

New Jersey Health Care Central Service Association



**Water, water everywhere nor
any drop to drink**

AAMI TIR34:2014

Water for the reprocessing of medical devices

Presented by Fred Alston, CSPDT
Director of Clinical Sales and Services, Eastern Region



December 2, 2019
Kenilworth, NJ



Disclosure

- I am an employee of Healthmark Industries Fraser, Michigan USA
- I am involved with the manufacture and distribution of medical products to healthcare facilities and healthcare professionals
- No compensation has been received for this presentation or for travel to and from the seminar
- All opinions are those of the presenter

Healthmark Policy & Philosophy

Healthmark's Policy

Is to provide our customers and the healthcare community with the highest quality, state of the art medical products and support services in a timely and cost effective manner.

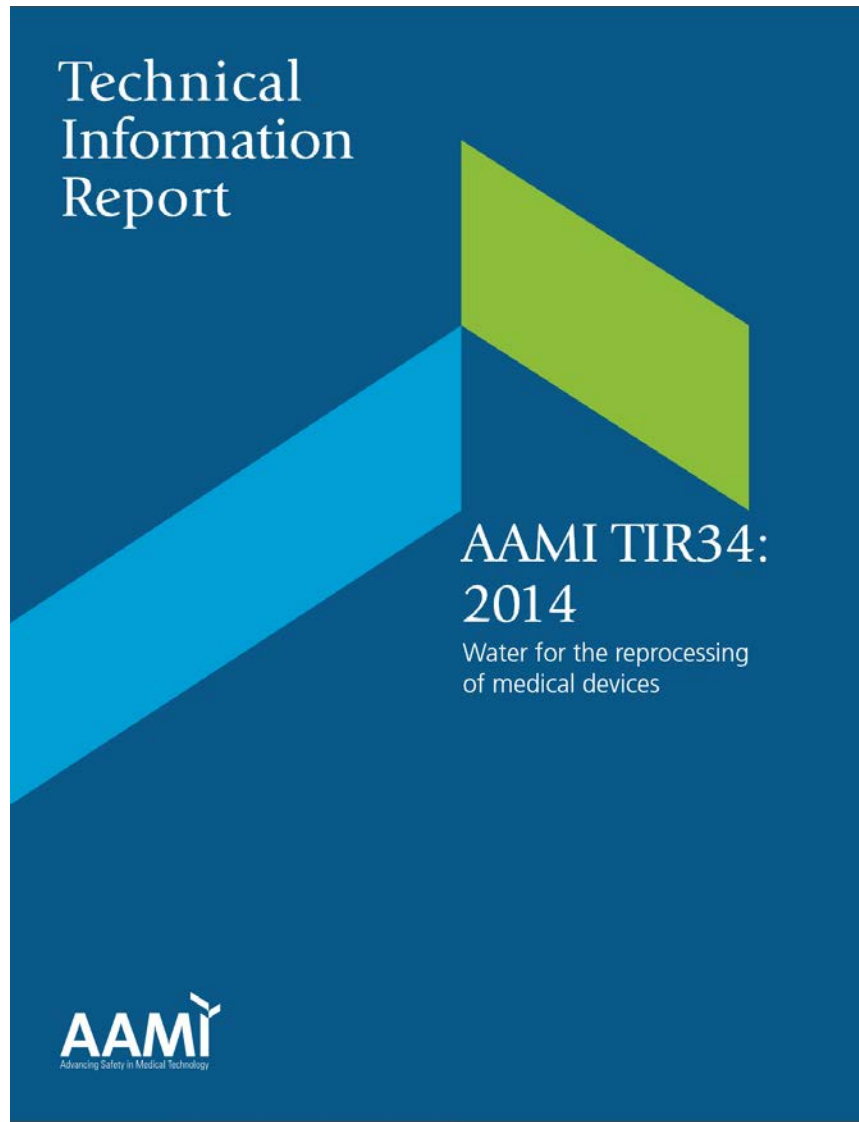
This goal is supported by a staff committed to individual accountability, professionalism, mutual respect, collaboration and service excellence. This presentation is part of that commitment, educating our customers.

Healthmark's Philosophy

It is more than just buying a product or running a test.

It is about having clinically relevant, evidence-based, products. Along with support for Healthmark products both clinically and educationally with the understanding that an educated customer is our Best Customer.

Water for the reprocessing of medical devices



An immersion into the AAMI TIR34:2014 (Water for the reprocessing of medical devices) and understanding how appropriate water quality can improve the entire sterile process.

