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LEARNING OBJECTIVES

1. *Describe recommendations for adequate water quality for cleaning medical devices*
2. *Identify the impact of water quality on medical device reprocessing*
3. *Relate water quality to adverse events described in the scientific literature*

SELF-STUDY SERIES

Water for cleaning medical devices

by Jeane Aparecida Gonzalez Bronzatti and Rafael Queiroz de Souza

Cleaning is considered a fundamental step in the processing of healthcare products. It removes a variety of organic and inorganic dirt from instruments used in surgical procedures such as blood, proteins, lipids, bone, and ophthalmic viscosurgical devices, among others. In practice, medical devices are immersed, rinsed, or sprayed with water or solutions with surfactants to prevent the dirt from drying out. There are cases in which a pre-cleaning procedure in care areas needs to be carried out, for example, when there is a large amount of organic matter such as feces, blood, or other contaminants[1].

To make the removal of dirt to safe levels possible, it is necessary to use either manual or automated cleaning methods - or a combination of both. In all cases it is necessary to use water, which acts as a solvent, and is one of the essential elements of the Sinner's circle[2] along with four other factors: time, mechanical action, temperature, and chemical activity[3].

Considering water as an essential element, its use occurs in several stages of processing: displacement of dirt through spraying in thermo-disinfecting washers and cavitation in ultrasonic washers, dilution of cleaning solutions, and in rinsing of medical devices. Thus, water quality control is essential for the cleaning process to be effective. (See Table 1.)

Additionally, there are documents that supplement the AAMI TIR34:2014 with product-specific recommendations as well as local guidelines and regulations. These additional guidelines should be consulted in the instructions for use of each product. For example, the TIR34 provides different indications for rinsing after high-level disinfection, while the Gastroenterological Society of Australia – GESA[5] has specific and additional recommendations for the quality of water used in the processing of endoscopes (Tables 3 and 4).

In ophthalmology, there are specific recommendations due to the occurrence of acute inflammations of the anterior chamber, or segment, of the eye following cataract surgery characterized as TASS: Toxic Anterior Segment Syndrome. That said, the guidelines of the American Society of Cataract and Refractive Surgery (ASCRS), American Academy of Ophthalmology (AAO), and Ophthalmic Outpatient Surgery Society (OOSS) recommends the use of tap water only when specified by the product's instructions for use, the latest critical water rinse[6], as well as the Association periOperative Registered Nurses[7].

Although there are differences in terms of recommendations, it is important to establish a control and monitoring program aimed at reducing risks for the patient and for maintaining instruments and equipment.

Water Quality Impacts on the Sterile Processing Department

Detergent interactions

Chemical activity is a component of the Sinner's circle and is essential for efficient cleaning to be carried out[2]. Detergent formulations contain surfactants, whose function is to allow water-insoluble dirt to become soluble through its molecule that contains a hydrophilic and a hydrophobic portion, acting as a bridge between water and dirt[8].

Surfactants interact with water contaminants in the same way. During cleaning,

Table 1. Categories and recommended levels of water quality for medical device reprocessing

Specifications	Units	Utility water	Critical water
Hardness	mg/L	< 150	<1
Conductivity	µS/cm	< 500	<10
pH		6 - 9	5-7
Chlorides	mg/L	< 250	<1
Bacteria	cfu/mL	n/a (< 10)*	<10
Endotoxin	EU/mL	n/a (< 20)*	<10

*After high-level disinfection
Source: AAMI TIR34, 2014[4].

Table 3. Water quality for pre-cleaning, cleaning and rinsing (before disinfection)*

Substance or parameter	Before disinfection
Water hardness	< 150 mg/L
Chloride	< 120 mg/L

*Source: Gastroenterological Society of Australia, 2021[5].

Table 4. Water quality for automated flexible endoscope reprocessors final rinse water*

Substance or parameter	Before disinfection
Chemical purity	As per manufacturer's instructions
Total viable count	≤ 10 cfu/100 mL
Pseudomonas aeruginosa and atypical Mycobacterium species	Nil detected/100 mL
Endotoxin	≤30 EU/mL

*Source: Gastroenterological Society of Australia, 2021[5].

the use of hard water with a high concentration of calcium and magnesium ions reduces the surfactant available for cleaning medical devices because of the formation of insoluble and chemically inactive salts, compromising the cleaning efficiency[8,9].

