

# American National Standard



## ANSI/AAMI/ ISO 23500-2: 2019

Preparation and quality  
management of fluids for  
haemodialysis and related  
therapies—Part 2: Water  
treatment equipment for  
haemodialysis applications  
and related therapies

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**American National Standard**

**ANSI/AAMI/ISO 23500-2:2019**  
(Revision of ANSI/AAMI 26722:2014)

# **Preparation and quality management of fluids for haemodialysis and related therapies—Part 2: Water treatment equipment for haemodialysis applications and related therapies**

Approved 23 December 2019 by  
**AAMI**

Approved 28 January 2020 by  
**American National Standards Institute, Inc.**

**Abstract:** Covers devices used to treat potable water intended for use in the delivery of haemodialysis and related therapies, including water used for the preparation of concentrates from powder or other highly concentrated media at a dialysis facility; the preparation of dialysis fluid, including dialysis fluid that can be used for the preparation of substitution fluid; the reprocessing of dialysers intended for single use where permitted for multiple uses, and the reprocessing of dialysers not specifically marked as intended for single use.

**Keywords:** action, acid, biofilm, chlorine, compliance, endotoxin, labeling pyrogen

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## Committee representation

### Association for the Advancement of Medical Instrumentation

#### Renal Disease and Detoxification Committee

This standard was developed by the AAMI Renal Disease and Detoxification Committee. Committee approval of the 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:

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

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## Background of AAMI adoption of ISO 23500-2:2019

The International Organization for Standardization (ISO) published ISO 23500-2:2019, *Preparation and quality management of fluids for haemodialysis and related therapies—Part 2: Water treatment equipment for haemodialysis applications and related therapies* as a revision of ISO 26722:2014. 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 guidance on the user's responsibility for the dialysis fluid once the equipment used in its preparation has been delivered and installed. The 2019 ISO revision editorially aligns with the ISO dialysis fluid standards ISO 23500-1, ISO 23500-3, ISO 23500-4, and ISO 23500-5.

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.

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.

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NOTE Users of this standard are advised that this document is an AAMI identical adoption of an ISO document and that the following international conventions have been carried over to the AAMI publication:

- British English spelling (e.g. colour instead of color)
- Use of SI units (e.g. metres instead of feet, Celsius instead of Fahrenheit, etc.)
- Decimal comma instead of a decimal point (e.g. 1 000,15 instead of 1,000.15)

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

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NOTE Beginning with the ISO foreword on page vii, this American National Standard is identical to ISO 23500-2:2019.

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This first edition cancels and replaces ISO 26722:2014, which has been technically revised. The main changes compared to the previous edition are as follows:

- The document forms part of a revised and renumbered series dealing with the preparation and quality management of fluids for haemodialysis and related therapies. The series comprise ISO 23500-1 (previously ISO 23500), ISO 23500-2, (previously ISO 26722), ISO 23500-3, (previously ISO 13959), ISO 23500-4, (previously ISO 13958), and ISO 23500-5, (previously ISO 11663).

A list of all parts of the ISO 23500 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

## Introduction

This document reflects the conscientious efforts of concerned physicians, clinical engineers, nurses, dialysis technicians, and dialysis patients, in consultation with device manufacturers and regulatory authority representatives, to develop an International Standard for performance levels that could be reasonably achieved at the time of publication. The term "consensus," as applied to the development of voluntary medical device documents, does not imply unanimity of opinion, but rather reflects the compromise necessary in some instances when a variety of interests should be merged.

This document applies to individual water treatment devices and to water treatment systems assembled from one or more of these devices. In the first instance, this document is directed at the individual or company that specifies the complete water treatment system and, second, at the supplier who assembles and installs the system. Since systems can be assembled from a number of individual water treatment devices, the provisions of this document are also directed at the manufacturers of these devices, provided that the manufacturer indicates that the device is intended for use in haemodialysis applications. This document is written principally to address water treatment systems for dialysis facilities treating multiple patients. However, many of its provisions apply equally to water treatment systems used in applications where a single patient is treated, such as in a home dialysis or acute hospital dialysis setting. Specifically, requirements for the chemical and microbiological quality of water are considered to apply in all settings, regardless of whether a single patient or many patients are being treated.

Increasingly, self-contained, integrated systems designed and validated to produce water and dialysis fluid are becoming available and used clinically. The provisions included in this document apply to systems assembled from individual components. Consequently, some of the provisions in ISO 23500-1 and ISO 23500-2 might not apply to integrated systems, however such systems are required to comply with ISO 23500-3, ISO 23500-4, and ISO 23500-5. In order to ensure conformity when using such systems, the user shall follow the manufacturer's instructions regarding the operation, testing, and maintenance of such systems in order to ensure that the system is being operated under the validated conditions.

This document helps protect haemodialysis patients from adverse effects arising from known chemical and microbial contaminants found in water supplies. However, dialysis and patient safety is ultimately dependent on the quality of the dialysis fluid. Since the manufacturer or supplier of water treatment equipment does not have control over the dialysis fluid, any reference to dialysis fluid in this document is for clarification only and not a requirement of the manufacturer. The responsibility for assuring that the dialysis fluid is not contaminated, mismatched, or otherwise damaging to the patient rests with the clinical professionals caring for the patient under the supervision of the medical director. Requirements and recommendations on the preparation and handling of water and dialysis fluid in a dialysis facility are provided in ISO 23500-5. The rationale for the development of this document is given in Annex A.

Since the chemical and microbiological content of the water produced need to meet the requirements of ISO 23500-3, the maximum allowable levels of contaminants are listed in Annex B (Tables B.1 and B.2). The values shown include the anticipated uncertainty associated with the analytical methodologies listed in Table B.3.

# **Guidance for the preparation and quality management of fluids for haemodialysis and related therapies—Part 2: Water treatment equipment for haemodialysis applications and related therapies**

## **1 Scope**

### **1.1 General**

This document is addressed to the manufacturer and/or supplier of water treatment systems and/or devices used for the express purpose of providing water for haemodialysis or related therapies.

### **1.2 Inclusions**

This document covers devices used to treat potable water intended for use in the delivery of haemodialysis and related therapies, including water used for:

- a) the preparation of concentrates from powder or other highly concentrated media at a dialysis facility;
- b) the preparation of dialysis fluid, including dialysis fluid that can be used for the preparation of substitution fluid;
- c) the reprocessing of dialysers intended for single use where permitted for multiple uses,
- d) the reprocessing of dialysers not specifically marked as intended for single use.

This document includes all devices, piping and fittings between the point at which potable water is delivered to the water treatment system, and the point of use of the dialysis water. Examples of the devices are water purification devices, online water quality monitors (such as conductivity monitors), and piping systems for the distribution of dialysis water.

### **1.3 Exclusions**

This document excludes dialysis fluid supply systems that proportion water and concentrates to produce dialysis fluid, sorbent dialysis fluid regeneration systems that regenerate and recirculate small volumes of the dialysis fluid, dialysis concentrates, haemodiafiltration systems, haemofiltration systems, systems that process dialysers for multiple uses, and peritoneal dialysis systems. Some of these devices, such as dialysis fluid delivery systems and concentrates, are addressed in other documents such as ISO 23500-4 and ISO 23500-5,

This document also excludes the on-going surveillance of the purity of water used for dialysis fluid, concentrate preparation, or dialyser reprocessing which is addressed in ISO 23500-1.

## **2 Normative references**

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 23500-1:2019, Preparation and quality management of fluids for haemodialysis and related therapies—Part 1: General requirements