Introduction to ST108: Water Quality for Processing Medical Devices

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Disclaimer

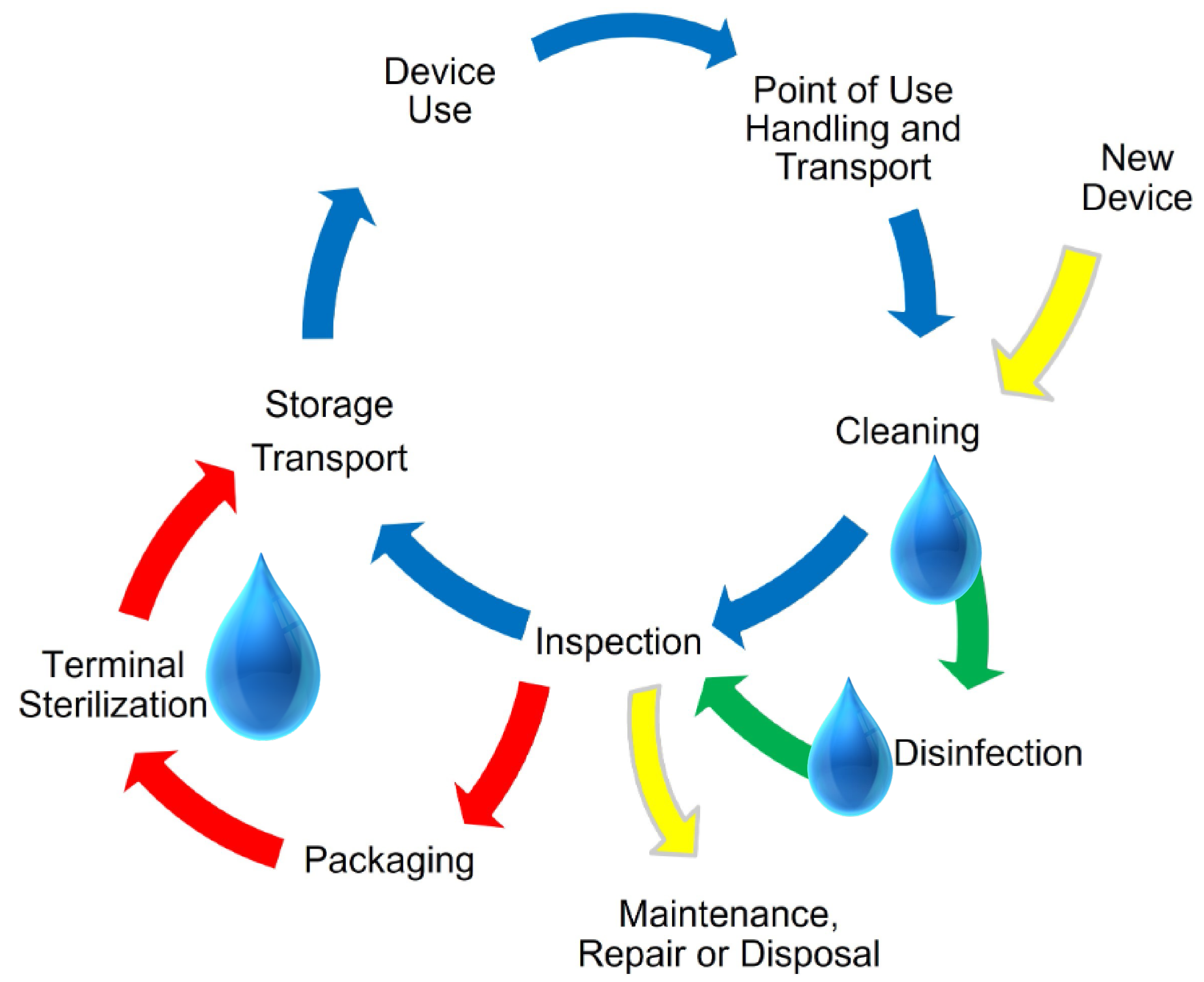
- The presentation is intended for educational purposes only and does not replace independent professional judgment. Statements of fact and opinions expressed are those of the participant individually and, unless expressly stated to the contrary, are not the opinion or position of Johnson & Johnson or its affiliates.

Objectives

- Overview of water quality & reason for ST108
- Roles & Responsibilities of Multidisciplinary Team
- Risk Analysis
- Categories of water and why
- Water quality selection
- How to get the water you need (Water treatment systems)
- Maintaining water treatment systems
- How to use the annexes of AAMI ST108

Water for Device Processing

- Required for device processing
- Water quality can impact processing outcome
  - Cleaning agent performance
  - Detergent residuals



Poor Water Quality

INEFFECTIVE cleaning / disinfection because of chemical integration with water contaminants

