

American
National
Standard



ANSI/AAMI
RD47:2020

Reprocessing of
hemodialyzers

Reprocessing of hemodialyzers

Approved 23 December 2019 by
AAMI

Approved 16 January 2020 by
American National Standards Institute, Inc.

Abstract: This recommended practice is addressed to the physician responsible for reprocessing hemodialyzers. It covers personnel and patient considerations, records, equipment, physical plant and environmental safety, reprocessing material, patient identification and hemodialyzer labeling, reprocessing and storage procedures, disposition of rejected dialyzers, preparation for subsequent use, patient monitoring, and quality assurance and quality control. This document does not endorse either single use or reuse of dialyzers.

Keywords: blood, dialysis, labeling, medical equipment, packaging, personnel, records, reprocessing, reuse, test

AAMI Recommended Practice

This Association for the Advancement of Medical Instrumentation (AAMI) recommended practice implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI recommended practice does not in any respect preclude anyone, whether they have approved the recommended practice or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the recommended practice. AAMI recommended practices are subject to periodic review, and users are cautioned to obtain the latest editions.

CAUTION NOTICE: This AAMI recommended practice may be revised or withdrawn at any time.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

All AAMI standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Published by

AAMI
901 N. Glebe Road, Suite 300
Arlington, VA 22203
www.aami.org

© 2020 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this document should be submitted to AAMI. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, contact AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203. Phone: (703) 525-4890; Fax: (703) 276-0793.

Printed in the United States of America

ISBN 978-1-57020-738-9

Contents

Page

Committee representation	iv
Foreword.....	vi
Introduction: Need for this AAMI recommended practice	vii
1 Scope	9
2 Normative references	9
3 Definitions.....	10
4 Records.....	12
5 Personnel qualifications and training.....	13
6 Patient considerations	14
7 Equipment.....	14
8 Physical plant and environmental safety considerations	15
9 Reprocessing supplies	16
10 Hemodialyzer labeling.....	17
11 Reprocessing	17
12 Preparation for dialysis and testing for chemical germicides and potentially toxic residues	21
13 Monitoring.....	22
14 Quality assurance	23
Annexes	
A (informative) Rationale for the development and provisions of this recommended practice.....	26
B (normative) Systems diagram for reprocessing dialyzers.....	40
C (informative) Self-assessment of compliance with recommendations for hemodialyzer reprocessing	41
Bibliography	64
Tables	
1 OSHA environmental exposure limits (29 CFR 1910, 2018), except as indicated	15
2 Quality assurance audit schedule.....	24

Committee representation

Association for the Advancement of Medical Instrumentation

Renal Disease and Detoxification Committee

This recommended practice was developed by the AAMI Renal Disease and Detoxification Committee. Committee approval of the recommended practice 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: Jo-Ann Maltais, PhD
Denny Treu, BSME

Members: Tom Allocco, US Renal Care
Matthew J. Arduino, DrPH, U.S. Centers for Disease Control and Prevention
Christian Bluchel, Temesek Polytechnic
Aaron Brown, Baxter Healthcare
Karla Byrne, Rockwell Medical
Danilo B. Concepcion, CBNT, CCHT-A, FNKF, St. Joseph Health System
Deborah Cote, MSN, RN, CNN, National Renal Administrators Association
Martin Crnkovich, BSEE, Fresenius Medical Care
Conor Curtin, Boston, MA
Pamela Elliott, MHA, BSN, Florence, SC
Gema Gonzalez, U.S. Food and Drug Administration/CDRH/ODE
Kalub Hahne, PhD, Cook Research
Joe Haney, AmeriWater
Peter F. Haywood, AWAK Technologies
Steven Hoffman, CBET, Children's Hospital of Pittsburgh
Robert Hootkins, MD, PhD, FASN, ESRD Consulting, Texas
Byron Jacobs, CBET, GE Healthcare
Ted A. Kasperek, Davita
Kristi Keller, Iredell Health System
Kendall Larson, Mar Cor Purification
Robert Levin, Renal Research Institute
Jo-Ann Maltais, PhD, Maltais Consulting
Duane Martz, AAEE/MBA, B Braun of America
Bruce H. Merriman, Central Florida Kidney Centers
Klemens Meyer, MD, Tufts Medical Center
Thomas Meyer, Medtronic
Emily Michalak, AAS, BS, Satellite Healthcare
Paul E. Miller, MD, Dialysis Clinic/Kidney Consultants of Louisiana
Glenda Payne, RN, MS, CNN, American Nephrology Nurses Association
Toshiya Roberts, American Renal Associates
Joseph Sala, BSc Ed, Mount Sinai Medical Center
David Schmidt, Mayo Clinic
Chris Skarzynski, RN, McLeod Regional Medical Center
Vern S. Taaffe, Reprocessing Products Corporation
Denny Treu, BSME, NxStage Medical
Ashish Upadhyay, Boston University

