ICS 11.040.40 SLOVENSKÁ TECHNICKÁ NORMA Október 2024

STN	**Príprava a manažérstvo kvality tekutín pre hemodialýzu a súvisiace terapie Časť 2: Zariadenia na úpravu vody pre hemodialyzované aplikácie a súvisiace terapie (ISO 23500-2: 2024)**	**STN EN ISO 23500-2** 85 6122

Preparation and quality management of fluids for haemodialysis and related therapies - Part 2: Water treatment equipment for haemodialysis applications and related therapies (ISO 23500-2:2024)

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. 09/24

Obsahuje: EN ISO 23500-2:2024, ISO 23500-2:2024

Oznámením tejto normy sa ruší
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Supersedes EN ISO 23500-2:2019

English Version

Preparation and quality management of fluids for haemodialysis and related therapies - Part 2: Water treatment equipment for haemodialysis applications and related therapies (ISO 23500-2:2024)

Préparation et management de la qualité des liquides d'hémodialyse et de thérapies annexes - Partie 2: Équipement de traitement de l'eau pour des applications en hémodialyse et aux thérapies apparentées (ISO 23500-2:2024)

Herstellung und Qualitätsmanagement von Flüssigkeiten für die Hämodialyse und verwandte Therapien - Teil 2: Ausstattung zur Wasseraufbereitung zur Verwendung in der Hämodialyse und in verwandten Therapien (ISO 23500-2:2024)

This European Standard was approved by CEN on 23 May 2024.

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

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

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European foreword

This document (EN ISO 23500-2:2024) 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of an identical text or by endorsement, at the latest by January 2025, and conflicting national standards shall be withdrawn at the latest by January 2025.

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 23500-2:2019.

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 23500-2:2024 has been approved by CEN as EN ISO 23500-2:2024 without any modification.

International Standard

ISO 23500-2

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

Part 2: Water treatment equipment for haemodialysis applications and related therapies

Préparation et management de la qualité des liquides d'hémodialyse et de thérapies annexes —

Partie 2: Équipement de traitement de l'eau pour des applications en hémodialyse et aux thérapies apparentées

Second edition
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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 23500-2:2019), which has been technically revised. The main changes are as follows:

— alternative water treatment technologies (e.g. reverse osmosis pre-treatment with ultrafiltration) have been added;

— alternatives to classic microbial analytical methods [endotoxin testing using involving recombinant Factor C (rFC)] have been added.

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

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 can be reasonably achieved at the time of its 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. This document is applicable, firstly, to the individual or company that specifies the complete water treatment system and, secondly, to 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 applicable to 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 do not apply to integrated systems, however such systems are required to comply with ISO 23500-3, ISO 23500-4[47] and ISO 23500-5[48].

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 23500-3 and ISO 23500-5[48] respectively. 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 given in Tables B.1 and B.2. The values shown include the anticipated uncertainty associated with the analytical methodologies, which are listed in Table B.3.

International Standard **ISO 23500-2:2024(en)**

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

Part 2: Water treatment equipment for haemodialysis applications and related therapies

1 Scope

This document specifies requirements and recommendations for individual water treatment devices and water treatment systems assembled from one or more of such devices. This document is directed at the individual or company that specifies the complete water treatment system and, 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 to be used to supply water for haemodialysis and related therapies.

This document is applicable to all devices, piping and fittings between the point at which water is delivered to the water purification system and the point of use of the purified water. Such components include but are not necessarily limited to water purification devices, online water quality monitors (such as conductivity monitors) and piping systems for the distribution of purified water.

This document does not apply to

— equipment used in the preparation of concentrates from powder or other highly concentrated media at a dialysis facility either for a single patient or multiple patients,

— 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 or haemofiltration systems,

— systems that process dialysers for multiple uses, and

— peritoneal dialysis systems.

Requirements for the ongoing monitoring of water purity in terms of chemical and microbiological quality are given in ISO 23500-3.

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*

IEC 60601-1-11, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*