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American National Standard

ANSI/AAMI RD5:2003

Hemodialysis systems

AAMI 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 fume 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 decisionmaking.

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 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*.

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American National Standard

ANSI/AAMI RD5:2003
(Revision of ANSI/AAMI RD5:1992)

Hemodialysis systems

Developed by
Association for the Advancement of Medical Instrumentation

Approved 12 June 2003 by
American National Standards Institute, Inc.

Abstract: This standard covers apparatus for preparing dialysate, monitors of the dialysate, and accessories for monitoring the extracorporeal blood circuit. The requirements established by this standard will, at a minimum, help ensure the effective, safe performance of hemodialysis systems, devices, and related materials.

Keywords: blood, dialysate, dialysis, extracorporeal therapy, labeling, marking, medical equipment, packaging

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AAMI Standard

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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 60601-1-2:2001	ANSI/AAMI/IEC 60601-1-2:2001	Identical
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 ID26:1998	Major technical variations
ISO 5840:1996	ANSI/AAMI/ISO 5840:1996	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001	Identical
ISO 7199:1996	ANSI/AAMI/ISO 7199:1996/(R)2002	Identical
ISO 10993-1:1997	ANSI/AAMI/ISO 10993-1:1997	Identical
ISO 10993-2:1992	ANSI/AAMI/ISO 10993-2:1993/(R)2001	Identical
ISO 10993-3:1992	ANSI/AAMI/ISO 10993-3:1993	Identical
ISO 10993-4:2002	ANSI/AAMI/ISO 10993-4:2002	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 10993-8:2000	ANSI/AAMI/ISO 10993-8:2000	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999	Identical
ISO 10993-10:2002	ANSI/AAMI BE78:2002	Minor technical variations
ISO 10993-11:1993	ANSI/AAMI 10993-11:1993	Minor technical variations
ISO 10993-12:2002	ANSI/AAMI/ISO 10993-12:2002	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999	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
ISO 11134:1994	ANSI/AAMI/ISO 11134:1993	Identical
ISO 11135:1994	ANSI/AAMI/ISO 11135:1994	Identical
ISO 11137:1995 and Amdt 1:2001	ANSI/AAMI/ISO 11137:1994 and A1:2002	Identical
ISO 11138-1:1994	ANSI/AAMI ST59:1999	Major technical variations
ISO 11138-2:1994	ANSI/AAMI ST21:1999	Major technical variations
ISO 11138-3:1995	ANSI/AAMI ST19:1999	Major technical variations

International designation	U.S. designation	Equivalency
ISO TS 11139:2001	ANSI/AAMI/ISO 11139:2002	Identical
ISO 11140-1:1995 and Technical Corrigendum 1:1998	ANSI/AAMI ST60:1996	Major technical variations
ISO 11607:2003	ANSI/AAMI/ISO 11607:2000	Identical
ISO 11737-1:1995	ANSI/AAMI/ISO 11737-1:1995	Identical
ISO 11737-2:1998	ANSI/AAMI/ISO 11737-2:1998	Identical
ISO TR 13409:1996	AAMI/ISO TIR13409:1996	Identical
ISO 13485:1996	ANSI/AAMI/ISO 13485:1996	Identical
ISO 13488:1996	ANSI/AAMI/ISO 13488:1996	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 14969:1999	ANSI/AAMI/ISO 14969:1999	Identical
ISO 14971:2000	ANSI/AAMI/ISO 14971:2000	Identical
ISO 15223:2000	ANSI/AAMI/ISO 15223:2000	Identical
ISO 15223/A1:2002	ANSI/AAMI/ISO 15223:2000/A1:2001	Identical
ISO 15225:2000	ANSI/AAMI/ISO 15225:2000	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 TR 15844:1998	AAMI/ISO TIR15844:1998	Identical
ISO TR 16142:1999	ANSI/AAMI/ISO TIR16142:2000	Identical
ISO 25539-1:2003	ANSI/AAMI/ISO 25539-1:2003	Identical

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:
LeRoy J. Fischbach
Richard A. Ward, PhD

Members:
G. Steven Acres, MD, Carolina Regional Nephrology Associates
Mathew J. Arduino, DrPH, U.S. Centers for Disease Control and Prevention
D. Michael Blankenship, MD, Texarkana Kidney Disease & Hypertension Center
Danilo B. Concepcion, CHT, CCHT, St. Joseph Hospital Renal Center
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Robert Dudek, USFilter
Mark David Einzinger, MS, Church & Dwight Company, Inc.
Martin S. Favero, PhD, Johnson & Johnson
LeRoy J. Fischbach, Minntech Corporation
Gema Gonzalez, U.S. Food and Drug Administration/CDRH
Anders G. Hultsten, Gambro Lundia AB
Bertrand L. Jaber, MD, New England Medical Center
Jerome C. James, III, PhD, Aksys Limited
James M. Kaar, Baxter Healthcare Corporation
Rodney S. Kenley, Orth Assist LLC, *representing American Association of Kidney Patients*
Nathan W. Levin, MD, Renal Research Institute, LLC
John Lohr, PhD, Associates of Cape Cod, Inc.
Douglas A. Luehmann, DaVita, Inc.
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Barbara I. McCool, U.S. Food and Drug Administration/CDRH
Gregory Montgomery, USFilter

Dedication

This standard is dedicated to Dr. John Sadler, whose more than 20 years of service as a cochair of the AAMI Renal Disease and Detoxification Committee have been the most productive years of this committee.

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 Renal Disease and Detoxification Committee of the Association for the Advancement of Medical Instrumentation (AAMI).

The American National Standard, *Hemodialysis systems*, was first approved in May 1982 and published under the designation ANSI/AAMI RD5:1981. In 1996, during the five year review of RD5, second edition (approved in 1992), the AAMI Renal Disease and Detoxification Committee determined that the renal community would be better served by this standard if it were divided into three parts:

— hemodialysis concentrates,

— water, and

— equipment.

This standard, designated as ANSI/AAMI RD5:2003, *Hemodialysis systems*, represents the work done to update and revise the equipment portion of the previous edition to reflect the many technological changes that have taken place since the 1992 document was published.

This revised standard is addressed to the manufacturer of hemodialysis equipment. The standard may also be useful to users in evaluating new or existing equipment. Together with ANSI/AAMI RD61:2000, *Concentrates for hemodialysis*, and ANSI/AAMI RD62:2001, *Water treatment equipment for hemodialysis applications*, this completes the three-part revision of the 1992 RD5 standard.

In addition, a new AAMI project is in development, addressing the user responsibilities in caring for the water system and dialysate systems (AAMI RD52, *Dialysate for hemodialysis*).

This standard reflects the conscientious efforts of concerned physicians, clinical engineers, nurses, dialysis technicians, and patients, in consultation with device manufacturers, to develop a standard for those performance levels that could be reasonably achieved as of this writing. The term “consensus,” as applied to the development of voluntary medical device standards, does not imply unanimity of opinion; rather, it reflects the compromises that are often necessary when a variety of viewpoints and interests must be merged.

As used within the context of this document, “shall” indicates requirements to be strictly followed to conform to the recommended practice. “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 is better avoided but not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the recommended practice. “Can” is used as a statement of possibility and capability. “Must” is used only to describe “unavoidable” situations, including those mandated by federal regulation.

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

American National Standard **ANSI/AAMI RD5:2003**

Hemodialysis equipment

1 Scope

1.1 General

This standard covers the dialysis machine used to proportion and monitor dialysate and the accessories normally found on the dialysis machine.

1.2 Inclusions

This standard covers apparatus for preparing dialysate; monitors of the dialysate including blood leak detectors, ultrafiltration monitors, and controllers; integral blood pumps and heparin infusion pumps; and extracorporeal blood circuit monitors such as air detectors and pressure and flow monitors that are customarily supplied as a single comprehensive system. Some systems include monitors of patient blood pressure, blood volume, and online clearance, and others have the capability for computer interface with automated data systems. Where applicable, the monitoring for hemodiafiltration, hemofiltration, and home hemodialysis systems are also included. The requirements established by this standard will, at a minimum, help ensure the effective, safe performance of hemodialysis systems, devices, and related materials.

