American National Standard

ANSI/AAMI RD62:2006
and
ANSI/AAMI RD62:2006/A1:2009

Water treatment equipment for hemodialysis applications

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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.

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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.

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(Consolidated Text)

(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
Amendment 1 approved 24 April 2009 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

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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 60601-1:2005	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

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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

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Committee representation

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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:

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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.

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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.

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2 Normative references

The following normative documents contain provisions which, 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. AAMI maintains a register of currently valid AAMI technical documents.

2.1 U.S. FOOD AND DRUG ADMINISTRATION. *Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis*. Rockville, MD: U.S. Food and Drug Administration, 1997. <http://www.fda.gov/cdrh/ode/hemodial.pdf>

2.2 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Hemodialysis Systems* (ANSI/AAMI RD5:2003). American National Standard. Arlington (Vir.): AAMI, 2003.

2.3 AMERICAN PUBLIC HEALTH ASSOCIATION. *Standard Methods for the Examination of Water and Wastewater,* 20th ed. Washington, DC: APHA, 1998.

2.4 U.S. ENVIRONMENTAL PROTECTION AGENCY. *Methods for the Determination of Metals in Environmental Samples, Supplement 1* (EPA-600-R-94-111). Cincinnati (Ohio): Environmental Monitoring Systems Laboratory, 1994. <http://www.epa.gov/OGWDW/methods/methods.html>

2.5 THE UNITED STATES PHARMACOPEIAL CONVENTION, INC. *United States Pharmacopoeia – National Formulary* (USP-27-NF22). Rockville (MD): United States Pharmacopeial Convention Inc.

2.6 U.S. ENVIRONMENTAL PROTECTION AGENCY. *Safe Drinking Water Act, 1996* (Public law 104-182). Washington, DC: EPA, 1996.

[See *National Primary and Secondary Drinking Water Regulations*. U.S. Environmental Protection Agency, Office of Ground Water and Drinking Water. <http://www.epa.gov/OGWDW/ creg.html>]

3 Terms and definitions

For the purposes of this standard, the following terms and definitions apply.

3.1 action level: Concentration of a contaminant at which steps should be taken to interrupt the trend toward higher, unacceptable levels.

3.2 bacteriology: Area of study within the field of microbiology that deals with the study of bacteria.

3.3 chlorine, combined: Chlorine that is chemically combined, such as in chloramine compounds.

NOTE—No direct tests exist for measuring most forms of combined chlorine. Monochloramine is an exception (see A.5.1.2). Total combined chlorine can be measured indirectly by measuring both total chlorine and free chlorine and calculating the difference.

3.4 chlorine, free: Dissolved molecular chlorine.

3.5 chlorine, total: Sum of combined chlorine and free chlorine.

3.6 device: Individual water treatment unit, such as a softener, carbon adsorption bed, reverse osmosis unit, or deionizer.

NOTE—This term is synonymous with the term “component” as used by the U.S. Food and Drug Administration in its *Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for Hemodialysis* (see 2.1).

3.7 dialysate: Aqueous fluid containing electrolytes and usually dextrose, which is intended to exchange solutes with blood during hemodialysis.

NOTE—The word “dialysate” is used throughout this document to mean the fluid made from water and concentrate that is delivered to the dialyzer by the dialysate supply system. Such phrases as “dialyzing fluid” or “dialysis solution” may be used in place of dialysate. It does not include peritoneal dialysis fluid.

3.8 dialysate supply system: Devices that prepare dialysate on line from water and concentrate or store and distribute premixed dialysate; circulate the dialysate through the dialyzer; monitor the dialysate for temperature, conductivity (or equivalent), pressure, flow, and blood leaks; and prevent dialysis during disinfection or cleaning modes.

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NOTE—The term includes reservoirs; conduits; proportioning devices for the dialysate; and monitors, associated alarms, and controls assembled as a system for the characteristics listed above. The dialysate supply system is often an integral part of single-patient dialysis machines (see 2.2).

3.9 disinfection: Destruction of pathogenic and other kinds of microorganisms by thermal or chemical means.

