Recommendations by the Quality Task Group (87)

Water for reprocessing medical devices (Part 1)

Recommendations 87 and 88 replace Recommendations 25 and 26 (2002/2003)

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General

➜ **WATER QUALITY** plays a major role in determining the reprocessing results.

The ➜ **WATER QUALITY** used to reprocess medical instruments and other medical devices (MDs) plays a major role in helping to preserve their value and in determining the reprocessing results.

Water has various functions in the reprocessing process, e. g.:

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

➜ **WHEN PLANNING WATER SUPPLY SYSTEMS** the quality and quantity required must be taken into account.

Water of unfavourable composition can have a lasting impact on the reprocessing process as well as on the appearance of the instruments and their materials. Therefore already at the time of ➜ **PLANNING WATER SUPPLY SYSTEMS** (or the reprocessing media supply), the quality of the water, and the anticipated quantity required, must be taken into account.

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 resourced.

The water constituents can cause the following problems when reprocessing instruments:

➜ **WATER CONSTITUENTS** can cause problems in MD reprocessing.

Table 1: Water constituents causing problems in MD reprocessing

Hardening constituents (calcium and magnesium salts)	Deposit formation, lime formation due to calcium and magnesium carbonate
Heavy and non-ferrous metals, e.g. iron, manganese, copper	Brownish-red deposits
Silicates/silicic acid	Glasslike, coloured thin deposits
Chlorides	Pitting corrosion
Evaporation residues	Stains/marks and deposits

Apart from its natural constituents, drinking water also sometimes contains rust. This rust almost invariably originates from corroded water-supply pipes which is then deposited during the process on the instruments and the chamber walls, giving rise to ➜ **RUST** marks (extraneous rust) and subsequent corrosion.

➜ **RUST** will lead to stains and subsequent corrosion and has to be avoided.

Measures must be taken to protect against the introduction of extraneous rust into washer-disinfectors (WDs) and endoscope washer-disinfectors (EWDs) from the water supply system (water containing iron or rust). The reasons for this must be identified and eliminated as quickly as possible.

Hardening constituents

The hardening constituents found in water are the salts of calcium (Ca) and magnesium (Mg), and are also called alkaline earths. These are to be found dissolved in water at room temperature or lower temperatures. Carbonate hardness is classified as temporary hardness and is the product of magnesium and calcium carbonates. When water is heated they disintegrate, releasing carbonic acid and water-indissoluble salts and then precipitate. They form ➜ **DEPOSITS** of calcium carbonate ($CaCO_3$) and magnesium carbonate ($MgCO_3$), also commonly known as lime or (boiler) scale.

The lime deposits inside a machine or on the items being sterilised do not form an impermeable layer. Rather, they give rise to cavities in which microorganisms can replicate unhindered. They thus pose a hygiene risk and must be prevented. If they are formed, they must be immediately dissolved and removed by descaling with appropriate descalers (acids).

Depending on the water hardness in the individual case, at high temperatures hardening constituents give rise to deposit formation that is very difficult to dissolve (lime). In some cases this can even cause corrosion beneath the deposit formation.

➜ **DEPOSITS** of calcium and magnesium carbonate pose a hygiene risk and must be avoided or dissolved and removed.

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.

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

Iron can be present as a component of drinking water up to 0.2 mg/l (pursuant to the German Drinking Water Regulation from 2001, as amended on 5 December 2012). The iron (II) compounds, which are water soluble, undergo oxidation when they come into contact with oxygen, thus forming iron (III) hydroxide and then iron (III) oxide = rust.

➜ **COLOURED DEPOSITS** are caused by heavy and non-ferrous metals.

Silicates/silicic acid

Silicic acid (silicon oxide = SiO_2) is also often present in drinking water. In practice it has been noted that the SiO_2 content increases just before the capacity of the exchanger system is exhausted, and this cannot be impeded by the exchange resins. This phenomenon is known as "silicic acid slippage".

A higher ➜ **SILICIC ACID** content in the last hot rinse water can result in glasslike deposits inside the machine and on the instruments. These are mainly a bluish iridescent discoloration, and occasionally give rise to rainbow colours through the layers of different thickness. While these bluish glasslike deposits do not pose a hygiene risk, they are often classified as blemishes or ineffective cleaning.