Water for the reprocessing of medical devices

Introduction

Course objectives

In this course, we will present the following topics:

- WIIFM (What's In It For Me?)
- Explain how water quality was defined before TIR34:2007
- Discuss the changes between TIR34:2007 and TIR34:2014
- Understand the newly defined categories of water quality.
- Discuss the proper applications for the different categories.
- Understand how water quality directly affects my sterile process.



Water for the reprocessing of medical devices

WIIFM

- Good quality water is vital in all areas to insure a successful processing department and outcomes.
- Where is water used in my department and how does it affect my processes and budget?

- Sinks
- Sonics
- Automatic Endoscope Reprocessors (AER)
- Washer Disinfectors
- Cart Washers
- Sterilizers



Water for the reprocessing of medical devices

Before TIR34:2007

Water Treatment

“Any procedure or method used to alter the chemical composition of natural ‘behavior’ of a water supply.”
CLSI:2005

“Water Treatment is the removal of unwanted contaminants from water...” TIR34:2007, 6.1

Water Supplies

Classified as either Surface Water or Groundwater. (CLSI: 2005)

Water for the reprocessing of medical devices

Before TIR34:2007

- Clinical and Laboratory Standards Institute (CLSI) established three levels of water quality for use in research and diagnostic laboratories (CLSI, 2005)
- Type I, Type II and Type III
- Type I is the purest and Type III is equated to tap water.
- CLSI did not really define water types and their applications for use in healthcare.
- AAMI documentation touched on water quality but never defined it and its applications.
- TIR34:2007 Released in 2008 and updated in 2014.

Water for the reprocessing of medical devices

AAMI TIR34:2014

TIR34:2014

Water for the reprocessing of medical devices

- Scope
- Definitions
- The importance of water quality and effective water treatment
- Categories of water quality for medical device reprocessing
- Selection of water quality
- Water treatment systems
- Monitoring water quality
- Strategies for bacterial control
- Personnel considerations
- Continuous quality improvement

There are also 8 Annexes, A - H.

Water for the reprocessing of medical devices

AAMI TIR34:2014

Section 3.4 defines three different categories of medical devices:

Critical Devices: “Instruments or objects that are introduced directly into the human body, either into or in contact with the bloodstream or into other normally sterile areas of the body, and products with sterile fluid pathways.”

Semicritical Devices: “ Instruments or objects that contact intact mucosal membranes or non-intact skin of the patient during use but do not usually penetrate the blood barrier or other normally sterile areas of the body.”

Noncritical Devices: “ Instruments or objects that usually contact only the intact skin of the patient.”

Water for the reprocessing of medical devices

AAMI TIR34:2014

Section 4.2 in **2007** created four categories of water quality

Potable Water: (water as it comes from the tap) requires no further treatment, provided that it meets some basic criteria. (described in Table 1 on pages 14,15)

Softened Water: “...water that received limited treatment (softening) to reduce scaling by replacing calcium and magnesium ions with more soluble sodium ions. This treatment process will not reduce microbial levels, nor will it remove organic material from the water.”

Deionized Water: “...water that receives limited treatment (deionization) to remove inorganic material from the water. This treatment process will not reduce microbial levels, nor will it remove organic material from the water.”

High-Purity Water: “...water that is extensively treated (usually by a multi step treatment process that may include a carbon bed, softening, DI, and RO or distillation) to insure that the microorganisms and the inorganic and organic material are removed from the water; a final submicron filtration may also occur as part of the treatment process.”

Water for the reprocessing of medical devices

AAMI TIR34:2014

Section 4.2 in **2014** has reduced it to TWO categories of water quality

Utility Water:

“Water as it comes from the tap that might require further treatment to achieve the specifications. This water is mainly used for flushing, washing, and rinsing.”

“Tap Water” is referenced frequently.

Critical Water:

“ Water that is extensively treated (usually by a multistep treatment process that could include a carbon bed, softening, DI, and RO or distillation) to ensure that the microorganisms and the inorganic and organic material are removed from the water; a final submicron filtration could also be part of the treatment process. This water is mainly used for the final rinse or steam generation.”

Water for the reprocessing of medical devices

Water treatment methods

Annex A

Sediment Filters/Coarse Filtration

- Removes particulates and relatively coarse particulate materials from incoming water.
- Pre-treatment for additional water conditioning.
- Replacement of Filters.
- Bed filters contain multiple layers.

Softening

- Accomplished typically by using “Sodium” to remove hardness.
- If not maintained properly, the “Sodium” can create challenges.

