Recommendations by the Quality Task Group (87)

Water for reprocessing medical devices (Part 1)


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**General**

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

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:

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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.

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.

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

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

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

**RUST** will lead to stains and subsequent corrosion and has to be avoided.
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 (CaCO₃) and magnesium carbonate (MgCO₃), 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.

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.

Silicates/silicic acid
Silicic acid (silicon oxide = SiO₂) is also often present in drinking water. In practice it has been noted that the SiO₂ content increases just before the capacity of the exchange 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.

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.

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.

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

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

SILICIC ACID causes glasslike, bluish iridescent deposits.

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

DEMINERALIZED OR SOFTENED WATER should be preferably used for certain reprocessing steps.
THE ALKALINITY of softened water can rise considerably.

DEMINERALIZED WATER is recommended for the final rinse.

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

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.

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.

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.

Further information/References
- German Drinking Water Regulation 2001, as amended on 5 December 2012
- EN 285 Steam sterilizers
- 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)
- DIN EN ISO 15883-1 and 15883-4
- AKI Brochure “Proper Instrument Processing” (www.a-ki.org), 10th edition
- Recommendation 86 of the Quality Task Group (AKQ)
- Information instructions supplied by the manufacturers of process chemicals