

American
National
Standard

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

Currently in preview, click buy full version

Quality of dialysis fluid for hemodialysis and related therapies

Approved 21 July 2014 by
Association for the Advancement of Medical Instrumentation

Approved 8 August 2014 by
American National Standards Institute, Inc.

Abstract: Specifies minimum quality requirements for dialysis fluids used in hemodialysis and related therapies. Includes dialysis fluids used for hemodialysis and hemodiafiltration, including substitution fluid for hemodiafiltration and hemofiltration.

Keywords: action, chemical, contaminant, endotoxin, microbiological, compliance

AAMI Standard

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

CAUTION NOTICE: This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than five years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI, or by visiting the AAMI website at www.aami.org.

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

Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Drive, Suite 301
Arlington, VA 22203-1633
www.aami.org

© 2014 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

Publication, reproduction, photocopying, storage, or transmission, electronically or otherwise, of all or any part of this document without the prior written permission of the Association for the Advancement of Medical Instrumentation is strictly prohibited by law. 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, complete the reprint request form at www.aami.org or contact AAMI at 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203. Phone: (703) 525-4890; Fax: (703) 525-1067.

Printed in the United States of America

ISBN 1-57020-547-7

Contents

Page

Glossary of equivalent standards.....	iv
Committee representation.....	v
US deviation to ISO 11663:2014.....	vi
Introduction	v
1 Scope.....	1
2 Normative references	1
3 Terms and definitions.....	1
4 Requirements.....	6
4.1 Microbiological contaminants in dialysis fluid	6
4.2 Chemical contaminants in dialysis fluid.....	7
5 Tests for compliance with microbiological requirements.....	7
Annex A (informative) Rationale for the development and provisions of this International Standard	9
Annex B (informative) Reference tables from ISO 13959	12
Bibliography	16

Currently in preview, click buy full version

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

Currently in preview, click buy full version

Committee representation

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

This American National Standard was developed by the AAMI Renal Disease and Detoxification Committee. Approval of the American National 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:

<i>Chairs:</i>	Conor Curtin David Roer, MD, FACP, FASN, FASH
<i>Members:</i>	G Steven Acres, MD, Carolina Regional Nephrology Associates James Weldon Baker, AmeriWater Alex Barten, Baxter Healthcare Corporation Christian Gert Bluchel, AWAK Technologies Pte Ltd. Karla S. Byrne, Rockwell Medical Inc Danilo B. Concepcion, CBNT, CCHT-A, St Joseph Hospital Renal Center Deborah A. Cote, MSN, RN, CNN, National Renal Administrators Association Conor Curtin, Fresenius Medical Care North America Jim Curtis, Portland, OR R. Barry Deeter, RN MSN, University of Utah Dialysis Program Martin T. Gerber, Medtronic Inc. Gema Gonzalez, FDA/CDRH/ODE Elizabeth Howard, DaVita, Inc. Byron L. Jacobs, CBET, Sanford USD Medical Center Judith Kari, Health Care Financing Administration Kendall Larson, Mar Cor Purification Nathan W. Levin, MD, Renal Research Institute LLC Jo Ann Maltais, PhD, Maltais Consulting Duane Martz, B Braun of America Inc. Lane McCarthy, CCHT, Hometown & Louis Rubin Dialysis Center Bruce H. Merriman, Central Florida Kidney Centers Klemens Meyer, MD, Tufts Medical Center Paul E. Miller, MD, Kidney Consultants of Louisiana Judith Noble-Wang, Centers for Disease Control and Prevention Glenda Payne, RN, MS, CNN, American Nephrology Nurses Association David Roer, MD, FACP, FASN, FASH, Nephrology and Hypertension Associates David Schmitt, Mayo Clinic, Rochester, MN James D. Stewardson, Brighton, CO Vern S. Taaffe, Reprocessing Products Corp Dennis Teu, BSME, NxStage Medical Inc Robert Vargo, Dialysis Clinic Inc.
<i>Alternates:</i>	Roger Hall, Reprocessing Products Corp Ted A. Kasperek, DaVita, Inc. Robert Levin, Renal Research Institute LLC Ken Leyboldt, Baxter Healthcare Corporation Anthony Messana, National Renal Administrators Association Thomas Meyer, Medtronic Inc. Martin Roberts, AWAK Technologies Pte Ltd Brooks E. Rogers, Fresenius Medical Care North America Teri B. Spencer, RN, TB Spencer Consulting LLC Michael Verguldi, Mar Cor Purification

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

US deviation to ISO 11663:2014

The International Organization for Standardization (ISO) published ISO 11663:2014, *Quality of dialysis fluid for haemodialysis and related therapies* as a revision of ISO 11663:2009 on 2014-04-01. The United States is one of the ISO members that took an active role in the development of this standard, which was developed by ISO Technical Committee 150, Subcommittee 2, *Cardiovascular implants and extracorporeal systems*, to fill a need for minimum quality requirements for dialysis fluids used in haemodialysis and related therapies. The 2014 ISO revision editorially aligned ISO 11663 with the ISO dialysis fluid standards ISO 13958, ISO 13959, ISO 23500, and ISO 26722 which had been developed serially over several years.

