Recommendation of the Committee for Hygiene, Construction and Technology

Requirements for construction, reconstruction and operation of a Reprocessing Unit for Medical Devices (RUMED)

Part 17: Water treatment for the RUMED

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In medical device reprocessing demineralized (deionized) water with very low conductivity values is needed in various applications and processes.

The German Society of Sterile Supply (DGSV) has already issued recommendations for water treatment in its Specialist Committee for Hygiene, Construction and Technology and in the Quality Task Group as well as in the guidelines for validation (see References). The technical possibilities today go beyond these requirements and should be observed to preserve the value of the medical devices.

The following text focuses on the technology needed for water treatment to reliably and continuously assure the quality of the medium "water" required as per the current state of the art.

Note: The recommendations by the Specialist Committee for Hygiene, Construction and Technology of the German Society of Sterile Supply (DGSV) are not a planning template but rather serve as guidance.

Why water treatment?

For various reasons the water in the RUMED must undergo special treatment.

The instruments used in a hospital or medical practitioner's office must meet special requirements in terms of hardness and corrosion resistance. Therefore, for these stainless steels special chromium-nickel alloys are used. At the same time, certain cleaning and disinfection targets have to be met, which accordingly put a strain on the materials. Furthermore, the equipment and machines used must be fail-safe and economical to operate in the long term. But these too are subjected to the influences of the water, used as a medium, and the steam generated from it.

Therefore, as regards the technical supply of the operating media needed for the process technology within the RUMED, water treatment plays a key role.

EFFECT of the water on processes

The **WATER QUALITY** affects the:

- the cleaning outcome
- the disinfection outcome
- the optical appearance of the surfaces (instruments/equipment)
- the sterilization outcome
- the value retention of the instruments
- the service life of the reprocessing equipment (e.g. washer-disinfectors [WDs]/ automated endoscope reprocessors [AERs]/sterilizers)
- the pipeline system/fittings
- the efficacy of the process chemicals

Water constituents that can cause problems when reprocessing medical devices (MDs) include:

- **Hardening constituents** (calcium and magnesium salts) lead to the formation of deposits or limescale due to calcium and magnesium carbonates/sulphates
- **Heavy and non-ferrous metals** (e.g. iron, manganese, copper) lead to brownish-red deposit formations
- **Silicates/silicic acid** produce glaze-like, coloured, thin coatings
- **Chlorides** can cause pitting corrosion

Residues in the process water and sterilization steam result in stains/deposits on instruments, equipment and packaging. Therefore it is imperative that the “municipal water” provided by the supplier be treated in accordance with its intended purpose.

See also the AKI Red Brochure and publications by the Quality Task Group of the DGSV e.V.

Techniques / water treatment steps

WATER TREATMENT STEPS

The municipal water fed into the main supply pipeline of the building must have of a quality that meets the Drinking Water Regulation. This means that water that is chemically, biologically and hygienically safe for human consumption must already be provided by the supplier (see also the Recommendation by the Specialist Committee for Hygiene, Construction and Technology Part 6). From the transfer point (water meter), the economic operator is responsible.

The following methods are used to produce a suitable process water/medium:

Filters in the pipeline network

FILTERS in the drinking water network

Filtration may be required within the building already immediately after the water supplier transfer point, if rust particles or soils could be carried in older pipeline networks into the drinking water.

- Mechanical fine filter systems
- Activated charcoal filters that:
  - are the first water treatment step and
  - are used in addition to drinking water treatment for retention of chlorine-based media (which have a negative impact on the water treatment technology connected downstream).

Water hardness

WATER HARDNESS

The water hardness depends on the geological composition of the ground and varies from region to region. Rainwater seeps into the soil and absorbs alkaline earth salts (hardening constituents) such as calcium and magnesium compounds.

The degree of water hardness can be determined with a good approximation using a conductivity meter. It depends mainly on the concentration of dissolved calcium and magnesium ions and (in Germany) is expressed in German degrees of hardness (°dH). Here, 1°dH corresponds to a conductivity value of 30 µS/cm.

