American National Standard

ANSI/AAMI BF64:2012

Leukocyte reduction filters

AAMI
Advancing Safety in Medical 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.

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 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.

INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

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*.

American National Standard

ANSI/AAMI BF64:2012
(Revision of ANSI/AAMI BF64:2002/(R)2011)

Leukocyte reduction filters

Developed by
Association for the Advancement of Medical Instrumentation

Approved 29 November 2012 by
American National Standards Institute, Inc.

Abstract: This standard contains labeling requirements, performance requirements, test methods, and terminology for disposable filters used for the reduction of leukocytes from blood or blood components.

Keywords: blood, filter, leukocyte, leukoreduction, reduction, safety

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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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 Filter Committee

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

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

Cochairs:
David Louis Reich, MD
Donald Sherratt

Members:
Phillip Bendick, Beaumont Services Company LLC
Dawn Desiderio, MD, Memorial Sloan Kettering Cancer Center
Trevor C. Huang, PhD MBA, Medtronic Perfusion Systems
Melissa S. Pessin, MD PhD, Memorial Sloan Kettering Cancer Center
Betsy Poindexter, U.S. Food and Drug Administration/Center for Biologics Evaluation and Research
David Louis Reich, MD, Mount Sinai School of Medicine
Donald Sherratt, Terumo BCT, Inc.
George Silvay, MD, PhD, Mount Sinai Medical Center
Ralph Slepian, MD, New York Presbyterian Hospital
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Alternates:
Lauren Clark, Terumo BCT
Jaroslav G. Vostal, MD, PhD, U.S. Food and Drug Administration/Center for Biologics Evaluation and Research

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 standard was developed by the Blood Filter Committee of the Association for the Advancement of Medical Instrumentation. The objective of this standard is to describe those requirements for leukocyte reduction filters that will ensure the safe, effective, and reproducible reduction of the leukocyte content of blood components. This standard also contains referee test methods used to ensure that the performance requirements are met.

Establishing compliance with this standard might involve the use of hazardous materials, operations, or equipment. Therefore, users of this document should establish appropriate safety practices and proceed with caution.

This standard reflects the conscientious efforts of concerned health care professionals, in consultation with medical device manufacturers, to develop a standard for those performance levels that could be reasonably achieved at this time.

AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication.

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 technological advances are made and as new data come to light.

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

NOTE—This foreword is not a part of the American National Standard *Leukocyte reduction filters* (ANSI/AAMI BF64:2012).

Leukocyte reduction filters

1 Scope

1.1 General

This standard describes safety and performance requirements for disposable filters used for the reduction of leukocytes from blood or blood components before, during, or after storage.

1.2 Inclusions

Included within the scope of this standard are disposable filters for the reduction of leukocyte content of blood and blood components. These are sometimes also referred to as leukocyte reduction filters.

1.3 Exclusions

Excluded from the scope of this standard are filters used for extracorporeal service and other filters not intended for blood transfusion. Also excluded are components of standard infusion sets designed to remove readily visible particulates.

NOTE—For an explanation of the need for this standard, and the rationale for its provisions, see Annex A.

2 Normative references

The following normative references contain provisions that, through reference in this text, constitute provisions of this standard. For dated references, subsequent amendments to or revisions of any of these publications do not apply. However, parties to agreements based on this 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.

NOTE—In addition to the following normative references, other requirements for leukoreduction filter use and performance might apply, such as those in the pertinent sections of Title 21 of the *Code of Federal Regulations* (CFR), guidance memoranda issued by the U.S. Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research, and the current version of the *Circular of Information for the Use of Human Blood and Blood Components* (AABB, 2009).

2.1 U.S. Pharmacopeial Convention. *United States Pharmacopeia*. Taunton (MA): Rand McNally.

2.2 ASTM International. *Standard Test Methods for Microscopical Sizing and Counting Particles from Aerospace Fluids on Membrane Filters*. ASTM F312-08. West Conshohocken (PA): ASTM International, 2008.

2.3 SAE International. *Aerospace—Evaluation of Particulate Contamination in Hydraulic Fluid—Membrane Procedure.* ARP 4285-2001. Warrendale (PA): SAE International, 2001.

2.4 Roback JD, Grossman BJ, Harris T, Hillyer CD. Eds. AABB *Technical manual*. 17th ed. Bethesda (MD): AABB, 2011.

2.5 Association for the Advancement of Medical Instrumentation. *Biological evaluation of medical devices—Part 1: Evaluation and testing.* ANSI/AAMI/ISO 10993-1:2009. Arlington (VA): AAMI, 2009.

2.6 U.S. Food and Drug Administration/Center for Devices and Radiological Health. *Policy for Expiration Dating*. Memorandum RB92-G. Rockville (MD): FDA/CDRH, 30 October 1992.

2.7 Prati D, Brandwein H, Capelli C, et al. Multicenter evaluation of the 3 % paraformaldehyde method for white cell counting in leukocyte-reduced red blood cells. *Vox Sang*. 1996 ;70 :241–245.

2.8 Dzik S, Moroff G, Dumont L. A multicenter study evaluating three methods for counting residual WBCs in WBC-reduced blood components: Nageotte hemocytometry, flow cytometry, and microfluorimetry. *Transfusion.* 2000;40:513-20.