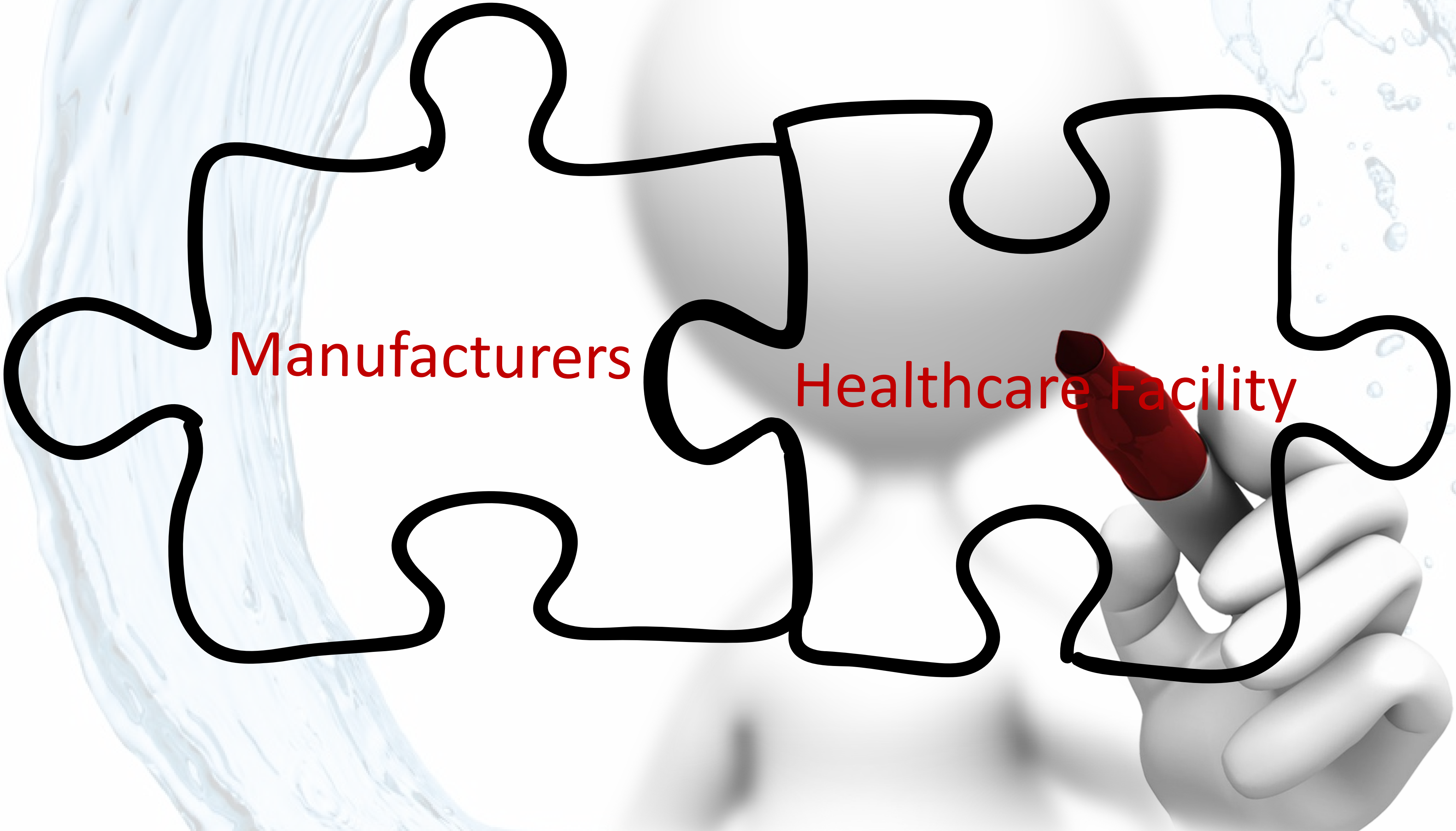
Steam PURITY with water contaminants

Device MALFUNCTION during a patient procedure

TOXIC effects and tissue irritation resulting from residuals

Patient INFECTION resulting from the use of contaminated devices

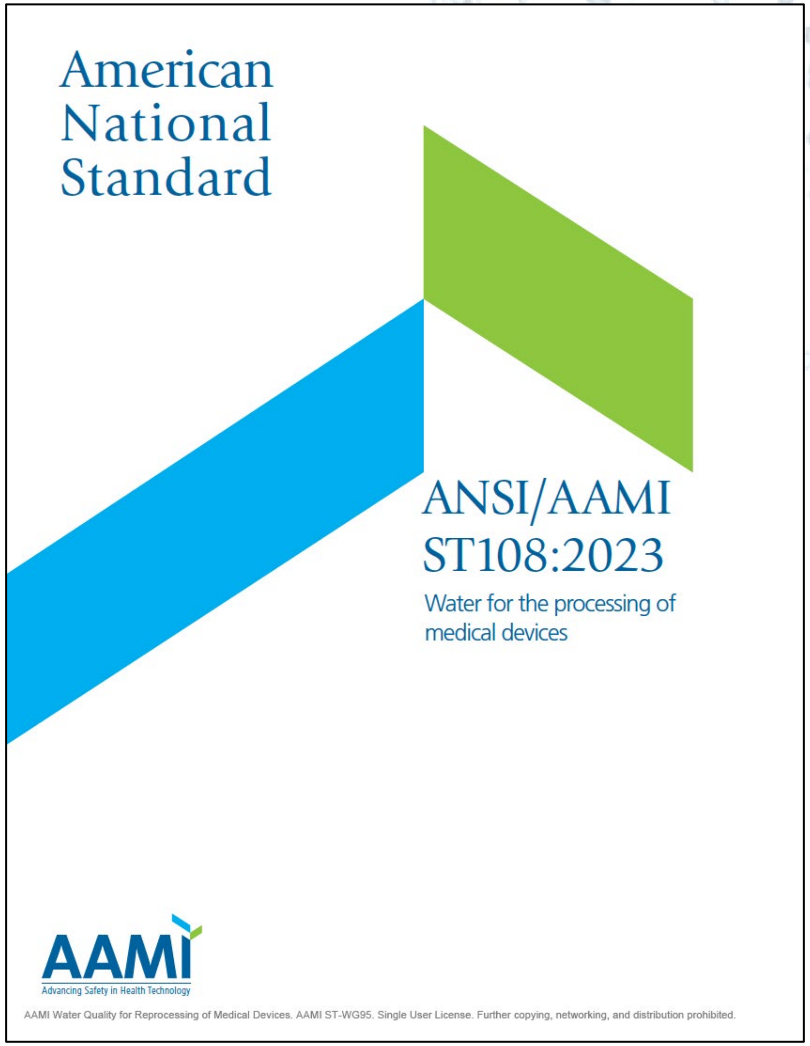
Device Performance Responsibility



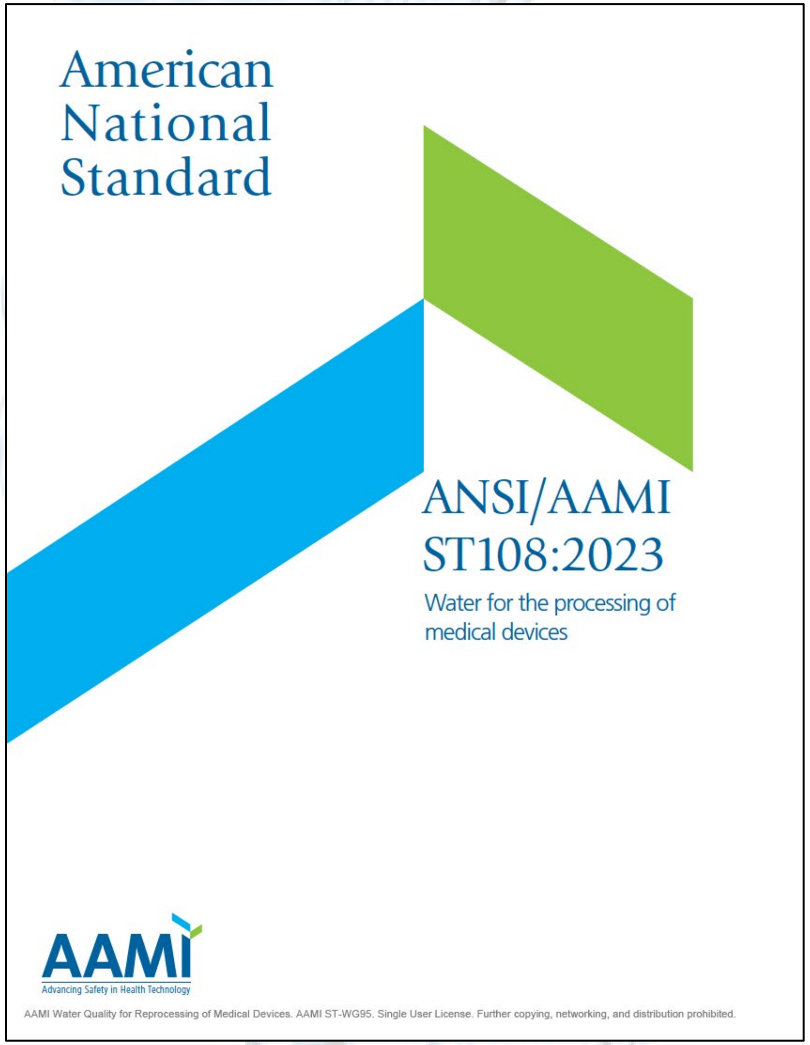
ANSI/AAMI ST108 – Communication Bridge

The What

- Roles & Responsibilities
- Risk Analysis
- Categories of Water Quality
- Water Quality Requirements
- Water System Installation / Operational / Performance Qualification
- Routine Monitoring
- Continuous Improvement
- Water System Maintenance



