

American
National
Standard

ANSI/AAMI
AT6:2013

Autologous transfusion
devices

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, method 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, as well as to 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* (i.e., 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 decision-making.

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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Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. 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*.

Autologous transfusion devices

Developed by
Association for the Advancement of Medical Instrumentation

Approved 27 August 2013 by
American National Standards Institute

Abstract: This standard establishes labeling and performance requirements, test methods, and terminology that will help define a reasonable level of safety and efficacy for autologous transfusion devices. Specifically, it includes requirements for sterile, disposable systems and associated electromechanical hardware designed to collect and filter or process, or both, extravasated blood for reinfusion of erythrocytes or filtered whole blood into the patient's circulation. Aspects of these systems related to collection, anticoagulation (systemic and device), storage, processing and filtration, and reinfusion are within the scope of this standard.

Keywords: autologous, transfusion, blood, hemoglobin, reinfusion, infusion

AAMI Standard

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Published by

Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633
www.aami.org

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Printed in the United States of America

ISBN 1-57020-503-5

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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

AAMI Blood Filter/Cell Salvaging Committee

This standard was developed by the Blood Filter/Cell Salvaging Committee. Committee approval of this standard does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Blood Filter/Cell Salvaging Committee** had the following members:

Cochair: Ralph Slepian, MD
Members: Corey Bercaw, Zimmer, Inc.
Dawn Desiderio, MD, Memorial Sloan Kettering Cancer Center
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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.

Foreword

This AAMI standard was developed by the Blood Filter/Cell Salvaging Committee as the result of a periodic review of ANSI/AAMI AT6:2006/(R)2011. Now in its fourth edition, this document was originally approved as an American National Standard in May, 1982 under the title *Autotransfusion devices*.

The objective of this standard is to provide labeling and performance requirements, test methods, and terminology that will help establish a reasonable level of safety and efficacy for autologous transfusion devices. The most significant differences between the third and fourth editions of this standard are updates intended to reflect current technology and updates to references.

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 document 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 new data are presented.

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 22203-1600.

NOTE—This foreword does not contain provisions of the American National Standard, *Autologous transfusion devices* (ANSI/AAMI AT6:2013), but it does provide important information about the development and intended use of the document.

Autologous transfusion devices

1 Scope

1.1 General

This standard establishes requirements for sterile, disposable systems and associated electromechanical hardware designed to collect and filter or process, or both, extravasated blood for reinfusion of erythrocytes or filtered whole blood into the patient's circulation. Aspects of these systems related to collection, anticoagulation (systemic and device), storage, processing and filtration, and reinfusion are within the scope of this standard.

1.2 Inclusions

1.2.1 Emergency/trauma devices

Traumatic or spontaneous rupture of blood vessels may result in substantial blood accumulation in the thorax and other body cavities. This blood may be removed for subsequent reinfusion into the patient by the appropriate use of autologous transfusion devices that are variously composed of a suction catheter, tubing, reservoirs, an anticoagulation system, processing or filtration systems (or both), and a reinfusion system. Devices designed for this purpose fall within the scope of this standard.

1.2.2 Intraoperative retrieval devices

Intraoperative retrieval devices are also included within the scope of this standard and may consist of a suction catheter, tubing, reservoirs, an anticoagulation system, processing or filtration systems (or both), and a reinfusion system.

1.2.3 Postoperative devices

These devices are similar to chest drainage systems described in 1.2.1 and are included within the scope of this standard.

2 Normative references

The following referenced documents are indispensable for the application 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.

2.1 ASTM INTERNATIONAL. *Standard test method for microscopic sizing and counting particles from aerospace fluids on membrane filters*, ASTM F312-97. Philadelphia: ASTM.

2.2 Carso, TH, editor. *Standards for blood banks and transfusion services*, 27th ed. Bethesda (MD): AABB, 2011.

2.3 INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC). *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance*, IEC 60601-1. Geneva: IEC.

2.4 INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC). *Medical electrical equipment—Part 1-2: General requirements for safety—2. Collateral standard: Electromagnetic compatibility—Requirements and tests*, IEC 60601-1-2. Geneva: IEC.