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American National Standard

ANSI/AAMI/ISO 15675:2001

Cardiovascular implants and artificial organs—Cardiopulmonary bypass systems—Arterial blood line filters

AAMI Association for the Advancement of Medical Instrumentation

The Objectives and Uses of AAMI Standards and Recommended Practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a fume of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards health care professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decisionmaking.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the Manager for Technical Development. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

American National Standard ANSI/AAMI/ISO 15675:2001

Cardiovascular implants and artificial organs— Cardiopulmonary bypass systems— Arterial line blood filters

Approved 13 March 2001 by
Association for the Advancement of Medical Instrumentation

Approved 11 May 2001 by
American National Standards Institute, Inc.

Abstract: This American National Standard specifies requirements for sterile, single-use, arterial filters intended to filter and remove emboli, debris, blood clots, and other potentially hazardous solid and gaseous material from the blood of humans during cardiopulmonary bypass surgery.

Keywords: biocompatibility, blood, cell, connector, filtration, flow rate, nonpyrogenicity, packaging, sterility, volume

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AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

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Published by

Association for the Advancement of Medical Instrumentation
1110 N. Glebe Road, Suite 220
Arlington, VA 22201-4795

Printed in the United States of America

ISBN 1–57020–166–8

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Glossary of equivalent standards

International standards adopted in the United States may include normative references to other international standards. For each international standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the international standard. (Note: Documents are sorted by International designation.)

Other normatively referenced international standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 & Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:1998	Major technical variations
ISO 5840:1996	ANSI/AAMI/ISO 5840:1996	Identical
ISO 7198:1998	ANSI/AAMI VP20:1994	Major technical variations
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996	Identical
ISO 10993-1:1997	ANSI/AAMI/ISO 10993-1:1997	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993	Identical
ISO 10993-3:1992	ANSI/AAMI/ISO 10993-3:1993	Identical
ISO 10993-4:1992	ANSI/AAMI/ISO 10993-4:1993	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995	Identical
ISO 10993-8:2000	ANSI/AAMI/ISO 10993-8:2000	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:1995	ANSI/AAMI/ISO 10993-10:1995	Identical
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:1996	ANSI/AAMI/ISO/CEN 10993-12:1996	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997	Identical
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995	ANSI/AAMI/ISO 11137:1994	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations
ISO 11607:200x[1]	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical

International designation	U.S. designation	Equivalency
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO TR 13409:1996	AAMI/ISO TIR 13409:1996	Identical
ISO 13485:1996	ANSI/AAMI/ISO 13485:1996	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	Identical
ISO 14155:1996	ANSI/AAMI/ISO 14155:1996	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998	Identical
ISO 14161: 2000	ANSI/AAMI/ISO 14161:2000	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO 14969:1999	ANSI/AAMI/ISO 14969:1999	Identical
ISO 14937:2000	ANSI/AAMI/ISO 14937:2000	Identical
ISO 14971:2000	ANSI/AAMI/ISO 14971:2000	Identical
ISO 15223:2000	ANSI/AAMI/ISO 15223:2000	Identical
ISO 15225:2000	ANSI/AAMI/ISO 15225:2000	Identical
ISO 15674:2001	ANSI/AAMI/ISO 15674:2001	Identical
ISO 15675:2001	ANSI/AAMI/ISO 15675:2001	Identical
ISO TS 15843:2000	ANSI/AAMI/ISO TIR15843:2000	Identical
ISO TR 15844:1998	AAMI/ISO TIR15844:1998	Identical
ISO TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical

[1] FDIS approved; being prepared for publication.

Committee representation

Association for the Advancement of Medical Instrumentation

Blood/Gas Exchange Device Committee

The adoption of ISO 15675:2001 as an American National Standard was initiated by the AAMI Blood/Gas Exchange Device Committee. The AAMI Blood/Gas Exchange Device Committee also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Standardization (ISO). U.S. representatives from the AAMI Blood/Gas Exchange Device Committee (U.S. Sub-TAG for ISO/TC 150/SC 2/WG 4) played an active part in developing the ISO standard.