➜ **SILICIC ACID** causes glasslike, bluish iridescent deposits.

Chlorides

The maximum content of chlorides permitted in drinking water is 250 mg/l. If there is a higher content, the water will have a salty taste (seawater). Chloride-induced pitting corrosion can occur if water with high chloride content is allowed to act on the steel of instruments or if ➜ **WATER CONTAINING CHLORIDE** dries by evaporating, thus becoming concentrated, on stainless steel surfaces. This is an irreversible process and results in destruction of stainless steel instruments.

➜ **WATER CONTAINING CHLORIDE** can result in chloride-induced pitting corrosion.

Evaporation residues

Drinking water may contain yet other salts depending on its source. The total salt content can be determined as evaporation residues by analysing the drinking water. When the water evaporates, e. g. when the instruments dry in the washer-disinfector or in the air, the salts and any other non-volatile compounds will remain on the instruments. Depending on their substrate and quantity, they manifest more or less clearly as striae, streaks or curls and give the impression that the instruments are not clean.

Drinking water cannot be recommended for all automated and manual reprocessing steps because of its constituents. Therefore the respective limit values are specified in the corresponding guidelines compiled by the German Society of Hospital Hygiene (DGKH), German Society of Sterile Supply (DGSV) and Working Group Instrument Preparation (AKI). Drinking water should be ➜ **SOFTENED OR DEMINERALIZED** in accordance with its intended use.

➜ **DEMINERALIZED OR SOFTENED WATER** should be preferably used for certain reprocessing steps.

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. These aspects must be taken into account in the different applications.

➜ **THE ALKALINITY** of softened water can rise 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 which takes place in a reverse osmosis system and/or mixed bed ion exchanger. To remove any remaining water constituents e. g. to prevent silicic acid ″slippage“, the use of a subsequent demineralization step by means of a second ion exchanger or electrodionization has proved beneficial.

The requirements to be met by the quality of the water used for reprocessing medical devices during the cleaning step as well as for the final rinse step are set out in various guidelines drafted by the DGKH, DGSV and AKI, in the instructions supplied by the manufacturers of the process chemicals as well as in Recommendation 86.

➜ **DEMINERALIZED WATER** is recommended for the final rinse for the following reasons:

– No formation of marks/spots;
– No rise in the concentration of corrosive constituents, e. g. chlorides;
– No crystalline drying residues that could adversely affect the ensuing sterilization process;
– Protection and stabilization of anodized aluminium surfaces.

➜ **DEMINERALIZED WATER** is recommended for the final rinse.

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 (apart from pre-cleaning).

Hygiene requirements to be met by the final rinse water

In terms of its microbiological count, the final rinse water in the pipe leading into the WDs/EWDs must be at least of the same quality (standard) as that of drinking water (≤ 100 cfu/ml).

The final rinse water in the WD chamber must not exceed 100 cfu/ml, while that in the EWD chamber must not exceed 10 cfu/100 ml.

In addition ➜ **WATER SAMPLES** must be taken regularly from the WD water-supply pipes during running operation and subjected to microbiological testing to demonstrate that these limits are being observed.

➜ **WATER SAMPLES** must be taken regularly from the WD water supply pipes during running operation and subjected to microbiological testing.

Further information/References

- German Drinking Water Regulation 2001, as amended on 5 December 2012
- DIN EN ISO 15883 Part 1, Part 2, Part 4 and ISO/TS 15883-5
- EN 285 Steam sterilizers
- RKI/BfArM: ″Hygiene requirements for reprocessing medical devices“ Federal Health Gazette 2012, 55: 1244–1910) (www.rki.de)
- Guideline compiled by the DGKH, DGSV and AKI for validation and routine monitoring of automated cleaning and thermal disinfection processes for medical devices (4th edition 2014)
- Guideline for validation of automated cleaning and disinfection processes for reprocessing heat-sensitive endoscopes (1st edition 2011).
- DIN EN ISO 15883-1 and 15883-4
- Guideline for validation of manual cleaning and manual chemical disinfection of medical devices (1st edition 2013).
- AKI Brochure ″Proper Instrument Processing“ (www.a-k-i.org), 10th edition
- Recommendation 86 of the Quality Task Group (AKQ)
- Information instructions supplied by the manufacturers of process chemicals