NOTE—Disinfection is a less lethal process than sterilization, since it destroys most recognized pathogenic microorganisms, but not necessarily all microbial forms. This definition of disinfection is equivalent to low-level disinfection in the Spalding classification.

3.10 empty bed contact time (EBCT): Empty bed contact time is a measure of how much contact occurs between particles, such as activated carbon, and water as the water flows through a bed of the particles.

NOTE—EBCT (minutes) is calculated from the following equation:

$$EBCT = (7.48 \times V)/Q$$

where

V is the volume of particles in the bed (ft^3), Q is the flow rate of water through the bed (gal/min), and 7.48 is the conversion factor for gallons to ft^3.

3.11 endotoxin: Endotoxins, which are lipopolysaccharides consisting of a polysaccharide chain covalently bound to lipid A, are the major component of the outer cell wall of gram-negative bacteria

NOTE—Endotoxins can acutely activate both humoral and cellular host defenses, leading to a syndrome characterized by fever, shaking chills, hypotension, multiple organ failure, and even death if allowed to enter the circulation in a sufficient dose. Long-term exposure to low levels of endotoxin has been implicated in a chronic inflammatory response, which may contribute to some of the long-term complications seen in hemodialysis. However, the mechanisms of this process remain incompletely understood. (See also 3.23 pyrogen.)

3.12 endotoxin-retentive filter: Membrane filter specifically proven to remove bacteria and endotoxin.

NOTE—Endotoxin removal is accomplished by size exclusion and/or adhesion to the membrane surface of the filter. Endotoxin-retentive filters are used in the treated water distribution system. (See also 3.20 microfilter and 3.26 ultrafilter.)

3.13 EU: Endotoxin units as assayed by the *Limulus* Amebocyte Lysate (LAL) method when testing for endotoxins.

NOTE 1—Because endotoxins differ in their activity on a mass basis, their activity is referred to a standard endotoxin. The relationship between mass of endotoxin and its activity varies with both the lot of LAL and the lot of control standard endotoxin being used. Since standards for endotoxin were harmonized in 1983, the relationship between mass and activity of endotoxin has been approximately 10 EU/ng.

NOTE 2—In some countries, endotoxin concentrations are expressed in international units (IU). Since the 1983 harmonization of endotoxin assays, EU and IU are equivalent.

3.14 feed water: Water supplied to a water treatment system or individual component thereof.

3.15 germicide: Agent that kills microorganisms.

3.16 hemodiafiltration: Form of renal replacement therapy in which waste solutes are removed from blood by a combination of diffusion and convection through a high-flux membrane.

NOTE—Diffusive solute removal is achieved using a dialysate stream as in hemodialysis. Convective solute removal is achieved by adding ultrafiltration in excess of that needed to obtain the desired weight loss; fluid balance is maintained by infusing replacement solution into the blood either before (pre-dilution hemodiafiltration) or after (post-dilution hemodiafiltration) the dialyzer.

3.17 hemofiltration: Hemofiltration is a form of renal replacement therapy in which waste solutes are removed from blood by convection.

NOTE—Convective transport is achieved by ultrafiltration through a high-flux membrane. Fluid balance is maintained by infusing replacement solution into the blood either before (pre-dilution hemofiltration) or after (post-dilution hemofiltration) the hemofilter. (Note that there is no dialysate stream in hemofiltration.)

3.18 manufacturer: Person who designs, manufactures, fabricates, assembles, or processes a finished device.

NOTE—Manufacturers include, but are not limited to, those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking or specification development, and initial distributors of foreign entities performing these functions.

3.19 microbial: Microscopic organisms, bacteria, fungi, etc. (see also 3.2 bacteriology).

3.20 microfilter: Filter designed to remove particles in the range 0.1 to 3 μm in diameter.

NOTE—Microfilters have an absolute size cut-off and are available in both dead-end and cross-flow configurations. Some microfilters remove endotoxin by a process of adsorption.

3.21 product water: Water produced by a water treatment system or individual component thereof.

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