Alternates: Logan Cabral, AmeriWater
Bruce Fife, Reprocessing Products Corporation
Anthony Messina, National Renal Administrators Association
Mark Metzger, Fresenius Medical Care
Mark Pasmore, PhD, Baxter Healthcare
Martin Roberts, PhD, AWAK Technologies
Ronald Trammell, American Renal Associates
Michael Verguldi, Mar Cor Purification
Keith D. Wheeler, NxStage Medical

Steven White, Medical Risk Management Consulting
Richard Williams, U.S. Food and Drug Administration/CDRH

NOTE—Participation by federal agency representatives in the development of this recommended practice does not constitute endorsement by the federal government or any of its agencies.

Foreword

This recommended practice was developed by the AAMI Renal Disease and Detoxification Committee. The committee's objectives are to acknowledge the practice of hemodialyzer reprocessing, without endorsement or criticism; to indicate risks associated with hemodialyzer reprocessing; and to provide recommendations for optimal hemodialyzer reprocessing, as a service to patients, physicians, and facilities.

This recommended practice reflects the conscientious efforts of health care professionals, patients, and medical device manufacturers to develop recommendations for optimal hemodialyzer reprocessing procedures. These recommendations are not meant to be construed as universally applicable in all circumstances. This document is intended to guide physicians in charge of hemodialyzer reprocessing, particularly the directors of dialysis facilities, in initiating a new hemodialyzer reprocessing program or evaluating an existing program against present day technology and accepted practices.

This recommended practice should be considered flexible and dynamic. As technology advances and new data are brought forward, this recommended practice will be reviewed and, if necessary, revised. The term "should" as used in this recommended practice reflects the committee's intent to define goals, not requirements. The term "shall" as used here denotes quality recommendations and procedures that are required by applicable standards. The term "must" is used only to describe unavoidable situations, including those mandated by government regulation.

The use of phrases such as "have been shown," "an established procedure," "demonstrated success," or others of similar words signifies that the basis for the process may be found in a manufacturer's labeling, medical or scientific literature, standards or publications from authoritative agencies, or clearly documented, scientifically sound studies performed locally.

These guidelines were developed by professionals and are not designed for regulatory applications but have been put into service as such.

The concepts incorporated in this recommended practice should not be considered inflexible or static. The recommendations presented here should be reviewed and updated periodically to assimilate technological developments.

The rationale for this recommended practice (annex A) not only contains explanations of the need for the provisions of the recommended practice, but also gives proposed revisions that were not included in this recommended practice and the reasons for those exclusions. The reader is encouraged to review the rationale for each section carefully to better understand the recommended practice itself and the state of the art in reprocessing hemodialyzers.

AAMI standards and guidelines are based on the national consensus of physicians, engineers, other health care professionals, government representatives, patients, and industry. This consensus has traditionally focused on technology design, performance, and testing—areas in which the AAMI membership has considerable knowledge and experience. During the development of this document, several interest groups requested detailed requirements for informed patient consent with respect to the reuse of hemodialyzers. It is unclear whether informed patient consent requirements can or should be developed by a consensus of the groups mentioned. It may be more appropriate for informed patient consent requirements to be developed by physicians, patients, and their representatives. This document does not go as far as the patients' representatives requested on that subject, although it does go further than previous documents of this type. The extent to which AAMI or any standards organization should develop informed patient consent requirements can be determined as this guideline is evaluated during its use.

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

NOTE—This foreword does not contain provisions of the American National Standard ANSI/AAMI RD47:2020, *Reprocessing of hemodialyzers*, but it does provide important information about the development and intended use of the document.

Introduction: Need for this AAMI recommended practice

In June 1980, the Bureau of Medical Devices of the U.S. Food and Drug Administration (FDA), now the Center for Devices and Radiological Health, transmitted to AAMI the final report of an FDA-sponsored study, "An Investigation of the Risks and Hazards Associated with Hemodialysis Devices," that was undertaken to recommend ways of controlling these risks and hazards. This information was compiled to assist the medical community and to provide data to support the development of recommended practices.

