, less the percentage reduction in an identical control circuit without a venous bubble trap, as a function of time

3.7
air removal efficiency
ability of the venous bubble trap to remove air from the blood, 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

The 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 tested in accordance with 5.3.1, the blood pathway shall not leak.

4.2.2 Prime volume

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

4.2.3 Connectors

Connectors for connection to the blood pathway shall, when tested in accordance with 5.3.3, allow a secure connection.

NOTE 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 ISO 7199, have been found satisfactory.

Connection for accessory ports shall meet the requirements of ISO 594-2.

4.3 Performance characteristics

4.3.1 Blood cell damage

When determined in accordance with 5.4.1, the percentage change (positive or negative) of plasma-free haemoglobin, platelets, and white blood cells, shall be within the range of values specified by the manufacturer.

4.3.2 Air removal efficiency

When tested in accordance with 5.4.2, the air removal efficiency shall be as expressed as a percentage. The manufacturer should specify the air challenge conditions. The test methodology should account for and measure gaseous microemboli for size and number and a second measurement of gross air volume.

4.3.3 Flow rate capacity

When tested in accordance with 5.4.3, test results shall demonstrate the flow rate and pressure limitation(s), as specified by the manufacturer.

4.3.4 Shelf life

When tested in accordance with 5.4.4, test results shall demonstrate the rated shelf life, as specified by the manufacturer.

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 in its terminally sterilized form and 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 °C ± 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 shall 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.

5.2.2 Biocompatibility

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