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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

ICS 11.040.40

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92 **Foreword**

93 ISO (the International Organization for Standardization) is a worldwide federation of national
94 standards bodies (ISO member bodies). The work of preparing International Standards is normally
95 carried out through ISO technical committees. Each member body interested in a subject for which a
96 technical committee has been established has the right to be represented on that committee.
97 International organizations, governmental and non-governmental, in liaison with ISO, also take part in
98 the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all
99 matters of electrotechnical standardization.

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

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

106 Attention is drawn to the possibility that some of the elements of this document may be the subject of
107 patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

110 Introduction

111 This International Standard reflects the conscientious efforts of concerned physicians, clinical
112 engineers, nurses, dialysis technicians, and dialysis patients, in consultation with device
113 manufacturers and government representatives, to develop an International Standard for performance
114 levels that could be reasonably achieved at the time of publication. The term "consensus," as applied
115 to the development of voluntary medical device International Standards, does not imply unanimity of
116 opinion, but rather reflects the compromise necessary in some instances when a variety of interests
117 must be merged.

118 The provisions of this International Standard apply to individual water treatment devices and to water
119 treatment systems assembled from one or more of these devices. In the first instance, this
120 International Standard is directed at the individual or company that specifies the complete water
121 treatment system and, second, at the vendor who assembles and installs the system. Since systems
122 may be assembled from a number of individual water treatment devices, the provisions of this
123 International Standard are also directed at the manufacturers of these devices, provided that the
124 manufacturer indicates that the device is intended for use in haemodialysis applications. This
125 International Standard is written principally to address water treatment systems for dialysis facilities
126 treating multiple patients. However, many of its provisions equally apply to water treatment systems
127 used in applications where a single patient is treated, such as in a home dialysis or acute hospital
128 dialysis setting. Specifically, requirements for the chemical and microbiological quality of water are
129 considered to apply in all settings, regardless of whether a single patient or many patients are being
130 treated.

131 The physician in charge of dialysis has the ultimate responsibility for selecting a water treatment
132 system and maintaining the performance of that system once it has been installed and its
133 performance has been verified.

134 The requirements established by this International Standard will help protect haemodialysis patients
135 from adverse effects arising from known chemical and microbial contaminants found in water supplies.
136 However, proper dialysis and patient safety is ultimately dependent on the quality of the dialysis fluid.
137 Since the manufacturer or provider of water treatment equipment does not have control over the
138 dialysis fluid, any reference to dialysis fluid in this International Standard is for clarification only and
139 not a requirement of the manufacturer. The responsibility for assuring that the dialysis fluid is not
140 contaminated, mismatched, or otherwise damaging to the patient rests with the clinical professionals
141 caring for the patient under the supervision of the medical director. Recommendations on the
142 preparation and handling of water and dialysis fluid in a dialysis facility are provided in ISO 23500,
143 *Guidance for the preparation and quality management of fluids for haemodialysis and related*
144 *therapies.*

145 Water treatment equipment for haemodialysis applications 146 and related therapies

147 1 Scope

148 1.1 General

149 This International Standard is addressed to the manufacturer and/or provider of water treatment
150 systems and/or devices used for the express purpose of providing water for haemodialysis or related
151 therapies.

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

157 1.2 Inclusions

158 Included within the scope of this International Standard are all devices, piping, and fittings between
159 the point at which potable water is delivered to the water purification system and the point of use of
160 the dialysis water. Examples of devices included within the scope of this International Standard are
161 water purification devices, online water quality monitors (such as conductivity monitors), and piping
162 systems for the distribution of dialysis water.

163 1.3 Exclusions

164 Excluded from the scope of this International Standard are dialysis fluid supply systems that
165 proportion water and concentrates to produce dialysis fluid, sorbent dialysis fluid regeneration
166 systems that regenerate and recirculate small volumes of the dialysis fluid, dialysis concentrates,
167 haemodiafiltration systems, haemofiltration systems, systems that process dialysers for multiple uses,
168 and peritoneal dialysis systems. Some of these devices, such as dialysis fluid supply systems and
169 concentrates, are addressed in other International Standards. Also excluded from the scope of this
170 International Standard are requirements for the ongoing monitoring of the purity of water used for
171 dialysis fluid, concentrate preparation, or dialyser reprocessing.

172 2 Normative references

173 The following referenced documents are indispensable for the application of this document. For dated
174 references, only the edition cited applies. For undated references, the latest edition of the referenced
175 document (including any amendments) applies.

176 ISO 13959, *Water for haemodialysis and related therapies*.

177 3 Terms and definitions

178 For the purposes of this International Standard, the following terms and definitions apply.

179 **3.1**
 180 **action level**
 181 concentration of a contaminant at which steps should be taken to interrupt the trend toward higher,
 182 unacceptable levels

183 **3.2**
 184 **chlorine, combined**
 185 chlorine that is chemically combined, such as in chloramine compounds

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

188 **3.3**
 189 **chlorine, free**
 190 dissolved molecular chlorine

191 **3.4**
 192 **chlorine, total**
 193 sum of combined chlorine and free chlorine

194 NOTE chlorine can exist in water as dissolved molecular chlorine (free chlorine) or in chemically combined forms
 195 (combined chlorine). Where chloramine is used to disinfect water supplies, chloramine is usually the principal
 196 component of combined chlorine.

