American National Standard

ANSI/AAMI RD62:2006

PREVIEW COPY

This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document before making a purchasing decision.

For a complete copy of this AAMI document,
contact AAMI at (877) 249-8226
or visit www.aami.org.

Water treatment equipment for hemodialysis applications

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 frame 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 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 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 RD62:2006
Revision of ANSI/AAMI RD62:2001

Water treatment equipment for hemodialysis applications

Developed by
Association for the Advancement of Medical Instrumentation

Approved 5 December 2006 by
American National Standards Institute, Inc.

Abstract: This American National Standard addresses devices used to treat water intended for use in the delivery of hemodialysis. Included in the scope of the standard is water used for (1) the preparation of concentrates from powder at a dialysis facility, (2) the preparation of dialysate, and (3) the reprocessing of dialyzers for multiple use.

Keywords: dialysis, water quality, concentrates, dialyzing fluids, medical equipment, reuse

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.

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than 5 years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI.

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.

Published by

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

Printed in the United States of America

ISBN 1–57020–277–X

Contents

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 60601-1:2005	ANSI/AAMI ES60601-1:2005	Major technical variations
IEC 60601-1-2:2001 and Amendment 1:2004	ANSI/AAMI/IEC 60601-1-2:2001 and Amendment 1:2004	Identical
IEC 60601-2-2:2006	ANSI/AAMI/IEC 60601-2-2:2006	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:1990 and Amendment 1:1996	ANSI/AAMI II36:2004	Major technical variations
IEC 60601-2-20:1990 and Amendment 1:1996	ANSI/AAMI II51:2004	Major technical variations
IEC 60601-2-21:1994 and Amendment 1:1996	ANSI/AAMI/IEC 60601-2-21 and Amendment 1:2000 (consolidated texts)	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004	Major technical variations
IEC 60601-2-50:2001	ANSI/AAMI/IEC 60601-2-50:2006	Identical
IEC/TR 60878:2003	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2003	ANSI/AAMI/IEC TIR62296:2003	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:2003	ANSI/AAMI/ISO 10993-1:2003	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002 and Amendment 1:2006	Identical
ISO 10993-5:1999	ANSI/AAMI/ISO 10993-5:1999	Identical
ISO 10993-6:1994	ANSI/AAMI/ISO 10993-6:1995/(R)2001	Identical
ISO 10993-7:1995	ANSI/AAMI/ISO 10993-7:1995/(R)2001	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999/(R)2005	Identical
ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002 ANSI/AAMI BE78:2002/A1:2006	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2003	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002	Identical

International designation	U.S. designation	Equivalency
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-5:2000	ANSI/AAMI ST66:1999	Major technical variations
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO 11737-3:2004	ANSI/AAMI/ISO 11737-3:2004	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003	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/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2000 and A1:2003	ANSI/AAMI/ISO 14971:2000 and A1:2003	Identical
ISO 15223:2000, A1:2002, and A2:2004	ANSI/AAMI/ISO 15223:2000, A1:2001, and A2:2004	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	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 15882:2003	ANSI/AAMI/ISO 15882:2003	Identical
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2006	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003 and A1:2005	Identical

[1]In production
[2]Final approval pending

Last updated 1/10/2007

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Renal Disease and Detoxification Committee

This standard was developed by the AAMI Renal Disease and Detoxification 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 Renal Disease and Detoxification Committee** had the following members:

Cochairs:
Conor Curtin
Richard A. Ward, PhD

Members:
G. Steven Acres, Carolina Regional Nephrology Associates
Larry Alexander, Florian Services
Matthew J. Arduino, DrPH, U.S. Centers for Disease Control and Prevention
Robert Berube, Church & Dwight Company, Inc.
Danilo B. Concepcion, CHT, CCHT, St. Joseph Hospital Renal Center
Conor Curtin, Fresenius Medical Care, NA Dialysis Products Division
R. Barry Deeter, RN, MSN, University of Utah Dialysis Program
Robert Dudek, Siemens Water Technologies Corporation
Martin S. Favero, PhD, Johnson & Johnson
Gema Gonzalez, U.S. Food and Drug Administration/Center for Devices and Radiological Health/Office of Device Evaluation
Susan Hansen, Renal Solutions West
Bertrand Jaber, MD, Caritas St. Elizabeth's Medical Center
Byron Jacobs, CBET, Sioux Valley Hospital
Fei M. Law, Gambro Renal Products, Inc.
Nathan W. Levin, MD, Renal Research Institute, LLC
Douglas Luehmann, DaVita, Inc.
Shincy Maliekkal, Baxter Healthcare Corporation, Renal Division
Bruce H. Merriman, Central Florida Kidney Centers
Glenda Payne, RN MS, CNN, Centers for Medicare & Medicaid Services
Clayton Poppe, Aksys Limited
John Rickert, Minntech Corporation
James D. Stewardson, Brighton, CO
David S. Utterberg, Medisystems Services Corporation
Richard A. Ward, PhD, University of Louisville School of Medicine, Kidney Disease Program
Michael Webb, BSIE, MBA, NxStage Medical, Inc.

