SLOVENSKI STANDARD
oSIST prEN ISO 23500-2:2023

01-januar-2023

Priprava in vodenje kakovosti tekočin za hemodializo in podobne terapije - 2. del: Oprema za pripravo vode za uporabo pri hemodializi in podobnih terapijah (ISO/DIS 23500-2:2022)

Preparation and quality management of fluids for haemodialysis and related therapies - Part 2: Water treatment equipment for haemodialysis applications and related therapies (ISO/DIS 23500-2:2022)

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/DIS 23500-2:2022)

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/DIS 23500-2:2022)

Ta slovenski standard je istoveten z: **prEN ISO 23500-2**

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics

oSIST prEN ISO 23500-2:2023 **en,fr,de**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 23500-2

ISO/TC **150**/SC **2** Secretariat: **ANSI**

Voting begins on: **2022-11-18**

Voting terminates on: **2023-02-10**

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

ICS: 11.040.40

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 23500-2:2022(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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 second edition cancels and replaces ISO 23500-2:2019, which has been technically revised. The main changes compared to the previous edition are as follows:

— Incorporation of alternative water treatment technologies (e.g. reverse osmosis pre-treatment with ultrafiltration).

— Incorporation of alternatives to classic microbial analytical methods [endotoxin testing using rFC (tp)].

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 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 23500-3 and ISO 23500-5 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 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.

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 multiple times for a single patient if permitted by local/national clinical practice guidelines,

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 degree of contamination of the 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, *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 60601-1-8, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

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*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
microfilter
filter designed to remove particles down to 0,1 µm in size

Note 1 to entry: Microfilters have an absolute size cut-off and are available in both dead-end and cross-flow configurations. Some microfilters can reduce the concentration of endotoxins by adsorption.

4 Requirements

4.1 Dialysis water quality requirements

4.1.1 General

The requirements contained in this document apply to the dialysis water as it enters the equipment used to prepare concentrates from powder or other concentrated media at a dialysis facility, to prepare dialysis fluid, or to reprocess dialysers. As such, these requirements apply to the water treatment system as a whole including the distribution network and not only to each of the individual devices that make up the system.

4.1.2 Chemical contaminant requirements

Dialysis water used to prepare dialysis fluid or concentrates from powder at a dialysis facility, or to reprocess dialysers for multiple uses, shall not contain chemical contaminants at concentrations in excess of those in ISO 23500-1, Tables 1 and 2 (reproduced as Tables B.1 and B.2). The manufacturer or supplier of a complete water treatment system shall recommend a system capable of meeting the requirements of this clause based on the analysis of the feed water. The system design should reflect possible seasonal variations in feed water quality. The manufacturer or supplier of a complete water

treatment and distribution system shall demonstrate that the complete water treatment, storage, and distribution system is capable of meeting the requirements of this document at the time of installation.

NOTE If the manufacturer or supplier does not install the water storage and distribution system, then the responsibility of the manufacturer or supplier is limited to demonstrating that the water treatment system, excluding the water storage and distribution system, meets the requirements of this document. If individual devices of the water treatment system are provided by different manufacturers or suppliers, the person or organization specifying the devices is responsible for demonstrating that the complete system meets the requirements of this document at the time of installation.

For disposable water treatment and distribution systems that have been validated to produce dialysis water meeting the quality requirements of this document for a specified time, surveillance of the incoming potable water is required to ensure that the input to the treatment system is in the range for which the system has been validated. The manufacturer's recommendation for surveilling the final dialysis water can be followed when the system is operated according to the manufacturer's instructions. Alternatively, the quality of the dialysis water can be closely observed as outlined for non-validated systems.

NOTE Following the installation of a water treatment, storage, and distribution system, the user is responsible for continued surveillance of the levels of chemical contaminants in the water and for complying with the requirements of this document.

4.1.3 Organic Carbon, pesticides and other chemicals

The presence of organic compounds, such as pesticides, polycyclic aromatic hydrocarbons and other chemicals such as pharmaceutical products and endocrine disruptors in respect of hemodialysis patients are difficult to define. Consequences of exposure are probably of a long-term nature and it is technically difficult and costly to measure these substances on a routine basis. Furthermore, there is an absence of evidence of their widespread presence in water although it is recognized that inadvertent discharges are possible. In view of this, it is not possible to currently define limits for their presence in water used in the preparation of dialysis fluid.

Nanofiltration and reverse osmosis are capable of significant rejection of many such compounds. Granular Activated Carbon (GAC) is also highly effective at removing majority of such compounds. However, as Granular Activated Carbon is widely used in the removal of chlorine/chloramine, their use in the removal of organic carbons, pesticides and other chemicals will be dependent upon the size of the carbon filters and/or beds and users shall be aware of appropriate dimensioning since the majority of carbon valences might be already occupied and not available for further removal activity.

4.1.4 Microbiology of dialysis water

Dialysis water used to prepare dialysis fluid or concentrates from powder at a dialysis facility, or to reprocess dialysers for multiple uses, shall contain a total viable microbial count and endotoxin levels as specified in ISO 23500-3.

The manufacturer or supplier of a complete water treatment and distribution system shall demonstrate that the complete water treatment, storage, and distribution system meets the requirements of this document, including those related to action levels at the time of installation.

NOTE If the manufacturer or supplier does not install the water storage and distribution system, then the responsibility of the manufacturer or supplier is limited to demonstrating that the water treatment system, excluding the water storage and distribution system, meets the requirements of this document. If individual devices of the water treatment system are provided by different manufacturers or suppliers, the person or organization specifying the devices is responsible for demonstrating that the complete system meets the requirements of this document at the time of installation.