1.3 Exclusions

Excluded from the scope of this standard are sorbent dialysate regeneration systems that regenerate and recirculate small volumes of dialysate (although their monitors should meet this standard); peritoneal dialysis systems; central delivery systems; water treatment systems; concentrates and concentrate preparation and distribution systems; hemodialyzers; blood tubing; individual infusion pumps; and blood access devices. Some of these devices, such as hemodialyzers and blood tubing, along with water treatment equipment and concentrates, are addressed in other American National Standards.

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

2 Normative references

The following standards contain provisions that, through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. The Association for the Advancement of Medical Instrumentation (AAMI) maintains a register of currently valid AAMI/American National Standards.

2.1 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Hemodialyzers*. ANSI/AAMI RD16:1996. Arlington (VA): AAMI, 1996. As amended, 2002. American National Standard.

2.2 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Hemodialyzer blood tubing*. ANSI/AAMI RD17:1994. Arlington (VA): AAMI, 1994. As amended, 2002. American National Standard.

2.3 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Concentrates for hemodialysis*. ANSI/AAMI RD61:2000. Arlington (VA): AAMI, 2000. American National Standard.

2.4 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Water treatment equipment for hemodialysis applications*. ANSI/AAMI RD62:2001. Arlington (VA): AAMI, 2001. American National Standard.

2.5 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Safe current limits for electromedical apparatus*. ANSI/AAMI ES1:1993. Arlington (VA): AAMI, 1993. American National Standard

2.6 ECRI. Hemodialysis machines. *Health Devices* 20:6. Plymouth Meeting (PA): ECRI, 1991.

2.7 U.S. PHARMACOPEIAL CONVENTION. *United States Pharmacopeia XXIV*. Easton (PA): Mack Publishing, 2000 or subsequent version.

2.8 INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC). *Medical electrical equipment—Part 1-4: General requirements for safety—Collateral standard: Programmable electrical medical systems* IEC 60601-1-4: 2000. Geneva: IEC, 2000.

2.9 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Medical electrical equipment, Part 1-2: General requirements for safety—Collateral standard: Electromagnetic compatibility—Requirements and tests*. ANSI/AAMI/IEC 60601-1-2:2001. Arlington (VA): AAMI, 2002. American National Standard.

2.10 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Manual, electronic, or automated sphygmomanometers*. ANSI/AAMI SP10:2002. Arlington (VA): AAMI, 2002. American National Standard.

2.11 ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION. *Biological evaluation of medical devices—Part 1: Evaluation and testing*. ANSI/AAMI/ISO 10993-1:1997. Arlington (VA): AAMI, 1997. American National Standard.

3 Definitions

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

3.1 air detector: Device (sensor) that detects air or foam in the extracorporeal circuit.

3.2 blood line, arterial: Blood line leading from the patient to the hemodialyzer.

3.3 blood line, venous: Blood line leading from the hemodialyzer to the patient.

3.4 batch system: Apparatus in which the dialysate is prepared in bulk before each dialysis session.

3.5 dialysate: Aqueous fluid containing electrolytes and usually dextrose, which is intended to exchange solutes with blood during hemodialysis. The word “dialysate” is used throughout this document to mean the fluid made from water (see normative reference 2.4) and concentrate(s) that is delivered to the dialyzer by the dialysate supply system. It does not include peritoneal dialysate. Such phrases as “dialyzing fluid” or “dialysis solution” may be used in place of dialysate.

3.6 dialysate supply system: Devices that prepare dialysate online from water and dialysis concentrate(s) 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. The term includes reservoirs, conduits, proportioning devices for the dialysate, and monitors and 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 normative reference 2.6).

3.7 dialysis concentrate: Fluid containing high concentrations of electrolytes. It is intended to be diluted with purified water to form dialysate. Dialysis concentrate comes in various formulations and concentrations (dilution ratios). It comes in liquid form or can be mixed at the point of use from powder or cartridges containing powder (see normative reference 2.3). It is referred to as “concentrate” throughout this document.

3.8 transmembrane pressure: As related to the dialysis machine, transmembrane pressure is the pressure difference between the blood compartment and dialysate compartment of the dialyzer. In some dialysis machines, the transmembrane pressure (TMP) is approximated as the difference between the pressure measured at the outlet of the blood compartment (P_{bo}) and outlet of the dialysate compartment (P_{do}), or $TMP = P_{bo} – P_{do}$.

3.9 labeling: Any written material accompanying the hemodialysis machine or instructions or control feature markings attached to the machine.

3.10 manufacturer: Entity that designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and foreign distributors performing these functions.

3.11 proportioning system: Apparatus that proportions water and dialysate concentrate(s) to prepare dialysate.

3.12 user: Physician (medical director) or his or her representative (i.e., the clinical team responsible for installing, using, or repairing the equipment).

4 Requirements

4.1 Labeling

4.1.1 Device markings

Each device shall exhibit the following markings:

1) name and address of manufacturer;
2) model and serial number;
3) operating controls labeled so as to minimize the possibility of misinterpretation of function;
4) proper labeling of displays, including design and scale, to enhance legibility;
5) trade name of the product;
6) specific electrical information such as voltage, amperage, and relevant cautions and warnings; and
7) color-coded fluid pathway connectors.

With respect to item 7, the dialysate inlet line to the dialyzer shall be labeled in blue, and the dialysate outlet line from the dialyzer shall be labeled in red. The bicarbonate concentrate connector shall be labeled in blue, and the acid concentrate connector shall be labeled in red. If provided, a chemical germicide connection shall be labeled in yellow.

4.1.2 Descriptive labeling

The manufacturer shall provide labeling to the user that contains, but is not necessarily limited to, the following information:

1) requirements for utilities such as electrical power, water pressure, and drain size or capacity;
2) identification of accessories provided by the manufacturer that are compatible with the system;
3) total available power in volts and amps of accessory outlets on the equipment;
4) physical dimensions and weight of the equipment;
5) environmental conditions such as temperature, humidity, light, noise, or atmospheric pressure necessary for operating the equipment or known to be detrimental to equipment function;
6) a description, where appropriate, of the equipment, including a list and specifications of monitors, alarms, and component devices provided as standard equipment;
7) safety features and warnings concerning the consequences if these features are circumvented;
8) the dimensions of blood tubing sets, including pump segment diameter, that may be used with the machine (see labeling requirements in normative reference 2.2);
9) limitations, if any, on the range of blood circuit pressures that allow accurate functioning of the heparin infusion pump;
10) a warning that the displayed blood flow rate may overstate the actual blood flow rate, depending on the prepump arterial pressure, or disclosure of any automatic correction of the blood flow rate to counter this tendency;
11) a warning that blood line separation or needle pullout resulting in loss of blood will not be reliably detected by a standard monitor, and that the user should secure connections and maintain observation to protect against this hazard;
12) information about chemicals that are known to be compatible with materials used in the device;
13) installation procedures expected of the user, including instructions for unpacking, initial inspection, assembly, testing, and calibration or adjustments of monitors, alarms, and controls, as well as a start-up checklist;
14) detailed instructions for use, including calibration, connections to other equipment, operational adjustments, and operation and meaning of alarms;

15) procedures for discontinuing use, including procedures for shutdown, cleanup, sanitizing, or disinfection, and any additional procedures that may be required when routine disinfection does not address all parts of the machine, including a specific warning that the water line from wall to machine must be disinfected;

16) repair and service procedures, parts lists, and schematic electrical and hydraulic drawings—or a statement that these items are available on request—including preventive maintenance and troubleshooting guidelines intended for the user and company service information;

17) conditions and procedures for storage;

18) warnings and precautions about known adverse effects from improper installation or use;

19) disclosure that the risk current classification is “nonisolated patient connection” according to normative reference 2.5 and disclosure of the specific limits defined for this category related to the use of central venous catheters;

20) operating and maintenance instructions that specify how the apparatus should be operated and maintained to prevent its risk current from increasing beyond the limits set for the nonisolated patient connection classification;

21) construction materials, identified generically, that contact water, concentrate(s), or dialysate;

22) if applicable, a statement that the temperature of the dialysate entering the dialyzer may be lower than the set temperature on the machine because of environmental conditions (such as heat loss in the tubing);

23) a warning that restrictions in the extracorporeal circuit (such as kinking of the blood line or undersize needles) may cause mechanical hemolysis and this problem may not be detected by any alarm system;

24) if applicable, a statement that there is an internal transducer protector which will need to be replaced or decontaminated if there is a suspicion of contamination;

NOTE—An internal transducer protector normally should be separated from the blood pathway by means of an external transducer protector. If the membrane of this external protector has been wetted by blood, this may indicate a potential contamination of the internal protector.