Another important variable that can interfere with enzymatic activity is pH, especially in the cleaning steps when detergent is used, thus, the instructions for use of each solution must be considered so that the enzymatic activity is not compromised[4].

Instrument conservation

Surgical instruments are made of stainless steel; however, they are not indestructible. Stainless steel is composed of iron, carbon, chromium, nickel, manganese, silica, and other metals. Surgical instruments made of stainless steel undergo a process called passivation, which makes them less "reactive" and therefore less susceptible to corrosion[10,11].

The process of forming the passive layer can be carried out by treating the instrument's surfaces with substances that remove iron from the surface, but maintain the chromium, which is the metal responsible for the "passive" characteristic of the instrument. When broken, the passive layer can "regenerate" when exposed to air, however in the presence of dirt there will be no exposure to air and regeneration will not occur[11].

Certain chemicals and contaminants in the water used in reprocessing can also damage the passive layer, in addition to various stains on instruments and equipment. Table 5 summarizes the most common problems related to poor water quality and their potential causes.

In general, the investigation to determine the causes of stains involves the following activities (Table 6).

In the case of new surgical instruments, they must be removed from the plastic packaging as this material allows condensation which can cause rust. Additionally, they must undergo reprocessing to remove oils and other residues derived from the manufacturing process[10].

Adverse events

Adverse events resulting from contamination of the water used in the reprocessing of medical devices can be TASS, aseptic loss of implants, and pyrogenic reactions. Cases listed below will be described to illustrate the importance of using critical water for the last rinse, and also in the generation of steam as preventive measures.

Ophthalmology: The reported cases of TASS are associated with contamination of the instruments due to water. There are cases involving endotoxins[12] and inorganic contaminants[13]. One study evaluated the cytotoxicity of cannulas for hydrodissec-

Table 5. Examples of observed problems during device reprocessing that can be caused by poor water quality:

Problems	Potential causes
Residual dirt	Inefficient cleaning.
Instrument surface damage: Corrosion Pitting Rusting Stress fracture	• Drying of dirt on the surface • Exposure to some chemicals (e.g. saline solutions, chlorine, and low acidic or high alkaline chemistries) • Chlorinated water (especially when heated) or high/low pH water
Loss of color	• Exposure to some chemicals (e.g. chlorine solutions, and low acidic or high alkaline chemistries) • Chlorinated water (especially when heated) or high/low pH water
Discoloration	Excessive heating to stainless steel surfaces, combined with various water deposits
Gold-brown	
Orange-brown	Phosphate layer developing on surface (from poor water quality and even some phosphate-containing cleaning chemistries that are not rinsed correctly); often seen as orange-brown discoloration
"Rainbow"	Chromium oxide development observed as a "rainbow" stain that develops over time (and can include various blue-brown colors from the presence of copper and iron)
Black or purple staining (commonly observed after steam sterilization)	• High or low pH residuals remaining on the device following cleaning • Can be from water quality or insufficient rinsing (or neutralization) with low acidic or highly alkaline cleaning chemistries
White staining or deposits (observed following drying or steam sterilization)	• Water hardness • Combination with Other chemical contaminants (such as copper and iron) to give different colors • Other chemical residuals (e.g., residuals from inadequate rinsing of cleaning chemistries, other water contaminants such as silicon oxide)
White, chalky buildup in the water lines, lumens, and valves of an automated processor	High volume of water with high mineral content, resulting in mineral buildup
Biofilm (Slime development over time, often appearing as different colors)	• Ineffective maintenance of devices/equipment • Inadequate contact (during cleaning/ disinfection) and poor water draining (e.g., pooling)
Source: Adapted from AAMI, 2014[4].	

Self-Study Test Answers: 1. B, 2. A, 3. B, 4. A, 5. A, 6. B, 7. B, 8. A, 9. A, 10. A

Table 6. Investigation of stains on surgical instruments: activities and verification items.

Activity	Items to be verified:
Audit the instrument processing steps	Point-of-use cleaning procedures, disassembly of surgical instruments for cleaning, bristles of cleaning brushes, dilution of chemical solutions, manual and automated cleaning procedures, drying, inspection, packing, instructions for use compliance.
Review cleaning and sterilization equipment maintenance	Maintenance and qualification of cleaning and sterilization equipment, steam generator, steam supply network and pipes, water treatment systems, instructions for use compliance.
Inspect and remove instruments with rust	Visible rust, corrosion, and pitting (rust may transfer and "seed" onto quality instruments.*)
Review storage conditions (*instruments stored wet are subject to rust)	Instrument and packaging humidity, ambient humidity within acceptable limits, furniture and surfaces clean and dry.
Test water quality used in the various stages of processing	Control and monitoring of water according to each stage of reprocessing and the conditions required by the TIR34 and other applicable documents.

