List of Titles

American National Standard

ANSI/AAMI/ISO 15674:2001

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

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 15674:2001

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

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

Keywords: biocompatibility, blood, connector, hold-up, gas, exchanger, oxygenator, packaging, priming, 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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All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

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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 15674:2001 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 15674:2001

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 extracorporeal hard-shell cardiotomy/venous reservoir systems and soft venous reservoir bags.

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 extracorporeal hard-shell cardiotomy/venous reservoir systems and soft venous reservoir bags with a framework of requirements and tests that can be used to evaluate the minimum safety and performance characteristics of extracorporeal hard-shell cardiotomy/venous reservoir systems and soft venous reservoir bags intended for use as a blood reservoir during cardiopulmonary bypass (CPB) 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 15674:2001.

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 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.

American National Standard ANSI/AAMI/ISO 15674:2001

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: 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 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: The volume present in the device during passage of fluid through the device.

3.10 break-through volume: The 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: The priming volume of the filter is the volume required to fill the filter.

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 General

When tested in accordance with 5.3.1, 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 inner diameter of 4.8, 6.3, 9.5, 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 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 section 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 section 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 section 6.3(n).

4.3.6 Filtration efficiency

The efficiency of the filter shall be determined by the manufacturer according to its protocol. The filter efficiency shall be reported in section 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 in section 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 in section 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 ± 1 °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 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 inspection of the manufacturer's documentation on biocompatibility for the finished device in accordance with ISO 10993-1 and 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 (labeling)

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; and

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 nonpyrogenicity;

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; and

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 nonpyrogenicity;

e) special handling, storage, or unpacking instructions; and

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, as 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); and

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; and

   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 13488 and with ISO 11607.

Annex A
(normative)

Factors to be considered in evaluating performance characteristics

NOTE—To help clarify section 4.3.1 through section 4.3.8, the following shall be considered where (a) refers to 4.3.1, (b) refers to 4.3.2, etc.

a) The cell-damage data reported in 6.3(p) shall include but not be limited to the following: plasma hemoglobin, generated plasma hemoglobin, index of hemolysis, white cell count, and platelet count.

b) The air handling characteristics shall be determined for both large boluses of air and for small air bubbles over time. The characteristics shall be determined over at least 6 h or for the time specified in the labeling as the maximum usable time of the reservoir. Measurements of air handling capacity shall be both static and dynamic.

c) The priming volume of the filter is the volume required to fill the filter.

d) The ability of the reservoir to defoam the blood shall be measured. Defoaming may be tested as part of the air handling characteristics.

e) The accuracy of the volume measurement markings shall be tested and the tolerance calculated over the entire range and the results published in the labeling.

f) The filter efficiency shall be measured using a technique that is sufficient to determine the size of particles that will be held up in the filter (e.g., 40 µm 78 %).

g) The breakthrough volume of the reservoir is defined in 3.10.

h) The dynamic priming volume is based on the volume in the reservoir as the flow increases over the entire range of operations.

Bibliography

[1] ISO 594-2, *Conical fittings with a 6 % (Luer) taper for syringes, needles, and certain other medical equipment—Part 2: lock fittings.*

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

[3] ISO 8637:1989, *Haemodialysers, haemofilters and haemoconcentrators.*