25) a statement that, following disinfection of the machine, the user should test for residual disinfectant in the machine before initiating dialysis;

26) a statement as to where the arterial pressure is monitored (prepump or postpump);

27) the maximal possible deviation from the set value under single-fault condition without activation of an alarm system; and

28) a listing of the alarm systems and how their functionality is checked, and, if the alarm systems are to be checked by the user, instructions on how to perform the appropriate check.

4.2 Alarm systems

4.2.1 Deaeration system

Dialysis systems shall be equipped with effective water deaeration systems to prevent air bubbles from forming in the dialysate.

4.2.2 Back-siphon protection from the drain

The machine shall be designed to avoid backflow from the drain system into the hemodialysis machine. This is usually accomplished by an air break at the drain or by one-way check valves.

4.2.3 Water system backflow protection

Devices that prevent reduced-pressure backflow at the connection of the hemodialysis machine to treated water are unnecessary, inappropriate, and potentially hazardous. (See annex A.) The machine should be designed to avoid backflow from the machine to the inflow water system in the event of a loss of pressure in the treated water supply.

4.2.4 Monitors and alarms for dialysate systems and blood circuits

4.2.4.1 General

Monitors and alarms designed for bedside surveillance shall be placed so that all controls and displays can be clearly seen by patients with vision corrected to 20/20 in an adjacent bed or chair, attending personnel with vision corrected to 20/20 standing at the bedside, or both. Temperature readings shall be in centigrade (°C), and pressure measurements shall be in millimeters of mercury (mmHg). Scale increments shall be sufficient to permit resolution in accordance with the stated accuracy. (For a summary of monitor and alarm requirements, see Table 1, which appears at the end of clause 4.)

The equipment manufacturer shall provide a means by which the user may verify the functional integrity of each monitor. This means may consist of a manual verification procedure described in the operator's manual, an automatic verification procedure built into the equipment, or any combination of manual and automatic means. The verification means shall be capable of detecting the proper functioning of the monitoring systems. Furthermore, in the case of the air detector described in 4.2.4.8, the verification means shall be capable of detecting any malfunction in either branch of any parallel signal channel that may be used to detect air in the blood circuit. The equipment manufacturer shall recommend procedures in the operator's manual by which the user may verify safe monitor function before each dialysis treatment.

4.2.4.2 Temperature monitor

If the equipment regulates temperature of the dialysate, then the temperature of the dialysate shall be monitored online. Under normal operating conditions, the system shall maintain the temperature of the dialysate between 33 °C and 40 °C and within ± 1 °C of its set point value. No single fault of the temperature control and monitor system shall allow dialysis when the dialysate temperature is above 42 °C. An alarm condition shall interrupt delivery of dialysate to the hemodialyzer, activate audible and visual alarms, and stop the blood flow in the extracorporeal circuit. If hot-water sanitization or disinfection is used, the alarm may be overridden as long as a means of protection is provided to prevent patient use of the hemodialysis system during this mode of operation.

4.2.4.3 Transmembrane pressure monitor

Devices that monitor and display transmembrane pressure, which may be automatically estimated from the blood circuit pressure at a single point and the dialysate pressure at a single point, shall function with an accuracy of ± 20 mmHg or 10 %, whichever is greater. For systems in which ultrafiltration control is achieved by using servocontrol of transmembrane pressure, redundant monitors based on either pressure measurement or another relevant parameter shall be used.

Transmembrane pressure monitors serving as alarm systems shall have both high and low alarm limits and corresponding audible and visual alarms, and shall minimize the ultrafiltration, if activated. Alarms may be manually adjustable by the operator or preset internally at the factory. Manually adjustable alarms shall not allow limit settings beyond the monitor's scaled range and shall be easily set and understood. The indicated pressure at the alarm threshold shall agree with the alarm limit to within ± 20 mmHg or ± 10 % of the indicated pressure, whichever is greater.

4.2.4.4 Ultrafiltration control system

For a device to be considered an "ultrafiltration control" system, it must function with an overall accuracy of ± 5 % of the selected ultrafiltration rate or ± 100 mL/h, whichever is greater, over the specified range of operation. Ultrafiltration control systems shall display the ultrafiltration rate or, alternatively, the ultrafiltration time, current volume removed, target ultrafiltration volume, and units of measure. Ultrafiltration control systems shall minimally have an automated or manual method of verifying the integrity of the ultrafiltration control or balancing system at the beginning of each dialysis session. If monitored, audible and visual alarms should indicate the nature of the malfunction.

4.2.4.5 Blood circuit pressure monitor

All dialysis systems shall have an indicating monitor that measures the pressure in the extracorporeal blood circuit distal to the hemodialyzer (venous segment). Both low- and high-pressure alarm limits shall be provided. Pressures outside of these alarm limits shall shut off the blood pump, clamp the venous return line, or otherwise prevent air from reaching the patient, and shall activate audible and visual alarms within a response time that minimizes the risk of patient injury. A pressure monitor of the inlet (arterial) segment should be included. Indicated blood circuit pressure shall have an accuracy of ± 20 mmHg (2.66 kPa) or ± 10 % of indicated reading, whichever is greater. The indicated pressure at the alarm threshold shall agree with the alarm set point to within ± 20 mmHg (2.66 kPa) or ± 10 % of indicated pressure, whichever is greater. Venous pressure alarm systems shall not permit alarm settings outside the monitor's scale indication. When the patient is being dialyzed and the low-limit venous alarm is adjusted below + 10 mmHg, a warning indicator shall be activated. The indicator shall be located in the immediate vicinity of

the alarm adjustment control and clearly visible to the equipment operator. Alarms that stop the blood pump shall activate a mechanism that minimizes ultrafiltration so as to avoid hemoconcentration of the blood in the extracorporeal circuit and possible clotting. A means for easy verification of monitor alarm response shall be provided for operators to include in routine clinical procedures.

4.2.4.6 Conductivity monitor

Proportioning delivery systems shall have an online conductivity monitor, and it shall not be possible to dialyze the patient without this monitor in operation. No single fault shall allow dialysis when dialysate conductivity varies more than ± 5 % from its nominal value without activating an alarm. Detected errors in the conductivity of the dialysate shall activate audible and visual alarms, interrupt delivery of the dialysate to the hemodialyzer, or stop the blood flow in the extracorporeal circuit. If adjustable high and low limits are provided, the set points shall be confined to either ± 5 percent of the zero deviation point or the nominal monitor indication known to indicate correctly the proper proportioning of the concentrate in use. The set points shall be easily set and understood. If a front panel display is provided, it shall have a resolution no larger than 1 % of total scale. Conductivity monitors shall compensate for temperature.

Systems for dual proportioning to produce bicarbonate dialysate using conductivity servocontrol or equivalent systems shall have independent online conductivity cells to control and monitor each proportioning system, plus a conductivity monitor to monitor the final dialysate delivered to the hemodialyzer. Final conductivity shall be displayed to the operator.

A volumetric proportioning system must have an online conductivity monitor downstream of the mixing point. Final conductivity shall be displayed to the operator.

Some device systems may use other techniques such as osmolarity to monitor the proportioning system. If used, such methods shall be subject to all of the requirements of this clause.

4.2.4.7 Blood leak detector

All hemodialysis systems shall have a method of detecting blood in the dialysate. In an alarm condition, the detector shall initiate audible and visual alarms. The blood leak alarm shall shut off the blood pump automatically. The high alarm limit for the blood leak rate shall be not more than 0.35 mL/minute of blood loss for a fixed alarm limit and not more than 0.45 mL/minute of blood loss for a variable alarm limit at a hematocrit of 25 % (.25) and over the range of specified dialysate flow rates. Alarms that stop the blood pump should activate a mechanism that minimizes ultrafiltration and hemoconcentration so as to avoid hemoconcentration of the volume of blood in the extracorporeal circuit and possible clotting. The blood leak detector shall be provided with a convenient means of checking its function and calibrating in the field.

4.2.4.8 Blood circuit air protection

Hemodialysis systems shall include an alarm system to detect air in the blood circuit before the blood is returned to the patient.

