AAMI TIR77: 2018
Sorbent-based regenerative hemodialysis systems
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Abstract: Provides useful technical information that addresses common aspects pertaining to development and use of sorbent-based regenerative hemodialysis systems and a review of existing hemodialysis standards within the context of sorbent-based regenerative hemodialysis systems.

Keywords: clinical, fluid, solute, source, water
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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

Published by
AAMI
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633
www.aami.org

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Printed in the United States of America
ISBN 978-1-57020-703-7
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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf
Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Renal Disease and Detoxification Committee

This Technical Information Report was developed by the AAMI Renal Disease and Detoxification Committee. Committee approval of the Technical Information Report 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:

Co-chairs: Jo-Ann Maltais, PhD
Denny Treu, BSME

Members:
Matthew Arduino, DrPH, Centers for Disease Control and Prevention
Christian Gert Bluchel, Temasek Polytechnic, Singapore
Aaron W. Brown, Baxter Healthcare Inc.
Karla S. Byrne, Rockwell Medical Inc.
Monet Carnahan, Nephros Inc.
Danilo B. Concepcion, CBN, CCHT-A, FNKF, St. Joseph Hospital Renal Center
Deborah Cote, MSN RD CNN, National Renal Administrators Association
Martin Crnkovich, Fresenius Medical Care N.A.
Conor Curtin, Massachusetts, USA
R. Barry Deeter, RN, MSN, University of Utah Dialysis Program
Gema Gonzalez, U.S. Food and Drug Administration/CDRH/ODE
Joe Haney, Ameriwater
Peter Ferdinand Haywood, AWAK Technologies
Steven J. Hoffman, CBET, Children’s Hospital of Pittsburgh, PA
Robert Hootkins, MD PhD FASN, Austin, TX
Elizabeth Howard, DaVita Inc.
Byron L. Jacobs, CBET, GE Healthcare
Kendall Larson, MarCor Purification
Robert L. Levin, MD, Renal Research Institute
Jo-Ann Maltais, PhD, Maltais Consulting
Duane Martz, AAEE/MBA, B Braun of America Inc
Bruce H. Merriman, Central Florida Kidney Centers
Klemens Meyer, Tufts Medical Center
Thomas Meyer, Medtronic, Inc.
Emily Michalak, AAS BS, Satellite Healthcare
Paul E. Miller, MD, Dialysis Clinic Inc./Kidney Consultants of Louisiana
Glenda Payne, MS, RN, CNN, American Nephrology Nurses’ Association
Toshiya Roberts, American Renal Associates
Joseph Sala, SSCE, Mount Sinai Medical Center
David Schmidt, Mayo Clinic, MN
Chris Skarzynski, RN, McLeod Regional Medical Center
Vern S. Taaffe, Reprocessing Products Corp (RPC)
Denny Treu, BSME, NxStage Medical Inc.
Ashish Upadhyay, Boston U. School of Medicine
Robert J. Vargo, Dialysis Clinic Inc., PA

Alternates:
Gregory Collins, PhD, Nephros Inc.
Diane Dolan, Ameriwater
Martin T. Gerber, Medtronic, Inc.
Roger Hall, Reprocessing Products Corp (RPC)
Ted A. Kasparek, DaVita Inc.
Anthony Messana, National Renal Administrators Association
Mark Metzger, Fresenius Medical Care
Mark Pasmore, PhD, Baxter Healthcare
Martin Roberts, AWAK Technologies Pte. Ltd.)
AAMI also acknowledges the **Sorbent Task Group**, comprising the following members, for its special contribution in the development of this document:

*Task group leader:* Thomas Meyer, Medtronic, Inc.

*Members:*
- Christian Gert Bluchel, PhD, Temasek Polytechnic, Singapore
- Stephen Merchant, PhD, Fresenius Medical Care
- Fokko Pieter Wieringa, PhD, Dutch Kidney Foundation & imec, Netherlands

**NOTE** Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.
Foreword

This technical information report was developed by the AAMI Renal Disease and Detoxification Committee. The objective is to provide useful technical information that addresses common aspects pertaining to development and use of sorbent-based regenerative hemodialysis systems and a review of existing hemodialysis standards within the context of sorbent-based regenerative hemodialysis systems.

