American National Standard

ANSI/AAMI/ISO 18241:2016

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

AAMI
Advancing Safety in Healthcare Technology

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 frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare 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.

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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.

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

Approved 2 September 2016 by
AAMI

Approved 7 November 2016 by
American National Standards Institute

Abstract: 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.

Keywords: biocompatibility, blood, cell, connectors, flow, packaging, sterility

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

Blood/Gas Exchange Device Committee

The adoption of ISO 18241:2016 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 the 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** (U.S. Sub-TAG for ISO/TC 150/SC 2/WG 4) had the following members:

Cochairs:	Trevor Huang, PhD MBA
	Mark Kurusz, CCP
Members:	Richard Chan, CCP, Northshore University Hospital
	Drew Holmes, Baxter Healthcare
	Tsuyoshi Hosoi, Terumo Cardiovascular Systems
	Trevor Huang, PhD MBA, Medtronic Perfusion Systems
	George Silvay, MD PhD, Mount Sinai Medical Center
	Catherine Wentz, FDA/CDRH
Alternates:	David M. Fallen, CCP, Terumo Medical
	Qijin Lu, FDA/CDRH
	Rakesh Sethi, Medtronic

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 AAMI adoption of ISO 18241:2016

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 (TC) 150 Subcommittee (SC) 2, *Cardiovascular implants and extracorporeal systems,* 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 labeling the device.

U.S. participation in this ISO SC 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).

AAMI encourages its committees to harmonize their work with international standards as much as possible. The U.S. adoption of ANSI/AAMI/ISO 18421:2016 was approved by the American National Standards Institute (ANSI) on 7 November 2016. The AAMI Blood/Gas Exchange Device Committee (U.S. Sub-TAG for ISO/TC 150/SC 2/WG 4, Blood/gas exchangers) initiated the U.S. adoption of ISO 18241:2016.

AAMI and ANSI procedures require that standards be reviewed and, if necessary, revised every five 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.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the standard. “Should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the standard. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

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 come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

NOTE Beginning with the ISO foreword on page vii, this American National Standard is identical to ISO 18241:2016.

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 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

Introduction

This document 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 labeling the device.

This document 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 document 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 document 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 document.

Such studies may be part of a manufacturer's quality system.

This document 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 document 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 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 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 10993-4, *Biological evaluation of medical devices — Part 4: Selection of tests for interaction with blood*

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.

ISO and IEC maintain terminological databases for use in standardization at the following addresses.

— ISO Online browsing platform: available at https://www.iso.org/obp/

— IEC Electropedia: available at http://www.electropedia.org/

3.1
venous bubble trap
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, as a function of time

3.5
plasma-free hemoglobin level
difference between the concentration of plasma-free hemoglobin in a circuit incorporating a venous bubble trap, as a function of time

3.5.1
normalized index of hemolysis
NIH
grams of plasma-free hemoglobin released after pumping 100 l of blood

$$NIH\left\{g\,/\;100\,L\right\} = \Delta fHb \times V \times \frac{100 - Hct}{100} \times \frac{100}{Q \times T}$$

where

ΔfHb is the increase of plasma free hemoglobin concentration (g/L) over the sampling time interval;

V is the circuit volume (L);

Q is the flow rate (L/min);

Hct is the hematocrit (%);

T is the sampling time interval (min)

3.6
white blood cell reduction
percentage reduction of white blood cells contained in a circuit incorporating 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

3.8
blood analogue
test solution which simulates blood viscosity between 2.0×10^{-3} Pa·s (2.0 cP), to 3.5×10^{-3} Pa·s (3.5 cP)

3.9
predicate venous bubble trap
similar venous bubble trap to the test venous bubble trap that has previously been approved and used for the same intended clinical use

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 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 ISO 8637:2010, Figure 1, or a type that complies with ISO 594-2, have been found satisfactory.

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

NOTE 2 Connectors corresponding to ISO 8637:2010, Figure 3, are considered as one way to comply with this requirement.

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.

The hemolysis results shall be reported as mg/dL and NIH.

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, the 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, the test results shall demonstrate the rated shelf life, as specified by the manufacturer.

5 Tests and measurements to determine compliance with this document

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 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.

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 10993-11, ISO 11135-1, ISO 11137-1, ISO 14937 or ISO 17665-1, 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 Blood pathway integrity

Fill the blood pathway of the device with water and subject it to a negative pressure of 1.5 × the manufacturer's rated negative pressure and maintain the pressure for 6 h or for the intended time of use specified by the manufacturer. Visually inspect the device for evidence of air entrainment.

5.3.2 Prime volume

The test liquid shall be anticoagulated whole blood or water. The volume of the blood pathway shall be determined as specified by the manufacturer.

5.3.3 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.

5.4 Performance characteristics

5.4.1 Blood cell damage

5.4.1.1.1 Test liquid

The test liquid for the blood pathway shall be anticoagulated whole blood.