1) The system should detect an individual bolus of air larger than 1 mL, at operating pressure, or the presence of a series of microbubbles that occur within a short period of time and total more than 1.5 mL/30 s. The system shall include a clamp that is capable of occluding the venous return line. The manufacturer shall disclose the sensitivity of the air detector and the method used for testing. The test method used shall be described in sufficient detail to permit reproducible results and verification of sensitivity by the user.

2) Detection of air shall cause the alarm system to operate.

3) When activated, the alarm system shall meet all of the following conditions:

   a) activation of both audible and visual alarms,

   b) arrest of the blood pump,

   c) occlusion of the venous return line or execution of some other method to prevent air from reaching the patient, and

   d) minimization of ultrafiltration.

   NOTE—Considering the time at which a potential bolus of air or bubbles are detected or pass the detection point, elements (a), (b), and (c) must be achieved within a subsequent time interval, t_o, defined as that time required for a bolus to travel from the point of detection to the venous cannula at the maximum flow rate of the blood pump.

4) Loss of power to the air detector shall cause the blood pump to be turned off and the venous return line clamp to occlude the venous line. Means shall be provided for manual release of the venous clamp to allow for return of blood in emergency situations.

5) If the air detector has not been activated and the system is being operated when the patient is connected to the dialysis machine, both audible and visual indicators shall alert the operator that the air detector is not activated (see 4.4.1).

6) The air detector shall not cause chemical changes in the blood or adversely affect formed elements of the blood.

7) The failure of any single component of the air detector shall not compromise the functioning of the alarm system and shall cause the alarm system to operate as if a bolus of air or air bubbles were detected. Implementation of this requirement may be achieved by means of

   a) a "fail safe" system in which a component failure results in either

      i) the immediate activation of the alarm system; or

      ii) continued monitoring for air and, in the event of a potential air infusion, activation of the alarm system;

   b) a circuit consisting of two parallel channels, the failure of either of which results in the remaining channel immediately taking over the function of the defective channel;

   c) a circuit that automatically validates itself at a regular interval no longer than t_o and that responds to validation failure with an alarm condition; or

   d) any combination of these types of circuits.

4.2.4.9 Disinfection protection

Activating the disinfection system of the dialysate circuit during dialysis shall result in the activation of a visual indicator. It shall not be possible to treat the patient while the equipment is in the disinfection/sanitization mode.

4.3 Other features and monitoring accessories

A number of additional features and monitors are available from various manufacturers. Many times, these features are provided as options and are not available on all machines. They include but are not limited to

1) point-of-use dialysate filters to reduce bacteria or endotoxin contamination of the dialysate;

2) dry powder cartridges or bag-handling systems to generate the acid or bicarbonate concentrate;

3) patient blood pressure monitors;

4) dialyzer clearance monitoring devices;

5) blood volume monitoring devices;

6) blood temperature monitoring and/or control devices;

7) access flow or recirculation monitoring capability;

8) dialyzer reuse capability (cleaning, testing, and disinfection);

9) patient data cards.

If such accessories are included as either a standard or optional feature, appropriate operating and maintenance instructions shall be provided. The manufacturer shall have sufficient test data and reports to support the safety and efficacy of these accessories. Patient blood pressure monitors shall meet the requirements of the ANSI/AAMI standard for freestanding automated blood pressure monitors (normative reference 2.10).

4.4 Safety requirements

4.4.1 General safety requirements

Each device shall exhibit the following minimum safety features (see normative reference 2.8):

1) a safe configuration, which shall be entered if any monitored variable exceeds control limits;

2) sensor sensitivity and sensor location that shall be appropriate for the intended use of the sensor while minimizing the occurrence of false (nuisance) alarms;

3) operating controls that are positioned to minimize inadvertent resetting;

4) alarm systems designed so that the system cannot be overridden while the patient is connected to the dialysis machine, except for brief necessary periods of manual control with the operator in constant attendance (see Table 1);

5) audible alarms that may be adjusted to at least 65 decibels ("A" scale) at 1 m;

6) blood leak detector, air detector, TMP, and arterial and venous pressure audible alarms that may be mutable for up to 180 s to allow for correction of an alarm condition; and

7) a design that minimizes entrapment of blood or contaminants in order to facilitate cleaning.

4.4.2 Electrical safety requirements

Each device shall meet the following requirements with respect to electrical safety:

1) electrical apparatus shall meet the requirements for nonisolated patient connection of the American National Standard ANSI/AAMI ES1:1993, *Safe current limits for electromedical apparatus* (normative reference 2.5) or another equivalent international or national standard;

2) an electrical ground shall be provided according to applicable electrical codes;

3) machine accessory outlets and panel seams shall be shielded from liquid spills or designed in a manner to prevent liquid from affecting the safety of the machine;

4) electrical circuits shall be separate or sealed from hydraulic circuits and adequately protected from fluid leaks; and

5) failure of electrical supply mains to a system shall be indicated by an audible alarm.

4.4.3 Electromagnetic compatibility requirements

Electromagnetic compatibility testing shall be performed and the results evaluated. If ANSI/AAMI/IEC 60601-1-2:2001 (normative reference 2.9) is not followed, a rationale should be given.

4.4.4 Fluid contact compatibility

Materials that contact water, blood, or dialysate shall be specified by the manufacturer to be of composition known to be nonreactive and nontoxic in their application.

Table 1—Chart of monitor and alarm requirements

Condition	Equipment response	Document reference
1) Dialysate temperature (above 42 °C)	Audible and visual alarms; interrupt delivery of dialysate to hemodialyzer; stop blood flow in the extracorporeal circuit	4.2.4.2
2) Transmembrane pressure	Audible and visual alarms; minimize ultrafiltration	4.2.4.3
3) Blood circuit pressure (high or low)	Audible and visual alarms; shut off blood pump; clamp venous return line or otherwise prevent air from reaching the patient; minimize ultrafiltration	4.2.4.5
4) High or low dialysate conductivity	Audible and visual alarms; interrupt delivery of dialysate to hemodialyzer and/or stop blood flow in the extracorporeal circuit	4.2.4.6 (Not applicable to batch systems)
5) Blood leak	Audible and visual alarms; shut off blood pump; minimize ultrafiltration	4.2.4.7

Table 1 *(continued)*

Condition	Equipment response	Document reference
6) Blood circuit air protection	Audible and visual alarms (for alarm conditions or when monitor has not been activated and patient is connected to the dialysis machine); turn off blood pump to prevent air in venous bloodline from reaching patient (alarm condition only, to prevent pressure in the blood circuit from forcing air toward the patient); minimize ultrafiltration	4.2.4.8
7) Disinfection protection	Visual alarm; prevent dialysis of patient	4.2.4.9
8) Ultrafiltration control/monitor	If monitored, audible and visual alarms should be included indicating nature of malfunction	4.2.4.4
9) Power failure	Audible alarm	4.4.2(5)

5 Tests

This clause defines reference test methods by which compliance with the requirements of clause 4 can be verified. The paragraph numbers below correspond to the paragraph numbers of clause 4.

NOTE—The test methods listed do not represent the only acceptable test methods available but are intended to provide examples of acceptable methods. Other test methods may be used if comparable validity is demonstrated.

5.1 Labeling

Compliance with the labeling requirements of 4.1 can be determined by inspection.

5.2 Alarm systems

5.2.1 Deaeration system

Compliance with this requirement can be determined by inspection. Three suggested inspection methods are (1) inspect the inner surface of the dialysate lines for very small air bubbles, (2) inspect the venous drip chamber for foaming at the blood–air interface, and (3) measure the partial pressure of the dissolved gases.

5.2.2 Back-siphon protection from the drain

Compliance with the requirements of 4.2.2 can be determined by visual inspection of the installed air breaks. Where one-way check valves are used, a test can be performed in which the outflow pressure is elevated above the inflow pressure and it is demonstrated that no backflow into the machine occurs.

5.2.3 Water system backflow protection

Compliance with the requirements of 4.2.3 can be determined by visual inspection of the inflow water circuit to confirm that attention has been paid to the prevention of backflow of water into the purified water system.

5.2.4 Monitors and alarms for dialysate systems and blood circuits

5.2.4.1 General

Compliance with the requirements of 4.2.4.1 can be determined by inspection.