Suggestions for improving this technical information report are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

NOTE  This foreword does not contain provisions of the AAMI TIR77, Sorbent-based regenerative hemodialysis systems, but it does provide important information about the development and intended use of the document.
Introduction

This technical information report (TIR) addresses the development and safe use of sorbent-based regenerative hemodialysis systems. Sorbent-based regenerative hemodialysis systems differ from other common hemodialysis systems (so-called “single pass” systems). Sorbent-based regenerative hemodialysis systems recycle dialysis fluid that has passed through the dialyzer (which in a single pass system would be discarded as spent dialysis fluid) by a regenerative process that removes unwanted substances from the spent dialysis fluid and replaces desired substances to produce a regenerated fresh dialysis fluid. The regenerated fresh dialysis fluid is passed again through the dialyzer to repeat the cycle.

Many aspects of the existing standards for hemodialysis relate to single pass hemodialysis systems that expose the patient to dialysis fluid produced from large volumes of source water. As stated in the introduction to ANSI/AAMI 13959, “Hemodialysis and hemodiafiltration can expose the patient to more than 500 l of water per week across the semi-permeable membrane of the hemodialyzer or hemodiafilter. Healthy individuals seldom have a weekly oral intake above 12 l. This over 40-fold increase in exposure requires control and monitoring of water quality to avoid excesses of known or suspected harmful substances.” These large volumes of water are characteristic of conventional single pass hemodialysis delivery systems.

Sorbent-based regenerative hemodialysis systems have two distinguishing characteristics. First, water for dialysis, as described in ANSI/AAMI 13959, may not be present as an intermediate stage of dialysis fluid preparation in sorbent-based regenerative hemodialysis systems. Also, the volume of water that a patient is exposed to can be much less (for example, 20L weekly vs 500L weekly).

Although sorbent-based regenerative hemodialysis systems were first marketed in 1973 and successfully used for decades, existing hemodialysis standards do not address some common aspects of sorbent-based regenerative hemodialysis systems. Hence there is a need to provide technical information related to these systems. This TIR seeks to provide useful technical information that addresses common aspects of sorbent-based regenerative hemodialysis systems and highlight relevant connections with existing hemodialysis standards within the context of sorbent-based regenerative hemodialysis systems.

Because sorbent-based regenerative hemodialysis system concepts can vary greatly, depending on how engineering trade-offs are configured, this Technical Information Report pertains to a wide variety of possible configurations.
Sorbent-based regenerative hemodialysis systems

1. Scope

This Technical Information Report (TIR) addresses common aspects that pertain to the development and safe use of sorbent-based regenerative hemodialysis, hemodiafiltration, and hemofiltration systems. This TIR also provides a review of existing hemodialysis standards within the context of sorbent-based regenerative hemodialysis systems.

1.1 General

Sorbent-based regenerative hemodialysis systems prepare dialysis fluid by a regenerative process that removes unwanted substances from spent dialysis fluid and replaces desired substances to produce a regenerated fresh dialysis fluid to continue a hemodialysis treatment. Such systems may prepare the starting dialysis fluid from source water and electrolytes or may start from pre-manufactured dialysis fluid.

1.2 Inclusion

This TIR addresses hemodialysis systems that regenerate dialysis fluid by exposing the dialysis fluid to materials that act by means of adsorption, catalysis, filtration, and exchange and infusing desired substances. Unless otherwise noted, references in this document to sorbent-based regenerative hemodialysis include sorbent-based hemodiafiltration and sorbent-based hemofiltration.

1.3 Exclusion

This TIR does not include:

- Peritoneal Dialysis Systems
- Single Pass Hemodialysis Systems
- Batch Hemodialysis Systems
- Non Sorbent-Based Dialysis fluid Regeneration Systems

2 Informative references

The following documents contain provisions that, through reference in this text, constitute provisions of this TIR. Only the dated edition cited below applies. Note that as a Technical Information Report (TIR) this document is not a standard, and therefore not normative. This section is provided for information only.

ANSI/AAMI 23500:2014, Guidance for the preparation and quality management of fluids for hemodialysis and related therapies

ANSI/AAMI 26772:2014, Water treatment equipment for hemodialysis and related therapies

ANSI/AAMI 13959:2014, Water for hemodialysis and related therapies

ANSI/AAMI 13958:2014, Concentrates for hemodialysis and related therapies

ANSI/AAMI 11663:2014, Quality of dialysis fluid for dialysis and related therapies

NOTE At the time of publication, 23500, 26772, 13959, 13958, and 11663 were in development in ISO as 23500 series standards.

AAMI TIR43:2011, Ultrapure dialysate for hemodialysis and related therapies

ANSI/AAMI/IEC 60601-2-16:2012, Medical Electrical Equipment – Part 2-16: Particular requirements for the basic