HEALTHCARE PURCHASING NEWS

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Importance of Water Quality for Medical Device Reprocessing

by Ana Laura Villalón

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Water quality is critical in any process within a Sterile Processing Department (SPD). Inadequate water quality during medical device reprocessing can cause a number of negative outcomes, including:

1. Malfunction of the device during the patient's procedure, such as corrosion and difficulties with mechanical movement of surgical instruments due to salt deposits and debris.
2. A shortened service life of equipment and medical devices due to the gradual accumulation of organic and inorganic deposits.
3. Tissue irritation resulting from residues in a device or implant. For example, pyrogenic reactions due to high levels of endotoxins or other pyrogenic agents left as residues from water containing high microbial levels.
4. Infection of the patient resulting from the use of contaminated devices. Salt or organic deposits from water used in reprocessing could inactivate disinfectants or sterilizers, protecting microorganisms from the disinfection or sterilization process.
5. Non-condensable gases in the steam supply to sterilizers, which can significantly affect sterilizer performance and process efficiency, causing inconsistencies in sterilizer performance and Bowie-Dick test results.

Therefore, water quality and its effective treatment are issues of relevance in the reprocessing of medical devices.

Water plays various roles during medical device reprocessing, such as solvent for cleaning products and other chemicals used in processes, mechanical and thermal transmission, dissolution of water-soluble waste, and steam source for sterilization. Water can contain various undesirable substances that adversely affect all stages of medical device reprocessing. For this reason, water quality must be carefully considered, beginning with the planning phase of sanitary facilities.

The AAMI defines two categories of water quality for medical device reprocessing: utility water and critical water.[1] Utility water is water from the tap that is predominantly used in medical device washing and rinsing. This water should have a hardness level below 150 mg/L, chloride concentration below 250 mg/L, and pH ranging from 6 to 9. Conditioning (such as with a water softener) may be required for tap water to meet these specifications. Critical water is treated using a multi-step process to ensure the removal of microorganisms, organic and inorganic material. This water is mainly

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LEARNING OBJECTIVES

1. *Understand the importance of water quality in the reprocessing of medical devices and its impact on patient safety and device performance.*
2. *Identify the types of water hardness and their effects on medical device reprocessing, including the formation of lime crusts and deposit accumulation.*
3. *Describe various methods of water treatment and their role in improving water quality for medical device reprocessing.*

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used for final rinsing after washing and steam generation, and has more stringent quality limitations. Critical water hardness should be below 1 mg/L, chlorides should be maintained under 1 mg/L, and the recommended pH is 5-7.[1]

Water Hardness

Water hardness is dependent upon the amount of minerals dissolved into it. Hard water contains a high concentration of soluble salts, primarily calcium and magnesium.[2] It is classified into two types: temporary hardness and permanent hardness. Temporary hardness is caused by soluble salts of calcium and magnesium bicarbonates. When water is heated to high temperatures, these salts convert into insoluble salts of calcium and magnesium carbonates. These insoluble salts form a hard lime crust that settles on surfaces in contact with water (Figure 1). Permanent hardness is typically caused by calcium and magnesium sulfates, which do not precipitate when heated.

Treating Water for the SPD

Water incoming to the SPD is first treated via filtration, with the aim of removing as many suspended particles as possible. The quality of the filtered water depends on the pore size of the filters used in the water treatment system, and different types of filters can be employed in sequence (Figure 2).[3] The type of filtration system depends on the water source and intended use in the SPD.

Water softeners are systems that retain the salts responsible for the formation of limescale when the water is heated. These water softeners use the ion exchange principle, by using exchange resins containing sodium cations. When hard water passes through these columns, the resins trade the sodium cations for calcium and magnesium cations. Water containing calcium and magnesium bicarbonates exits with sodium bicarbonate (i.e., baking soda). Softeners are effective at removing temporary hardness, but will not address the permanent hardness of water.

Reverse osmosis is a process by which pressure is used to pass water through a semipermeable membrane from a more concentrated solution to a less concentrated solution (Figure 3). This process removes most dissolved minerals, as well as virtually all microorganisms, endotoxins, colloids and organic compounds. Water treated by reverse osmosis meets the requirements for use in steam generation for sterilization and in the final rinses of washers/disinfectors.[1]

Water Quality Testing and Monitoring

Testing is necessary to assess the quality of water received from utilities. These tests must be performed by an accredited external company with experience in water quality. The goal is to determine whether the inlet water requires treatment and, if so, what type of treatment is needed. These tests should consider the geographic location of the facility and seasonal variations. The water quality specification must ensure that no contaminants are present in concentrations that could damage the sterilizer, affect process performance, or damage the product. Contaminant levels in supplied water may be specified by the manufacturer or provided by international, regional or national standards or guidelines.[1] Failure to comply with these recommendations may shorten the life of the sterilizer and invalidate the manufacturer's warranty.