5.2.4.2 Temperature monitor

Continuous temperature measurements shall be taken over a period of 1 h at the inlet to the hemodialyzer, at a fixed specified ambient temperature. The accuracy of the indication shall be checked by comparing the indicated temperature with the temperature of dialysate at the inlet to the hemodialyzer, as measured using an external sensor calibrated against a standard traceable to the National Institute of Standards and Technology (NIST) or other equivalent national or international standard. Measurements shall be taken at least at the minimum, midscale, and maximum dialysate flow, if the flow is adjustable. Dialysate temperature alarms shall be checked by exceeding the upper temperature alarm limit. Inspection shall confirm that the alarm is activated when the alarm set temperature is exceeded.

5.2.4.3 Transmembrane pressure monitor

Compliance with the requirements of 4.2.4.3 shall be tested by using external sensors that have been calibrated against a standard traceable to NIST or other equivalent national or international standard. The sensors shall be placed in the dialysate flow path at the location and height intended for hemodialyzers. Tests shall be performed over the entire range of pressures encompassed by the monitor.

5.2.4.4 Ultrafiltration control system

The following tests demonstrate compliance with 4.2.4.4. More than one of the influencing variable conditions may be applied to the system under test at the same time, using the same hemodialyzer and test apparatus. If this is done, the sequence of applying the variable conditions shall be such that the reliability of any test is not adversely influenced by the test sequence.

The temperature of the test solution shall be 37 °C ± 1.5 °C. Reservoirs shall be calibrated so that measurements over the period of observation vary by ± 2 % or less. The error of a graduated cylinder shall be at most ± 2 %. Flow rates shall be determined volumetrically or with flowmeters that have a maximum error of ± 10 %. Reservoirs and pumps other than those commonly used in clinical dialysis may be used, provided that they in no way diminish the accuracy of the measurements.

Hemodialyzers used in the ultrafiltration control system test circuit shall be prepared according to the manufacturer's directions for use. Blood compartment and dialysate compartment integrity shall be verified (see normative reference 2.1).

Ultrafiltration control accuracy tests shall be performed using dialysate for both the blood circuit and dialysate circuit to prepare the hemodialyzer. The preliminary perfusion of the hemodialyzer may be done while connected to the machine. Care shall be taken to clear all air from the dialysate and blood compartments of the hemodialyzer. Any drip chambers in the test circuit shall be adjusted to a specific level throughout the test duration. Any measurements taken from the "patient" reservoir (graduated cylinder) that are used for determining total volume removed or rate of removal from the test circuit shall be measured at equal test circuit pressures to eliminate system compliance effects.

The *in vitro* test runs shall be performed while experiencing the normal, minimum, and maximum values of variables that may influence operation of the ultrafiltration control system. At the end of the test, the volume removed from the "patient" reservoir shall be compared with the ultrafiltration control system volume display.

Testing of the ultrafiltration control system monitor shall be performed to determine accuracy deviations in the presence of a single fault in the control system. The monitor shall either automatically take appropriate control actions to minimize the risk of fluid removal error or clearly signal to the system operator to take appropriate actions to minimize fluid removal error.

Given the variety of different control system techniques, fault conditions cannot be defined fully in this document but shall be determined by the machine manufacturer. Test operating periods shall be sufficient to support reliability claims.

5.2.4.5 Blood circuit pressure monitor

Monitors of blood circuit pressure shall be tested using sensors that have been calibrated against a standard traceable to NIST or other equivalent national or international standard. Blood circuit alarms shall be checked by exceeding the upper alarm pressure limit. Inspection shall confirm that the alarm is activated when the alarm set pressure is exceeded. Tests shall be performed over the entire range of pressures encompassed by the monitor.

5.2.4.6 Conductivity monitor

Alarm responses shall be verified by inspection. Conductivity alarm limits shall be verified by first operating the hemodialysis equipment in its normal dialyzing mode at a predetermined value of concentration within the usual operating range. The average value of conductivity shall be determined by numerically averaging the measured concentration values of five samples taken from the hemodialyzer inlet line at 2 minute intervals over a 10 minute time span. (If applicable, care should be exercised to ensure that the sampling interval is not synchronous with the natural conductivity control cycle of the machine.) The concentration control system shall then be perturbed an amount necessary to create the high-conductivity alarm condition and then as necessary to create the low-conductivity alarm condition. For each alarm condition, five samples taken from the circuit immediately adjacent to the monitoring conductivity sensor at the time of alarm shall not vary by more than ± 5 % from the average value of conductivity previously calculated. Concentration may be determined by measuring the concentration of a particular ion by such methods as flame photometry or ion-selective electrode. Over a range of ± 5 % from nominal, electrolyte concentration can be considered directly proportional to the conductivity of the solution.

Manufacturers of equipment, conductivity test meters, and standard solutions shall make their conductivity standards traceable to standard solutions such as those obtainable from NIST or other equivalent national or international standards. For clinical use, similar standard solutions may be obtained from various manufacturers in a range of values.

When using standard solutions to calibrate a dialysis machine or test conductivity measuring equipment, the temperature of the test solution shall be considered.

5.2.4.7 Blood leak detector

Blood leak detectors shall be tested using fresh whole bovine blood adjusted to a hematocrit of 25 % (.25). Blood shall be infused into the dialysate flow path distal to the hemodialyzer connection point. Testing is to be performed with safe operating conditions for both dialysate conductivity and temperature. All tests are to be performed under "worst case" conditions of the specified dialysate flow rate (manufacturer's recommended minimum and maximum dialysate flow rates).

5.2.4.8 Blood circuit air protection

Compliance with the requirements of 4.2.4.8 can be determined by introducing graded amounts of air or foam into the blood circuit *in vitro*, while the device is perfused at the maximum venous pressure capability of the equipment and with a test solution temperature in the usual operating range. The test solution shall be saline; saline mixed with bovine blood having hematocrits of 5 %, 10 %, and 15 %; or whole bovine blood. Separate tests shall be conducted for boluses of air and foam. Infusing hydrogen peroxide into the system (see normative reference 2.6) may simulate foam.

NOTE—In today's market, there are a number of different locations of the air detector and different ways of detecting air in the extracorporeal circuit. The test method designed to comply with 4.2.4.8 should take into account the principle of detection of air and the location of the air detector.

5.2.4.9 Disinfection protection

Compliance with the requirements of 4.2.4.9 can be determined by inspection.

5.3 Other features and monitoring accessories

Compliance with 4.3 shall be determined by inspecting the operational and maintenance instructions provided with the equipment. When necessary, an evaluation of the safety and efficacy reports from the manufacturer's files can be performed to ensure that sufficient testing has been done to support the functionality of the device.

If the dialysis machine incorporates a patient blood pressure monitor, this accessory shall be evaluated against the ANSI/AAMI standard for freestanding automated blood pressure monitors (see normative reference 2.10).

5.4 Safety requirements

5.4.1 General safety requirements

1) Compliance with this requirement can be determined by inspecting the system configuration after causing an alarm condition.

2) Compliance with this requirement can be determined by inspection.

3) Compliance with this requirement can be determined by inspection.

4) Compliance with this requirement can be determined by inspection.

5) Compliance with this requirement shall be determined by use of an audiometer. Sound level measurements shall be made at a point 1 m from the front of the dialysis equipment. The standard "A" scale frequency response characteristics shall be used. Alarms capable of being silenced shall be made to alarm and then be silenced. A stopwatch shall be used to verify that the alarm sounds again after an interval of no more than 180 s.

6) Compliance with this requirement can be determined by inspection.

5.4.2 Electrical safety requirements

1) Compliance with this requirement can be determined by the tests for nonisolated patient connection found in the American National Standard ANSI/AAMI ES1:1993, *Safe current limits for electromedical apparatus* (normative reference 2.5). In defining the risk current for patient connection, care should be taken to include the resistance of recommended blood and monitoring line connections and avoid test artifact.

2) Compliance with this requirement can be determined by inspection.

3) Compliance with this requirement can be determined by inspection of the material specification.

4) The hemodialysis equipment shall be placed in the position of normal use and subjected for 30 s to an artificial rainfall of 3 mm/minute falling vertically from a height of 0.5 m above the top of the equipment. The test shall be carried out using water. Immediately after the 30 s exposure, visible moisture on the body of the equipment shall be removed. Immediately after this test, inspection shall show that test solution that may have entered the equipment cannot adversely affect the safety of the equipment.

5) Compliance with this requirement can be determined by inspection.

