Irish Standard
I.S. EN ISO 23500-1:2019

Preparation and quality management of fluids for haemodialysis and related therapies - Part 1: General requirements (ISO 23500-1:2019)

I.S. EN ISO 23500-1:2019

Incorporating amendments/corrigenda/National Annexes issued since publication:

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National Foreword

I.S. EN ISO 23500-1:2019 is the adopted Irish version of the European Document EN ISO 23500-1:2019, Preparation and quality management of fluids for haemodialysis and related therapies - Part 1: General requirements (ISO 23500-1:2019)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 23500-1

March 2019

ICS 11.040.40

Supersedes EN ISO 23500:2015

English Version

Preparation and quality management of fluids for haemodialysis and related therapies - Part 1: General requirements (ISO 23500-1:2019)

Préparation et management de la qualité des liquides d'hémodialyse et de thérapies annexes - Partie 1: Exigences générales (ISO 23500-1:2019)

Leitfaden für die Vorbereitung und das Qualitätsmanagement von Konzentraten für die Hämodialyse und verwandte Therapien - Teil 1: Allgemeine Anforderungen (ISO 23500-1:2019)

This European Standard was approved by CEN on 18 January 2019.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 23500-1:2019) 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of an identical text or by endorsement, at the latest by September 2019, and conflicting national standards shall be withdrawn at the latest by September 2019.

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 23500-1:2019 has been approved by CEN as EN ISO 23500-1:2019 without any modification.

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INTERNATIONAL STANDARD

ISO 23500-1

First edition
2019-02

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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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).

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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 first edition cancels and replaces ISO 23500:2014, which has been technically revised. The main changes compared to the previous edition are as follows:

— 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).

A list of all parts in 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 is the base standard for a number of other standards dealing with water treatment and the production of dialysis fluid (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, 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 be required and how it should be configured; they are not intended as 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 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 might be found in improperly prepared dialysis fluid. Annexes F and G provide further information in respect of special considerations for home and acute haemodialysis The standard 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.

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

Part 1: General requirements

1 Scope

1.1 General

This document is the base standard for a number of other standards dealing with water treatment equipment, water, dialysis water, concentrates, and dialysis fluid (ISO 23500 series) and provides dialysis practitioners with guidance on the preparation of dialysis fluid for haemodialysis and related therapies and substitution fluid for use in online therapies, such as haemodiafiltration and haemofiltration. As such, this document functions as a recommended practice.

This document does not address clinical issues that might be associated with inappropriate usage of the water, dialysis water, concentrates, or dialysis fluid. Healthcare professionals involved in the provision of treatment for kidney failure should make the final decision regarding the applications with which these fluids are used, for example, haemodialysis, haemodiafiltration, high-flux haemodialysis, and the reprocessing of dialysers, and need to be aware of the issues that the use of inappropriate fluid quality raises in each of the therapies.

The concepts incorporated in this document should not be considered inflexible or static. The recommendations presented here should be reviewed periodically in order to assimilate increased understanding of the role of dialysis fluid purity in patient outcomes and technological developments.

1.2 Inclusions

This document addresses the user's responsibility for dialysis fluid once the equipment used in its preparation has been delivered and installed.

For the purposes of this document, dialysis fluid includes:

a) dialysis water (see 3.17 for definition) used for the preparation of dialysis fluid and substitution fluid,

b) dialysis water used for the preparation of concentrates at the user's facility,

c) concentrates,

d) the final dialysis fluid and substitution fluid.

The scope of this document includes

a) the quality management of equipment used to treat and distribute water used for the preparation of dialysis fluid and substitution fluid, from the point at which municipal water enters the dialysis facility to the point at which the final dialysis fluid enters the dialyser or the point at which substitution fluid is infused,

b) equipment used to prepare concentrate from powder or other highly concentrated media at a dialysis facility, and

c) preparation of the final dialysis fluid or substitution fluid from dialysis water and concentrates.