Beginning in 1980, the reported incidence of hemodialyzer reuse rose dramatically, from an estimated 16 % of patients in 1980 to an estimated 82 % of clinics in 1997. This increase was attributable, in part, to the increasing pressure of federal measures to contain the costs of health care implemented by the prospective reimbursement regulations initiated on 1 August 1983. The percentage of centers practicing reuse declined after 1997 to 63 % in 2002 (Finelli, et al., 2005), and in 2005, it was estimated that 61 % of patients were being treated with single-use dialyzers (Lacson and Lazarus, 2006).

Although good results have been demonstrated by the practitioner experienced in hemodialyzer reprocessing, the widespread application of this technique in the absence of detailed consensus guidelines has created greater opportunities for the nonexpert practitioner to use inadequate methods. Moreover, cost saving by any procedure that adds risks to the patient if improperly done may cause some patients and health care professionals to suspect that the welfare of the patient may not be the primary concern. These fears may be justified, because merely claiming that reuse is safe, without defining details of the process, allows unsafe procedures to appear under the guise of acceptable medical practice. Thus, failure to ensure that reuse is done safely for all patients causes the brush of mistrust to paint all practitioners alike, when, in fact, the multiple use of hemodialyzers may actually improve the quality of care and access to dialysis. Those who are expert in reprocessing hemodialyzers can, therefore, perform a valuable service by developing guidelines for the less experienced practitioner that will achieve the high quality of care that health care professionals want for their patients. This recommended practice has been written to respond to the concern of patients, health care professionals, and manufacturers that dialyzer reprocessing be conducted safely and effectively.

It was against this background that AAMI convened a consensus-development conference in May 1983 to examine the issues surrounding reuse of hemodialyzers and to discuss the position of the medical and scientific community on the subject. One recommendation emerging from this conference, in which representatives from many medical and scientific societies participated, was that approval by consensus of a nationally developed recommended practice for the reprocessing of hemodialyzers was desirable and necessary for patient safety and continued clinical efficacy. Another recommendation was that the guidelines be developed under the auspices of AAMI because AAMI could coordinate the development of a national consensus. AAMI subsequently established the Hemodialyzer Reuse Subcommittee of the Renal Disease and Detoxification Committee. The subcommittee's membership includes representatives of manufacturers, patients, health care organizations, government agencies, and health care professionals.

In November 1984, an AAMI technology assessment conference was held on the subject of hemodialyzer reuse. The conference attendees reviewed the fourth draft of the recommended practice being written by the AAMI subcommittee. Presentations were also made about the results of a survey of hemodialyzer reprocessing in the United States, water for reprocessing, germicides, statistical analysis, methods of performance testing, reprocessing machines, the perspective of patients, the viewpoint of manufacturers, reprocessing in the home, and the FDA's position on the reprocessing of medical devices. Future revisions of the recommended practice incorporated information gleaned from the conference and comments from other interested parties. In October 1987, the Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration, adopted the recommended practice as part of their regulations governing Medicare reimbursement. Because the guideline was not constructed as a regulation, many questions arose as surveyors attempted to enforce compliance. The AAMI Hemodialyzer Reuse Subcommittee issued an interpretive guideline in 1991 that clarified the issue of dialyzer performance verification, the most common source of misunderstanding in the previous version. When the reuse document was reviewed in 1993, the interpretation was incorporated. Subsequently, the CMS adopted the 1993 revisions in a manner similar to their adoption of the 1987 version. Dialyzer manufacturers are now expected to follow the FDA guidance document titled "Guidance for Hemodialyzer Reuse Labeling" (6 October 1995). This guidance Galvreuse, the FDA guidance document requires that the manufacturer perform certain bench testing using simulated reuse and then perform a limited clinical trial to support the bench results. Those data are submitted to the FDA and reviewed as part of the 510(k) Premarket Notification for the reusable dialyzer.