197 **3.5**
 198 **device**
 199 individual water purification unit, such as a softener, carbon adsorption bed, reverse osmosis unit, or
 200 deionizer

201 NOTE This term is synonymous with the term "component" as used by the U.S. Food and Drug Administration in
 202 its *Guidance for the Content of Premarket Notifications for Water Purification Components and Systems for*
 203 *Hemodialysis*.

204 **3.6**
 205 **dialysis fluid**
 206 aqueous fluid containing electrolytes, buffer and, usually, glucose, which is intended to exchange
 207 solutes with blood during haemodialysis

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

211 NOTE 2 In some cases glucose is also known as dextrose.

212 **3.7**
 213 **dialysis fluid supply system**
 214 devices that: (1) prepare dialysis fluid online from dialysis water and concentrates or that store and
 215 distribute premixed dialysis fluid; (2) circulate the dialysis fluid through the dialyser; (3) monitor the
 216 dialysis fluid for temperature, conductivity (or equivalent), pressure, flow, and blood leaks; and (4)
 217 prevent dialysis during disinfection or cleaning modes

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

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

222 **3.8**
 223 **dialysis water**
 224 water that has been treated to meet the requirements of ISO 13959 and which is suitable for use in
 225 haemodialysis applications, including the preparation of dialysis fluid, reprocessing of dialysers,
 226 preparation of concentrates and preparation of substitution fluid for online convective therapies

227 **3.9**
 228 **disinfection**
 229 destruction of pathogenic and other kinds of microorganisms by thermal or chemical means

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

232 NOTE This definition of “disinfection” is equivalent to low-level disinfection in the Spalding classification.

233 **3.10**
 234 **EBCT**
 235 **empty bed contact time**
 236 measure of how much contact occurs between particles, such as activated carbon, and water as the
 237 water flows through a bed of the particles

238 NOTE EBCT (min) is calculated from the following equation:

$$239 \quad \text{EBCT} = V/Q$$

240 where

241 V is the volume of particles in the bed (m^3), and Q is the flow rate of water through the bed (m^3/min).

242 **3.11**
 243 **endotoxin**
 244 major component of the outer cell wall of gram-negative bacteria

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

249 **3.12**
 250 **feed water**
 251 water supplied to a water treatment system or individual component of the system

252 **3.13**
 253 **germicide**
 254 agent that kills microorganisms

255 **3.14**
 256 **haemodiafiltration**
 257 form of renal replacement therapy in which waste solutes are removed from blood by a combination of
 258 diffusion and convection through a high-flux membrane

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

263 **3.15**
 264 **haemodialysis**
 265 form of renal replacement therapy in which waste solutes are removed primarily by diffusion from
 266 blood flowing on one side of a membrane into dialysis fluid flowing on the other side

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

270 **3.16**

271 **haemofiltration**

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

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

276 NOTE There is no dialysis fluid stream in haemofiltration.

277 **3.17**

278 **manufacturer**

279 person who designs, manufactures, fabricates, assembles, or processes a finished device

280 NOTE Manufacturers include, but are not limited to, those who perform the functions of contract sterilization,
281 installation, relabelling, remanufacturing, repacking or specification development, and initial distributors of foreign
282 entities performing these functions.

283 **3.18**

284 **microbial**

285 referring to microscopic organisms, bacteria, fungi, and so forth

286 **3.19**

287 **microfilter**

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

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

292 **3.20**

293 **product water**

294 water produced by a water treatment system or individual device thereof

295 **3.21**

296 **source water**

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

298

299 NOTE Source water is assumed to be potable water

300

301 **3.22**

302 **TDS**

303 **total dissolved solids**

304 sum of all ions in a solution, often approximated by means of electrical conductivity or resistivity
305 measurements

306 NOTE TDS measurements are commonly used to assess the performance of reverse osmosis units. TDS values
307 are often expressed in terms of CaCO₃, NaCl, KCl, or 442 equivalents (mg/L).

308 **3.23**

309 **user**

310 physician or his or her representative

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

313 **3.24**
 314 **water treatment system**
 315 collection of water purification devices and associated piping, pumps, valves, gauges, etc., that
 316 together produce dialysis water meeting the requirements of ISO 13959 for haemodialysis
 317 applications and deliver it to the point of use (see also 3.5 device)

318 **4 Requirements**

319 **4.1 Dialysis water quality requirements**

320 **4.1.1 General**

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

327 **4.1.2 Microbiology of dialysis water**

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

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

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

340 NOTE 1 If the manufacturer or supplier does not install the water storage and distribution system, then the
 341 responsibility of the manufacturer or supplier is limited to demonstrating that the water treatment system,
 342 excluding the water storage and distribution system, meets the requirements of this International Standard.

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

346 **4.1.3 Maximum level of chemical contaminants**

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