Carbon Filtration (Absorption)

- Removal of Chlorine and Chloramines.
- Replacement of filters .(Regenerated Carbon should not be used for medical reprocessing applications.)

Water for the reprocessing of medical devices

Water treatment methods

Annex A

Reverse Osmosis

- Removes dissolved inorganic solutes.
- Removes microorganisms including bacterial endotoxins.
- Requires regular maintenance including membrane replacement and pre-filter replacements.

Deionization

- Removes anions and cations.
- Regular replacement of pre-treatment filters and regeneration of resin filters.
- Does not remove bacteria and bacterial endotoxins.
- Use as a primary means of purification is not recommended.

Ultrafiltration

- Membrane based device used to remove particles down to 1,000 daltons.
- Can remove bacteria and endotoxins.

Distillation

- Removes bacteria, inorganic and organic solutes, and endotoxins.
- Storage tanks require regular sanitizing.
- Resistivity of the water requires regular monitoring.

Water for the reprocessing of medical devices

Why is water treatment necessary?

General Information

Untreated tap water is generally considered hard water.

Hard Water is typically made up of the following contaminants:

- Iron
- Chlorine
- Manganese
- Silica's
- Sulfates
- Aluminum
- Chlorides
- Sodium
- Alkalinity
- Potassium
- Nitrates and Nitrites
- Phosphates

Iron: Rusty Brown Appearance. Can cause challenges with valves, piping.

Manganese: Can form a dark nearly black precipitate.

Water for the reprocessing of medical devices

Why is water treatment necessary?

- **Chlorides:** At higher levels can corrode metals in water supply systems and stainless steel.
- **Alkalinity:** Can contribute to scaling and raise the pH of water.
- **Chlorine:** Good bactericidal qualities, bad for instrumentation and equipment.
- **Silica:** Occurs naturally, at higher temps can cause scaling. Difficult to remove.
- **Sodium:** Used in water softening. Can cause corrosion of boilers and if concentrated enough, will corrode stainless steel.

Water for the reprocessing of medical devices

Why is water treatment necessary?

How does “Water Quality” affect me in my CS or OR Department?

- Ever notice a trend with intermittent occurrences of Wet packs or poor results in washer verification tests typically twice a year, April and October?
- Sterilizers use a lot of water during a cycle. The harder the water the greater the chance for premature failure of valves, ejectors and clogged strainers.
 - Water Types: Utility
- Sterilizers with integral Steam Generators are especially susceptible to Scale, Chlorides, Silica and Sodium levels.
- As steam is generated the water is “Boiled” off and a greater concentration of these potentially dangerous and metal damaging precipitates remain.
 - Water Types: Utility, Critical (Softened, DI or RO only with additional treatment.)

Water for the reprocessing of medical devices

Applications in my department

- **Cart Washers:** use a large amount of water. As the quality of the water decreases, the greater the possibility of scale build up on the chamber walls and sump.
 - Water Types: Utility, Critical (Softened, DI or RO)
- **House Steam Quality:** Often overlooked but if the chemical treatment is not properly managed, damage or discoloration of stainless instruments can occur as well as premature failure of sterilizer valves and check valves. Discoloration of Sterilizer chamber can occur as well.
 - Water Types: Utility, Critical (Softened, DI or RO, only with further treatment)
- **Scope Washers** utilize Pre-Filters. The harder the water, the more frequently these sometimes expensive filters need changing.
 - Water Types: Utility, Critical Based on Manufacturers IFU.

Water for the reprocessing of medical devices

Applications in my department

- **Sinks and Sonics:** As hardness increases so does detergent or enzyme amounts to achieve the same effectiveness.
 - Water Types: Utility. For Final Rinse, Critical
- **Washer Disinfectors:** The more the water is treated, the better the quality of instrumentation. Less enzyme and detergent are needed to achieve quality results. Water valves require less maintenance and the likelihood of scaling in the chamber diminishes.
 - Water Types: Utility. For Final Rinse, Critical

Water for the reprocessing of medical devices

Applications in my department

Section 5 Selection of Water Quality

Manual Cleaning

- **Pre-Cleaning and Cleaning:** Utility water is suitable for cleaning the device.
- **Rinsing:** Utility water is suitable unless the device will touch the bloodstream where Critical water is recommended.

AAMI TIR34:2014, 5.2.1

Water for the reprocessing of medical devices

Automated cleaning (washer/disinfector)

All treatment stages require water. The quality of water is important in all stages of the cleaning , decontamination, and disinfection process. Utility water is the minimum acceptable quality. However the water quality should be compatible with the items being processed, detergents being used and based on applicable IFU's.

