

## **Water for Instrument Processing**

by Marcia Frieze, Case Medical

Water, the universal solvent

Water can dissolve more substances than any other liquid. It is essentially nonionic or neutral. While alkaline and acid solvents can only remove compounds of the same pH, water being neutral can dissolve solutions and compounds of any pH. Water is the body's way of purifying itself. Our bodies are 73% water, over 80% of our blood and brain are water. In addition, as a solvent, water washes through our kidneys and takes toxins out of our bodies. Simply put without water, we would be poisoned and we would cease to exist.

Water is important in all stages of medical device re-processing. In fact water is required for each step in the decontamination process from soaking to manual or automated cleaning to rinsing including the final disinfecting rinse. Furthermore even concentrated instrument cleaners are composed primarily of water, the solvent for all chemicals in the solution.

Water that is safe to drink may not be acceptable for re-processing or for sterilizing surgical devices. Water quality varies from place to place and according to the season of the year. Most public water systems include additives such as chlorine, dissolved salts and sometimes significant naturally occurring mineral content, and even organic contaminants, bacteria and endotoxins. Depending on water hardness and temperature, fresh water used can lead to the formation of hard water deposits, a layer of lime or scale that is difficult to dissolve. And, corrosion may occur under these deposits. When water evaporates, some substances can remain as visible mineral residues. Furthermore any procedure requiring water in its operation presents a potential hazard. This is particularly true if water is not continually changed or sinks cleaned after use. Water supports the growth of gram-negative bacteria. Calcium, magnesium and pH can stain instruments and inactivate disinfectants. That is why distilled, reverse osmosis (RO), or deionized (DI) water is recommended for use dilution with all concentrated instrument cleaners and approved disinfectants.

Our tap water is contaminated with toxic heavy metals, synthetic organic chemicals, chlorine, biological parasites and thousands of other harmful contaminants. According to a research group, "EPA reports show that U.S. water supplies contain over 2300 cancer causing chemicals." In addition, all the chemicals we use will ultimately show up in our tap water. There is no new water. Our planet keeps recycling the same water. Furthermore, our water treatment facilities are not designed to remove organic chemicals and toxic heavy metals, like lead.

Water treatment today is similar to practices 100 years ago as water is flown through sand beds to remove visible particles and then bleach or chlorine is added to kill bacteria. Furthermore, even treated water can contribute to the problem. In softened water, the hard water ions are replaced by sodium salts, but this does not reduce the substances in the water and alkalinity can greatly increase as a function of exposure and temperature. When a thermal disinfecting rinse is used as the final rinse, metals such as aluminum might be subject to attack. Deionized water (DI)

removes charged ions, but has no capacity for removal of non charged ions including bacteria and bacterial endotoxins. Polymeric materials used for instrument processing including plastic trays can absorb endotoxins. DI water treatment requires close monitoring for when its capacity is exceeded the treated water can have dangerously high levels of previously removed contaminants. Ultra filtration or UV may be required after deionized water treatment.

Chlorides induce pitting:

Water can also damage stainless steel instruments. Stainless instruments are susceptible to pitting when there is an increase in the chloride content in the water, when there is an increase in temperature, with decreasing pH values, increased exposure times, insufficient drying and concentration of chloride from dry residues to instrument surfaces after evaporation.

In recent years, there has been growing awareness about the importance of water in the decontamination of surgical devices and the harmful effects of even minute quantities of contaminants on patients. This is of particular concern because certain medical devices may introduce contaminants directly into the body that are normally protected by skin and mucous membranes. Metals, organic compounds, microorganisms and pyrogens can lead to adverse reactions. Furthermore patients are particularly susceptible when surgical instruments bypass the body's defenses.

Water fulfills a variety of functions in the decontamination process:

First it dissolves cleaners and other treatment agents.

It provides both mechanical action as well as transfer of heat to the surface of items to be cleaned.

It dissolves soluble dirt and impurities and it flushes away instrument chemistries and soil.

In addition, water is the source for steam used to sterilize most surgical devices and patient care items.

