



# International Standard

Redline version  
compares Second edition  
to First edition



## ISO 23500-1

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

#### Part 1: General requirements

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

*Partie 1: Exigences générales*

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All changes in this document have yet to reach consensus by vote and as such should only be used internally for review purposes.

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This Redline version provides you with a quick and easy way to compare all the changes between this standard and its previous edition. A vertical bar appears in the margin wherever a change has been made. Additions and deletions are displayed in red, with deletions being struck through.



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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 documents ~~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](http://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](http://www.iso.org/patents)).~~

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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](http://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 ~~first~~ **second** edition cancels and replaces ~~the first edition (ISO 23500:2014-1:2019)~~, which has been technically revised. ~~The main changes compared to the previous edition are as follows:~~

The main changes are as follows:

- WHO Drinking Water Guideline has been used as the main drinking water quality reference instead of the US EPA or other European standards;
- thallium has been removed from the list of contaminants, as no studies have reported data to indicate that this contaminant is of particular concern in the haemodialysis setting;
- alternative water treatment technologies (e.g. reverse osmosis pre-treatment with ultrafiltration) have been included in the subclauses dealing with water treatment technology (refer to [B.2.7](#) and [B.2.8](#));
- a new annex ([Annex H](#)) has been added to provide clarification of the different water quality monitoring approaches (online versus offline monitoring);

~~The document forms part of a revised and renumbered series dealing with the preparation and quality management of fluids for haemodialysis and related therapies. The series comprise ISO 23500-1 (previously ISO 23500), ISO 23500-2, (previously ISO 26722), ISO 23500-3, (previously ISO 13959), ISO 23500-4, (previously ISO 13958), and ISO 23500-5, (previously ISO 11663).~~

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the microbiological analytic methods have been updated to include endotoxin testing using recombinant Factor C (rFC), flow cytometry, autofluorescence and rapid tests (e.g. ATP);

— a new annex ([Annex I](#)) has been added to provide guidance on risk assessment;

— the validation of water treatment systems has been revised to include validation steps (e.g. installation qualification, operational qualification, performance qualification and revalidation);

— further guidance has been added on technical needs after the typical technical interventions in [Clause E.4](#).

A list of all parts in the ~~ISO~~ [ISO 23500 series](#) ~~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](http://www.iso.org/members.html).

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## Introduction

This document is the base standard for ~~a number of other~~ standards dealing with water treatment and the production of dialysis fluid ~~(in the ISO 23500 series).~~

The objective of the ISO 23500 series is to provide users with guidance for handling water and concentrates and for the production and quality oversight of dialysis fluid used for haemodialysis. The need for such guidance is based on the critical role of dialysis fluid quality in providing safe and effective haemodialysis, and the recognition that day-to-day dialysis fluid quality is under the control of the healthcare professionals who deliver dialysis therapy.

[Annex A](#) provides further information on the rationale for the development and provisions of this document.

The equipment used in the various stages of dialysis fluid preparation is generally obtained from specialized vendors. Dialysis practitioners are generally responsible for maintaining that equipment following its installation. Therefore, this document provides guidance on quality oversight and maintenance of the equipment to ensure that dialysis fluid quality is acceptable at all times. At various places ~~throughout this International Standard~~ ~~in this document~~, the user is advised to follow the manufacturer's instructions regarding the operation and maintenance of equipment. In ~~those~~ instances in which the equipment is not obtained from a specialized vendor, it is the responsibility of the user to validate the performance of the equipment in the haemodialysis setting and to ensure that appropriate operating and maintenance manuals are available.

[Annex B](#) ~~to this document~~ provides further information on the system components that are used for water treatment, concentrate and dialysis fluid preparation at a dialysis facility. These descriptions are intended to provide the user with a basis for understanding why certain equipment ~~might~~ ~~can~~ be required and how it should be configured; ~~they~~ ~~the descriptions~~ are not intended ~~as to be~~ detailed design standards. Requirements for water treatment equipment are provided in ISO 23500-2.

Increasingly, self-contained, integrated systems designed and validated to produce water and dialysis fluid are becoming available and used clinically. This document applies to systems assembled from individual components. Consequently, some of the requirements in ISO 23500-1 and ISO 23500-2 ~~might~~ ~~do~~ not apply to integrated systems, however such systems are required to comply with the requirements of ISO 23500-3, ISO 23500-4 and ISO 23500-5. In order to ensure conformity when using such systems, adherence to the manufacturer's instructions regarding the operation, testing and maintenance of such systems is required to ensure that the system is being operated under the validated conditions.

This document reflects the conscientious efforts of healthcare professionals, patients and medical device manufacturers to develop recommendations for handling water and concentrates and for the production and surveillance of dialysis fluid for haemodialysis and protecting haemodialysis patients from adverse effects arising from known chemical and microbial contaminants that can be found in improperly prepared dialysis fluid.

~~This document reflects the conscientious efforts of healthcare professionals, patients, and medical device manufacturers to develop recommendations for handling water and concentrates and for the production and surveillance of dialysis fluid for haemodialysis and protecting haemodialysis patients from adverse effects arising from known chemical and microbial contaminants that might be found in improperly prepared dialysis fluid.~~ [Annexes F and G](#) provide further information ~~in respect of~~ ~~regarding the~~ special considerations for home and acute haemodialysis. ~~The standard.~~ ~~This document~~ together with its constituent parts is directed towards the healthcare professionals involved in the management or routine care of haemodialysis patients and responsible for the quality of 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 requirements of all applicable quality standards.

~~The provisions contained in this document might not be applicable in all circumstances and they are not intended for regulatory application.~~