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Water treatment equipment for haemodialysis applications and related therapies

Équipement de traitement de l'eau pour des applications en hémodialyse et aux 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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 26722 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

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Introduction

This International Standard reflects the conscientious efforts of concerned physicians, clinical engineers, nurses, dialysis technicians and dialysis patients, in consultation with device manufacturers and government 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 International Standards, does not imply unanimity of opinion, but rather reflects the compromise necessary in some instances when a variety of interests must be merged.

The provisions of this International Standard apply to individual water treatment devices and to water treatment systems assembled from one or more of these devices. In the first instance, this International Standard 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 may be assembled from a number of individual water treatment devices, the provisions of this International Standard 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 International Standard is written principally to address water treatment systems for dialysis facilities treating multiple patients. However, many of its provisions equally apply 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.

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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:

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

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

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

The requirements established by this International Standard will help protect haemodialysis patients from adverse effects arising from known chemical and microbial contaminants found in water supplies. However, proper 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 International Standard 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. Recommendations on the preparation and handling of water and dialysis fluid in a dialysis facility are provided in ISO 23500.

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Water treatment equipment for haemodialysis applications and related therapies

1 Scope

This International Standard 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.

This International Standard covers devices used to treat water intended for use in the delivery of haemodialysis and related therapies. Included in the scope of this International Standard is water used for: (1) the preparation of concentrates from powder or other highly concentrated media at a dialysis facility; (2) the preparation of dialysis fluid that may be used for the preparation of substitution fluid; (3) the reprocessing of dialysers for multiple uses.

Included within the scope of this International Standard are 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 devices included within the scope of this International Standard are water purification devices, online water quality monitors (such as conductivity monitors), and piping systems for the distribution of dialysis water.

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Excluded from the scope of this International Standard are 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 International Standards. Also excluded from the scope of this International Standard are requirements for the ongoing monitoring of the purity of water used for dialysis fluid, concentrate preparation or dialyser reprocessing.

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2 Normative references

The following referenced documents are indispensable for the application 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 13959:2009, *Water for haemodialysis and related therapies*

3 Terms and definitions

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

3.1
action level
concentration of a contaminant at which steps should be taken to interrupt the trend toward higher, unacceptable levels

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3.2
chlorine, combined
chlorine that is chemically combined, such as in chloramine compounds

NOTE No direct test exists for measuring combined chlorine, but it can be measured indirectly by measuring both total and free chlorine and calculating the difference.

3.3
chlorine, free
dissolved molecular chlorine

3.4
chlorine, total
sum of **combined chlorine** (3.2) and **free chlorine** (3.3)

NOTE Chlorine can exist in water as dissolved molecular chlorine (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.

3.5
device
individual water purification unit, such as a softener, carbon adsorption bed, reverse osmosis unit or deionizer

NOTE This term is synonymous with the term "component" as used by the U.S. Food and Drug Administration (see Reference [26]).

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3.6
dialysis fluid
aqueous fluid containing electrolytes and usually buffer and glucose, which is intended to exchange solutes with blood during haemodialysis

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NOTE 1 The word "dialysis fluid" is used throughout this document to mean the fluid made from dialysis water and concentrates which is delivered to the dialyser by the dialysis fluid delivery system. Such phrases as "dialysate," "dialysis solution," or "dialysing fluid" may be used in place of dialysis fluid.

NOTE 2 The dialysis fluid entering the dialyser is referred to as "fresh dialysis fluid," while the fluid leaving the dialyser is referred to as "spent dialysis fluid."

NOTE 3 Dialysis fluid does not include prepackaged parenteral fluids used in some renal replacement therapies, such as haemodiafiltration and haemofiltration.

3.7
dialysis fluid delivery system
device that: (1) prepares dialysis fluid online from dialysis water and concentrates or that stores and distributes premixed dialysis fluid; (2) circulates the dialysis fluid through the dialyser; (3) monitors the dialysis fluid for temperature, conductivity (or equivalent), pressure, flow and blood leaks; (4) prevents dialysis during disinfection or cleaning modes

NOTE 1 The term includes reservoirs, conduits, proportioning devices for the dialysis fluid, and monitors and associated alarms and controls assembled as a system for the purposes listed above.

NOTE 2 The dialysis fluid supply system can be an integral part of the single patient dialysis machine or a centralized preparation system which feeds multiple bedside monitoring systems.

NOTE 3 Dialysis fluid delivery systems are also known as proportioning systems and dialysis fluid supply systems.

3.8
dialysis water
water that has been treated to meet the requirements of ISO 13959 and which is suitable for use in haemodialysis applications, including the preparation of dialysis fluid, reprocessing of dialysers, preparation of concentrates and preparation of substitution fluid for online convective therapies

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3.9
disinfection
destruction of pathogenic and other kinds of microorganisms by thermal or chemical means

NOTE 1 Disinfection is a less lethal process than sterilization, because it destroys most recognized pathogenic microorganisms but does not necessarily destroy all microbial forms.

NOTE 2 This definition of "disinfection" is equivalent to low-level disinfection in the Spaulding classification.