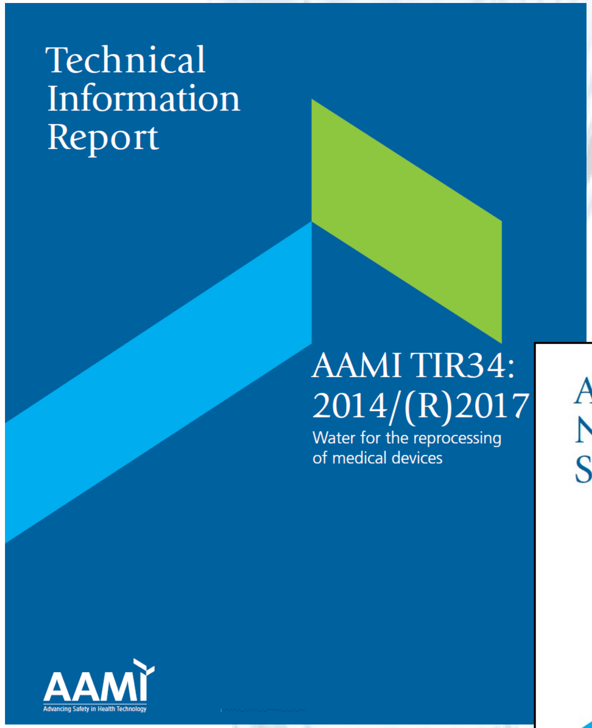
ANSI/AAMI ST108 – Communication Bridge

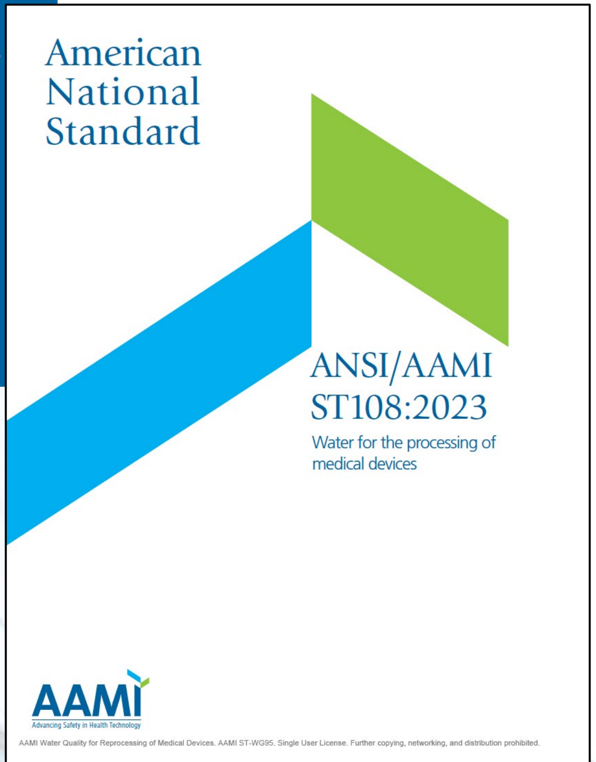


The How

- Application of Normative Requirements
- Risk Analysis
- Automated Endoscope Reprocessor
- Water in Cleaning and Heat Processes
- Water Treatment Technologies
- Water Treatment System Design
- Routine Monitoring
- Typical Water Quality Issues

AAMI TIR34 compared to ANSI/AAMI ST108





The What

- Roles & Responsibilities
- Risk Analysis
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- Water System Installation / Operational / Performance Qualification
- Routine Monitoring
- Continuous Improvement
- Water System Maintenance

Multidisciplinary Team...the needed expertise

- Local building code and infrastructure
- Infection prevention principles
- Operations unique to the facility, organization, health system
  - Sterile processing functions and equipment
    - Decontamination
    - Sterilizers
  - End-users of surgical instruments/medical devices
  - Capital planning
  - Risk management
  - Quality
- Water treatment
- Executive authority

Water Management Program

ASHRAE 188:2018 – Legionellosis: Risk Management for Building Water Systems

Integrate water management into existing programs

Multidisciplinary Team…Who to include?

- Senior organizational leaders (Executive sponsorship)
- Facilities engineering
- Infection preventionist
- Sterile processing technicians and leaders
- Clinical engineering
- Perioperative team members
- Endoscopy team members
- Water treatment specialist
- Laboratory personnel
- Risk managers
- Quality improvement specialists
- Change management specialists

Table 1—Multidisciplinary team responsibilities

Primary responsibility	Action
Facilities engineering personnel, multidisciplinary water management consultant or other external contracted personnel	General assessment of water quality. Per manufacturer guidelines routinely sample water and determine if values are within specified ranges per management plan
Facilities engineering personnel in conjunction with medical device processing personnel, multidisciplinary team, water management consultant or other external contracted personnel	Implementation of water treatment processes; determine appropriate method/equipment required for the facility's water supply
Medical device processing personnel in conjunction with clinical engineering personnel, external contracted personnel, or consultant	Assurance of proper water quality for the various stages in medical device processing using water quality monitoring
All members of the multidisciplinary team	Manages the water management program

Risk Analysis

ADVERSE EFFECT TO THE MEDICAL DEVICE

ADVERSE EFFECTS TO THE PROCESS

ADVERSE EFFECTS TO THE PATIENT

ADVERSE EFFECT TO PERSONNEL

Water Categories

Utility Water – cleaning and rinsing

Critical Water – final steps of processing

Steam - sterilization

Water Quality Requirements

- Rationales for each value are included in section 6.3
- Updated quality requirements from TIR34
  - Alkalinity
  - TOC
  - Ionic Contaminates

Table 2—Categories and performance qualification levels of water quality for medical device processing

Water Quality Measurement	Units	Utility Water	Critical Water	Steam*
pH @ 25 °C:	pH	6.5 – 9.5	5.0 – 7.5	5.0 – 9.2**
Total Alkalinity	mg $CaCO_3$/L	<400	<8	<8
Bacteria	CFU/mL	<500***	<10	N/A
Endotoxin	EU/mL	N/A***	<10	N/A
Total Organic Carbon (TOC)	mg/L (ppm)	N/A	<1.0	N/A
Color and Turbidity	Visual	Colorless, clear, without sediment	Colorless, clear, without sediment	Colorless, clear, without sediment
Ionic Contaminants				
Aluminum	mg/L	<0.1	<0.1	<0.1
Chloride	mg/L	<250	<1	<1
Conductivity	µS/cm	<500	<10	<10
Copper	mg/L	<0.1	<0.1	<0.1
Iron	mg/L	<0.1	<0.1	<0.1
Manganese	mg/L	<0.1	<0.1	<0.1
Nitrate	mg/L	<10	<1	<1
Phosphate	mg/L	<5	<1	<1
Sulfate	mg/L	<150	<1	<1
Silicate	mg/L	<50	<1	<1
Total Hardness	mg $CaCO_3$/L	<150****	<1	<1
Zinc	mg/L	<0.1	<0.1	<0.1