At the time this document was published, the **AAMI Blood/Gas Exchange Device Committee** had the following members:

Cochairs:	Leonard Berman, PhD Arthur Ciarkowski, PhD
Members:	Leonard Berman, PhD, Pall Corporation Arthur Ciarkowski, PhD, Office of Device Evaluation, Center for Devices and Radiological Health, U.S. Food and Drug Administration LeRoy Fischbach, Minntech Corporation Debra Kridner, Medtronic Perfusion Systems Mark Kurusz, CCP, University of Texas Medical Branch Suzanne Parisian, MD, Medical Device Assistance, Inc. George Silvay, MD, PhD, Mount Sinai Medical Center Marc Voorhees, Consultant Warren Zapol, MD, Massachusetts General Hospital
Alternate:	Ronald Robinson, Office of Standards and Technology, Center for Devices and Radiological Health, U.S. Food and Drug Administration

NOTE—Participation by federal agency representatives in the development of this standard does not constitute endorsement by the federal government or any of its agencies.

Background of ANSI/AAMI adoption of ISO 15675:2001

As indicated in the foreword to the main body of this document (page viii), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard, which was developed by ISO Technical Committee 150/SC 2, *Cardiovascular implants*, to fill a need for requirements for arterial blood line filters for cardiopulmonary bypass systems.

U.S. participation in this ISO TC is organized through the U.S. Technical Advisory Group for ISO/TC 150/SC 2, administered by the Association for the Advancement of Medical Instrumentation (AAMI). The U.S. TAG for ISO/TC 150/SC 2 supports the intent of this standard, which is to provide designers and manufacturers of arterial blood line filters with a framework of requirements and tests that can be used to evaluate minimum safety and performance characteristics of arterial blood line filters for cardiopulmonary bypass systems intended to filter and remove emboli, debris, blood clots, and other potentially hazardous solid and gaseous material from the blood of humans during cardiopulmonary bypass surgery. AAMI and ANSI procedures require that standards be reviewed and, if necessary, revised every 5 years to reflect technological advances that may have occurred since publication.

AAMI (and ANSI) have adopted other ISO standards. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI which gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—Beginning with the foreword on page viii, this American National Standard is identical to ISO 15675:2001.

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 15675 was prepared by Technical Committee ISO/TC TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants*.

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American National Standard ANSI/AAMI/ISO 15675:2001

Cardiovascular implants and artificial organs— Cardiopulmonary bypass systems— Arterial line blood filters

1 Scope

This International Standard specifies requirements for sterile, single-use, arterial filters intended to filter and remove emboli, debris, blood clots, and other potentially hazardous solid and gaseous material from the blood of humans during cardiopulmonary bypass surgery.

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 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.*

ISO 10993-7, *Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals.*

ISO 10993-11, *Biological evaluation of medical devices—Part 11: Test 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 purpose of this International Standard, the following terms and definitions apply.

3.1 arterial line blood filter: Accessory device used as part of the cardiopulmonary bypass system in the arterial blood return line for filtering particles such as blood clots, debris, and gas emboli from the blood.

3.2 blood pathway: Paths of the arterial filter containing blood during its intended clinical use.

3.3 blood: Heparinized human or bovine blood, whole or diluted with physiological saline solution.

3.4 blood cell damage: Loss or destruction of cellular components of the blood components.

3.5 platelet percentage reduction: Percentage reduction of platelets contained in a circuit incorporating an arterial line blood filter, less the percentage reduction in an identical control circuit without an arterial line blood filter, as a function of time.

3.6 plasma-free hemoglobin generation: Difference between the concentration of plasma-free hemoglobin in a circuit incorporating an arterial blood filter and the concentration in an identical control circuit without an arterial blood filter, as a function of time.

3.7 white blood cell percentage reduction: Percentage reduction of white blood cells contained in a circuit incorporating an arterial line blood filter, less the percentage reduction in an identical control circuit without an arterial line blood filter, as a function of time.

