BS EN ISO 23500-3:2024

BSI Standards Publication

Preparation and quality management of fluids for haemodialysis and related therapies

Part 3: Water for haemodialysis and related therapies

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National foreword

This British Standard is the UK implementation of EN ISO 23500-3:2024. It is identical to ISO 23500-3:2024. It supersedes BS EN ISO 23500-3:2019, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/150/2, Cardiovascular implants.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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European foreword

This document (EN ISO 23500-3:2024) 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of an identical text or by endorsement, at the latest by October 2024, and conflicting national standards shall be withdrawn at the latest by October 2024.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 23500-3:2019.

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.

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The text of ISO 23500-3:2024 has been approved by CEN as EN ISO 23500-3:2024 without any modification.

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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 23500-3:2019), which has been technically revised.

The main changes are as follows:

— the use of WHO Drinking Water Guideline as the drinking water quality reference has replaced the previously used EPA Water quality requirements;

— thallium has been removed from the list of contaminants of other trace elements in dialysis water as no published study reports that this contaminant is of particular concern in the setting of haemodialysis;

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

A list of all parts in the ISO 23500 series can be found on the ISO website.

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Introduction

Assurance of adequate water quality is one of the most important aspects of ensuring a safe and effective delivery of haemodialysis, haemodiafiltration or haemofiltration.

This document contains the minimum chemical and microbiological requirements for the water to be used for preparation of dialysis fluids and concentrates, and for the reprocessing of haemodialysers and the necessary steps to ensure conformity with those requirements.

Haemodialysis and related therapies such as haemodiafiltration can expose the patient to more than 500 l of water per week across the semi-permeable membrane of the haemodialyser or haemodiafilter. Healthy individuals seldom have a weekly oral intake above 12 l. This over 40-fold increase in exposure requires control and regular surveillance of water quality to avoid excesses of known or suspected harmful substances. Since knowledge of potential injury from trace elements and contaminants of microbiological origin over long periods is still growing and techniques for treating drinking water are continuously developed, this document will evolve and be refined accordingly. The physiological effects attributable to the presence of organic contaminants in dialysis water are important areas for research, however, the effect of such contaminants on patients receiving regular dialysis treatment is largely unknown, consequently no threshold values for organic contaminants permitted in water used for the preparation of dialysis fluids, concentrates and reprocessing of haemodialysers has been specified in this document.

Within this document, current measurement techniques at the time of publication 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 final dialysis fluid is produced from concentrates or salts manufactured, packaged and labelled according to ISO 23500-4 mixed with water meeting the requirements of this document. The operation of water treatment equipment and haemodialysis systems, including ongoing surveillance of the quality of water used to prepare dialysis fluids, and handling of concentrates and salts are the responsibility of the haemodialysis facility and are addressed in ISO 23500-1. Haemodialysis professionals make choices about the various applications (haemodialysis, haemodiafiltration, haemofiltration) and should understand the risks of each and the requirements for safety for fluids used for each.

This document is directed towards manufacturers and providers of water treatment systems and also to haemodialysis facilities.

The rationale for the development of this document is given in Annex A.

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

Part 3: Water for haemodialysis and related therapies

1 Scope

This document specifies the minimum chemical and microbiological quality requirements, for water used for preparation of dialysis fluids, concentrates, and for the reprocessing of haemodialysers, together with the necessary steps to ensure conformity with the requirements. The document also provides guidance for the ongoing monitoring of the purity of such water in terms of chemical and microbiological quality.

This document is applicable to

— water used in the preparation of dialysis fluids for haemodialysis, haemodiafiltration and haemofiltration and the reprocessing of haemodialysers, and

— water used in the preparation of concentrates.

This document does not apply to dialysis fluid regenerating systems.

The operation of water treatment equipment and the final mixing of treated water with concentrates to produce dialysis fluid are the sole responsibility of dialysis professionals.

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*

3 Terms and definitions

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

ISO and IEC maintain terminology 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/

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