Alternates:
Marilyn Brierton, Baxter Healthcare Corporation
Gregory Montgomery, Siemens Water Technologies Corporation
Brooks E. Rogers, Fresenius Medical Care, NA Dialysis Products Division
Steve Rowles, Church & Dwight Company, Inc.
Denny Treu, BSME, NxStage Medical, Inc.
Gary Warns, Gambro Renal Products
Derek Wiebenson, Aksys Limited

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 voluntary standard was developed by the AAMI Renal Disease and Detoxification Committee.

The American National Standard, *Hemodialysis systems* was first published under the designation ANSI/AAMI RD5:1981. In 1996, during the 5 year review of RD5:1992, the AAMI Renal Disease and Detoxification Committee determined that the hemodialysis community would be better served by this standard if it were divided into three parts: (1) hemodialysis concentrates, (2) water, and (3) equipment. ANSI/AAMI RD62:2006 is a revision of ANSI/AAMI RD62:2001, *Water treatment equipment for hemodialysis applications*.

This standard reflects the conscientious efforts of concerned physicians, clinical engineers, nurses, dialysis technicians, and dialysis patients, in consultation with device manufacturers and government representatives, to develop a standard for performance levels that could be reasonably achieved at the time of publication. The term "consensus," as applied to the development of voluntary medical device standards, does not imply unanimity of opinion, but rather reflects the compromise necessary in some instances when a variety of interests must be merged.

When this standard was undergoing its mandatory 5 year review in 2005, the committee recognized that differences in feed water quality and municipal water treatment practices could have a major impact on the removal of some chemical contaminants. This dependence on local conditions was particularly evident for chloramines. To address this issue, sections dealing with alternative and supplementary methods to carbon adsorption were added to the standard.

The term "should" as used in this document reflects the committee's intent to define goals, not requirements. The term "shall" as used here denotes quality recommendations and procedures that are required by this or other applicable standards. The term "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 advances are made in technology and as new data come to light.

This is a voluntary standard, developed for use by manufacturers and health care professionals. The format and structure of this standard make it unsuitable for use as an enforced regulation.

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

NOTE—This foreword does not contain provisions of the AAMI recommended practice *Water treatment equipment for hemodialysis applications* (ANSI/AAMI RD62:2006), but it does provide important information about the development and intended use of the document.

Water treatment equipment for hemodialysis applications

1 Scope

1.1 General

This standard covers devices used to treat water intended for use in the delivery of hemodialysis. Included in the scope of the standard is water used for: (1) the preparation of concentrates from powder at a dialysis facility, (2) the preparation of dialysate, and (3) the reprocessing of dialyzers for multiple uses. The provisions of this standard apply to individual water treatment devices and to water treatment systems assembled from one or more of these devices. In the first instance, this standard is directed at the individual or company that specifies the complete water treatment system and, second, at the vendor who assembles and installs the system. Since systems may be assembled from a number of individual water treatment devices, the provisions of this standard are also directed at the manufacturers of these devices, provided that the manufacturer indicates that the device is intended for use in hemodialysis applications. This standard is written principally to address water treatment systems for dialysis facilities treating multiple patients. However, all of its provisions equally apply to water treatment systems used in applications where a single patient may be treated, such as in a home dialysis or acute hospital dialysis setting, except where stated otherwise.

The physician in charge of dialysis has the ultimate responsibility for selecting a water treatment system. The physician in charge of dialysis also is responsible for maintaining the performance of that system after control of the system has been transferred formally from the installer to the physician. Generally, this transfer takes place after the installer of the system has demonstrated that the performance of the system meets the requirements of this standard. Recommendations for ongoing monitoring and maintenance of the system are provided in ANSI/AAMI RD52:2004, *Dialysate for hemodialysis*.

The requirements established by this standard will help protect hemodialysis patients from adverse effects arising from known chemical and microbial contaminants found in water supplies. However, proper dialysis and patient safety is ultimately dependent on the quality of the dialysate. Since the manufacturer of water treatment equipment does not have control over the dialysate, any reference to dialysate in this standard is for clarification only and not a requirement of the manufacturer. The responsibility for assuring that the dialysate is not contaminated, mismatched, or otherwise damaging to the patient rests with the clinical professionals caring for the patient under the supervision of the medical director. Recommendations on the preparation and handling of dialysate in a dialysis facility are provided in ANSI/AAMI RD52:2004, *Dialysate for hemodialysis*.

1.2 Inclusions

The scope of this standard includes all devices, piping, and fittings between the point at which potable water is delivered to the water treatment system and the point of use of the treated water. Examples of components included within the scope of this standard are water treatment devices, on-line water quality monitors (such as conductivity monitors), and piping systems for the distribution of treated water. Also included in the scope of this standard is the quality of water used to prepare dialysate, to prepare concentrates from powder at a dialysis facility, and to reprocess dialyzers for multiple use.

1.3 Exclusions

Excluded from the scope of this standard are dialysate supply systems that proportion water and concentrates to produce dialysate, sorbent dialysate regeneration systems that regenerate and recirculate small volumes of the dialysate, dialysate concentrates, hemodiafiltration systems, hemofiltration systems, systems that process dialyzers for multiple uses, and peritoneal dialysis systems. Some of these devices, such as dialysate supply systems and concentrates, are addressed in other American National Standards. Also excluded from the scope of this standard are requirements for the ongoing monitoring of the purity of water used for dialysate, concentrate preparation, or dialyzer reprocessing.

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