3.8 filtration efficiency: Ability of the filter to remove particles from the simulated blood suspension test fluid, expressed as a percentage.

3.9 blood analog: Test solution which simulates blood viscosity.

4 Requirements

4.1 Biological characteristics

4.1.1 Sterility and nonpyrogenicity

The blood pathway shall be sterile and nonpyrogenic. 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 Blood pathway integrity

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

4.2.2 Blood volume

The volume of the blood pathway shall be within the tolerance 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. Connection for accessory ports shall meet the requirements of ISO 594-2.

NOTE—Connectors of a type that allows connection of tubes with an inside diameter of 4.8, 6.3, 9.5, or 12.7 mm, or a type that complies with ISO 7199 have been found satisfactory.

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 hemoglobin, platelets, and white blood cells shall be within the range of values specified by the manufacturer (see 6.3).

4.3.2 Filtration efficiency

When tested in accordance with 5.4.2, the filtration efficiency of any individual test filter shall be at least 50 % in the range of 40 µm to 100 µm and test results will demonstrate the ability of the filter to remove an average of at least 80 % of the particles in that range.

4.3.3 Flow rate capacity

When tested in accordance with 5.4.3, test results will demonstrate the flowrate and pressure limitation(s) to ensure safe and effective performance.

4.3.4 Shelf life

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

4.3.5 Air handling capability

When tested in accordance with 5.4.5, test results shall demonstrate the air handling capability.

5 Tests and measurements to determine compliance with this 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 ± 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 and reproducibility.

5.2 Biological characteristics

5.2.1 Sterility and nonpyrogenicity

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 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.

5.3 Physical characteristics

5.3.1 Determination of blood pathway integrity (sterile final assembly)

Fill the blood pathway of the device with water and subject it to a 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 the 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 Test liquid

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

The volume of the blood pathway shall be determined (see 6.3).

5.3.3 Connectors

5.3.3.1 Procedure

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.

5.4 Performance characteristics

5.4.1 Blood cell damage

5.4.1.1 Test media

The test liquid for the blood pathway shall be heparinized human or bovine blood.

5.4.1.2 Procedure

Two sets of appropriate, identical circuit components, including a pump, connecting tubing, a reservoir (as specified by the manufacturer and of suitable size relative to the device under test), and a heat exchanger, shall be assembled. The device under test shall be placed in one of the circuits. The blood pathway test-liquid volumes shall, at the initiation of the test, be within 1 % of each other. Perform the test *in vitro* using the conditions given in Table 1.

Table 1—Conditions for *in vitro* testing of blood cell damage

Item	Level	Maximum variation
Blood flowrate	The maximum specified by the manufacturer for intended clinical use (see 6.3) or 6 l/min, whichever is less	± 5 %
Blood glucose	10 mmol/L	± 5 mmol/L
Hemoglobin	12 g/dL	± 1 g/dL

The sampling schedule shall be in accordance with Table 2.

Table 2—Sampling schedule

Parameter	Time, after initiation of test (min)			
	Prior to test	30	180	360
Plasma-free hemoglobin	X	X	X	X
White blood cell	X	X	X	X
Platelets	X	X	X	X
Hemoglobin	X	X	X	X
Glucose	X			
Activated coagulation time	X	X	X	X
Temperature	X	X	X	X
Flowrates	X	X	X	X

5.4.2 Filtration efficiency

5.4.2.1 Test liquid

The test liquid shall be a 33 % glycerin solution with a simulated suspension of 350 to 5000 particles per milliliter in the 40 µm to 100 µm range.

