Preparation and quality management of fluids for haemodialysis and related therapies—Part 4: Concentrates for haemodialysis and related therapies
Preparation and quality management of fluids for haemodialysis and related therapies—Part 4: Concentrates for haemodialysis and related therapies

Approved 23 December 2019 by
AAMI

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

Abstract: Specifies minimum requirements for concentrates to be used in haemodialysis and related therapies. Addressed to the manufacturer of such concentrates. Includes concentrates in both liquid and powder forms. Also included are additives, also called spikes, which are chemicals that may be added to the concentrate to increase the concentration of one or more of the existing ions in the concentrate and thus in the final dialysis fluid. Gives requirements for equipment used to mix acid and bicarbonate powders into concentrate at the user's facility.

Keywords: chemical, compliance, colony, endotoxin, fluid, microbiological, 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.
Background of AAMI adoption of ISO 23500-4:2019

The International Organization for Standardization (ISO) published ISO 23500-4:2019, Preparation and quality management of fluids for haemodialysis and related therapies—Part 4: Concentrates for haemodialysis and related therapies as a revision of ISO 13958:2014. 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 23500-2, ISO 23500-3, 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.

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)

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.

NOTE Beginning with the ISO foreword on page vii, this American National Standard is identical to ISO 23500-4:2019.
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).

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).

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.

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 13958:2014, which has been technically revised. The main changes compared to the previous edition are as follows:


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.
Introduction

The requirements and goals established by this document will help ensure the effective, safe performance of haemodialysis concentrates and related materials. This document reflects the conscientious efforts of concerned physicians, clinical engineers, nurses, dialysis technicians and dialysis patients, in consultation with device manufacturers and regulatory agency representatives, to develop a 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 standards does not imply unanimity of opinion, but rather reflects the compromise necessary in some instances when a variety of interests shall be merged.

The rationale for the development of this document is given in informative Annex A.

Throughout this document, requirements and recommendations are made to use ISO-quality water. Therefore, it is recommended to refer to ISO 23500-3 along with this document.

For the purpose of this document, “concentrates” are a mixture of chemicals and water, or chemicals in the form of dry powder or other highly concentrated media, which are delivered to the end user to make dialysis fluid used to perform haemodialysis and related therapies.
Guidance for the preparation and quality management of fluids for haemodialysis and related therapies—Part 4: Concentrates for haemodialysis and related therapies

1 Scope

This document specifies minimum requirements for concentrates used for haemodialysis and related therapies. This document is addressed to the manufacturer of such concentrates. In several instances in this document, the dialysis fluid is addressed, which is made by the end user, to help clarify the requirements for manufacturing concentrates. Because the manufacturer of the concentrate does not have control over the final dialysis fluid, any reference to dialysis fluid is for clarification and is not a requirement of the manufacturer.

This document includes concentrates in both liquid and powder forms. It also includes additives, also called spikes, which are chemicals that can be added to the concentrate to supplement or increase the concentration of one or more of the existing ions in the concentrate and thus in the final dialysis fluid.

This document also specifies requirements for equipment used to mix acid and bicarbonate powders into concentrate at the user's facility.

Concentrates prepared from pre-packaged salts and water at a dialysis facility for use in that facility are excluded from the scope of this document. Although references to dialysis fluid appear herein, this document does not address dialysis fluid as made by the end user. This document also excludes requirements for the surveillance frequency of water purity used for the making of dialysis fluid by the dialysis facility. This document does not address bags of sterile dialysis fluid or sorbent dialysis fluid regeneration systems that regenerate and recirculate small volumes of the dialysis fluid.

This document does not cover the dialysis fluid that is used to clinically dialyse patients. Dialysis fluid is covered in ISO 23500-5. The making of dialysis fluid involves the proportioning of concentrate and water at the bedside or in a central dialysis fluid delivery system. Although the label requirements for dialysis fluid are placed on the labelling of the concentrate, it is the user's responsibility to ensure proper use.

This document does not cover haemodialysis equipment, which is addressed in IEC 60601-2-16:2012.

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

ISO 23500-3, Preparation and quality management of fluids for haemodialysis and related therapies—Part 3: Water for haemodialysis and related therapies

ISO 23500-5, Preparation and quality management of fluids for haemodialysis and related therapies—Part 5: Quality of dialysis fluid for haemodialysis and related therapies

IEC 60601-1, Medical electrical equipment—Part 1: General requirements for basic safety and essential performance