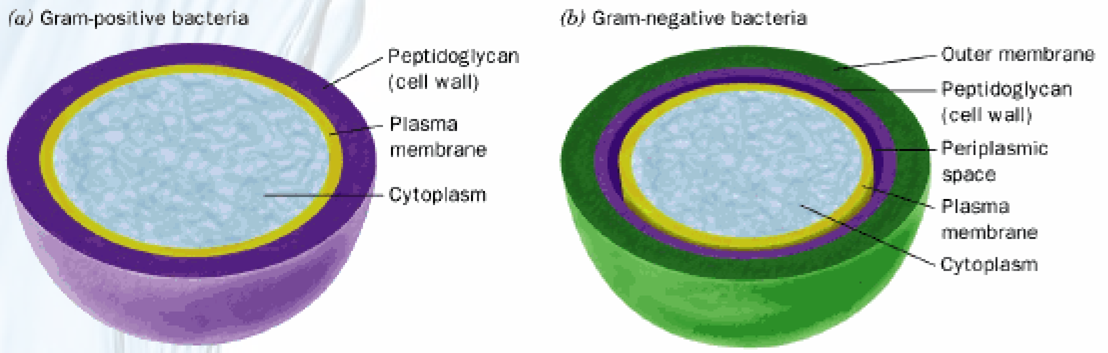
Tap Water Quality

DIFFERENT BASED ON GEOGRAPHICAL REGION

Common Tap Water Components:

- Inorganic & Organic components
  - Bacterial Endotoxins
  - Organic Pollutants (e.g., microorganisms, plants, animals, pesticides)
- Dissolved Salts (Hard Water)
- Ionic Molecules (Chlorine, Iron, Copper, etc..) - Usually chlorinated to prevent microbial replication

What is Bacterial Endotoxin



Schematic diagram comparing the cell envelopes of (*a*) gram-positive bacteria and (*b*) gram-negative bacteria

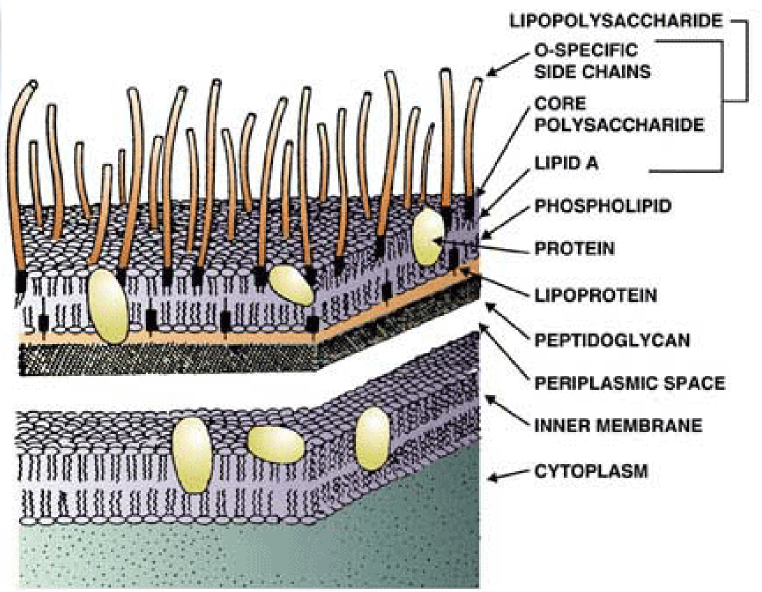
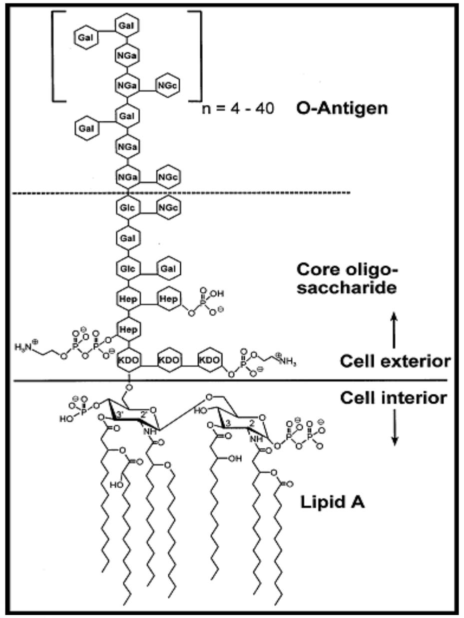


DIAGRAM OF A GRAM-NEGATIVE CELL MEMBRANE

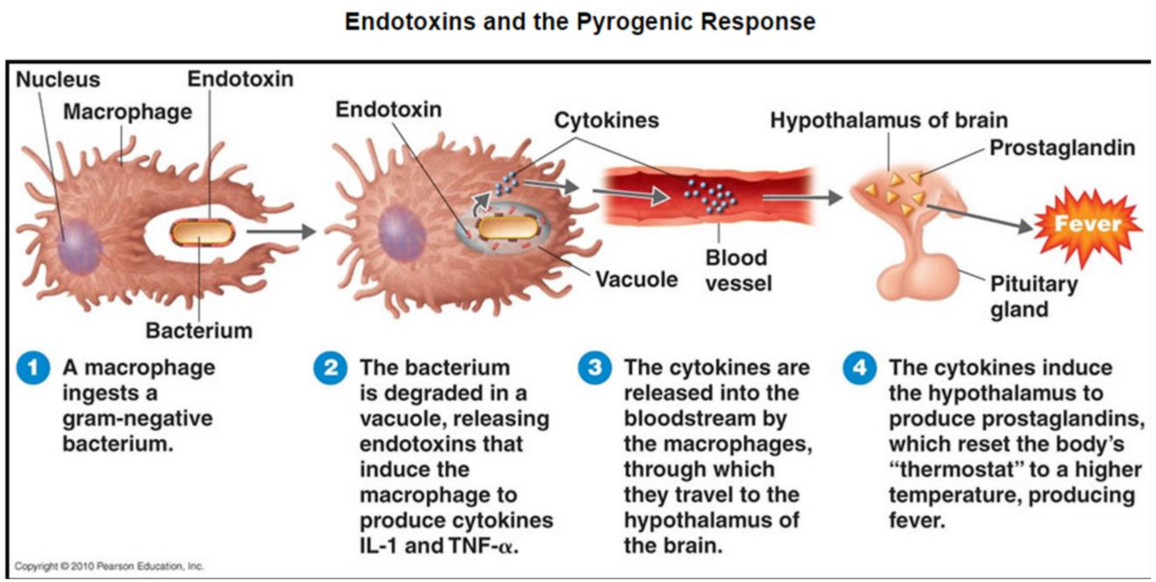


A high-molecular-weight complex that contains lipopolysaccharide (LPS), protein, and phospholipid originating from the outer membrane of Gram-negative bacteria.

