Technical Information Report

AAMI TIR43: 2021

Ultrapure dialysis fluid for hemodialysis and related therapies

AAMI
Advancing Safety in Health Technology

Ultrapure dialysis fluid for hemodialysis and related therapies

Approved 26 February 2021 by
AAMI

Abstract: Addresses preparation and use of ultrapure fluids to perform hemodialysis. Fluids include water and dialysis fluid. Includes the definition of ultrapure fluids, the rationale for their use, and the means by which they can be prepared. Does not cover peritoneal dialysis fluids.

Keywords: fluid, preparation, use, water

AAMI Technical Information Report

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N Glebe Rd., Suite 300, Arlington, VA 22203-1633

Published by

Association for the Advancement of Medical Instrumentation
901 N Glebe Rd., Suite 300
Arlington, VA 22203-1633
www.aami.org

Printed in the United States of America

ISBN 978-1-57020-815-7

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Committee representation

Association for the Advancement of Medical Instrumentation

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:

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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.

Foreword

This technical information report was developed by the AAMI Renal Disease and Detoxification Committee. The objective is to provide technical information that will assist medical device manufacturers in determining acceptable levels of particulate on medical device products used to deliver or implant into the vasculature, or both.

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- "shall" and "shall not" are used to express requirements;
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Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

NOTE This foreword does not contain provisions of the AAMI TIR43, *Ultrapure dialysis fluid for hemodialysis and related therapies* (AAMI TIR43:2021), but it does provide important information about the development and intended use of the document.

Introduction

Hemodialysis patients are directly exposed to large volumes of dialysis fluid, with the dialyser membrane being the only barrier against the transfer of potentially hazardous contaminants from the dialysis fluid to the patient. It has long been known that there could be contaminants in dialysis fluid that are hazardous to patients. To minimize this hazard, ANSI/AAMI/ISO 23500-5:2019, *Guidance for the preparation and quality management of fluids for haemodialysis and related therapies — Part 5: Quality of dialysis fluid for hemodialysis and related therapies* [1], establishes quality requirements for dialysis fluid used in hemodialysis and related therapies. These quality requirements define two classes of dialysis fluid: standard dialysis fluid and ultrapure dialysis fluid. The maximum allowable levels of chemical contaminants are the same for both standard dialysis fluid and ultrapure dialysis fluid; however, they differ in the maximum allowable levels of microbial contaminants. According to ANSI/AAMI/ISO 23500-1:2019, *Guidance for the preparation and quality management of fluids for hemodialysis and related therapies — Part 1: General requirements* [2], dialysis fluid complying with the requirements for standard dialysis fluid is the minimum quality acceptable for routine hemodialysis. However, it recommends that ultrapure dialysis fluid be used, even for routine hemodialysis. The recommendation is based on clinical and experimental observations that improving the microbiological purity of dialysis fluid is associated with reduced levels of inflammation and a reduction in morbidities associated with inflammation. These apparent advantages of ultrapure dialysis fluid might not be widely appreciated and implementing the routine use of ultrapure dialysis fluid could require changes in dialysis unit practices. For these reasons, this Technical Information Report was developed to provide background information on ultrapure dialysis fluid, and to review strategies that could be helpful in implementing its routine use.

This Technical Information Report is directed at healthcare professionals involved in the management of dialysis facilities (dialysis units) and the routine care of patients treated in dialysis facilities, because they are responsible for the final preparation of dialysis fluid.

Ultrapure dialysis fluid for hemodialysis and related therapies

1 Scope

This Technical Information Report (TIR) addresses the preparation of ultrapure dialysis fluid from water and concentrates and its use in performing hemodialysis and related therapies in dialysis facilities (dialysis units).

1.1 Inclusions

The Technical Information Report includes the definition of ultrapure dialysis fluid, the rationale for its use, and some means by which it can be prepared and other considerations. Manufacturer and user roles and responsibilities are presented.

1.2 Exclusions

This Technical Information Report does not cover peritoneal dialysis fluids or prepackaged dialysis fluids, such as those used in continuous renal replacement therapies (CRRT). This TIR does not apply to home dialysis systems.

NOTE While this TIR is primarily directed at the preparation of ultrapure dialysate in dialysis facilities, aspects of it might also apply to home dialysis with standard dialysis machines.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

Ultrapure dialysis fluid is defined by the level of microbiological contamination. While chemical contaminants in the dialysis fluid can harm patients, there is as yet no evidence to show that reducing chemical contaminant levels below those specified in ANSI/AAMI/ISO 23500-3, *Guidance for the preparation and quality management of fluids for haemodialysis and related therapies -- Part 3: Water for haemodialysis and related therapies* [3], improves patient outcomes. Therefore, this clause is limited to defining different levels of dialysis fluid quality based on microbiological contaminants.

3.1
dialysis fluid
dialysate
dialysis solution
aqueous fluid containing electrolytes and, usually, buffer and glucose, which is intended to exchange with blood contaminants during hemodialysis and hemodiafiltration.

Note 1 to entry: The term “dialysis fluid” is used throughout this document to mean the fluid made from dialysis water and concentrates that is delivered to the dialyser by the dialysis fluid delivery system. Such phrases as “dialysate” or “dialysis solution” are used in place of dialysis fluid in some countries; however, that usage is discouraged to avoid confusion.

Note 2 to entry: ANSI/AAMI/ISO 23500-5 [1] defines three levels of dialysis fluid: standard dialysis fluid, ultrapure dialysis fluid, and online-prepared substitution fluid used for haemodiafiltration.

Note 3 to entry: The dialysis fluid entering the dialyser is referred to as “fresh dialysis fluid”, while the fluid leaving the dialyser is referred to as “spent dialysis fluid.”