Water quality is an important consideration in the decontamination of surgical instruments. In Europe, HTM 2030 provides guidance on the choice, specification, purchase and validation as well as maintenance of automated washers and provides recommendations for purified water standards and system designs as well as steam quality. "The sterilization steam must be free from impurities and should neither impair the sterilization process nor damage the sterilizer or the items to be sterilized."

Clean steam

The use of feed water or steam containing substances in excess of the stated values in the table below can reduce the service life of the sterilizer and in Europe may also void the manufacturer's

warranty. As a result there are specific tolerances relating to the quality of the boiler feed water as follows:

### Acceptable levels for condensate impurities in steam

	Condensate
Evaporation	≤1,0 mg/kg
Silicon dioxide, SiO <sub>2</sub>	≤ 0,1 mg/kg
Iron	≤ 0,1 mg/kg
Cadmium	≤ 0,005 mg/kg
Lead	≤ 0,05 mg/kg
Heavy-metal traces (except iron, cadmium, lead)	≤ 0,1 mg/kg
Chlorides (Cl)	≤ 0,1 mg/kg
Phosphates (P <sub>2</sub> O <sub>5</sub> )	≤ 0,1 mg/kg
Conductivity (at 20° Celsius)	≤ 3 μS/cm
Ph-value (degree of acidity)	5 to 7
Color	Colorless  Clear  No residue
Hardness (Σ alkaline earth ions)	≤ 0,02 mmol/l

Steam quality is a measurement of the amount of moisture in steam. For steam sterilization, there is typically > 95% steam and <5% moisture. Steam purity is a measure of the amount of contaminants in steam usually coming from the boiler. Impurities in the steam source may have an adverse effect on patients, equipment and the sterilizer itself. Various contaminants may find their way into the steam source. As well as being an obvious risk to patients, these reactive contaminants in the steam may have a damaging effect on the materials in the load, may cause corrosion and impair the longevity and functionality of the devices to be sterilized. Reactions may occur when contaminants come into contact with the surgical devices either directly, or indirectly with materials that will come into contact with the sterilized product.

Recently AMMI published TIR34: 2007 which defines four levels of water quality and in what way reprocessing personnel and water maintenance personnel should collaborate with administrative personnel to implement the water quality initiatives:

**Step1 Assessment of water quality:** The potable water from public utilities should be analyzed by water maintenance personnel to determine whether the water requires treatment and if so what kind of treatment.

**Step2 Implementation of water treatment process:** Water maintenance personnel with device reprocessing personnel should ensure that water treatment provides the type of water quality needed for medical device re-processing.

Step3 Assurance of proper water quality: Water quality for the various stages in medical device reprocessing should be audited so that the proper water quality is used in each area.

Step4 Ongoing monitoring of water quality: Where applicable, monitoring procedures should be established to ensure that the treated water is of adequate quality for re-processing.

TIR 34 2007 identifies four categories of water quality, which is determined by the medical device to be cleaned and by the disinfection or sterilization process used. Portable water can be used for pre-cleaning and cleaning of critical devices and for rinsing of semi-critical and non-critical devices. High purity water is required for critical medical devices and recommended for semi-critical devices as well. Portable water is water that comes from the tap and requires no further treatment provided that it meets the characteristics in the table below.

**Categories of water quality for medical device reprocessing**

	Portable water	Softened water	Deionized water	High-purity (treated by RO or distillation)
Bacteria (cfu/mL)	< 200	< 200	< 200	≤ 10
Endotoxin (EU/mL)	NA	NA	NA	< 10
Total organic carbon (mg/L)	< 1.0	< 1.0	< 1.0	< 0.05
pH	6.5-8.5	6.5-8.5	NA	NA
Water hardness (ppm CaCO <sub>3</sub> )	< 150	< 10.0	< 1.0	< 1.0
Resistivity (MΩ-cm)	NA	NA	> 1.0	> 1.0
Total dissolved solids (mg/L CaCO <sub>3</sub> )	< 500	< 500	< 0.4	< 0.4
Ionic contaminants	< 250	< 250	< 1.0	< 0.2
Chloride (mg/L)	< 0.3	< 0.3	< 0.2	< 0.2
Iron (mg/L)	< 0.1	< 0.1	< 0.1	< 0.1
Copper (mg/L)	< 0.1	< 0.1	< 0.1	< 0.1
Manganese (mg/L)				
Color and turbidity	Colorless, clear, no residues			