In the early 1990s, a statistically significant association was reported between mortality and the use of low-flux dialyzers reprocessed with certain germicides in freestanding clinics (Held, et al., 1994; Feldman, et al., 1996). No cause-and-effect relationship was established in those studies, and potentially confounding variables, such as a "center effect" and the adequacy of dialysis, were not evaluated. Indeed, the results of more recent studies (Collins,

et al., 1998; Ebben, et al., 2000; Port, et al., 2001) suggest that factors other than the choice of germicide may have contributed to the differences in outcome. In addition, in 2011 Bond et al wrote that “Dialyzer reuse with peracetic acid does not impact patient mortality.” In 2012 Galvao et al concluded that “no significant differences were identified for the superiority or inferiority of dialyzer reuse versus single use when assessing the mortality of patients with end-stage renal disease”. The disinfectants used in the Galvao study on dialyzer reprocessing were hypochlorite, formaldehyde, glutaraldehyde, and peracetic acid.

In 2018, the percentage of centers practicing dialyzer reuse in the United States is estimated to have declined to less than 10 percent. While the practice of dialyzer reuse is no longer common within the United States, this document continues to be relevant and important for those centers in the United States (and outside the United States) that continue to practice dialyzer reuse. Moreover, in 2018, the Centers for Medicare and Medicaid Services (CMS)—in its Interpretive Guidance document (Version 1.1, October 3, 2008) used to survey (audit) dialysis centers—continues to incorporate by reference ANSI/AAMI RD47:2002/A1:2003. To withdraw RD47 would remove the document from publication and the ability to acquire the full stand-alone document for use in reference and self-assessment of a dialyzer reuse program. The AAMI RDD Committee also considered that in the event of a disaster scenario, it would be possible that it could become necessary to reuse dialyzers.

Reprocessing of hemodialyzers

1 Scope

This recommended practice describes the essential elements of good practice for reprocessing hemodialyzers to help ensure device safety and effectiveness. These practices embrace considerations of the device and the patient, as well as attention to equipment, facilities, cleaning and disinfection methods, labeling, preparation for multiple use, and quality control of the reuse process. This document does not endorse either single use or reuse of dialyzers.

Regardless of the labeling recommendations, prescription to reuse remains the sole responsibility of the patient's physicians. Therefore, this recommended practice is addressed to the physician responsible for the hemodialyzer reprocessing program. Users, however, should be aware that dialyzers intended for reuse shall be labeled for reuse in accordance with the Food and Drug Administration (FDA) document "Guidance for Hemodialyzer Reuse Labeling" (6 October 1995).

The committee recognizes that reuse may affect such dialyzer characteristics as biocompatibility and clearance of larger molecules. Changes in dialyzer performance and biocompatibility vary with the materials of construction and the reuse method employed. Detailed analysis of these factors is beyond the scope of this document. Specific information on the effects of reuse on dialyzer performance and biocompatibility may be obtained from the dialyzer manufacturer and the scientific literature (Cheung, et al., 1999). This recommended practice does not address every risk or benefit that may be associated with reuse.

1.1 Inclusions

This recommended practice is directed to the physician in charge of hemodialyzer reprocessing by either the manual or the automated method. Subjects included within the scope of this recommended practice are recordkeeping, personnel considerations, patient considerations, equipment considerations, physical plant and environmental safety, reprocessing material considerations, patient identification and hemodialyzer labeling, reprocessing and storage procedures, disposition of rejected dialyzers, preparation for subsequent use, patient monitoring, quality assurance, and quality control.

1.2 Exclusions

This recommended practice does not cover the reprocessing of blood tubing sets, nor does it address labeling and performance requirements for single-use hemodialyzers.

2 Normative references

The following documents contain provisions that, through reference in this text, constitute provisions of this AAMI recommended practice. At the time of publication, the editions indicated were valid. All recommended practices are subject to revision, and parties to agreements that are based on this AAMI recommended practice are encouraged to investigate the possibility of applying the most recent editions of the documents listed below.

International Organization for Standardization (ISO). ISO 23500-3, *Preparation and quality management of fluids for haemodialysis and related therapies -- Part 3: Water for haemodialysis and related therapies*. Geneva, Switzerland: ISO, 2019.

Bolyard EA, Tablan OC, Williams WW, Pearson ML, Shapiro CN, Deitchman SD, and Hospital Infection Control Practices Advisory Committee. Infection Control in Healthcare Personnel: Guideline for infection control in healthcare personnel, 1998. *Infection Control and Hospital Epidemiology*, 19:407–463,1998. (available from http://www.cdc.gov/ncidod/dhqp/gl_hcpersonnel.html)

Centers for Disease Control and Prevention. *Recommendations for preventing transmission of infections among hemodialysis patients*. *MMWR* 50, RR-5, 2001. (available from <http://www.cdc.gov/mmwr/PDF/rr/rr5005.pdf>)