3.10
empty bed contact time
EBCT
time taken by a fluid to pass through an empty volume equal to the volume of a particle bed

NOTE 1 EBCT (min) is calculated using the following equation:

$$\text{EBCT} = V/Q$$

where

V is the volume of the particle bed in cubic metres;

Q is the flowrate of water through the bed in cubic metres per minute.

NOTE 2 EBCT is used as an indirect measure of how much contact occurs between particles, such as activated carbon, and water as the water flows through a bed of particles.

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3.11
endotoxin
major component of the outer cell wall of gram-negative bacteria

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NOTE Endotoxins are lipopolysaccharides, which consist of a polysaccharide chain covalently bound to lipid A. Endotoxins can acutely activate both humoral and cellular host defences, leading to a syndrome characterized by fever, shaking, chills, hypotension, multiple organ failure and even death if allowed to enter the circulation in a sufficient dose.

3.12
feed water
water supplied to a water treatment system or an individual component of a water treatment system

3.13
germicide
agent that kills microorganisms

3.14
haemodiafiltration
form of renal replacement therapy in which waste solutes are removed from blood by a combination of diffusion and convection through a high-flux membrane

NOTE Diffusive solute removal is achieved using a dialysis fluid stream as in haemodialysis. Convective solute removal is achieved by adding ultrafiltration in excess of that needed to obtain the desired weight loss; fluid balance is maintained by infusing replacement solution into the blood either before (pre-dilution haemodiafiltration) or after the dialyser (post-dilution haemodiafiltration).

3.15
haemodialysis
form of renal replacement therapy in which waste solutes are removed primarily by diffusion from blood flowing on one side of a membrane into dialysis fluid flowing on the other side

NOTE Fluid removal that is sufficient to obtain desired weight loss is achieved by establishing a hydrostatic pressure gradient across the membrane. This fluid removal provides some additional waste solute removal, particularly for higher molecular weight solutes.

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3.16
haemofiltration
form of renal replacement therapy in which waste solutes are removed from blood by convection

NOTE 1 Convective transport is achieved by ultrafiltration through a high-flux membrane. Fluid balance is maintained by infusing a replacement solution into the blood either before the haemofilter (pre-dilution haemofiltration) or after the haemofilter (post-dilution haemofiltration).

NOTE 2 There is no dialysis fluid stream in haemofiltration.

3.17
manufacturer
person who designs, manufactures, fabricates, assembles, formulates or processes a finished device

NOTE Manufacturers include, but are not limited to, those who perform the functions of contract sterilization, installation, relabelling, remanufacturing, repacking or specification development, and initial distributors of foreign entities performing these functions. The term does not cover preparation of concentrates from prepackaged dry chemicals at a dialysis facility or the handling of bulk concentrates at a dialysis facility after responsibility for the concentrate is transferred from the manufacturer to the user.

3.18
microbial
referring to microscopic organisms, bacteria, fungi and so forth

3.19
microfilter
filter designed to remove particles larger than 0,1 µm in size

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NOTE Microfilters have an absolute size cut-off and are available in both dead-end and cross-flow configurations. Some microfilters remove endotoxin by a process of adsorption and endotoxin aggregates greater than 0,1 µm in size may be removed by size exclusion.

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3.20
product water
water produced by a water treatment system or individual device thereof

3.21
source water
water entering a dialysis facility from an external supplier, such as a municipal water supply

NOTE Source water is assumed to be potable water.

3.22
total dissolved solids
TDS
sum of all ions in a solution, often approximated by means of electrical conductivity or resistivity measurements

NOTE TDS measurements are commonly used to assess the performance of reverse osmosis units. TDS values are often expressed in terms of $CaCO_3$, NaCl, KCl or 442 equivalents (mg/l). [442 is a solution of sodium sulfate (40 %), sodium bicarbonate (40 %) and sodium chloride (20 %) that closely represents the conductivity to concentration relationship, on average, for naturally occurring fresh water.]

3.23
user
physician or physician's representative responsible for the actual production and handling of dialysis fluid

NOTE This medical device International Standard is mainly directed to device manufacturers, and in that context the “user” is as noted above.

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3.24
water treatment system
collection of water purification devices and associated piping, pumps, valves, gauges, etc., that together produce dialysis water meeting the requirements of ISO 13959 for haemodialysis applications and deliver it to the point of use

NOTE See also **device** (3.5).

4 Requirements

4.1 Dialysis water quality requirements

4.1.1 General

The requirements contained in this International Standard apply to the dialysis water as it enters the equipment used to prepare concentrates from powder or other concentrated media at a dialysis facility, to prepare dialysis fluid, or to reprocess dialysers for multiple uses. As such, these requirements apply to the water treatment system as a whole and not to each of the individual devices that make up the system. However, collectively the individual devices shall produce dialysis water that, at a minimum, meets the requirements of the clause.

4.1.2 Microbiology of dialysis water

Dialysis water used to prepare dialysis fluid or concentrates from powder at a dialysis facility, or to reprocess dialysers for multiple uses, shall contain a total viable microbial count and endotoxin levels as specified in ISO 13959.