5.4.3 Electromagnetic compatibility requirements

Compliance with this subclause shall be verified by a review of the test results of the electromagnetic compatibility testing.

5.4.4 Fluid contact compatibility

The compatibility of material components used in the hemodialysis system can be determined by verifying that the components in contact with the concentrate, water, or dialysate are nonreactive materials and these components are not those known to cause toxicity in dialysate systems. When there is uncertainty, samples for toxicity testing may be collected from the inflow to the hemodialyzer or from the dialysate reservoir. The samples shall be taken after the system has been in operation for 6 h or more at typical temperatures and the maximum flow rate, with a representative dialysate formula. Samples can be evaluated by using ANSI/AAMI/SO 10993-1, *Biological evaluation of medical devices—Part 1: Evaluation and testing* (normative reference 2.11), or *United States Pharmacopeia* Class VI for containers (normative reference 2.7).

Annex A
(informative)

Rationale for the development and provisions of this standard

A.1 Introduction

The items included within the scope of this standard are (1) the devices required to prepare dialysate, (2) associated monitors which ensure that the dialysate is maintained within physiologically defined limits, and (3) monitors of the hemodialyzer blood circuit. Monitors of the blood circuit are included because they are commonly components of dialysate supply systems and have features in common with monitors of dialysate.

The accessories associated with dialysis machines have proliferated greatly over the last 10 years as technology has advanced. Many types of machines that were included in the previous document have been eliminated from this document because of technological improvements. Today in the United States, most, if not all, machines incorporate ultrafiltration controllers which allow the machines to be used with high-flux dialyzers. Some systems include monitors of blood volume and online clearance, and others have the capability for computer interface with automated data systems. Many include automated blood pressure devices, which should meet the ANSI/AAMI standard for freestanding automated blood pressure monitors. The requirements established by this standard will, at a minimum, help ensure safe and effective treatment for dialysis patients.

Systems that regenerate dialysate by passing the dialysate through substances that restore dialysate, thereby leaving the dialysate in a condition comparable to fresh dialysate, have been specifically excluded from the scope of this standard. Nonetheless, because the monitors of those systems perform functions similar to those of any other dialysis machine, they should function within the same constraints as any other hemodialysis system.

The development of a hemodialysis systems standard began in the late 1960s as a collaborative effort between the American Society for Artificial Internal Organs and AAMI.

The AAMI Renal Disease and Detoxification Committee initiated a thorough review of the standard in 1986, recognizing that the technology of hemodialysis had changed in a number of respects since the standard was written. In particular, bicarbonate dialysis and “high-flux” dialysis had become common. Task groups were established in those areas that the committee felt needed most careful review, including bicarbonate dialysis, ultrafiltration rate controls, monitors, and microbiological aspects. As a result of the work of these task groups and review by the full committee, a revision of the standard was produced. The principal areas of change were the addition of provisions for bicarbonate dialysis, including color-coding and labeling requirements to distinguish among the types of concentrate and proportioning ratios, and the addition of requirements for ultrafiltration controls or monitors (see 4.1). The basic microbiological requirements were not changed, but a clause on bacteriology of aqueous bicarbonate concentrate was added. The committee concluded that, on the basis of available data, the introduction of highly permeable membranes did not require the establishment of limits on pyrogens in water for dialysis. The allowable levels of chemical contaminants in dialysis water were not changed.

In 1996, the committee decided to separate *Hemodialysis equipment*, *Water treatment for hemodialysis*, and *Concentrates for hemodialysis* for the sake of clarity, ease of access, and compatibility with international standards. This *Hemodialysis systems* standard derives directly from the original ANSI/AAMI RD5:1981.

A.2 Need for the standard

This standard seeks to prevent the use of options that are hazardous to patients treated with hemodialysis systems or personnel operating the equipment. Examples of the need for the standard are (1) injury of the patient or operator caused by equipment malfunction and (2) inadequate treatment of the patient caused by unsatisfactory performance of the equipment.

A.4 Rationale for the specific provisions of this standard

This clause contains the informative rationale for each of the requirements of clause 4 of this standard. The paragraph numbers below correspond to those of clause 4. This informative rationale is not meant to expand on the contents of the main body of this document but rather to help explain the reasons for the requirements.

A.4.1 Labeling

Existing federal regulations establish general requirements for the labeling of all medical devices, including such information as name and address of manufacturer and lot number. The committee believed, however, that redundancy of these requirements was preferable to omission and elected to require some of the same information

already mandated by federal law. The provisions of the other clauses of 4.1 are intended to ensure that certain information specifically necessary for the safe and effective use of hemodialysis systems will be included in the device labeling. For most of this information, the underlying reasoning for the requirement is self-evident. Additional rationale for certain of these requirements is provided below.

A.4.1.2 Descriptive labeling

The requirement that the manufacturer supply the user with detailed information about the setup, use, and technical aspects of the device was included in order to ensure that the user would have sufficient information to operate the device safely and effectively. Since risks are associated with even the uneventful operation of the device, the committee considered it important to require that the warning notices of paragraphs (5), (7), and (15) be provided with the device.

The designs of some machines do not require the use of a transducer protector.

During the review of this document, the committee determined that the requirement for a warning about the hazard of a high temperature was no longer needed.

A.4.2 Alarm systems

A.4.2.1 Deaeration system

Entrained and unequilibrated dissolved air in the dialysate circuit may adversely affect the dialysis system monitors, hemodialyzer efficiency, ultrafiltration control, and patient safety. This air can affect the operation of flowmeters, conductivity and temperature sensors, and blood leak detectors. It may reduce the efficiency of the hemodialyzer by masking portions of the membrane. It may also cross the membrane and enter the blood, causing foaming and possible air embolism in the patient. For these reasons, a deaeration system should be provided. An adequate deaeration device should remove all entrained air and any air which could come out of solution in the dialysate circuit at both maximum operational temperature and minimal operational pressures within the circuit, using feed water saturated with air at the lowest likely temperature.

There is insufficient data to permit setting a limit for deaeration. The following is for information only. Nitrogen is the air component of concern because of its poor solubility in aqueous solutions. It is difficult to measure, so oxygen may be used instead as an indicator because of the fixed ratio of the two gases in air. The maximum partial pressure of nitrogen in the blood at sea level is 563 mmHg (74.9 kPa). A partial pressure of 470 mmHg (62.5 kPa) with a corresponding partial pressure of oxygen of 125 mmHg (16.6 kPa) in dialysate has been suggested as representing an adequate margin of safety, regardless of feed water temperature.

Deaeration of the dialysate is not possible because doing so would drive off the CO_2 from the bicarbonate dialysate.

A.4.2.2 Back-siphon protection from the drain

The committee agreed that there should be some integral protection to ensure that the flow of “dirty” dialysate would be directed away from the flow of “clean” dialysate.

A.4.2.3 Water system backflow protection

The committee wishes to state that there is no hazard at the connection of the dialysis machine to the treated water, and placement of backflow protection devices is likely to insert into the circuit materials (e.g., brass) that would harm patients. Placement of backflow protection devices is likely to affect the incoming water quality microbiologically and chemically because of leaching of zinc and copper into the circuit, which could, in turn, harm patients.

A.4.2.4 Monitors and alarms for dialysate systems and blood circuits

During the review of this document, the committee considered including requirements for software. Because software is covered by the U.S. Food and Drug Administration’s Quality System Regulation (QSR) and good design practices, the committee decided that it was not necessary to include software requirements in this document.

A.4.2.4.1 General

It seemed reasonable, from a human factors engineering point of view, to require that monitors and alarms designed for bedside surveillance be readily visible and audible to attending personnel. Metric units of measure are specified, because these units are the standard for medical and scientific applications. A requirement for a flow-rate detector was not included, because a failure of dialysate flow does not pose an immediate risk to the patient, and the no-flow condition generally will be evident to the operator by inspection or activation of dialysate supply system alarms. In recognition of the work on single-fault mode safety for dialysis equipment performed by IEC Subcommittee 62D in the generation of its publication IEC 60601-2-16, *Medical electrical equipment, Part 2-16: Particular requirements for safety of haemodialysis, haemodiafiltration, and haemofiltration equipment*, a requirement has been added for the

equipment manufacturer to provide a means of periodic functional validation of the integrity of each monitor circuit, as has a recommendation to the user to validate the functional integrity of each monitor before each dialysis treatment.

