

HEMODIALÜÜSIS JA SELLETAOLISTES
RAVIPROTSEDUURIDES KASUTATAV VESI

Water for haemodialysis and related therapies (ISO
13959:2014)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 13959:2015 sisaldab Euroopa standardi EN ISO 13959:2015 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 13959:2015 consists of the English text of the European standard EN ISO 13959:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
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EUROPEAN STANDARD

EN ISO 13959

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English Version

Water for haemodialysis and related therapies (ISO 13959:2014)

Eau pour hémodialyse et thérapies apparentées (ISO 13959:2014)

Wasser für Hämodialyse und ähnliche Therapien (ISO 13959:2014)

This European Standard was approved by CEN on 23 November 2015.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

The text of ISO 13959:2014 has been prepared by Technical Committee ISO/TC 150 “Implants for surgery” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 13959:2015 by 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of an identical text or by endorsement, at the latest by June 2016, and conflicting national standards shall be withdrawn at the latest by June 2016.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

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Endorsement notice

The text of ISO 13959:2014 has been approved by CEN as EN ISO 13959:2015 without any modification.

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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 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 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. At the time this International Standard was published it was not possible to specify threshold values for organic contaminants permitted in water used for the preparation of dialysis fluids, concentrates, and reprocessing of haemodialysers. The issue of organic contaminants will be reassessed on the next revision of this International Standard.

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 13958 mixed with water meeting the requirements of this International Standard. Operation of water treatment equipment and haemodialysis systems, including ongoing 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. 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.

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 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1

action level

concentration of a contaminant at which steps should be taken to interrupt the trend toward higher, unacceptable levels

2.2

chlorine, combined

chlorine that is chemically combined, such as in chloramine compounds

Note 1 to entry: There is no direct test for measuring combined chlorine, but it can be measured indirectly by measuring both total and free chlorine and calculating the difference.

2.3

chlorine, free

chlorine present in water as dissolved molecular chlorine (Cl_2), hypochlorous acid (HOCl), and hypochlorite ion (OCl^-)

Note 1 to entry: The three forms of free chlorine exist in equilibrium.

2.4

chlorine, total

sum of free and combined chlorine

Note 1 to entry: Chlorine can exist in water as dissolved molecular chlorine, hypochlorous acid, and/or hypochlorite ion (free chlorine) or in chemically combined forms (combined chlorine). Where chloramine is used to disinfect water supplies, chloramine is usually the principal component of combined chlorine.

2.5

colony-forming unit

CFU

measure of bacterial or fungal cell numbers that theoretically arise from a single cell when grown on solid media

Note 1 to entry: Colonies can also form from groups of organisms when they occur in aggregates.