*Seavey, 2015[10].

tion subjected to challenge contamination, including cleaning based on a validated standard operating procedure (SOP) and final rinsing in different water qualities, demonstrating the absence of cytotoxicity, regardless of the quality of water used in the last rinse. However, the authors highlighted that the data were obtained from new instruments, that is, in a good state of conservation[14]. Considering the importance of water for the conservation of instruments, the authors did not recommend the use of tap water, therefore, the TIR34 recommendations must be followed. Another relevant aspect observed by the authors is the importance of adherence to cleaning SOPs, due to the high level of cytotoxicity of dirty instruments, since the last rinse will not compensate for poor cleaning.

Orthopedics: Instruments for orthopedic surgeries present a high level of complexity, favoring the retention of dirt[15-18] and endotoxins after cleaning and rinsing with drinking water, especially intramedullary cutters and femur scrapes[19]. In the case of flexible cutters, the retention of dirt can be cumulative between the steel blades that make up the flexible body and the toxicity of the accumulated residual is unacceptable for use[20]. It's likely this problem can be accentuated with endotoxins coming from rinse water when not properly treated. Endotoxins may also be related to the aseptic loss of implants, with adherence to cleaning and final rinsing SOPs with critical water being essential[21,22].

Cardiac catheterization: The main adverse event reported is the pyrogenic reaction caused by endotoxins after cardiac catheterization, in which patients developed fever and chills, with or without hypotension[23, 24]. A literature review on cardiac catheter reprocessing identified three articles reporting cases of pyrogenic reactions with a potential common cause: inappropriate water quality[25]. In one of the studies, an increase in the amount of endotoxins and microorganisms was observed in distilled water stored by the hospital and used in the processing of catheters[23]. The results demonstrated that water storage can be one of the critical factors in controlling water quality. In the studies found in the review, interventions to contain the cases were limited to the use of endotoxin-free water, sanitization of water distribution systems, and sterilization of catheters on the same day of reprocessing (possibly, the catheters would be less exposed to residual moisture and consequent contamination). These results reinforce the need to use critical water to prevent pyrogenic reactions.

Conclusion

The quality of cleaning water must be controlled for the following reasons:

- Ensure the effectiveness of dirt removal, avoiding the reduction of detergent activity.
- Avoid recontamination of instruments with rinse water residues, including microorganisms and endotoxins.
- Preserve surgical instruments, preventing pitting, corrosion, and various stains.
- Maintain equipment efficiency, avoiding encrustations in pipes, chambers, and resistances.
- Ensure that medical devices are free from toxic waste capable of causing adverse events. HPN

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CONTINUING EDUCATION TEST • FEBRUARY 2022

Water for cleaning medical devices

Circle the one correct answer:

1. **Cleaning is a procedure used to remove organic and inorganic matter, except hemoglobin.**
   A. True B. False
2. **The Sinner cycle requires time, mechanical action, temperature, and chemical activity.**
   A. True B. False
3. **Utility water is mainly used for flushing, washing, rinsing, and steam generation.**
   A. True B. False
4. **Medical devices such as endoscopes and ophthalmic instruments may require additional guidance on pre-cleaning and water quality. That said, additional manufacturer guidelines must be followed.**
   A. True B. False
5. **Cleaning can be compromised by both the pH of the water and the hardness of the water.**
   A. True B. False
6. **The passive layer of surgical instruments is formed by the enrichment of surface iron, which takes place through the removal of chromium, providing corrosion resistance.**
   A. True B. False
7. **Excessive chlorine in the water is responsible for the formation of deposits on the instrument surface and the clogging of water pipes.**
   A. True B. False
8. **Pooling in automated cleaning equipment, generally due to drainage failure, can induce the formation of biofilm on the equipment.**
   A. True B. False
9. **Adverse events resulting from contamination of the water used in the reprocessing of medical devices can be TASS, aseptic loss of implants, and pyrogenic reactions.**
   A. True B. False
10. **Instrument rinsing water can become contaminated during storage; therefore, this is one of the critical points in water quality control.**
    A. True B. False

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