Recommendation of the Committee for Hygiene, Construction and Technology

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

Part 18: Water for reprocessing medical devices (These Recommendations replace Recommendations 87 and 88 (2014) of the Quality Task Group.)

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General

The **QUALITY OF THE WATER** used to reprocess medical devices is important for helping to preserve their value and ensuring reprocessing quality. It influences the appearance and materials of medical devices. Therefore, the quality of the water, and the anticipated water quantities required, must be taken into account as early as during the planning stages of water supply systems.

WATER QUALITY helps preserve the value of medical devices.

This Recommendation addresses only water constituents. The microbiological requirements are described in the pertinent Guidelines and are not reported here.

Water has **MULTIPLE FUNCTIONS** in reprocessing, such as:

Water has **MULTIPLE FUNCTIONS.**

- Solvent for detergents and other process chemicals
- Transferring mechanical action and heat to the surfaces of medical devices
- Dissolution of water-soluble contaminants
- Rinsing off of contaminants and process chemicals
- Thermal disinfection in automated reprocessing
- Medium for steam sterilization

Water constituents and their impact on reprocessing

All natural forms of water contain dissolved salts. The nature and concentration of the water constituents of drinking water vary in accordance with the provenance of the water and how it is sourced.

Hardening constituents (calcium and magnesium salts)	Deposit formation, lime formation due to calcium and magnesium carbonates and -sulphates
Heavy and non-ferrous metals, such as iron, manganese, copper	Brownish-red deposits
Silicates/silicic acid	Glass-like, coloured thin deposits
Chlorides	Pitting corrosion
Evaporation residues (the sum of all dissolved and non-dissolved water constituents)	Stains/marks and deposits

WATER CONSTITUENTS can cause the following problems when reprocessing medical devices:

WATER CONSTITUENTS can cause problems.

Apart from its natural constituents, drinking water also sometimes contains rust particles. They mostly originate in corroded water-supply pipes. During reprocessing, these **RUST PARTICLES** are deposited on the medical devices and the chamber walls, where they can cause changes (deposits/discolouration) in surface characteristics.

RUST PARTICLES may cause surface changes.

Measures must be taken against the introduction of **EXTRANEOUS RUST AND FLASH RUST** into washer-disinfectors (WDs) and endoscope washer-disinfectors (EWDs) or the steam sterilizer from the water supply system (water containing iron or rust particles). Pertinent causes must be identified and eliminated as quickly as possible. When renewing or expanding existing piping systems, care must be taken to ensure that the materials are selected such that contact corrosion (bimetallic corrosion) can be ruled out. The processing methods used during installation must also be selected such that no undesirable processes will occur in the long term.

EXTRANEOUS RUST AND FLASH RUST in the WD/EWD must be avoided.

Hardening constituents

The hardening constituents found in water are the salts of calcium (Ca) and magnesium (Mg), which belong to the group of alkaline earth metals. Carbonate hardness is designated as temporary hardness and is the product of magnesium and calcium carbonates and bicarbonates. When water is heated, these release carbon dioxide and water to precipitate **WATER-INSOLUBLE SALTS**. These form deposits of calcium carbonate (CaCO3) and magnesium carbonate (MgCO3), also commonly known as lime or boiler scale.

WATER-INSOLUBLE SALTS form deposits.

Lime scale deposits within a reprocessing device (such as a clean-steam generator, washer-disinfector or sterilizer) and on the medical device form porous layers in which microorganisms multiply and under which corrosion can spread and hinder or prevent the cleaning of the surfaces. Deposits pose a **HYGIENE RISK** and must be avoided.

Deposits pose **HYGIENE RISKS**.

Any such deposits must be removed immediately by appropriate procedures, and the cause must be eliminated.

Heavy and non-ferrous metals

HEAVY AND NON-FERROUS METALS as well as their compounds contained in the water, can cause coloured deposits even at low concentrations.

HEAVY AND NON-FERROUS METALS may cause coloured deposits.

This group consists of hydroxides, oxides and other salts of metals such as iron, copper, manganese and zinc. The most common problems arise from iron oxide (rust).

The German Regulation for drinking water allows the presence of iron in drinking water at concentrations of up to 0.2 mg/l. The iron(II) compounds, which are soluble in water, undergo oxidation on contact with oxygen, forming iron(III) hydroxide and then iron(III) oxide (rust).

Silicates/silicic acid

Silicic acid (silicon oxide, SiO_2) is often present in drinking water. Its concentration can be reduced to an uncritical level using modern, state-of-the-art water treatment systems. To ensure this, several preparation stages are combined in actual practice (see also "Requirements for construction, reconstruction and operation of a Reprocessing Unit for Medical Devices (RUMED) – Part 17: Water treatment for the RUMED", published 09/2022). The SiO_2 content increases just before the capacity of the exchanger system is exhausted, which cannot be stopped by the exchange resins. This phenomenon is known as "silicic-acid slippage".

Silicic-acid slippage is accounted for by setting up serial treatment stages and monitoring them for threshold limits of 0.4 mg/l SiO_2.

SILICIC ACID can cause deposits inside the reprocessing device and on the medical devices.

Elevated **SILICIC ACID** levels in the last hot-rinse water can result in glass-like deposits inside the reprocessing device and on the medical devices. The deposits form a relief. These are usually bluish glass-like deposits that appear occasionally exhibit rainbow colours due to the different thicknesses of the various layers. Due to the physico-chemical properties of silicon dioxide (crystalline structure), these deposits can only be removed mechanically or chemically, for example with hydrofluoric acid. These deposits have a direct influence on the value of the medical devices and on the formation of the passivation layer.

The use of **DEMINERALIZED WATER** is recommended.