Why is Bacterial Endotoxin a Concern?

Endotoxin Risk

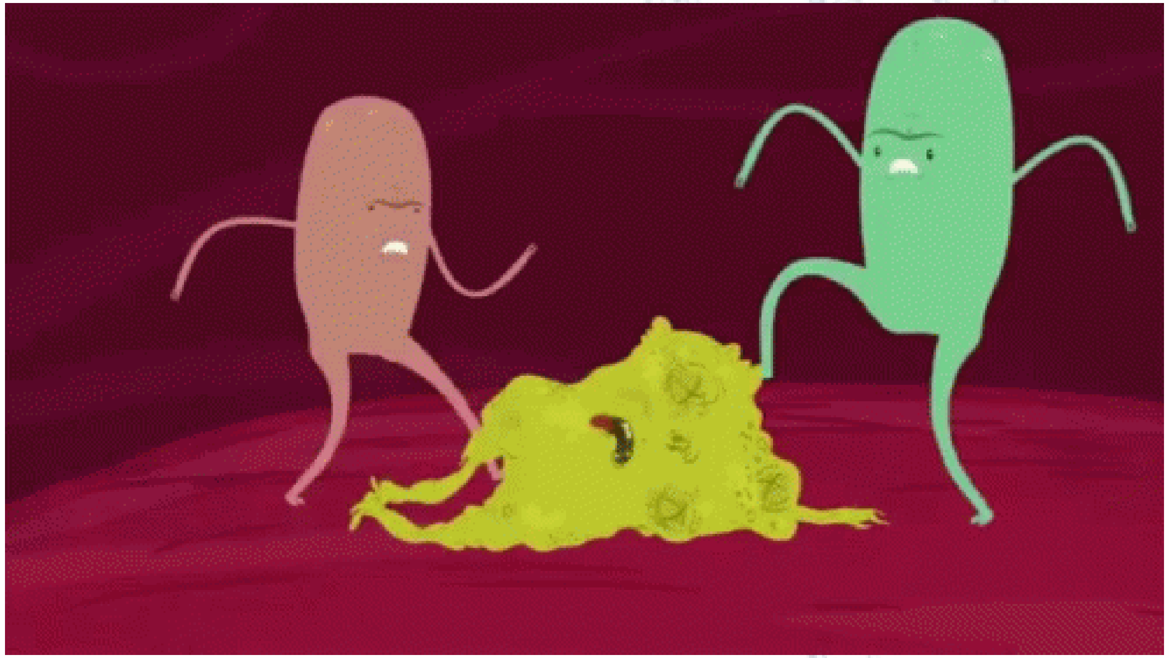
- The outer cell wall (LPS) is released into the environment when Gram-negative bacteria divide or lyse.
- Endotoxin can cause fever, meningitis, and a rapid fall in blood pressure if introduced into blood or tissues of the body
- Sterile Devices must have endotoxin levels within specified limits. - FDA Guidance 2016



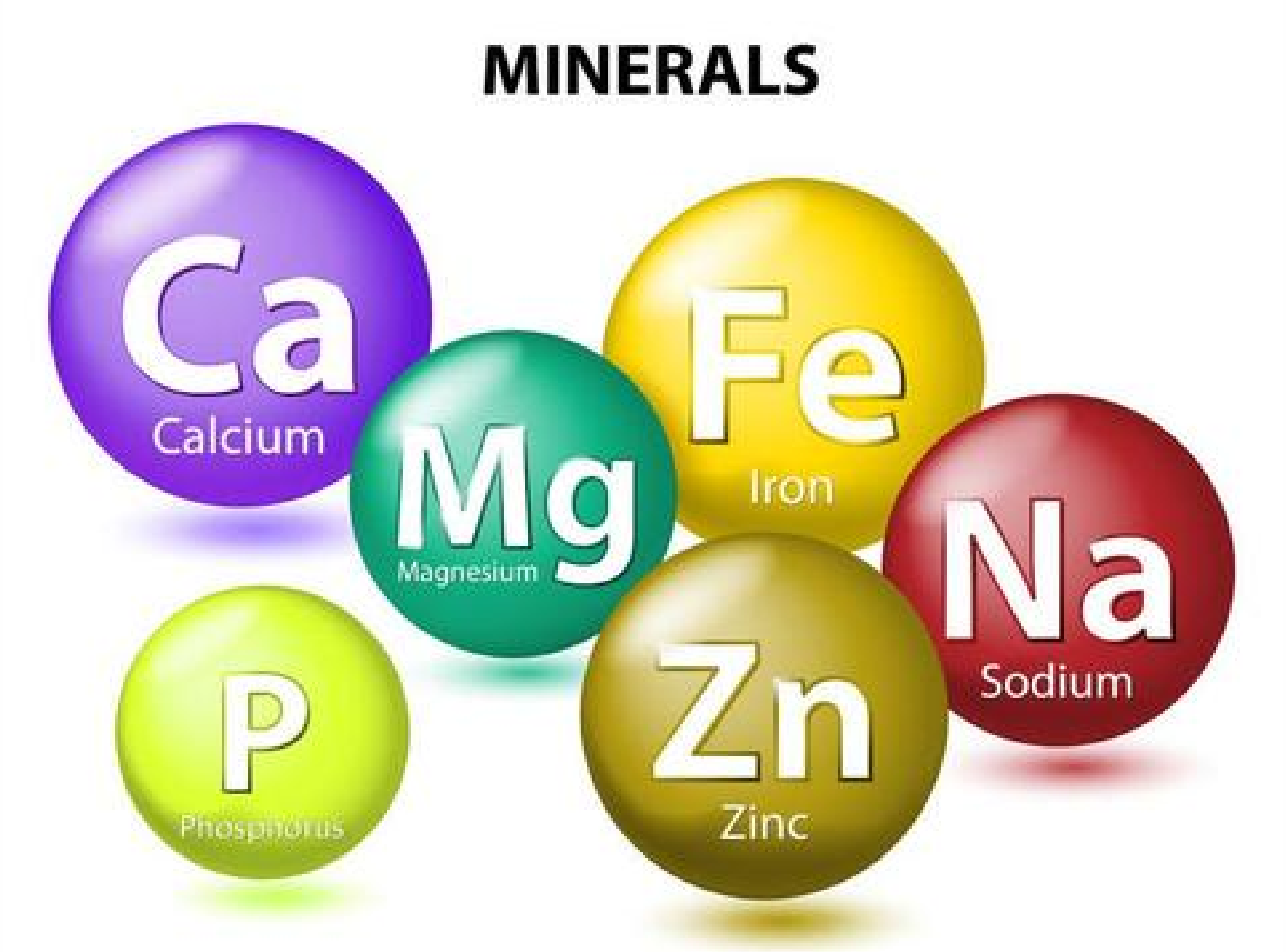
Organic Pollutants

Why is Total Organic Carbon (TOC) a Concern?

- Water residuals can discolor device
- Can interfere with the effectiveness of detergents, disinfectants or sterilants
- Provide nutrition to microorganisms and contribute to microbial growth



Dissolved Salts – Hard Water



Why are Dissolved Salts a Concern?