Blood line separation or needle pullout is uncommon but does occur, and can cause potentially lethal situations enabling air intake into the arterial system (which should be detected by the air detector) or significant blood loss from venous disconnection. No system in current use will reliably detect such a venous separation or needle pullout. Blood line separations may be partial and result in moderate leakage with little change in the monitored pressures. Needles pulling out from the access may lodge against clothing or furniture, creating resistance and minimizing changes in the monitored pressures. Catheter access is frequently done with relatively low blood flow rates resulting in a low pressure drop across the access device, so that a disconnect from the catheter may cause only a small change in monitored pressures. The patient may not be aware of even significant blood leakage from the circuit. Because no system in general use can protect against this serious potential hazard, users are cautioned to double check the security of connections, put into place procedures that ensure that connections are appropriately secured with tape or other devices, and keep access connections uncovered so that any leakage can be readily identified. Manufacturers are urged to apply labeling that makes the user aware of this potentially serious condition.

A.4.2.4.2 Temperature monitor

Failure to maintain dialysate temperature within the physiological range has caused patient complications. In instances where the temperature exceeded the physiological range, some patients complained of weakness and lethargy. Hemolysis was usually present, and at least one cardiorespiratory arrest has been reported (Fortner et al., 1970). Where the temperature is below the physiological range, only chilliness occurs, but the comatose patient may become hypothermic, and clotting of the hemodialyzer could occur. The high temperature limit of 42 °C was chosen because protein denaturation and hemolysis can take place above a temperature of 46 °C. Both visual and audible alarms are required because immediate recognition of the alarm condition is important. A low-limit alarm is not required because failure of the temperature controller is rare and the patient is usually aware of the failure (i.e., feels cool) before adverse effects can occur.

This standard points out that hemolysis and protein denaturation only occur at temperatures > 46 °C and failure of the temperature controller is rare. Overheated dialysate has not caused any serious problems for the last 20 years. Dialysate temperature is controlled and independently monitored automatically, and the user cannot adjust the temperature outside of the safe limits. Thermal hemolysis requires blood temperatures of > 45.6 °C.

Systems that do not regulate dialysate temperature are exempt from this requirement, because certain machines that provide continuous renal replacement therapy have no dialysate temperature control or monitoring but still fall under the scope of this standard.

A.4.2.4.3 Transmembrane pressure monitor

When this standard was first written, fluid removal by ultrafiltration was controlled by manual adjustment of the dialysate pressure; pressure detectors were then required to prevent excessive negative or positive pressures which could result in errors in the intended fluid removal. Extreme hypotension was often the result of excessively negative pressures in the absence of ultrafiltration control, and blood leaks were associated with both high negative and high positive pressures (Keshaviah, et al., 1980). The committee considered that requiring audible and visual alarms could largely prevent these adverse effects. A tolerance of ± 20 mmHg was selected for the upper pressure limit at which the device should alarm because this standard is readily achievable, and, as pointed out by Keshaviah, et al. (1980), “the cumulative effects of monitor error, placement errors, and variability of hydraulic permeability, and the influence of patient parameters such as oncotic pressure and hematocrit make accurate ultrafiltration pressure prediction difficult.” Consequently, the committee attempted to establish clinically realistic pressure standards. By the time this standard was revised, all dialysis machines incorporated ultrafiltration control systems. In these systems, the important operating variable is the transmembrane pressure, not the dialysate pressure. Therefore, the requirements to display the dialysate pressure and set alarm limits on the dialysate pressure were removed from the standard.

The displayed transmembrane pressure is usually estimated from the measured blood circuit pressure and measured dialysate pressure, each obtained at a single point. The committee recognizes that this method of estimating transmembrane pressure yields only an approximate value, as it does not take into account the pressure drop that occurs along the lengths of the blood and dialysate compartments of the dialyzer. Nevertheless, changes in transmembrane pressure can still serve as an indicator of changes in ultrafiltration conditions that may occur during dialysis as a result of changes in the dialyzer or possible malfunction of the ultrafiltration control system.

A.4.2.4.4 Ultrafiltration control system

Current hemodialysis systems incorporate a variety of ultrafiltration control systems that are based on a number of different principles and techniques of fluid and pressure measurement. The capabilities of these control systems to

monitor correct operation also vary from system to system. The goal of this revision is to standardize the qualification testing of ultrafiltration control systems under operating conditions likely to be experienced during dialysis. Because a single fault can harm patients through excessive fluid removal, failure of fluid removal, or unrecognized infusion of dialysate, the reliability of the entire system is critical.

The revision attempts to provide a uniform method of testing ultrafiltration control systems and monitors of these systems so that safe operation under a variety of operating conditions can be determined and stated in the associated labeling that accompanies the hemodialysis system.

The maximal deviation of set parameters under single-fault condition is not always obvious to the user. Failure of ultrafiltration controllers may cause unexpected large deviations without triggering the alarm systems. The manufacturer should inform the user about the maximal deviation that may occur without triggering an alarm. Thus, a requirement was added to the labeling requirements.

A.4.2.4.5 Blood circuit pressure monitor

Elevation of blood circuit pressure may result from blood line obstructions such as kinks, clogged filters, or clamps. Obstruction distal to the blood pump presents hazards to the patient in the form of tubing separations, membrane leaks, and possible hemolysis. A recent recall of a blocked blood tubing set that caused several patient deaths is yet another reason to carefully evaluate the use of monitors to check for blockage in the blood path. Thus, monitoring of the blood circuit pressure for high-pressure deviations is recommended for all systems. Most modern dialysis machines monitor arterial pressure either prepump or postpump. When the pressure is monitored only prepump, an occlusion downstream of the pump could allow sufficient pressure to build up to cause hemolysis, line separation, or membrane rupture. Without two monitors, it is not possible to guard against this situation, and it is the user's responsibility to monitor for possible problems (e.g., tubing kinks, clamps left on the tubing, or clots) that could lead to this pressure buildup.

Low-pressure deviations should also be monitored because a decrease in pressure indicates obstruction proximal to the monitor or line separation at some point in the circuit. Line separation in positive-pressure areas results in blood loss, whereas line separation in negative-pressure (prepump) areas causes air to enter the blood line, which can result in air embolism or clotting. Because of the serious risk of line separations that may not cause marked decrease in the blood circuit pressure, Keshaviah, et al. (1980) recommended that these monitors have an accuracy of ± 10 mmHg at pressures of < 50 mmHg and ± 10 % of the indicated pressure at pressures > 50 mmHg. Even with this degree of accuracy, the venous pressure monitor may not be sufficiently sensitive to detect the change in pressure that occurs when the venous needle pulls out of the access, because the magnitude of the pressure drop across the needle is much greater than that of the pressure in the blood access.

In setting venous pressure alarm limits, changes in pressure from the steady operating value are of concern. Therefore, alarm set-point accuracy refers to *indicated* pressure rather than actual pressure. Actual pressure at alarm is not as important as *change* in pressure from normal.

The requirement that a means be incorporated by which the operator is notified when the low-limit venous alarm is set below + 10 mmHg is intended to alert the operator to the fact that, at a setting below this level, the monitor may not detect a tubing separation. Internally set alarms need not meet this requirement because no devices with internally set alarms are set below + 10 mmHg.

A.4.2.4.6 Conductivity monitor

Both hyper- and hypo-osmolar dialysate have been reported as hazards in hemodialysis. Keshaviah, et al. (1980) reported that, in many cases, improper design can be identified as a partial, if not total, cause. Online conductivity monitors are, therefore, required for proportioning dialysate supply systems. The standard does not require a conductivity monitor for batch systems, because the possibility of a change in dialysate composition in a batch system during dialysis is remote.

During the review of the document, a suggestion was made to replace measurement of conductivity with a measurement of osmolarity. The committee considered the suggestion and declined to require osmolarity but rather allow its use. The committee believes that conductivity must be displayed because users are now controlling dialysis by adjusting/prescribing conductivity rather than concentration, and, therefore, any other monitor would cause user errors.