Water is designated as hard water if it contains, in particular, a large amount of calcium and magnesium. If the water contains only a small amount of such hardening constituents, it is called soft water.

In Germany, the quality is classified on the basis of the following values, whereby the water hardness is expressed in “degree of German hardness” (dH), as a function of the respective concentration of calcium carbonate:

Hardness range	° dH
Soft	Less than 8.4 °dH
Moderate	8.4 to 14 °dH
Hard	More than 14 °dH

Furthermore, up the 2007 the classification “very hard water” was used for values above 21.3 °dH. Many water suppliers still indicate this degree of hardness, although it is no longer officially used. The water suppliers publish the applied degree of hardness on their homepage. A more precise determination is possible by means of hand-held titration devices. Alternatively, this can be determined through laboratory analysis.

Water softening systems

In water softening, the hardening constituents are removed from the water by means of an **ION EXCHANGE PROCESS**. The ion exchanger is operated with the help of exchange material, also known as exchange resin, which removes the unwanted ions from the water. The technology used here is based on an exchange resin that is loaded with sodium. When water flows through this resin, sodium ions are released into the water and calcium and magnesium ions are deposited on the resin.

ION EXCHANGER for softening

Softening systems are available in different technical designs and sizes. For operation, the "capacity" of the system (volume of "hard" water to be "softened" in relation to the applied water hardness) represents one of the essential design parameters.

DOUBLE SOFTENING SYSTEMS

Since the availability of water as a medium is elementary for the reprocessing process, the use of a **DOUBLE SOFTENING SYSTEM** is recommended. A double softening system consists of two "filter elements", of which one is in operation and the second in regeneration or standby mode. When one filter is exhausted, the system switches to the other filter and the exhausted filter is automatically regenerated with saline brine. Due to the aforementioned fluctuations in water hardness, as well as the fluctuating quantities of ultrapure water withdrawn for instrument reprocessing, it is recommended that the quality of the softened water be monitored. Volume- or time-controlled regeneration can result in an overload of the softening system (technical term: overrun) or increased consumption of resources (water, salt, etc.). Any undetected hardness breakthroughs cause membrane blockages of the reverse osmosis unit used in the next process step.

Fluctuations in the raw water quality, which can occur regionally due to the catchment areas and/or the structure of the water supply network, must be taken into account when designing the system.

Inoculation crystallization process

INOCULATION CRYSTALLIZATION process, not suitable for the RUMED

The **INOCULATION CRYSTALLIZATION** process is based on the solubility of limescale and its attempts to form crystals. Its main role is to protect against limescale deposits in the pipeline network of the water distribution system, but it is not suitable for water treatment in the RUMED.

Reverse osmosis units

In the quest for a seawater desalination process, the principle of reverse osmosis was discovered.

REVERSE OSMOSIS UNITS

In the **REVERSE OSMOSIS PROCESS** pressurized water (softened water) is passed through a synthetic semipermeable membrane. This semipermeable membrane is permeable to water molecules but not to substances, such as salts, that are dissolved in the water.

UNDESIRABLE SUBSTANCES dissolved in the water

This gives rise to a concentrate on one side of the membrane and on the other side to purified water following removal of dissolved constituents. This is known as permeate. In this process up to 99% of all **UNDESIRABLE DISSOLVED SUBSTANCES** are removed from the treated water. Here, the pressure must be higher than the osmotic pressure. Since the concentration on one side of the membrane is permanently increased during this process and thus the difference in concentration increases, the pressure with which the treated water is pressed through the membrane must also be continuously increased. The maximum pressure is a function of the membrane type and the system operation mode.

The concentrate is rinsed off and discharged into the drain. With reverse osmosis there is therefore no waste water to be treated.

CONDUCTIVITY OF THE PERMEATE

The **PERMEATE CONDUCTIVITY** after single-stage reverse osmosis is usually less than 20 µS/cm. This value is always based on the baseline conductivity of the water to be treated and may be higher or lower depending on the water quality in a particular region.