- Decreases the effectiveness of most detergents / disinfectants
- Decreases the performance of washer / disinfectors

AAMI TIR34: 2014/(R)2017 Water for the Reprocessing of Medical Devices

Why are Ionic Molecules a Concern?

Pitting

Chlorine
17
Cl
35.453

Tarnish Stainless Steal

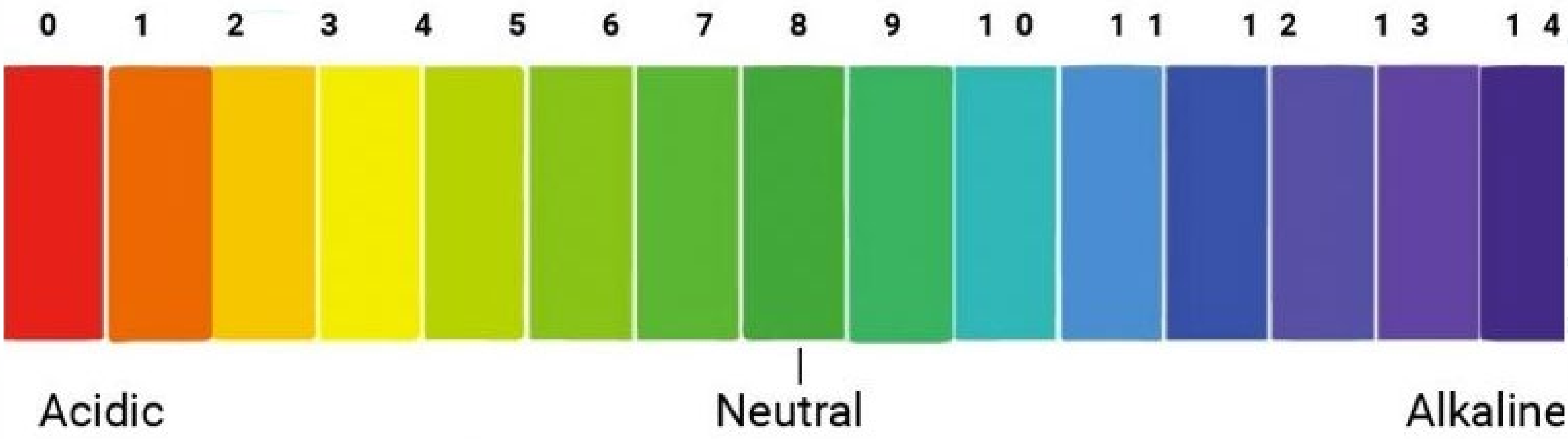
Manganese
25
Mn
54.938

Copper
29
Cu
63.546

Iron
26
Fe
55.845

AAMI TIR34: 2014/(R)2017 Water for the Reprocessing of Medical Devices

Why is pH a concern?



- Detergent Effectiveness
- Device Pitting or Corrosion

What is Point of Use?

3.58
point-of-use treatment (of clinically used medical devices)
point-of-use treatment refers collectively to the activities that the user of a medical device performs at the point of use (e.g., where the procedure was performed) to prepare it for processing; point-of-use treatment occurs immediately after patient use and can include rinsing, flushing, wiping (to prevent biofilm formation and drying of soil), disconnecting accessories, preparing handoff communication, and preparing the instrument/device for transport to the decontamination facility and placing it in an appropriately labeled container

3.59
point-of-water use
POU
closest point in the distribution loop where the water is exposed to a medical device during processing

3.60
point-of-water use system
POU system
water treatment system in which purification (usually filtration) takes place just before a single water supply outlet

Note to entry: Examples of a POU system are a filter in the line leading to the faucet (such as a filter under a kitchen sink) and a filter attached to the faucet (such as a screw-on tap filter).

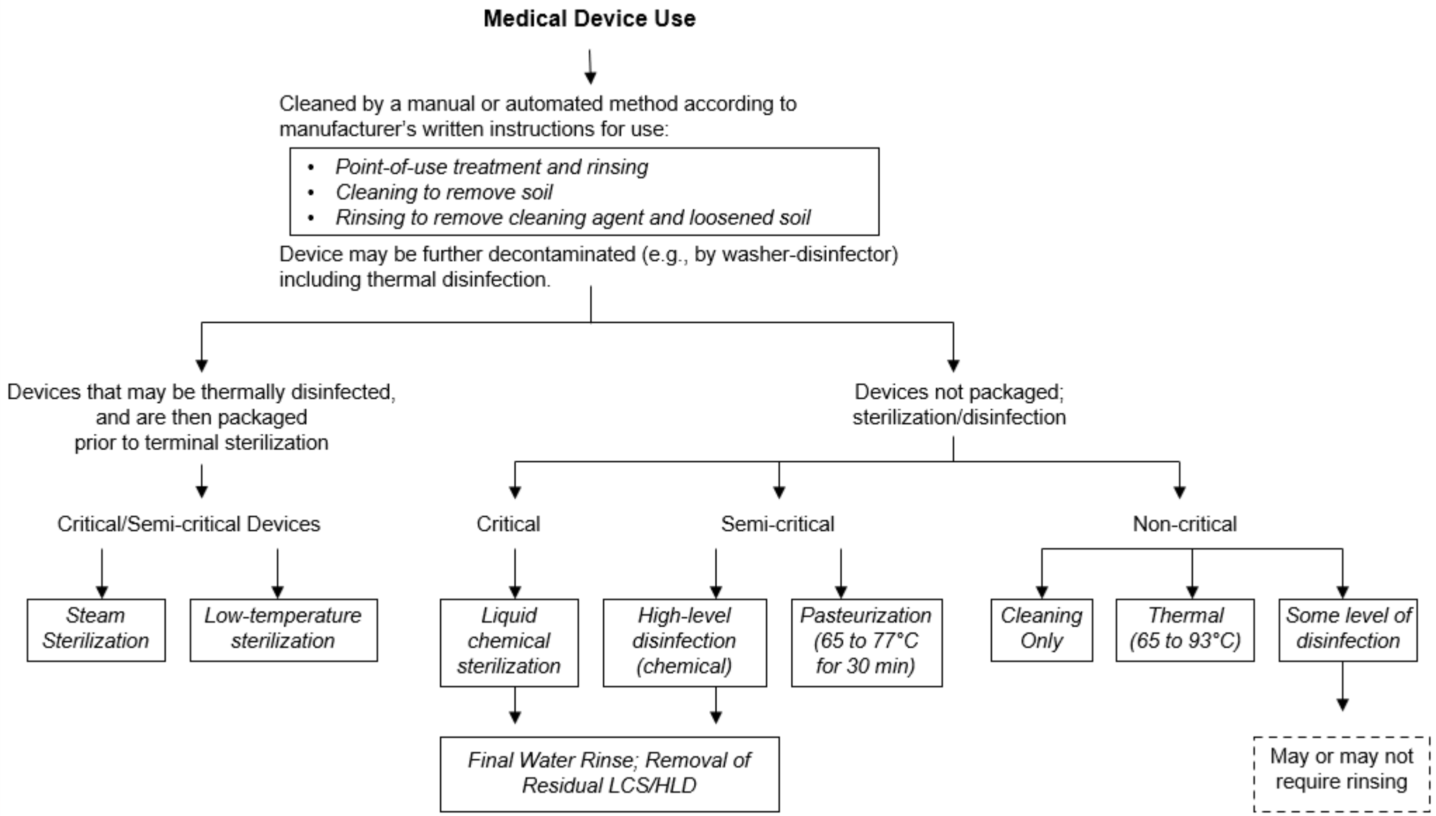
Water Quality Selection

Specify in Instruction for Use (IFU) Processing / Reprocessing Water Quality

- Utility Water
- Critical Water

Figure 1—Stages of medical device processing in which water quality is a consideration

Verify adequate water quality for each stage in the process indicated in boxed *italics*.