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The manufacturer or supplier of a complete water treatment and distribution system shall demonstrate that the complete water treatment, storage and distribution system meets the requirements of this International Standard, including those related to action levels, at the time of installation.

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NOTE 1 If the manufacturer or supplier does not install the water storage and distribution system, then the responsibility of the manufacturer or supplier is limited to demonstrating that the water treatment system, excluding the water storage and distribution system, meets the requirements of this International Standard. If individual devices of the water treatment system are provided by different manufacturers or suppliers, the person or organization specifying the devices is responsible for demonstrating that the complete system meets the requirements of this International Standard at the time of installation.

For disposable water treatment systems validated by the manufacturer to produce dialysis water meeting the quality requirements of this International Standard for a specified time, monitoring of the incoming feed water is required to assure that the input to the treatment system is in the range for which the system has been validated. The manufacturer's recommendations for monitoring the final dialysis water may be followed when the system is operated according to the manufacturer's instructions. Alternatively, the quality of the dialysis water may be monitored as outlined for non-validated systems.

NOTE 2 Following installation of a water treatment, storage and distribution system, the user is responsible for continued monitoring of the water bacteriology of the system and for complying with the requirements of this International Standard, including those requirements related to action levels.

4.1.3 Maximum level of chemical contaminants

Dialysis water used to prepare dialysis fluid or concentrates from powder at a dialysis facility, or to reprocess dialysers for multiple uses, shall not contain chemical contaminants at concentrations in excess of those in Tables 1 and 2 of ISO 13959 (reproduced as Tables B.1 and B.2). The manufacturer or supplier of a complete water treatment system shall recommend a system capable of meeting the requirements of this clause based on the analysis of the feed water. The system design should reflect possible seasonal variations in feed water quality. The manufacturer or supplier of a complete water treatment and distribution system shall demonstrate that the complete water treatment, storage and distribution system is capable of meeting the requirements of this International Standard at the time of installation.

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NOTE 1 If the manufacturer or supplier does not install the water storage and distribution system, then the responsibility of the manufacturer or supplier is limited to demonstrating that the water treatment system, excluding the water storage and distribution system, meets the requirements of this International Standard. If individual devices of the water treatment system are provided by different manufacturers or suppliers, the person or organization specifying the devices is responsible for demonstrating that the complete system meets the requirements of this International Standard at the time of installation.

For disposable water treatment and distribution systems that have been validated to produce dialysis water meeting the quality requirements of this International Standard for a specified time, monitoring of the incoming potable water is required to assure that the input to the treatment system is in the range for which the system has been validated. The manufacturer's recommendation for monitoring the final dialysis water may be followed when the system is operated according to the manufacturer's instructions. Alternatively, the quality of the dialysis water may be monitored as outlined for non-validated systems.

NOTE 2 Following installation of a water treatment, storage and distribution system, the user is responsible for continued monitoring of the levels of chemical contaminants in the water and for complying with the requirements of this International Standard.

4.2 Water treatment equipment requirements

4.2.1 General

4.2.1.1 Water treatment system

The supplier of the feed water or the supplier of the water treatment system or a laboratory specified by the user shall perform chemical analyses on feed water to determine the compatibility of the system with the feed water and the suitability of the system for providing dialysis water meeting the requirements of 4.1.3. The result of the chemical analyses shall be available to the user in charge of dialysis. In the case of an individual device, the person incorporating the device into the water treatment system is responsible for ensuring that incorporation of the device does not compromise the ability of the overall system to deliver dialysis water capable of meeting the requirements of 4.1.2 and 4.1.3.

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The water treatment and distribution system should include appropriate pressure gauges, flow meters, sample ports, and other ancillary equipment necessary to allow monitoring of the performance of individual system devices and the system as a whole.

Valves may be included in the water treatment system to allow individual devices to be bypassed when there is device failure or to facilitate replacement of a device. If it is possible to bypass a device of the water treatment system, then the manufacturer or installer of that component shall inform the user of the risks associated with bypassing that device and the need for clearly defining the responsibility for operating the bypass. Where such valves are installed, however, a means should be included to minimize the likelihood that the device will be inadvertently bypassed during normal operation of the system.

Operating controls shall be positioned so as to minimize inadvertent resetting.

Electrical circuits shall be separate from hydraulic circuits and adequately protected from fluid leaks.

4.2.1.2 Materials compatibility

Materials that contact dialysis water (including materials used in piping, storage, and distribution systems) shall not interact chemically or physically with that water so as to adversely affect its purity or quality. Water-contacting surfaces shall be fabricated from non-reactive materials (e.g. plastics) or appropriate stainless steel. The use of materials that are known to cause toxicity in haemodialysis, such as copper, brass, galvanized material or aluminium, is specifically prohibited at any point beyond the water treatment device used to remove contaminating metal ions, most commonly a reverse osmosis system or a deionizer. The materials of any water treatment devices (including piping, storage and distribution systems) shall be compatible with the means used to disinfect those devices. Chemicals infused into the water in the pre-treatment section, such as, chlorine, acid, flocculants and complexing agents, shall be adequately removed from dialysis water before they reach any point of use. Monitors or specific test procedures to verify removal of additives shall be provided.

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