- **Pre-cleaning:** Cold Utility water. Temp should not exceed ~~121~~ 123 °F.
- **Enzymatic wash:** Utility water. Water should meet the enzymatic detergent manufacturer's criteria. Temp range is typically 110°F to 130°F depending on detergent manufacturers IFU.
- **Main Detergent Wash:** Utility Water.
NOTE: The detergent selected should be compatible with the tap water in the region. Check with the detergent IFU before using the other water types for compatibility. Wash temp can range from 120°F to 160°F.

Water for the reprocessing of medical devices

Automated cleaning (washer/disinfector)

Rinse Phase: Warm or Hot Utility water although Critical water can be used depending on the category of the medical device being processed.

Final Rinse/Thermal Disinfection: Critical water should be considered based upon the category of the medical device being processed. Some manufactures recommend the use of Critical water for the final rinse of all categories of instruments. Temperature can range from 180°F to 194°F.

Maximum temperature of the water should be compatible with the items being processed.

AAMI TIR34:2014, 5.2.2.3

Also in Table 2 on page 22

Water for the reprocessing of medical devices

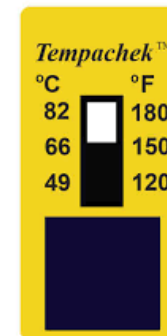
Section 6: Water treatment systems

- Utility (tap water) is often of insufficient quality to be used for specific reprocessing activities.
- When exploring water treatment systems, work with a water treatment specialist to help design a system to meet your needs.
- Water treatment systems should be located as close as possible to the area where the treated water is to be used.
- Alarms for the system should be located in both the area where the system is located and in the area where the water is used.

Water for the reprocessing of medical devices

Section 7: Monitoring water quality

- Water quality monitoring is primarily the responsibility of the facility's water maintenance staff. (additional detail is found in Annex B)
- Lack of monitoring can result in water heavily contaminated with microorganisms and other contaminants that could contribute to corrosion, staining, and increased microbial levels after processing.
 - (Table 6, on page 31, lists an overview of water quality monitoring)
- Using the correct water temperature along with the correct water type is critical to help insure a quality cleaning process.
- Temperature monitoring tools include:
 - Irreversible thermometers
 - Reversible thermometers
 - Thermologgers
 - Temperature probes



Water for the reprocessing of medical devices

What do I have control of?

Most likely your facility is already doing some water treatment, but there are several solutions to help minimize the remaining hard water effects in your department.

- For your large sterilizer using house steam, a steam separator or conditioning package can be installed to “Filter” contaminants from the steam. It also helps “Dry” the steam to help prevent Wet Packs.
- For smaller sterilizers utilizing integral steam generators, Small R.O. units can be installed to critical water for steam.

Two benefits:

- minimal maintenance required for the generator
- very good quality steam.

Water for the reprocessing of medical devices

What do I have control of?

Washer Disinfectors: Using Critical water in the final rinse is a preferred process method. If extreme hard water is present, using treated water for all phases can reduce enzyme and detergent usage and keep the chambers spotless as well as providing for cleaner instrumentation.

Critical water for the washer can be generated several ways:

- **Softening:** The challenge is that not all hardness is removed and the sodium used can tie up detergents in the washing rendering them less effective.
- **D.I. Water:** More pure than what is necessary. Low initial cost but frequent resin regeneration is costly. (Does not remove organics)
- **R.O. Water:** High quality water. Higher front end cost but will be less expensive than D.I. over time. Requires quarterly maintenance. (Process removes organics from the water)

Water Quality or something else?



Is this really hard water ?

- There has been a growing concern about the effectiveness of decontamination technique for reusable medical instrumentation in healthcare facilities. Studies have shown the ability of sterilization technologies, which under normal conditions, achieve acceptable sterility assurance levels, to be greatly impaired by the presence of residual soil containing serum and salt.*

*Alfa,M.,et al, Comparison of Ion Plasma, Vaporized Hydrogen Peroxide, and 100% Ethylene oxide Sterilization to the 12/88 Ethylene oxide gas Sterilizer, Infection Control and Hospital epidemiology, 1996; 17:92-100