5.4.2.2 Procedure

Pass 500 mL of the test liquid at room temperature (20 °C to 22 °C) through the arterial blood filter at a flowrate of not less than 100 mL/min and a pressure not exceeding 152 kPa (22 psi) gauge. Determine the pre- and postfiltration mean number of particles. A suggested method is contained in section 4.2.4 of ANSI/AAMI AT6-1991. Calculate the filtration efficiency using all readings in the 40 µm to 100 µm test range for each test sample, by subtracting the postfiltration mean number of particles from the prefiltration mean, dividing the quotient by the prefiltration mean number of particles, and multiplying by 100 to obtain a percentage. The test procedure shall be performed using 10 filters.

5.4.3 Filter flowrate

5.4.3.1 Test liquid

The test liquid shall be a blood analog (test fluid that simulates viscosity).

5.4.3.2 Procedure

Place the device under test in an appropriate test circuit. Set the flowrate at the maximum rated flow and monitor the inlet and outlet pressures across the filter for 6 h. Measure the flowrate using a calibrated flowmeter. Note any pressure changes during the test time.

This test shall not take into account the effects of formed elements or proteinaceous aggregates.

5.4.4 Shelf life or expiry date

Using a documented method, artificially age finished, packaged devices in order to determine nominal shelf life. Repeat aging process for five (5) finished filters to have a statistically relevant mean shelf life.

5.4.5 Air handling capability

5.4.5.1 Test liquid

The test liquid shall be heparinized human or bovine blood with a hemoglobin content of (12 ± 1) g/dL.

5.4.5.2 Procedure

Attach a 1 m vent tubing (3.2mm I.D.) to the filter vent port and open it to the atmosphere at the other end. The back pressure at the maximum test flow shall be 26.6 kPa (200 mmHg) ± 5 %. Use a bubble trap to measure any air downstream of the filter accumulated over a period of 5 min from bolus injection.

At flowrates of 33 %, 67 %, and 100 % of the specified maximum rated flowrate, 30 mL (10 mL for pediatric filters) of room air shall be injected as a single bolus.

5.4.5.3 Results

The results shall be reported as the percentage efficiency of gross air removal.

6 Information supplied by the manufacturer

6.1 Information to be given on the arterial filter

The following information shall be given on the arterial filter:

a) the manufacturer's identity;

b) model designation; and

c) the direction of blood flow.

6.2 Information to be given on the packaging

6.2.1 Information to be given on the unit container

The following shall be visible through or given on the unit container:

a) the manufacturer's name and address;

b) description of contents;

c) model designation;

d) statement on sterility and method of sterilization, and nonpyrogenicity;

e) expiry date;

f) batch, lot, or serial number designation;

g) the words, "Read instructions before use" or equivalent symbol;

h) any special handling or storage conditions; and

i) statement on single use.

6.2.2 Information to be given on the shipping container

The following information shall appear on the shipping container:

a) the manufacturer's name and address;

b) description of contents, including number of units;

c) model designation;

d) expiry date; and

e) any special handling, storage, or unpacking instructions.

6.3 Information to be given in the accompanying documents

Each shelf box 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, as applicable;

e) directions for placing the filter in a support or operational fixture;

f) placement, type, and securing of tubing connections;

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

h) priming procedure;

i) direction of blood flow;

j) general operating procedures for normal use;

k) air handling capability;

l) maximum and minimum recommended blood flowrates;

m) priming volume;

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

   1) a list of materials of blood pathway;

   2) blood pathway pressure drop at the maximum blood flowrate for intended clinical use specified by the manufacturer;

   3) data related to blood cell damage; and

   4) relevant tolerances for data presented;

o) statement on sterility, method of sterilization, and nonpyrogenicity.

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

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

a) flowrate limitations; and

b) other device limitations, for example, material incompatibility with known volatile anaesthetic agents, solvents, or disinfectants.

7 Packaging

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

Bibliography

[1] ISO 7199, *Cardiovascular implants and artificial organs—Blood–gas exchangers (oxygenators).*

[2] ISO 10993-10, *Biological evaluation of medical devices—Part 10: Tests for irritation and sensitization.*

[3] ISO 15223: *Medical devices—Symbols to be used with medical device labels.*

[4] ANSI/AAMI AT6-1991, *Autologous transfusion devices.*