A.4.2.4.7 Blood leak detector

The potential for loss of blood because of hemodialyzer membrane rupture constitutes a risk to the patient. Shutting off the blood pump reduces the amount of blood loss by reducing the transmembrane pressure and halting the flow of blood from the patient. It is not recommended that the blood pump be stopped and the air detector clamp be closed at the same time. Under these conditions, blood-side pressures would equilibrate with dialysate-side pressures, creating the possibility of infusing dialysate into the blood side of the hemodialyzer. It is generally

considered preferable to return the blood to the patient despite the blood leak, so the committee rejected the idea of requiring clamping of the tubing in addition to stopping the pump. There was even some discussion of the need for automatic blood pump shutoff, given that in most medical facilities, operation of the device is monitored closely enough to detect a blood leak before the patient is connected to the dialysis machine. This is not the case in many home dialysis settings, however, and an automatic shutoff of the pump in the presence of a blood leak was thought to be an essential safety feature. Ideally, the committee concluded, it should be possible to set the machine internally for either instance, but until this feature is widely available, the committee considered it prudent to require an automatic shutoff of the pump.

Maximum allowable leak rates are based on committee determination of maximum acceptable values of blood volume loss, given the infrequency of blood leaks and the potential for increased frequency of false alarms at more sensitive alarm thresholds. The higher threshold for systems containing adjustable alarm limits is based on the belief that a higher leak rate can be tolerated if the operator is made aware of the condition.

Bovine blood has been specified in the test method because it has a similar spectral absorption curve and similar-sized formed elements as (albeit a greater number of platelets than) human blood. Historically, blood leak sensitivity has been specified in milligrams of hemoglobin per liter (mgHb/L) of dialysate, probably because of the established spectrophotometric tests for determination of hemoglobin. Specification in mgHb, however, requires calculation to determine the quantity of blood lost, which is the parameter of interest to the practitioner. Therefore, the committee has specified that the blood loss be reported in mL/minute at a hematocrit of 25 % (0.25). The threshold limits of 55 mgHb/L and 70 mgHb/L were translated to 0.35 mL/minute and 0.45 mL/minute of blood, respectively. Calculations were based on the assumption of 14 grams Hb/100 mL blood in normal subjects, a hematocrit of 46 % (0.46) in normal subjects, a hematocrit possibly as low as 25 % (0.25) in typical dialysis patients, and a dialysate flow rate of 500 mL/minute.

A.4.2.4.8 Blood circuit air protection

Recognizing the critical need to detect air in the blood line circuit, the committee has elected to impose stringent safety requirements for protection of the blood circuit from air. Accordingly, the committee has taken advantage of the IEC work in this area and has imposed safety requirements consistent with the existing IEC publication on the safety of hemodialysis equipment, which is based on the philosophy of safety under the condition of a single fault.

Because there is not a standardized method of testing the sensitivity of air detectors, the committee specified a requirement for disclosure of sensitivity. Specifying foam is also a problem, because no method exists for manufacturing a standard foam to use in testing a performance requirement that will yield reproducible results. Foam containing a given ratio of blood–air volume can vary markedly in its structure, light transmission, and reflective characteristics. Until better data is available, generation of foam by hydrogen peroxide is recommended for testing the air detector system.

The committee specified that air detectors should alarm when not activated only when the patient is connected to the dialysis machine, because there are times when the patient is isolated from the detector, and it may ease use to inactivate the detector. Examples of this situation include during the sterilize mode or when the blood pump is not operational. The device calibration for sensitivity testing should not permit false or nuisance alarms in a steady-state operating condition and should be the same calibration at which the device is marketed.

The sensitivity of the air detector should be stated in terms of both a minimum volume of air when tested as a single bolus and a minimum infusion rate (volume/unit time) of microbubbles, suggested to be through a stated orifice size under conditions of atmospheric pressure into a test fluid flowing through a blood line intended for use with the detector. The test fluid should be 37 °C ± 1.5 °C, and sensitivity results should be reported at flows in 100 mL/minute increments beginning at 100 mL/minute, up to the maximum flow permitted by the extracorporeal circuit pump of the unit in which the device is to be installed. Air detectors should respond to air or foam in saline or saline–blood mixtures and air or foam in blood, because large, rapid infusions of saline may be used to treat hypotension during dialysis. In ultrasonic detectors, the use of blood or water does not affect the detection of air; therefore, the requirement was changed in the revision to allow blood, water, or saline.

A.4.2.4.9 Disinfection protection

The hazards associated with improper system disinfection include bacterial contamination and proliferation, improper drain connections, failure of the disinfectant dispensing pump, retention of disinfectant at the end of the disinfection cycle, and failure of some device designs to incorporate protection against dialyzing a patient during the disinfection cycle (Keshaviah, et al., 1980). Residual disinfectants, if released during dialysis, may cause toxic reactions. Providing a disinfection–rinse interlock switch is one means of preventing accidental dialysis during the disinfection mode. Commercially available test materials enable monitoring for adequate removal of disinfectants. Use of any disinfectant requires knowledge of its toxicity and test methods to monitor its use.

A.4.4 Safety requirements

A.4.4.1 General safety requirements

Although some of these requirements may seem obvious, the committee thought that these safety requirements should be specified. Discussion surrounded the question of audible alarms that can be silenced. Some thought that audible alarms should not be capable of being silenced because the alarm condition could be overlooked by an attendant and a dangerous situation could ensue. Others suggested, particularly in the case of the home dialysis patient, that an audible alarm capable of being temporarily silenced would give the patient/operator a relatively unhurried period of time in which to correct the fault condition. The committee concluded that silencing an audible alarm for up to 180 seconds was a reasonable requirement, because this feature has been in widespread use without evidence of adverse effect.

A.4.4.2 Electrical safety requirements

1) The high impedance of the blood lines minimizes the risk of shock from connection of the hemodialysis device to the patient. The committee, therefore, suggested that compliance with the nonisolated patient connection requirements of ANSI/AAMI ES1:1993, *Safe current limits for electromedical apparatus* (normative reference 2.5) be mandated. These requirements allow 100 μA of risk current for the patient connection. Chassis risk current is limited to 300 μA. Further rationale for this requirement is contained in normative reference 2.5.

2) This requirement is necessary to reduce the risk of electrical hazard.

3) Temperature, humidity, atmospheric pressure, mechanical shock, corrosive substances used for disinfection, and similar environmental constraints can affect the performance or reliability of the device. To minimize hazard to the patient and operator, the equipment must be designed so that adverse effects from substances in the environment are minimized. Any horizontal surface, including that of a medical device, may be used as a repository for vessels containing conductive fluid such as saline. Therefore, it is important that the device be shielded from liquid spills and electrical components be resistant to corrosion. Water is used as the test fluid because it is only a marker for fluids entering the equipment and is more feasible for large-scale tests.

4) Because liquids used in dialysis are highly conductive, it is reasonable to require that hydraulic circuits of the device be separate and protected from electrical circuits, so as to minimize the hazard of short-circuiting and damaging the device or harming the operator.

5) The committee considered that any interruption of electrical power to the system should be made known to the patient or operator by means of an audible alarm.

NOTE—Electrical safety requirements addressed to users appear in the following documents: *Accreditation Manual for Hospitals*, Joint Commission on Accreditation of Healthcare Organizations, 1988; *National Electrical Code*, NFPA 70, Article 517, National Fire Protection Association, 1987; *Health Care Facilities*, NFPA 99, National Fire Protection Association, 1987.

A.4.4.3 Electromagnetic compatibility requirements

During the review of this document, this subclause was added to ensure that dialysis equipment is appropriately tested for electromagnetic compatibility. Hemodialysis systems are used in clinical settings where other medical devices, cell phones, and other sources of electromagnetic energy may be present. During the review of this topic, it was determined that under ANSI/AAMI/IEC 60601-1-2 (normative reference 2.9), hemodialysis equipment would be classified as non-life-supporting devices. The committee therefore considered that ANSI/AAMI/IEC 60601-1-2 testing for electromagnetic compatibility for systems that are not life supporting may be performed (see normative reference 2.9).

A.4.4.4 Fluid contact compatibility

Nontoxicity of construction materials for hemodialysis equipment is of major importance. Data now available demonstrates that materials once regarded as inert may in fact be toxic in this application (e.g., copper, brass, zinc, iron, and aluminum); these materials should be avoided. Some well-recognized nontoxic materials include certain stainless steel formulations, silicon rubber, borosilicate glass, polypropylene, polyvinylchloride, high density polyethylene, and polytetrafluorethylene. The hidden hazard of construction materials derives from long-term cumulative toxicity. Experience to date of more than 30 years of maintenance hemodialysis has not shown harm from chronic exposure to commonly used materials.

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