Water Treatment Systems

Utility Water Generation

Tap Water

Course Filtration

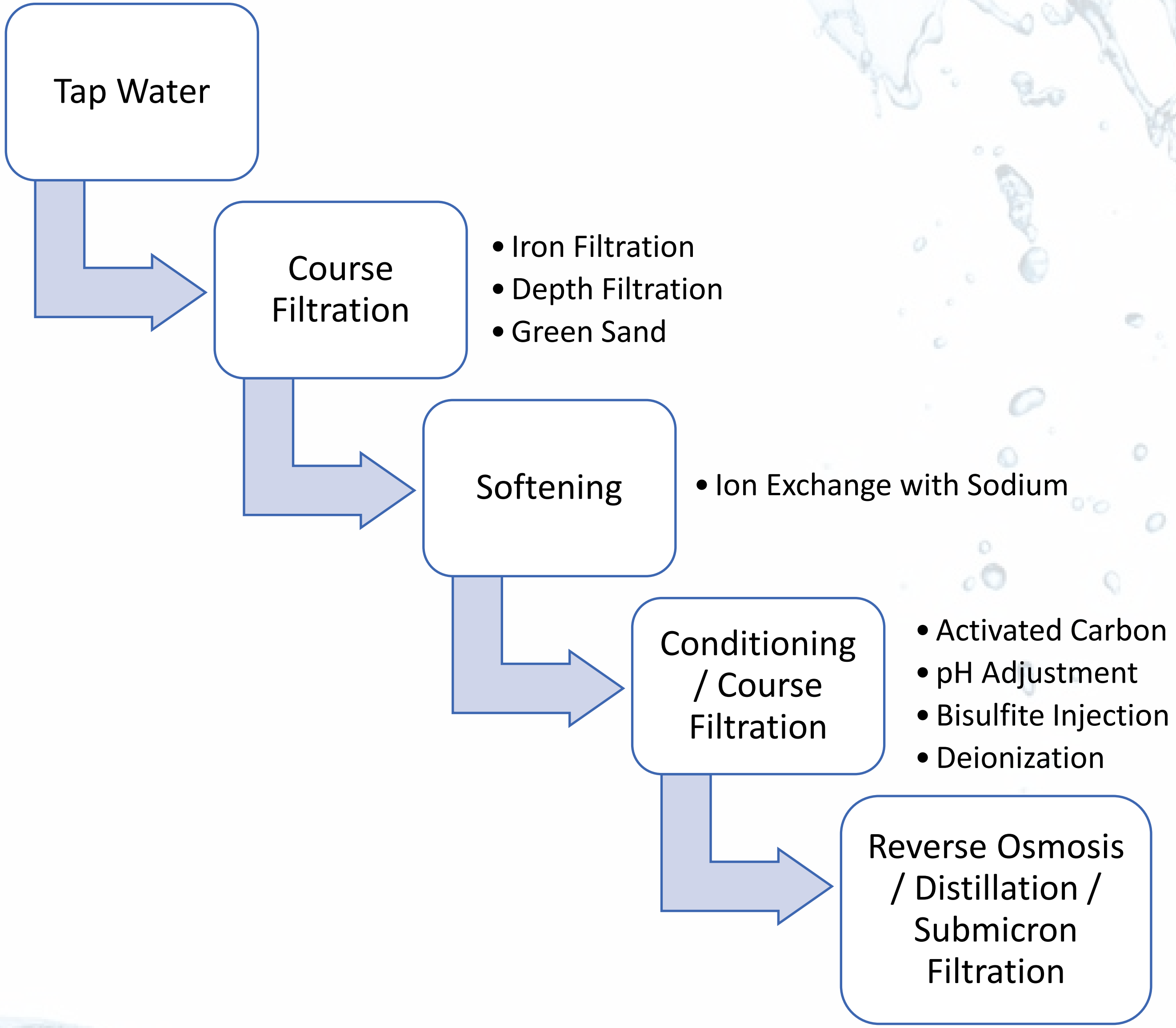
- Iron Filtration
- Depth Filtration

Softening

- Ion Exchange with Sodium

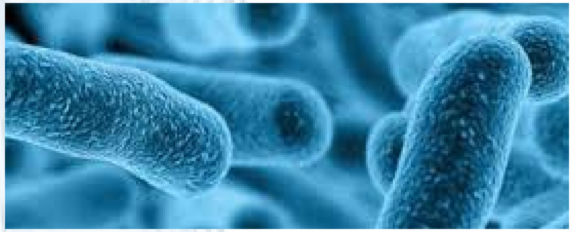
Critical Water Generation

Processing Steps Are Water Quality Dependent



Partner to Ensure Water Quality

Case Study: *Legionella* bacteria



https://www.beckershospitalreview.com/quality/ohio-hospital-confirms-hot-water-system-source-of-legionnaires-disease-outbreak.html

Maintaining Water Quality

Monitoring Requirements

Table 4—Water quality monitoring requirements

Water Quality Measurement	Units	Utility Water	Critical Water	Steam*
pH @ 25 °C:				
Conductivity				
Total Alkalinity				
Total Hardness				
Bacteria				
Endotoxin				
Color and Turbidity	Visual	Colorless, clear, without sediment	Colorless, clear, without sediment	Colorless, clear, without sediment

- pH – Measure of Hydrogen Ions
- Ionic Compounds – Measured by Conductivity
- Alkalinity – Dissolved Solids
- Hard Water - Concentration of $CaCO_3$
- Bacteria – Measured by a Bioburden Test
- Bacterial Endotoxin – Measured by a BET Test

Monitoring Frequency

- Intent to make it easy to sample
- Multiple tests using same sample

Table 5—Frequency for water quality monitoring at water generation system

Water quality measurement	Type of testing	Routine monitoring sampling site	Minimum frequency of testing*	
			Utility Water	Critical Water
pH	pH meter** or Colorimetric dipsticks (sample tested within 15 minutes)	After the last treatment step	Quarterly	Monthly
Conductivity	Conductivity meter (in line or by measurement of a collected sample)	After the last treatment step, Storage tanks (if used)	Quarterly	Daily
Total Alkalinity	Colorimetric dipsticks Alkalinity test kit**	After the last treatment step, storage tanks (if used)	Quarterly	Monthly
Total Hardness	Determination of ppm as $CaCO_3$ by Colorimetric dipsticks, Titration kit**, or Handheld meter**	After the last treatment step	Quarterly	Monthly
Bacteria	Heterotrophic plate count (see Annex H)	Loop out and loop return points	N/A	Monthly
Endotoxin	LAL test (see Annex H)	Loop out and loop return points	N/A	Monthly

