

Preparation and quality management of fluids for haemodialysis and related therapies - Part 5: Quality of dialysis fluid for haemodialysis and related therapies (ISO 23500-5:2024)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>See Eesti standard EVS-EN ISO 23500-5:2024 sisaldab Euroopa standardi EN ISO 23500-5:2024 ingliskeelset teksti.</p> <p>Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.</p> <p>Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 24.04.2024.</p> <p>Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.</p>	<p>This Estonian standard EVS-EN ISO 23500-5:2024 consists of the English text of the European standard EN ISO 23500-5:2024.</p> <p>This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.</p> <p>Date of Availability of the European standard is 24.04.2024.</p> <p>The standard is available from the Estonian Centre for Standardisation and Accreditation.</p>
--	---

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.40

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardimis- ja Akrediteerimiskeskusele. Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardimis- ja Akrediteerimiskeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardimis- ja Akrediteerimiskeskusega: Koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation and Accreditation. No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation and Accreditation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation and Accreditation: Homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

EUROPEAN STANDARD

EN ISO 23500-5

NORME EUROPÉENNE

EUROPÄISCHE NORM

April 2024

ICS 11.040.40

Supersedes EN ISO 23500-5:2019

English Version

Preparation and quality management of fluids for
haemodialysis and related therapies - Part 5: Quality of
dialysis fluid for haemodialysis and related therapies (ISO
23500-5:2024)

Préparation et management de la qualité des liquides
d'hémodialyse et de thérapies annexes - Partie 5:
Qualité des liquides de dialyse pour hémodialyse et
thérapies apparentées (ISO 23500-5:2024)

Herstellung und Qualitätsmanagement von
Flüssigkeiten für die Hämodialyse und verwandte
Therapien - Teil 5: Qualität von Flüssigkeiten für die
Hämodialyse und verwandte Therapien (ISO 23500-
5:2024)

This European Standard was approved by CEN on 18 April 2024.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

This document (EN ISO 23500-5:2024) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN/TC 205 "Non-active medical devices" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2024, and conflicting national standards shall be withdrawn at the latest by October 2024.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 23500-5:2019.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 23500-5:2024 has been approved by CEN as EN ISO 23500-5:2024 without any modification.

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements	2
4.1 Microbiological contaminants in dialysis fluid.....	2
4.1.1 General.....	2
4.1.2 Microbiological requirements for standard dialysis fluid.....	2
4.1.3 Microbiological requirements for ultrapure dialysis fluid.....	2
4.1.4 Microbiological requirements for online prepared substitution fluid.....	2
4.2 Chemical composition of dialysis fluid.....	3
4.3 Chemical contaminants in dialysis fluid.....	3
5 Tests for conformity	3
5.1 Microbiological requirements.....	3
5.1.1 Sampling.....	3
5.1.2 Culture methods.....	3
5.2 Chemical requirements.....	5
Annex A (informative) Rationale for the development and provisions of this document	6
Annex B (informative) Reference tables	9
Bibliography	11

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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 23500-5:2019), which has been technically revised.

The main changes are: alternatives to classic microbial analytical methods [endotoxin testing using rFC (tp)] have been incorporated.

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

Haemodialysis patients are directly exposed to large volumes of dialysis fluid, with the dialyser membrane being the only barrier against transfer of hazardous contaminants from the dialysis fluid to the patient. It has long been known that there can be hazardous contaminants in the water and concentrates used to prepare the dialysis fluid. To minimize this hazard, ISO 23500-3 and ISO 23500-4 set forth quality requirements for the water and concentrates used to prepare dialysis fluid. However, if the dialysis fluid is not prepared carefully, it can contain unacceptable levels of contaminants even though it is prepared from water and concentrates, conforming to the requirements of ISO 23500-3 and ISO 23500-4. Further, the dialysis fluid can 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 haemodiafiltration. For these reasons, this document was developed to complement the existing International Standards for water and concentrates, ISO 23500-3 and ISO 23500-4, respectively. Guidelines to aid the user in routinely meeting the requirements of this document and ISO 23500-3 can be found in ISO 23500-1.

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 are comparable to the cited methods. The rationale for the development of this document is given in [Annex A](#).

This document reflects the conscientious efforts of healthcare professionals, patients and medical device manufacturers to develop recommendations for the quality of dialysis fluid. This document is applicable to 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.

This document aims to help protect haemodialysis 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 applicable quality standards.

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

Preparation and quality management of fluids for haemodialysis and related therapies —

Part 5: Quality of dialysis fluid for haemodialysis and related therapies

1 Scope

This document specifies the minimum chemical and microbiological quality requirements for dialysis fluids used in haemodialysis and related therapies.

This document applies to

- dialysis fluids used for haemodialysis and haemodiafiltration,
- substitution fluid produced online for haemodiafiltration and haemofiltration based on dialysis fluid

This document does not apply to

- the water and concentrates used to prepare dialysis fluid or the equipment to produce dialysis fluid
- sorbent-based dialysis fluid regeneration systems that regenerate and recirculate small volumes of dialysis fluid,
- systems for continuous renal replacement therapy that use pre-packaged solutions, and
- systems and solutions for peritoneal dialysis.

The delivery and monitoring of the dialysis fluid composition and its permitted deviation from set points is governed by protective systems defined in IEC 60601-2-16.

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: Quality of water for haemodialysis and related therapies*

ISO 23500-4, *Preparation and quality management of fluids for haemodialysis and related therapies — Part 4: Concentrates for haemodialysis and related therapies*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 23500-1 apply.