

STN	Príprava a riadenie kvality tekutín pre hemodialýzu a súvisiace terapie Časť 5: Kvalita dialyzovanej tekutiny pre hemodialýzu a súvisiace terapie (ISO 23500-5: 2024)	STN EN ISO 23500-5 85 6122
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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)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 08/24

Obsahuje: EN ISO 23500-5:2024, ISO 23500-5:2024

Oznámením tejto normy sa ruší
STN EN ISO 23500-5 (85 6122) z augusta 2019

138809

Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, 2024
Slovenská technická norma a technická normalizačná informácia je chránená zákonom č. 60/2018 Z. z. o technickej normalizácii v znení neskorších predpisov.

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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EN ISO 23500-5:2024 (E)

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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of an identical text or by endorsement, at the latest by October 2024, and conflicting national standards shall be withdrawn at the latest by October 2024.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.

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Endorsement notice

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



International Standard

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

*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*

**Second edition
2024-04**

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Published in Switzerland

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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 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).

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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.

ISO 23500-5:2024(en)

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*

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