CSA Z23500-4:20
(ISO 23500-4:2019, MOD)
National Standard of Canada

CSA Z23500-4:20
Preparation and quality management of fluids for haemodialysis and related therapies — Part 4: Concentrates for haemodialysis and related therapies
(ISO 23500-4:2019, MOD)

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Although the intended primary application of this Standard is stated in its Scope, it is important to note that it remains the responsibility of the users to judge its suitability for their particular purpose.

National Standard of Canada

CSA Z23500-4:20

Preparation and quality management of fluids for haemodialysis and related therapies — Part 4: Concentrates for haemodialysis and related therapies

(ISO 23500-4:2019, MOD)

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CSA Z23500-4:20
Preparation and quality management of fluids for haemodialysis and related therapies — Part 4: Concentrates for haemodialysis and related therapies
(ISO 23500-4:2019, MOD)

CSA Preface

This is the first edition of CSA Z23500-4, *Preparation and quality management of fluids for haemodialysis and related therapies —Part 4: Concentrates for haemodialysis and related therapies,* which is an adoption, with Canadian deviations, of the identically titled ISO (International Organization for Standardization) Standard 23500-4 (first edition, 2019-02). It replaces CAN/CSA-ISO 13958:15 (adopted ISO 13958:2014), *Concentrates for haemodialysis and related therapies*.

For brevity, this Standard will be referred to as "CSA Z23500-4" 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 Z23500-4 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 Z23500-4 to the International Standard shall be replaced by a reference to the equivalent Canadian Standard.

CAN/CSA-C22.2 No. 60601-1:14 (R2018)
Medical electrical equipment — Part 1: General requirements for basic safety and essential performance

CAN/CSA-C22.2 No. 61010-1:12 (R2017)
Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements

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

CSA Z23500-5:20
Preparation and quality management of fluids for haemodialysis and related therapies — Part 5: Quality of dialysis fluid for haemodialysis and related therapies

5 Tests

Table 2 — Culture techniques used in bicarbonate concentrate

[Delete the third row and footnote [b]]

INTERNATIONAL STANDARD

ISO 23500-4

First edition
2019-02

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

Part 4: Concentrates for haemodialysis and related therapies

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

Partie 4: Concentrés pour hémodialyse et thérapies apparentées

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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).

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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*.

This first edition cancels and replaces ISO 13958:2014, 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 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

The requirements and goals established by this document will help ensure the effective, safe performance of haemodialysis concentrates and related materials. This document reflects the conscientious efforts of concerned physicians, clinical engineers, nurses, dialysis technicians and dialysis patients, in consultation with device manufacturers and regulatory agency representatives, to develop a 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 standards does not imply unanimity of opinion, but rather reflects the compromise necessary in some instances when a variety of interests shall be merged.

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

Throughout this document, requirements and recommendations are made to use ISO-quality water. Therefore, it is recommended to refer to ISO 23500-3 along with this document.

For the purpose of this document, “concentrates” are a mixture of chemicals and water, or chemicals in the form of dry powder or other highly concentrated media, which are delivered to the end user to make dialysis fluid used to perform haemodialysis and related therapies.

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

Part 4: Concentrates for haemodialysis and related therapies

1 Scope

This document specifies minimum requirements for concentrates used for haemodialysis and related therapies.

This document is addressed to the manufacturer of such concentrates. In several instances in this document, the dialysis fluid is addressed, which is made by the end user, to help clarify the requirements for manufacturing concentrates. Because the manufacturer of the concentrate does not have control over the final dialysis fluid, any reference to dialysis fluid is for clarification and is not a requirement of the manufacturer.

This document includes concentrates in both liquid and powder forms. It also includes additives, also called spikes, which are chemicals that can be added to the concentrate to supplement or increase the concentration of one or more of the existing ions in the concentrate and thus in the final dialysis fluid.

This document also specifies requirements for equipment used to mix acid and bicarbonate powders into concentrate at the user's facility.

Concentrates prepared from pre-packaged salts and water at a dialysis facility for use in that facility are excluded from the scope of this document. Although references to dialysis fluid appear herein, this document does not address dialysis fluid as made by the end user. This document also excludes requirements for the surveillance frequency of water purity used for the making of dialysis fluid by the dialysis facility. This document does not address bags of sterile dialysis fluid or sorbent dialysis fluid regeneration systems that regenerate and recirculate small volumes of the dialysis fluid.

This document does not cover the dialysis fluid that is used to clinically dialyse patients. Dialysis fluid is covered in ISO 23500-5. The making of dialysis fluid involves the proportioning of concentrate and water at the bedside or in a central dialysis fluid delivery system. Although the label requirements for dialysis fluid are placed on the labelling of the concentrate, it is the user's responsibility to ensure proper use.

This document does not cover haemodialysis equipment, which is addressed in IEC 60601-2-16:2012.

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*

ISO 23500-5, *Preparation and quality management of fluids for haemodialysis and related therapies — Part 5: Quality of dialysis fluid for haemodialysis and related therapies*