Water for the reprocessing of medical devices

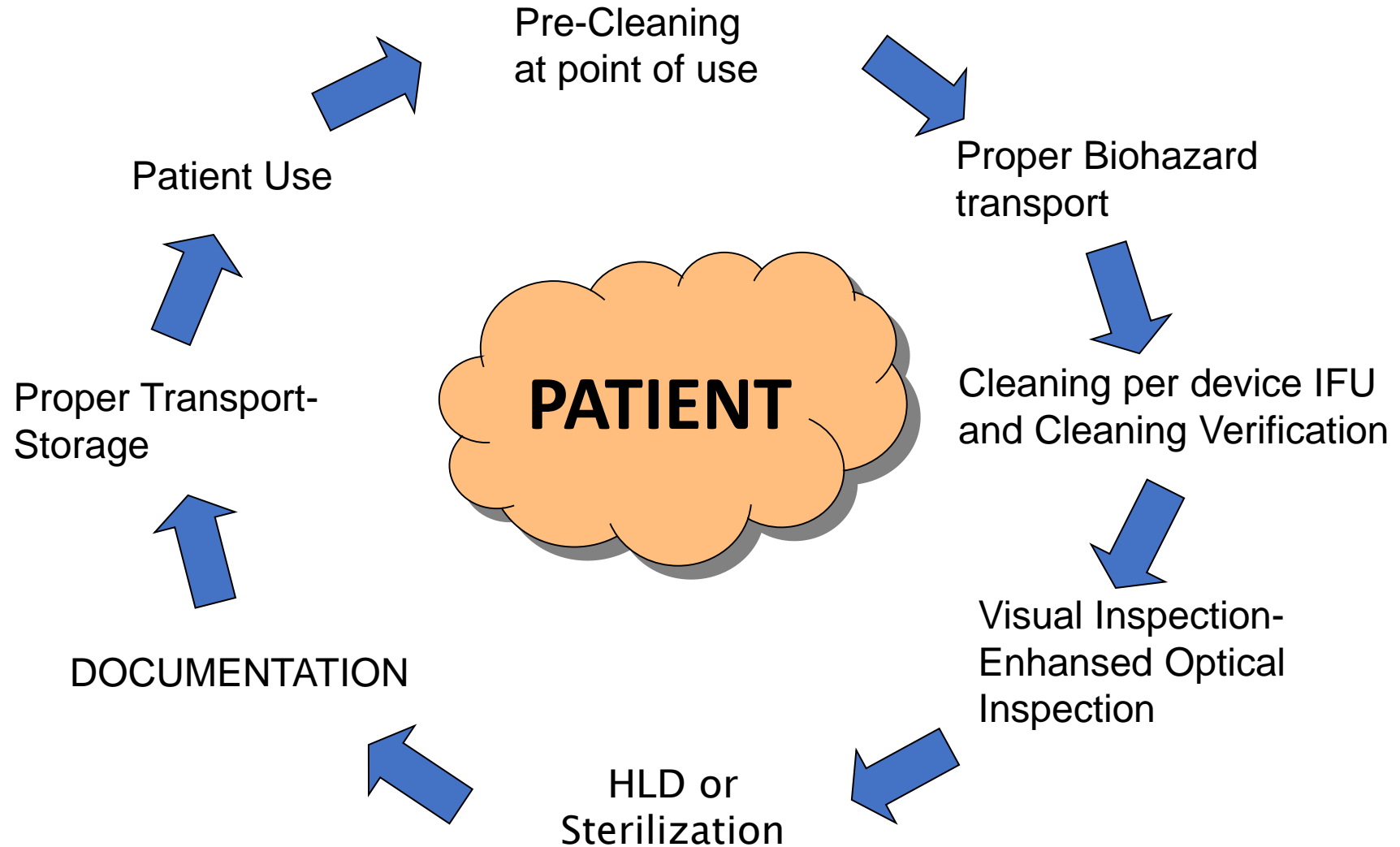
What do you think?

Water is a very complex, vital component in your department.

“Sterile is not Sterile unless Clean is Clean”

Managed and treated properly, water can enhance product quality and reduce equipment downtime.

The circle of life



Thank You!

Questions?

On behalf of Healthmark, I would like to thank you all for the opportunity to be here today.

THANK YOU!

Healthmark Support Team Information:

Chris Morrisey

Cell: 908.399.0938

Email: chris@morriseymedical.com



Fred Alston

Director, Clinical Sales and Services,
Eastern Region

Cell: 724.448.4121

Email: falston@hmark.com

www.hmark.com

www.healthmarkgi.com

On behalf of Healthmark, I would like to thank you all
for the opportunity to be here today.

We are here to help!

THANK YOU!

For what you all do each and every day to
help safeguard positive patient outcomes.

You do make a difference!