SLOVENSKI STANDARD
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Smernice za pripravo in vodenje kakovosti tekočin za hemodializo in podobne terapije - 3. del: Voda za hemodializo in podobne terapije (ISO/DIS 23500-3:2017)

Guidance for the preparation and quality management of fluids for haemodialysis and related therapies - Part 3: Water for haemodialysis and related therapies (ISO/DIS 23500 -3:2017)

Leitfaden für die Vorbereitung und das Qualitätsmanagement von Konzentraten für die Hämodialyse und verwandte Therapien - Teil 3: Wasser für die Hämodialyse und verwandte Therapien (ISO/DIS 23500-3:2017)

Document d'orientation pour la préparation et le management de la qualité des liquides d'hémodialyse et de thérapies annexes - Partie 3: Eau pour hémodialyse et thérapies apparentées (ISO/DIS 23500-3:2017)

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Guidance for the preparation and quality management of fluids for haemodialysis and related therapies —

Part 3:
Water for haemodialysis and related therapies

Directives concernant la préparation et le management de la qualité des fluides d'hémodialyse et de thérapies annexes —

Partie 3: Eau 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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This document, ISO 23500-3 cancels and replaces ISO 13959:2014, It has been technically revised and renumbered to form part of a new series of standards series dealing with guidance for the preparation and quality management of fluids for haemodialysis and related therapies (ISO 23500-1, previously ISO 23500); water treatment plant, (ISO 23500-2, previously ISO 26722); concentrates used for the preparation of dialysis fluid (ISO 23500-4, previously ISO 13958); and dialysis fluid quality (ISO 23500-5, previously ISO 11663).

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 International Standard contains minimum requirements, chemical and microbiological, for the water to be used for preparation of dialysis fluids, concentrates, and for the reprocessing of haemodialysers and the necessary steps to ensure compliance 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 monitoring 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 International Standard 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 revised document.

Within this International Standard, measurement techniques current at the time of publication have been cited. Other standard methods may be used, provided that such methods have been appropriately validated and compared 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 International Standard. Operation of water treatment equipment and haemodialysis systems, including on going monitoring 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.

The verbal forms used in this International Standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this International Standard, the auxiliary verb

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this International Standard,

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this International Standard, and

— “may” is used to describe a permissible way to achieve compliance with a requirement or test.

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

Guidance for the preparation and quality management of fluids for haemodialysis and related therapies — Part 3: Water for haemodialysis and related therapies

1 Scope

This International Standard specifies minimum requirements for water to be used in haemodialysis and related therapies.

This International Standard includes water to be used in the preparation of concentrates, dialysis fluids for haemodialysis, haemodiafiltration and haemofiltration, and for the reprocessing of haemodialysers.

The operation of water treatment equipment and the final mixing of treated water with concentrates to produce dialysis fluid are excluded from this International Standard. Those operations are the sole responsibility of dialysis professionals. This International Standard does not apply to dialysis fluid regenerating systems.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 23500-4, *Guidance for the preparation and quality management of fluids for haemodialysis and related therapies — Part 4: Concentrates for haemodialysis and related therapies*

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

ISO 23500-1, *Guidance for the preparation and quality management of fluids for haemodialysis and related therapies — Part 1: General requirements*

3 Terms and definitions

The terms and definitions applicable to this document are given in ISO 23500-1.

4 Requirements

4.1 Dialysis water quality requirements

The quality of the dialysis water, as specified in 4.2 and 4.3, shall be verified upon installation of a water treatment system. Monitoring of the dialysis water quality shall be carried out thereafter.

NOTE Throughout this document it is assumed that the water undergoing treatment is potable water and therefore meets the appropriate regulatory requirements for such water. If the water supply is derived from an alternate source such as a privately owned borehole, contaminant levels may not be as rigorously controlled.

4.2 Chemical contaminant requirements

Dialysis water shall not contain chemicals at concentrations in excess of those listed in Tables 1 and 2, or as required by national legislation or regulations. Table 1 does not include any recommendation in respect of organic carbon, pesticides and other chemicals such as pharmaceutical disruptors that can be present in feed water. It is technically difficult and costly to measure such substances on a routine basis. The effect of their presence on hemodialysis patients are difficult to define and consequences of exposure are probably of a long-term nature. Furthermore, there is an absence of evidence of their widespread presence in water although it is recognized that inadvertent discharges are possible. In view of this, It is not at present possible to define limits for their presence in water used in the preparation of dialysis fluid.

Nanofiltration and reverse osmosis are capable of significant rejection of many such compounds. Granular Activated Carbon (GAC) is also highly effective at removing majority of these chemicals. However, as Granular Activated Carbon is widely used in the removal chlorine/chloramine, their use in the removal or organic carbons, pesticides and other chemicals will be dependant upon the size of the carbon filters and/or beds and users must be aware of appropriate dimensioning since majority of carbon valences may be already occupied and not available for further removal activity.

NOTE 1 See A.2 for an explanation of values supplied.

NOTE 2 The maximum allowable levels of contaminants listed in Tables 1 and 2 include the anticipated uncertainty associated with the analytical methodologies listed in Table 3.

Where the dialysis water is used for the reprocessing of haemodialysers (cleaning, testing, and mixing of disinfectants), the user is cautioned that the dialysis water shall meet the requirements of this International Standard. The dialysis water should be measured at the input to the dialyser reprocessing equipment.

Table 1 — Maximum allowable levels of toxic chemicals and dialysis fluid electrolytes in dialysis water[a]

Contaminant	Maximum concentration mg/L[b]
Contaminants with documented toxicity in haemodialysis	
Aluminium	0,01
Total chlorine[1]	0,1
Copper	0,1
Fluoride	0,2
Lead	0,005
Nitrate (as N)	2
Sulfate	100
Zinc	0,1
Electrolytes normally included in dialysis fluid	
Calcium	2 (0,05 mmol/L)
Magnesium	4 (0,15 mmol/L)
Potassium	8 (0,2 mmol/L)
Sodium	70 (3,0 mmol/L)