Membrane degassing

In the water treatment process there is no retention of gases, in particular of carbon dioxide. Since gases pass through the reverse osmosis membranes the use of **MEMBRANE DEGASSING** is recommended downstream of the reverse osmosis and upstream of the electrodeionization (EDI) unit. With this method special membranes are used which are impermeable to the water itself but permeable to gases.

MEMBRANE DEGASSING after reverse osmosis

This method considerably reduces the corrosion risk to, for example, metal pipelines. At the same time, degassing in this process step enhances the effectiveness of the EDI unit connected downstream.

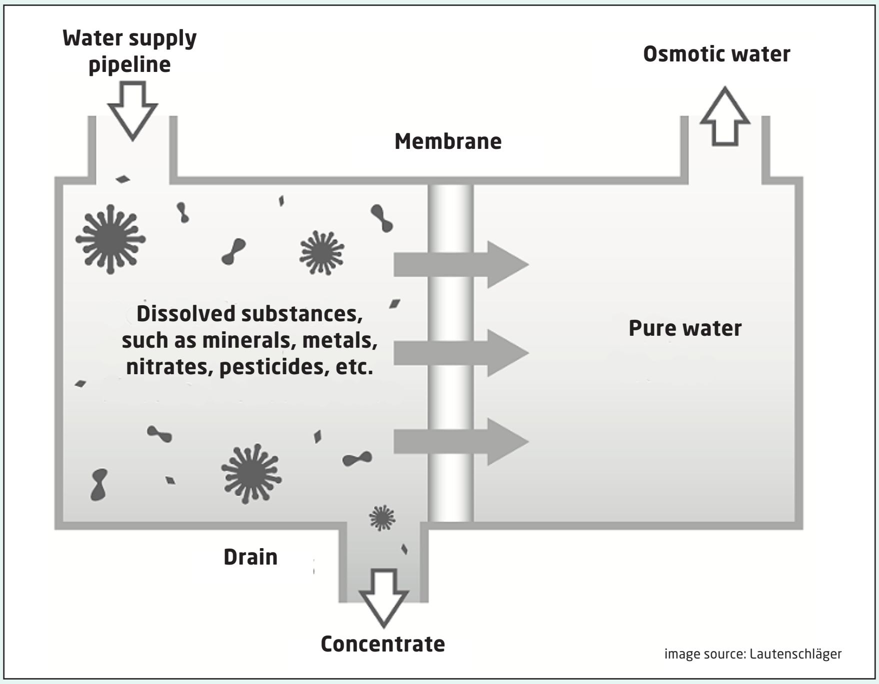

Figure 1: Principle of reverse osmosis

Electrodeionization (EDI) systems

Hitherto, **ELECTRODEIONIZATION** (EDI) has been seen as an alternative to the mixed bed exchanger. That recommendation is now changing because of the more stringent requirements addressed to the instrument surfaces and the desire to preserve the value of the instruments. EDI should be viewed as an adjunct rather than as an alternative process. Conductivity values of $< 0.1\ \mu S/cm$ can be obtained by using an EDI unit downstream of single-stage reverse osmosis.

ELECTRODEIONIZATION (EDI unit)

Ultrapure water is produced on using ion exchange membranes, ion exchange resins and electricity.

Within the EDI unit the water flows after reverse osmosis through chambers filled with mixed bed ion exchangers, a combination of anion and cation exchange resins. The respective end of the chamber is fitted with an anion exchange membrane and a cation exchange membrane. The application of an electric field causes a charge migration of the ions to the respective electrode.

The ions are thus concentrated in the concentrate chamber. The concentrate is discharged into the waste water.

At the same time, the effect of the electric field causes self-regeneration of the mixed bed exchange resin, assuring continuous and chemical-free regeneration operation without downtimes.