The maintenance of the water treatment system and the monitoring of its quality require collaboration between the personnel in charge of water maintenance in the sanitary institution and the staff of the SPD. Both must work together to ensure that the treatment system is properly maintained and that regular tests are carried out to verify water quality. They should receive education, training and verification of competencies with respect to their tasks in this regard.

Health institutions should provide for the maintenance of the water treatment system for the production of steam for sterilization through a monitoring system as described and an alarm system to timely alert about failures in the quality of the water supply. As an example, a monitoring system could implement the use of QR codes that allow users to send notifications via email.[4] Two types of QR codes can be made available: one for daily control, when routine tests are carried out, and another for maintenance or necessary corrective actions. Scanning these codes using a mobile device can open a form where monitoring information can be recorded and submitted. The forms can be set up to arrange the data in logs to be reviewed by the responsible persons, usually the heads of the SPD and Maintenance of the institution. Such a system offers the ability to verify whether the corresponding analyses have been completed, providing updated information on their execution. In addition, it supports immediate notification of those responsible in case of failure or incident during the process, which ensures a timely response to problems and provides traceability for future audits.

Conclusion

In conclusion, water quality is crucial in the reprocessing of medical devices. Inadequate water quality can lead to device malfunction, shortened service life, toxic effects, infections, and inconsistent sterilizer performance. Effective treatment is necessary to ensure the safety and efficacy of medical devices. Water hardness, both temporary and permanent, can cause issues like lime crust formation and deposit accumulation. Water softeners remove temporary hardness, while processes like distillation or reverse osmosis address permanent hardness. Filtration removes suspended particles, and reverse osmosis eliminates dissolved minerals and microorganisms. Regular testing and monitoring are vital to ensure the water treatment system meets specifications. Collaboration between water maintenance personnel and SPD staff is crucial. By prioritizing water quality and implementing appropriate treatment, healthcare institutions can ensure safe and effective medical device reprocessing, benefiting patient well-being. **HPN**

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

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Importance of Water Quality for Medical Device Reprocessing

Circle the one correct answer:

1. **What are some of the adverse events associated with inadequate water quality during medical device reprocessing?**
   A. Device malfunction and shortened service life
   B. Tissue irritation and infection
   C. Non-condensable gases in steam supply
   D. All of the above

2. **What is the main role of water in medical device reprocessing?**
   A. Solvent for cleaning products
   B. Mechanical and thermal transmission
   C. Dissolution of water-soluble waste
   D. All of the above

3. **What are the two categories of water quality defined by AAMI for medical device reprocessing?**
   A. Utility water and critical water
   B. Hard water and soft water
   C. Temporary hardness and permanent hardness
   D. Filtration and reverse osmosis

4. **What happens when water containing calcium and magnesium carbonates is boiled?**
   A. The water does not create steam.
   B. The salts stay in solution.
   C. The salts precipitate can form a lime crust on contacted surfaces.
   D. All of the above.

5. **Water softeners loaded with sodium cations exchange calcium and magnesium bicarbonates for _____.**
   A. calcium and magnesium carbonates
   B. oxygen and nitrogen
   C. sodium bicarbonate
   D. carbon dioxide

6. **What is the process by which water passes through a semipermeable membrane to remove dissolved minerals and microorganisms?**
   A. Filtration
   B. Water softening
   C. Reverse osmosis
   D. Distillation

7. **What is the recommended hardness level for utility water used in medical device washing and rinsing?**
   A. Below 150 mg/L
   B. Below 1 mg/L
   C. Below 250 mg/L
   D. Below 5 mg/L

8. **The type of water used for sterilizing steam generation must be _____.**
   A. Tap water
   B. Critical water
   C. Utility water
   D. None of the above

9. **What is the recommended pH range for critical water used in final rinsing and steam generation?**
   A. 1-3
   B. 4-6
   C. 5-7
   D. 8-10

10. **What is the purpose of collaboration between water maintenance personnel and SPD staff?**
    A. To ensure the water treatment system is properly maintained
    B. To conduct routine tests to verify water quality
    C. To provide education and training on water quality management
    D. All of the above

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