For disposable water treatment systems validated by the manufacturer to produce dialysis water meeting the quality requirements of this document for a specified time, surveillance of the incoming feed water is required to ensure that the input to the treatment system is in the range for which the system has been validated. The manufacturer's recommendations for surveilling the dialysis water can

be followed when the system is operated according to the manufacturer's instructions. Alternatively, the quality of the dialysis water can be observed as outlined for non-validated systems.

NOTE Following installation of a water treatment, storage, and distribution system, the user is responsible for continued surveillance of the water bacteriology of the system and for complying with the requirements of this document, including those requirements related to action levels.

4.2 Water treatment equipment requirements

4.2.1 General

4.2.1.1 Water treatment system

The supplier of the feed water or the supplier of the water treatment system or a laboratory specified by the user shall perform chemical analyses on feed water to determine the compatibility of the system with the feed water and the suitability of the system for providing dialysis water meeting the requirements of 4.1.2. The result of the chemical analyses shall be available to the user in charge of dialysis. In the case of an individual device, the person incorporating the device into the water treatment system is responsible for ensuring that incorporation of the device does not compromise the ability of the overall system to deliver dialysis water capable of meeting the requirements of 4.1.2 and 4.1.4.

The water treatment and distribution system should include appropriate pressure gauges, flow meters, sample ports, and other ancillary equipment necessary to allow surveillance of the performance of individual system devices and the system as a whole.

Valves can be included in the water treatment system to allow individual devices to be bypassed when there is device failure or to facilitate replacement of a device. Bypass valves should have a physical lockout installed and be labelled with a warning notifying the user of the result of its removal.

If it is possible to bypass a device of the water treatment system, then the manufacturer or installer of that component shall inform the user of the risks associated with bypassing that device and the need for clearly defining the responsibility for operating the bypass. Where such valves are installed, however, a means should be included to minimize the likelihood that the device will be inadvertently bypassed during normal operation of the system.

Bypass valves should not be used to bypass deionization tanks, carbons and other critical components. They should not be used on ultra filters used in conjunction with deionization tanks for patient treatment.

Operating controls shall be positioned so as to minimize inadvertent resetting.

Electrical circuits shall be separate from hydraulic circuits and adequately protected from fluid leaks.

4.2.1.2 Materials compatibility

Materials that are in contact with dialysis water (including materials used in piping, storage, and distribution systems) shall not interact chemically or physically with that water so as to adversely affect its purity or quality. Water-contacting surfaces shall be fabricated from non-reactive materials (e.g. plastics) or appropriate stainless steel. The use of materials known to cause toxicity in haemodialysis, such as copper, brass, galvanized metal, or aluminium, are specifically prohibited at any point beyond the water treatment device used to remove contaminating metal ions, most commonly a reverse osmosis system or a deionizer. The materials of any water treatment devices (including piping, storage, and distribution systems) shall be compatible with the means used to disinfect those devices. Chemicals infused into the water in the pre-treatment section, such as chlorine, acid, flocculants, and complexing agents, shall be adequately removed from dialysis water before they reach any point of use. Monitors or specific test procedures to verify removal of additives shall be provided.

4.2.1.3 Regenerated or reconstituted devices

All devices that are regenerated or reconstituted at a site remote from the dialysis facility, such as deionizers, shall be disinfected at the time of regeneration or reconstitution, so that contaminated water is not reintroduced into the system after regeneration or reconstitution. Separate processes shall be used to ensure no intermixing of devices or their component parts between devices returned from medical or potable water users and devices returned from non-potable water users.

4.2.1.4 Disinfection protection

When the manufacturer recommends the use of chemical disinfectants, means shall be provided to restore the equipment and the system in which it is installed, to a safe condition in respect of residual disinfectant presence prior to the dialysis water being used for dialysis applications. When recommending chemical disinfectants, the manufacturer shall also recommend methods for testing for residual levels of the disinfectants. When disinfection is accomplished automatically by chemical disinfectants, including ozone, or by high temperature procedures, activation of the disinfection system shall result in activation of a warning system and measures to prevent patient exposure to an unsafe condition.

If sodium hypochlorite (bleach) is used for cleaning or disinfecting the internal pathways of dialysis equipment, including but not limited to water treatment loops, concentrate containers, mixers, and delivery systems, the post rinse water residual level of free chlorine shall be as specified by the manufacturer's instructions.

4.2.2 Backflow prevention device

A backflow prevention device to isolate the water treatment system from the potable water supply according to local plumbing codes should be fitted to all water treatment systems and, where possible, allow for redundancy when servicing and testing.

The design and installation should allow for servicing and testing of the backflow prevention device without interruption of the dialysis water purification process or to be performed when the purification process is not operating. Consideration should be made for a parallel installation on each water source including domestic hot, domestic cold and back-up water sources where applicable.

NOTE The testing frequency of backflow prevention devices is specified by local plumbing codes or regulations.

4.2.3 Tempering valves

Tempering valves, if used, shall be sized to accommodate the anticipated range of flow rates of hot and cold water. They shall be fitted with a mechanism to prevent backflow of water into the hot and cold water lines and with a means to measure the outlet water temperature.

4.2.4 Sediment filters

Sediment filters should have an opaque housing or other means to inhibit proliferation of algae. Filters should be fitted with pressure gauges on the inlet and outlet water lines to measure the pressure drop, ΔP, across the filter.

NOTE Sediment filters are also known as multimedia or sand filters.

4.2.5 Cartridge filters

Cartridge filters should have an opaque housing or other means to inhibit proliferation of algae. Filters should be fitted with pressure gauges on the inlet and outlet water lines to measure the pressure drop, ΔP, across the filter during use.