Deionisation with mixed bed exchanger

Since the use of water as a medium for sterile supply sterilization is subject to very high purity requirements, a mixed bed is used as a "polisher" following EDI. For safety reasons, this system should comprise at least two **EXCHANGE CARTRIDGES** connected in series. A mixed bed is also an ion exchanger.

MIXED BED EXCHANGE CARTRIDGES should be connected in series

The mixed bed exchanger is filled with acidic exchange resin for cation exchange and alkali exchange resin for anion exchange to ensure that all dissolved constituents still remaining in the water up to this treatment stage will be reliably deposited on this mixed resin. At the same time, this process step serves as the final protective barrier against any process-related discharge of weakly bound substances from the reprocessing process.

SILICATE BREAKTHROUGH, in particular, must be mentioned here. Silicates (SiO_2) do not impart any conductivity to the water and, as such, cannot be detected through conductivity measurement. For the reasons mentioned above, qualitative silicate monitoring with a correspondingly sensitive measuring range is recommended downstream of the EDI as well as downstream of the first filter of the mixed bed system.

Protection against **SILICATE BREAKTHROUGH**

SILICATE MEASUREMENT

The first **SILICATE MEASUREMENT** serves as a safety check for correct operation of the upstream treatment stages. The second measurement performed downstream of the first mixed bed filter serves as a safety function for the entire process. If the 0.4 mg/l limit value recommended by the AKI (Working Group Instrument Preparation) is exceeded, shutdown of the entire system is recommended to prevent silicate entrainment into the treatment process. The absorption capacity of the filters is directly related to the process reliability. At the latest, the first filter must be replaced if there is evidence of silicate breakthrough on it.

EXCHANGE PRINCIPLE AND REGENERATION

The **SECOND MIXED BED EXCHANGE RESIN CARTRIDGE** is then placed at position 1. At the position of the second cartridge a regenerated cartridge is fitted. The saturated cartridge must be regenerated. Therefore, at least three cartridges plus reserve are needed.

TANK

The mixed bed should be installed upstream of the **PERMEATE TANK** to rule out contamination of the tank.

Failure safety

REDUNDANCY DESIGN of demineralized water system

Emergency bypass for **SHORT-TERM BRIDGING**

A **REDUNDANCY SYSTEM DESIGN** is recommended to ensure fail-safe operation. Moreover, an emergency bypass system should be installed.

This serves only to bridge any **SHORT-TERM** downtime in the event of system malfunctions. It should cover the water requirement for one work shift. It must be noted here that mixed bed cartridges are consumed much more quickly because the supplied water will not have passed through the treatment stages.