Surgical instrument cleaning needs high purity, low endotoxin water. Conductivity measures total dissolved solids. Elevated dissolved solids can cause “mineral tastes” in drinking water. In addition, water high in dissolved solids can cause problems with industrial equipment, automated washers, and boilers. According to the literature, conductivity of the water used for surgical instrument cleaning should be limited to 10uS/cm to a maximum of 30uS/cm. This can be achieved easily with an RO system. For example, even though our tap water in NJ has a conductivity level of 500 to start, which is extremely high, after using a relatively inexpensive RO system the conductivity level of tap water can be greatly reduced to below the recommended values.

Water containing calcium or magnesium can form hard water deposits. These deposits become less soluble as temperature increases and can trap spores on instrument surfaces, which can survive steam or gas penetration. Soft water treatment replaces these elements by sodium ion exchange. However, softened water has no effect on conductivity without partial ionic reduction that is why RO water treatment is important for surgical instrument cleaning preparation. A defective softener has sodium chloride and resin used in the process, which may be part of the back wash process. Chloride is present in most feed waters. Removal of chloride treated water can be read by a conductivity meter coupled with an automatic dump valve drain. Where the feed water is above 120 milligrams per liter ion exchange or reverse osmosis is required. Silica (silicate) is also not removed with water softeners. RO or DI water is required.

Water softening systems have little control over water purity and downstream protection from chloride corrosion of the hospital washer and surgical instruments. "Softened water is water that receives limited treatment (softening) to remove inorganic material from the water. It will not reduce microbial levels, nor will it remove organic material from the water." AAMI TIR34: 2007

According to TIR34:2007, Reverse Osmosis (RO) has become widely used in medical device water purification systems. The advantage of RO water is that it "filters out contaminants to a high of efficiency. RO removes particulate matter, organic molecules and pyrogens that DI cannot. It is less corrosive to steel and copper." It is cheaper to run and maintain than DI. HTM2030 suggests that Reverse Osmosis would be the obvious choice as a core treatment technology, given its excellent impurity removal spectrum across ionic, organic, and microbiological species.

The numbers, types and species of microorganisms in a water supply and in used cleaning supplies increases every time the cleaning products are re-used. Good housekeeping procedures need to be followed to contain and confine organisms to prevent contamination. AAMI and AORN recommend using de-mineralized water in the final cleaning step.

There is special concern when eye instruments are re-processed. Toxic anterior segment syndrome (TASS) is an acute inflammation of the anterior chamber of the eye following cataract surgery. It has been linked to irritants on the surfaces of intraocular surgical instruments, from detergent residues and from bacilli in water baths of ultrasonic cleaners. For example, potable or softened water in early processing steps may result in unacceptable endotoxin levels. In fact TIR34: 2007 recommends that high purity water be used for the final rinse when re-processing

medical devices that contact the blood stream, cerebral-spinal fluid or the anterior chamber of the eye.

Although the AAMI working group found insufficient evidence for using high purity water for instrument processing for every stage of the decontamination process, using purified water has its advantages. Some health care facilities have installed central water treatment facilities for various departments in the hospital. Others have found a cost effective way to install point of use water treatment units in the reprocessing area.

Health care professionals as well as the public recognize the importance of water as a universal solvent. Hard water ions and chlorides can affect the outcome of instruments processed in health care settings. It is important to understand the importance of water in the cleaning process. Water is required to thoroughly rinse off organic and inorganic contaminants and to remove chemicals including detergent residue from medical devices. In conclusion, each health care facility needs to determine how pure their water is and to regularly monitor water quality and steam quality, and take the necessary steps, if required, to obtain greater water purity when processing surgical devices and patient care items.

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