Technical Information Report

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Sorbent-based regenerative hemodialysis systems

AAMI
Advancing Safety in Health Technology

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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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

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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.

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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.

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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.

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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*