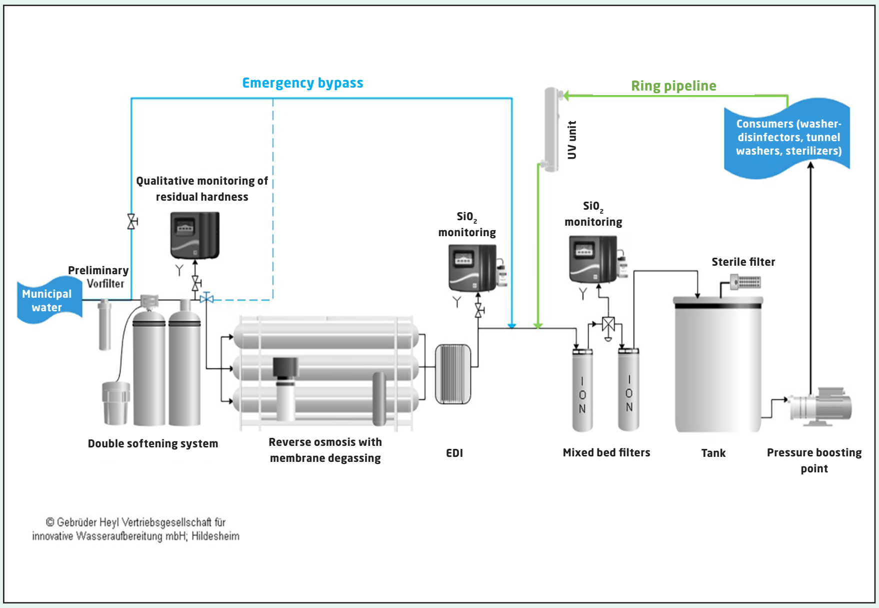

Figure 2: Example of a water treatment system design for the RUMED

Recommended design of **WATER TREATMENT SYSTEM**

To assure the best cleaning and disinfection results possible and offer maximum protection to the instruments, technical equipment and pipeline networks, it is recommended that the **WATER TREATMENT SYSTEM** be fitted with the following components:

- Activated charcoal filters
- Double softening system
- Reverse osmosis (with membrane degassing)
- EDI
- Mixed bed ion exchanger
- Tank with sterile filter

TANK SIZE

Installation of a **RING PIPELINE**

The **TANK SIZE** needed depends on the amount of demineralized water regularly needed in a work shift. An excessively large tank should be avoided. To prevent standstill contamination, the pipelines from the pressure boosting point/to the consumer should be designed as a **RING PIPELINE**. The water circulates continuously in the ring pipeline and is continuously fed in before the mixed bed.

This ensures that the treated water retains its high degree of purity even when not withdrawn.

The installation of a UV unit of appropriate size is recommended to prevent any microbial contamination from the ring pipeline network.

The pipeline network for distribution of the **DEMINERALIZED WATER** should be made of either demineralized water-resistant stainless steel or of synthetic material.

Materials for **DEMINERALIZED WATER PIPELINES**

The following MEASURED VALUES must be monitored (pursuant to DIN EN 285 as well as the AKI recommendations):

Monitoring of **MEASURED VALUES**

- Residual hardness downstream of the softening system (total alkaline earth ions): < 0.02 mmol/l
- Conductivity in reverse osmosis permeate: < 20 µS/cm+
- Conductivity downstream of EDI: < 0.1 µS/cm
- Silicate downstream of EDI (recommended): < 0.4 mg/l++
- Silicate downstream of the first mixed bed filter: < 0.4 mg/l++

Competencies/reporting chains:

COMPETENCIES AND REPORTING CHAINS

The reporting chain for faults and/or outages must be set down in writing in accordance with the quality management specifications and demonstrably brought to the attention of the employees.

The reporting chain includes the persons responsible for technical sign-off, e.g. RUMED management, engineering department, etc. as well as the technical departments, such as the building control technology.

Routine checks including maintenance and repairs:

ROUTINE CHECKS MAINTENANCE REPAIRS

Work must be carried out in accordance with the manufacturer's recommendations for both the water treatment technology and the equipment technology and documented in a service and maintenance log book.

References

- DIN EN 285
- Recommendation by the Specialist Committee for Hygiene, Construction and Technology Part 6: Technical Building Systems/Fittings
- Recommendation by the Quality Task Group Numbers 87 and 88
- AKI – Working Group Instrument Preparation
- Guideline by the German Society of Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI) for validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices, Information 3
- Guideline for validation of automated cleaning and disinfection processes for reprocessing heat-sensitive endoscopes (German Society of Hospital Hygiene (DGKH); German Society for Digestive and Metabolic Diseases (DGVS); DGSV; AKI; German Society of Endoscopy Nurses and Assistants (DEGEA), Annex 5
- Guideline for validation of automated cleaning and automated chemical disinfection of medical devices (DGKH); DGSV; AKI; German Association for Applied Hygiene (VAH), Annex 11
- Recommendation by the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and of the Federal Institute for Drugs and Medical Devices (BfArM): "Hygiene requirements for reprocessing medical devices"

+ The indicated value is intended as a guide value and is highly dependent on the raw water quality and the plant operation. To further reduce the conductivity to the recommended limit values for the individual processes, further treatment stages must be provided downstream (EDI, mixed bed).

++ Recommendation complies with the current state of knowledge and goes beyond the requirements of DIN EN 285 and meets the AKI recommendations.