To protect the reprocessing devices used and the medical devices, it is recommended to use **DEMINERALIZED WATER.** This is the only way to ensure that the silicates are not introduced into the process as a component of the water. Silicates have almost no conductivity. Silicic-acid slippage already occurs at values > 1 μS/cm.

Chlorides

Drinking water may contain a maximum of 250 mg/l chlorides. If water with a high chloride content acts on instrument steel or if water containing chloride dries by evaporation on stainless-steel surfaces and results in hioghern chloride concentrations in the process **CHLORIDE-INDUCED PITTING CORROSION** may occur. This is an irreversible process and will result in the destruction of the stainless steel instrument.

CHLORIDE-INDUCED PITTING CORROSION may occur.

Evaporation residues

Drinking water may contain additional salts, depending on its source The total salt content can be determined by analyzing the drinking water (evaporation residues). On **EVAPORATION OF THE WATER**, such as when medical devices are dried in the WD or in the air, the salts and any other non-volatile compounds will remain on the devices. Depending on their substrate and quantity, they manifest more or less clearly as striae, streaks or curls and give the impression that the devices are not clean.

EVAPORATION OF THE WATER leaves salts and non-volatile ingredients behind.

Water treatment methods

Softening

Water is softened by exchanging the calcium and magnesium cations (hardeners) it contains for sodium ions. These salts will now no longer precipitate at high temperatures, and no lime will be formed. However, this does not result in a reduction in the total amount of water constituents (evaporation residues). Indeed, the alkalinity of **SOFTENED WATER** can even rise because of sodium carbonate formation in line with the temperature, time and carbonate hardness of the source water used.

When using **SOFTENED WATER**, the alkalinity can increase considerably.

Demineralization

DEMINERALIZATION removes virtually all salts from drinking water. In general, water is first softened to produce optimal demineralized water. This is followed by the actual demineralization process. To meet the high process requirements and ensure the necessary media quality, the softened water is first fed into a reverse osmosis system. **REVERSE OSMOSIS** already eliminates up to 98% of the dissolved substances. Subsequently, the anions and cations still remaining in the water are removed by means of EDI (electro-deionization). The conductivity of water treated in this way is $< 0.1\ \mu S/cm$. As a final safety step for the reprocessing process, it is recommended to use a serially arranged **MIXED BED**. This treatment stage ensures that in the event of a process-related discharge of silicate and other dissolved substances, these are retained before the demineralized water is fed into the tank with a sterile filter.

DEMINERALIZATION removes all salts, to the extent possible.

REVERSE OSMOSIS eliminates up to 98% of dissolved substances.

The use of a **MIXED BED** is recommended.

Water quality requirements

Water quality requirements for the reprocessing of medical devices at the cleaning stage and for the final rinse are specified in the various guidelines of DGKH, DGSV and AKI, in the manufacturers' information brochures and in the Recommendations by the Committee for Hygiene, Construction and Technology, Part 17.

The use of **DEMINERALIZED WATER** treated in accordance with the above process is recommended for final rinsing for the following reasons:

- No formation of marks/spots.
- No increase in the concentration of corrosive constituents, such as chlorides.
- No crystalline drying residues that could adversely affect the ensuing sterilization process.
- Protection and stabilization of anodized aluminium surfaces.

DEMINERALIZED WATER must be used for final rinsing.

In the interest of process optimization and to assure results of unchanging quality, the use of demineralized water is also recommended for all other reprocessing steps (except pre-cleaning).

Automated reprocessing of heat-resistant and heat-sensitive medical devices

DIN EN ISO 15883, "Washer-disinfectors", Part 1, lists the parameters that must be checked during validation. Demineralized water is also recommended for the final rinse step in mechanical medical device reprocessing.

DIN EN 285, "Steam sterilizers" lists the parameters for the feed water of a steam sterilizer. DIN EN 13060, "Small steam sterilizers", lists the parameters for the feed water for small sterilizers.

The Recommendations by the Committee for Hygiene, Construction and Technology, Part 17: "Water treatment for the RUMED" goes beyond the requirements of these standards.

The water used for manual treatment must be of the **QUALITY OF DRINKING WATER**.

Manual reprocessing of heat-resistant and heat-sensitive medical devices

Here, too, the use of demineralized water is recommended.

The water must be at least of the **QUALITY OF DRINKING WATER** pursuant to the German Regulation for drinking water (TrinkwV).

If necessary, further measures such as water filters or process integration of UV disinfection are required. For the final rinse water when reprocessing of thermolabile endoscopes, reference is made to the requirements of Annex 8 of the KRINKO/BfArM recommendation "Hygiene requirements for the reprocessing of medical devices".

References

1. German Regulation for drinking water (TrinkwV)
2. EN ISO 15883, "Washer-disinfectors", Parts 1, 2 and 4; ISO/TS 15883-5
3. EN 285, "Steam Sterilizers"
4. EN 13060, "Small steam sterilizers"
5. KRINKO/BfArM: "Hygiene requirements for the reprocessing of medical devices", Federal Health Gazette 2012, 55: 1244–1910) (www.rki.de)
6. Guideline compiled by DGKH, DGSV and AKI for the validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices (5th ed., 2017)
7. Guideline for the validation of automated cleaning and disinfection processes for reprocessing heat-sensitive endoscopes (1st ed., 2011)
8. Guideline for the validation of manual cleaning and manual chemical disinfection of medical devices (1st ed., 2013)
9. AKI Brochure "Proper Instrument Processing" (www.a-k-i.org), 11th. ed.
10. Recommendations by the Committee for Hygiene, Construction and Technology, Part 17: "Water treatment for the RUMED"
11. Information brochures supplied by the manufacturers of process chemicals and reprocessing devices