5.4.1.1.2 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 means of controlling temperature, shall be assembled. The device under test shall be placed in one of the circuits between the inflow of a blood pump and the outlet of a patient simulating reservoir per the manufacturer's instructions for use. A predicate device shall be placed in the second test circuit. Priming and debubbling of the circuits by recirculating with an appropriate solution is recommended before blood is added. 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. If the instructions for use call for connection to ancillary devices, these should be connected and operated at the worst case conditions allowed per the manufacturer's instructions for use. A sufficient number of paired tests should be performed to support a statistical analysis. The predicate venous bubble trap should be tested under the same conditions. Compliance shall be verified by test or by inspection of the manufacturer's documentation on blood cell damage for the finished device, in accordance with ISO 10993-4, as applicable.

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

Item	Level	Maximum variation
Blood flow rate	The maximum specified by the manufacturer for intended clinical use (see 6.3)	±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. More frequent sampling times are optional.

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 clotting time	X	X	X	X
Temperature	X	X	X	X
Flow rates	X	X	X	X

5.4.2 Air removal efficiency

5.4.2.1.1 Test liquid

The test liquid shall be anticoagulated whole blood with a hemoglobin content of (12 ± 1) g/dl.

5.4.2.1.2 Procedure

Prepare a test set up which places the venous bubble trap, per the manufacturer's instructions for use, between the inflow of a blood pump and the outlet of a patient simulating reservoir. (If the instructions for use call for connection to ancillary devices such as active air removal systems, these should be connected per the instructions for use.)

The inflow tubing between the venous bubble trap and the reservoir should include an access connector located upstream of the venous bubble trap for injecting the air challenge and an inline micro bubble detector upstream from this connector. Another inline micro bubble detector should be located after the venous bubble trap and the pump.

The test liquid should have a baseline micro bubble value of <1% of the air challenge bolus volume.

After the baseline is stabilized, introduce air at the injected site. The volume of air injected and the method of injection must be defined in the test procedure. In addition, a bubble volume collection chamber placed before the micro bubble detector may be used as an adjunctive method to determine air removal efficiency. The test should be performed at the minimum and maximum flow rates recommended by the manufacturer as well at one flow rate midway between the minimum and maximum.

NOTE This procedure will produce bubbles of different sizes.

The total volume of air downstream of the venous bubble trap should be measured by the micro bubble detector placed between the venous bubble trap and the pump. If a bubble volume collection chamber is used, the volume of air collected should be measured and added to the volume of air measured by the micro bubble detector to document total volume of air downstream of the venous bubble trap. The volume of air collected should be measured and the bigger between the volume provided by the micro bubble detector and the air collected will be considered the total volume of air downstream of the venous bubble trap

5.4.2.1.3 Results

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

EFF = (BOLUS VOLUME – DOWNSTREAM VOLUME) / BOLUS VOLUME

NOTE The downstream volume is the sum of the volume measured by the microbubble detector plus the volume collected by the collection chamber.

5.4.3 Flow rate and pressure drop

5.4.3.1.1 Test liquid

The test liquid shall be anticoagulated whole blood with a hemoglobin content of (12 ± 1) g/dl or blood analogue.

NOTE This test may be performed concurrently with the blood trauma test (see 5.4.1).

5.4.3.1.2 Procedure

Place the device under test in an appropriate test circuit. Set the flow rate at the maximum rated flow and monitor the inlet and outlet pressures across the venous bubble trap for 6 h or greater according to the manufacturer's instructions for use. Measure the flow rate using a calibrated flow meter. Note any pressure changes during the test. If anticoagulated whole blood is used this test shall not take into account the effects of formed elements or proteinaceous aggregates.

5.4.4 Shelf life

Using a validated method, ageing should be performed on final, finished, sterilized, devices in primary packaging in order to determine nominal shelf life.

6 Information supplied by the manufacturer

6.1 Information on the venous bubble trap

The following information shall be given on the venous bubble trap:

a) the manufacturer's identity;

b) model designation;

c) the direction of blood flow.

6.2 Information on the packaging

6.2.1 Information 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 non-pyrogenicity;

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;

i) statement on single-use.

6.2.2 Information 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;

e) any special handling, storage or unpacking instructions.

6.3 Information 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 or fax numbers;

b) model designation;

c) required ancillary equipment;

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

e) directions for placing the bubble trap 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 removal efficiency;

l) maximum and minimum recommended blood flow rates;

m) blood pathway pressure drop over the range of blood flow rates specified by the manufacturer; for intended clinical use;

n) priming volume;

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

   1) a list of materials of the blood pathway;

2) data related to blood cell damage;

3) relevant tolerances for data presented;

p) statement on sterility, method of sterilization, and non-pyrogenicity.

6.4 Information in the accompanying documents in a prominent form

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

a) flow rate limitations;

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

7 Packaging

Packaging shall comply with the appropriate requirements of ISO 11607-1 and ISO 11607-2.

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