U.S. participation in this ISO TC is organized through the U.S. Technical Advisory Group for ISO/TC 150/SC 2, administered by the Association for the Advancement of Medical Instrumentation (AAMI). The U.S. TAG for ISO/TC 150/SC 2 supports the guidance provided in this document.

While considering the US adoption of ISO 11663:2014, the AAMI Renal Disease and Detoxification Committee (U.S. sub-TAG for ISO/TC 150/SC 2/WG 5, Renal replacement, detoxification and apheresis) approved a US deviation to the International Standard. ANSI/AAMI 11663:2014 deviates from ISO 11663:2014 in the following aspect:

The fifth paragraph of Clause 5, Tests for compliance with microbiological requirements, which in ISO 11663:2014 reads:

“Culture media shall be tryptone glucose extract agar (TGEA) or Reasoner’s 2A supplemented with 4 % sodium bicarbonate, or equivalent. Blood or chocolate agar shall not be used. Incubation temperatures of 17 °C to 23 °C, and an incubation time of 168 h (7 d) are recommended. Other test methods may also be used, provided such methods have been appropriately validated and compared to the cited methods.”

is replaced in ANSI/AAMI 11663:2014 by the following:

“Approved culture methods shall include one of the following:

- 1) tryptone glucose extract agar (TGEA) or Reasoner’s 2A supplemented with 4 % sodium bicarbonate, or equivalent. Blood or chocolate agar shall not be used. Incubation temperatures of 17 °C to 23 °C, and an incubation time of 168 h (7 d); or
- 2) Trypticase soy agar (TSA, a soybean casein digest agar) or standards method agar and plate count agar (also known as TGYE), incubated at 35 °C for 48 hours.

Other test methods may also be used, provided such methods have been appropriately validated and compared to the cited methods. See USP <1231> for guidance on adoption of alternative methods.”

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4300 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

Introduction

Hemodialysis patients are directly exposed to large volumes of dialysis fluid, with the dialyzer membrane being the only barrier against transfer of hazardous contaminants from the dialysis fluid to the patient. It has long been known that there could be hazardous contaminants in the water and concentrates used to prepare the dialysis fluid. To minimize this hazard, ISO 13958 and ISO 13959 set forth quality requirements for the water and concentrates used to prepare dialysis fluid. However, if the dialysis fluid is not prepared carefully, it could contain unacceptable levels of contaminants even though it is prepared from water and concentrates, meeting the requirements of ISO 13958 and ISO 13959. Further, the dialysis fluid might be used as the starting material for the online preparation of fluids intended for infusion into the patient, for example, in therapies such as online hemodiafiltration. For these reasons, this International Standard for dialysis fluid quality was developed to complement the existing International Standards for water and concentrates, ISO 13959 and ISO 13958, respectively. Guidelines to aid the user in routinely meeting the requirements of this International Standard and ISO 13959 can be found in ISO 23500.

Within these International Standards, measurement techniques current at the time of preparation have been cited. Other standard methods can be used, provided that such methods have been appropriately validated and compared to the cited methods. This International Standard reflects the conscientious efforts of healthcare professionals, patients, and medical device manufacturers to develop recommendations for the quality of dialysis fluid. This International Standard is directed at the healthcare professionals involved in the management of dialysis facilities and the routine care of patients treated in dialysis facilities, since they are responsible for the final preparation of dialysis fluid. The recommendations contained in this International Standard are not intended for regulatory application.

The requirements of this International Standard aim to help protect hemodialysis patients from adverse effects arising from known chemical and microbiological contaminants that can be found in improperly prepared dialysis fluid. However, the physician in charge of dialysis has the ultimate responsibility for ensuring that the dialysis fluid is correctly formulated and meets the requirements of all applicable quality standards.

The verbal forms used in this International Standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this International Standard, the auxiliary verb

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this International Standard,
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this International Standard, and
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

The concepts incorporated in this International Standard should not be considered inflexible or static. The recommendations presented here should be reviewed periodically in order to assimilate increased understanding of the role of dialysis fluid purity in patient outcomes and technological developments.

Currently in preview, click buy full version

Quality of dialysis fluid for hemodialysis and related therapies

1 Scope

This International Standard specifies minimum quality requirements for dialysis fluids used in hemodialysis and related therapies. This International Standard includes dialysis fluids used for hemodialysis and hemodiafiltration, including substitution fluid for hemodiafiltration and hemofiltration. This International Standard does not address the requirements for the water and concentrates used to prepare dialysis fluid or the equipment used in its preparation. Those areas are covered by other International Standards.

Sorbent-based dialysis fluid regeneration systems that regenerate and recirculate small volumes of dialysis fluid, systems for continuous renal replacement therapy that use prepackaged solutions, and systems and solutions for peritoneal dialysis are excluded from this International Standard.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 13958, *Concentrates for hemodialysis and related therapies*

ISO 13959, *Quality of water for hemodialysis and related therapies*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

acid concentrate

A-concentrate

acidified concentrated mixture of salts that, when diluted with dialysis water and bicarbonate concentrate, yields dialysis fluid for use in dialysis

Note 1 to entry: The term “acid” refers to the small amount of acid (for example, acetic acid or citric acid) that is included in the concentrate.

Note 2 to entry: Acid concentrate may contain glucose.

Note 3 to entry: Acid concentrate may be in the form of a liquid, a dry powder, other highly concentrated media, or some combination of these forms.