CSA Z23500-2:20
(ISO 23500-2:2019, MOD)
National Standard of Canada

CSA Z23500-2:20
Preparation and quality management of fluids for haemodialysis and related therapies — Part 2: Water treatment equipment for haemodialysis applications and related therapies
(ISO 23500-2:2019, MOD)

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National Standard of Canada

CSA Z23500-2:20

Preparation and quality management of fluids for haemodialysis and related therapies — Part 2: Water treatment equipment for haemodialysis applications and related therapies

(ISO 23500-2:2019, MOD)

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CSA Preface

This is the first edition of CSA Z23500-2, *Preparation and quality management of fluids for haemodialysis and related therapies — Part 2: Water treatment equipment for haemodialysis applications and related therapies,* which is an adoption, with Canadian deviations, of the identically titled ISO (International Organization for Standardization) Standard 23500-2 (first edition, 2019-02). It replaces CAN/CSA-ISO 26722:16 (adopted ISO 26722:2014), *Water treatment equipment for haemodialysis applications and related therapies.*

For brevity, this Standard will be referred to as "CSA Z23500-2" throughout.

This Standard was reviewed for Canadian adoption by the CSA Subcommittee on Quality Management for Kidney Dialysis, under the jurisdiction of the CSA Technical Committee on Kidney Dialysis and the CSA Strategic Steering Committee on Health and Well-being, and has been formally approved by the Technical Committee.

This Standard has been developed in compliance with Standards Council of Canada requirements for National Standards of Canada. It has been published as a National Standard of Canada by CSA Group.

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This Standard is subject to review within five years from the date of publication, and suggestions for its improvement will be referred to the appropriate committee. The technical content of IEC and ISO publications is kept under constant review by IEC and ISO. To submit a proposal for change, please send the following information to inquiries@csagroup.org and include "Proposal for change" in the subject line:

a) *Standard designation (number);*
b) *relevant clause, table, and/or figure number;*
c) *wording of the proposed change; and*
d) *rationale for the change.*

Canadian deviations

The following deviations are intended to align with local healthcare practices and to meet the requirements of Canadian healthcare regulators.

Introduction

[Add the following paragraph]

For instructions regarding installation, operation, and testing frequency, refer to CSA Z364.5. For instructions on quality management, refer to CSA Z364.6.

2 Normative references

[Add the following]

Any reference to International Standards that are adopted as National Standards of Canada subsequent to the publication of CSA Z23500-2 shall be replaced by the relevant National Standard of Canada.

Where reference is made to CSA Group publications, such reference shall be considered to refer to the latest edition and all amendments published to that edition. This Standard refers to the following publications, and the years shown indicate the latest editions available at the time of printing:

CSA Group

Z364.5-17
Safe installation and operation of hemodialysis and peritoneal dialysis in a home setting

Z364.6-17
Quality management for kidney dialysis providers

The following National Standards of Canada, published by CSA Group, are adoptions of IEC and ISO Standards. The requirements of these CSA Group Standards shall take precedence over the International Standards on which they are based. Any reference within CSA Z23500-2 to the International Standard shall be replaced by a reference to the equivalent Canadian Standard.

CAN/CSA-C22.2 No. 60601-1-8:08 (R2018)
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

CSA Z23500-1:20
Preparation and quality management of fluids for haemodialysis and related therapies — Part 1: General requirements

CSA Z23500-3:20
Preparation and quality management of fluids for haemodialysis and related therapies — Part 3: Water for haemodialysis and related therapies

4 Requirements

4.2 Water treatment equipment requirements

4.2.1.1 Water treatment system

[Add the following paragraph]

A bypass valve should have a physical lockout installed prior to its activation. The bypass valve should be labelled with a warning notifying the user of the result of its removal. Bypass valves should not be used on deionization tanks, carbons, and other critical components. Bypass valves should not be used on ultra filters that are being used in conjunction with deionization tanks for patient treatment.

4.2.2 Backflow prevention device

[Add the following]

Installation should be based on local plumbing codes and should be designed, where possible, to allow for redundancy when servicing and testing. Design and installation should allow for servicing and testing without interruption of the dialysis water purification process or during after hour periods. Consideration should be made for a parallel installation on each water source and can include domestic hot, domestic cold, and back-up water sources where applicable.

NOTE 1A: *The installation and testing frequency of backflow prevention devices in Canada might vary based on jurisdiction.*

4.2.8 Carbon media

[Add the following]

Empty-bed-contact-time of 10 min should be maintained for portable water treatment system installations in Canada due to the prevalent use of chlorine and chloramines, the increase in home therapies, and the use of portable water systems in critical care settings for sustained low efficiency dialysis (SLED) and other acute therapies.

NOTE 1A: *The design of parallel carbon beds can incorporate a flow regulation device to ensure balanced flow through each parallel branch. Flow rates can be used as an assessment tool to apply corrective measures when deemed appropriate.*

5 Testing

5.1 Conformity with dialysis water quality requirements

5.1.3 Microbiology of dialysis water

[Replace the fifth and sixth paragraphs with the following]

Recommended methods and cultivation conditions are Tryptone Glucose Extract Agar (TGEA) and Reasoner's Agar No. 2 (R2A) incubated at 17 to 23° C for a period of 7 days. (See CSA Z23500-3, Table 3.)

INTERNATIONAL STANDARD

ISO 23500-2

First edition
2019-02

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 connexes —

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

Reference number
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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).

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 first edition cancels and replaces ISO 26722:2014, 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 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 23500-5. 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 intended for single use where permitted for multiple uses,

d) the reprocessing of dialysers not specifically marked as intended for single use.

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 purity of 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.