Table 6—Frequency for water quality monitoring at point-of-water-use

Water quality measurement	Type of testing	Routine monitoring sampling site	Minimum frequency of testing*		
			Utility Water	Critical Water	Steam
pH	pH meter** or Colorimetric dipsticks (sample tested within 15 minutes)	At the point the distribution loop enters the processing area or first POU on the distribution loop	Quarterly	Monthly	Quarterly
Conductivity	Conductivity meter** or Colorimetric dipsticks	At the point the distribution loop enters the processing area or first POU on the distribution loop	Quarterly	Monthly	Quarterly
Total Alkalinity	Colorimetric dipsticks or Alkalinity test kit**	At the point the distribution loop enters the processing area or first POU on the distribution loop	Quarterly	Monthly	Quarterly
Total hardness	Determination of ppm as $CaCO_3$ by Colorimetric dipsticks, Titration kit** ,or Handheld meter**	At the point the distribution loop enters the processing area or first POU on the distribution loop	Quarterly	Monthly	Quarterly
Bacteria	Heterotrophic plate count (see Annex H)	Each location of point-of-use in department	Quarterly	Monthly	N/A
Endotoxin	LAL test (see Annex H)	Each location of point-of-use in department	N/A	Monthly	N/A
Visual Inspection	Visual Inspection of inside of equipment - Look for residue, staining, scaling, and discoloration (Annex I)	Spray Arms/Inside Chamber Walls/Inside Interior of Machine	Daily	Daily	Daily

Tools for Success – How to use the Annexes

Annex A- Guidance on the application of the normative requirements

- More information around water quality levels
- Water characteristics
- Water quality selection

Table A.1—Water descriptions

Terminology	Description/Definition	Typical Use Examples
Potable Water	Water that has been treated and delivered in a manner as to meet EPA guidelines intended for direct or indirect human consumption (see 3.56).	Water used for drinking fountain or hand washing station.
Utility Water	Water that may come from the tap but may need some form of treatment to achieve these specifications (criteria defined in Table 2) (see 3.86).	Water used for flushing, washing, and rinsing as part of the processing of medical devices.
Critical Water	Water that is usually extensively treated (Criteria defined in Table 2) (see 3.20).	Water used for final rinse prior to sterilization of a critical device, or after high-level disinfection, as part of the processing of medical devices.
Non-potable Water	Water that does not meet the EPA drinking guidelines.	Reclaimed water used for facility utilities.
Feedwater	Water as it is being fed to water treatment equipment or steam generator (see 3.33).	Water sourced to equipment (e.g., boiler) and is representative of the

Annex B - Risk Analysis

- Guidance for performing a risk analysis for the selection of water quality.

Water Quality	Secondary Factor	Point-of-use Rinse	Cleaning Agent Soak and Manual Cleaning	Final Rinse
Utility Water	Water Purity			
	Low Conductivity	Helps to loosen soil	Allows use of less cleaning agent*	Improved rinsing
	High Conductivity	Soil is more difficult to remove	Requires more cleaning agent*	Hinders rinsing performance
		May leave deposits		
	High TOC	Soil is more difficult to remove	Requires more cleaning agent*	May leave film on instruments
	High chloride	May corrode metal (e.g., instruments, pans, carts)		
	High metal ion content	May cause metal deposits on instruments (e.g., rust, color changes, corrosion)		
Critical Water	Water purity			
	In specification	Helps to loosen soil, adds cost for water production	Allows use of less cleaning agent, adds cost for water production*	Optimal rinsing, decreased potential for instrument spotting, staining, and corrosion
	Out of specification	See Utility Water	Cleaning performance diminished*	See Utility Water

Annex C – Automated Endoscope Reprocessor

Table C.1—Water quality for LCSPS

Stage in Process	Function	Water Quality
1. Point-of-use treatment	Reduce the level of soil to prepare the device for transport for subsequent decontamination and ensure that clinical soil is not allowed to dry on the device or inside lumens	Utility Water is acceptable, at a temperature not exceeding 45 °C (113 °F).
2. Cleaning with cleaning agent solution	Remove patient organic and inorganic material (clinical soil) that is not removed by point-of-use treatment (Stage 1)	Utility Water is acceptable to dilute cleaning agent, unless otherwise directed by the cleaning agent manufacturer's written IFU.
3. Post-wash rinse	Remove cleaning agent residues and any loosened clinical soil	Utility Water is acceptable as incoming water to an AER, unless otherwise indicated by AER manufacturer's written IFU. Water changes and multiple rinses may be indicated.
4. Dilution of liquid chemical sterilant (if applicable) and liquid chemical exposure	Sterilization	Water quality for sterilant dilution is defined by the AER manufacturer written IFU for dedicated chemistries and by the sterilant manufacturer's written IFU if a non-dedicated chemistry.
5. Final rinse after liquid chemical sterilization	Remove residual LCS and reduce likelihood of pyrogens on device	In the case of HLD and LCS processed devices that will not be used immediately, sterile water or water that meets sterile water criteria should be used for the final rinse so as not to contaminate the device.

Annex D – Water used in cleaning and moist heat processes

Cleaning

Sterilization

Annex E – Water Treatment Technologies

Table E.1—Summary of water treatment methods

	Water treatment system component options	What it does		Location in water treatment system		Design considerations	
		Removes	Adds	Place before	Place after	Advantages	Disadvantages
Pretreatment	Green sand depth filter	Iron and manganese by oxidation and filters out the precipitates:	n/a	Initial water treatment step	Tap water sources	Prevents iron and manganese from precipitating on softener and DI resins and inactivating them	
Pretreatment	Water softener	Magnesium Calcium Barium Strontium	Sodium	Coarse filter Carbon or bisulfite	Tap water sources	Prevents hard water scaling and deposits from forming on the equipment and reprocessed device	Need for monitoring and replacement Sheds particles
Pretreatment	Submicron filter[1]	Particles >0.2, 0.2, or 0.5µm	n/a		DI Any water treatment component that can generate bacteria		May shed particles
Pretreatment	pH adjustment	Aids removal of dissolved carbon dioxide by converting carbon dioxide to carbonate that RO can exclude Aids removal of colloids	Acid or base (usually NaOH)	RO	Softener		
Pretreatment	Activated carbon[2]	Chlorine Chloramines Organics	Carbon fines and Bacterial endotoxin (normally removed by submicron filtration following the carbon filter)	Softener (for high organics in incoming water; reduces ability of carbon to remove TOC) RO DI	Softener (keeping chlorine in during softening helps control microorganisms)	Protects RO and distillation from fouling organics. It does not remove hard-water deposits. Protects RO membranes and DI resins of degradation by chlorine	Supports bacterial growth, which increases endotoxin levels, and may cause fouling of filters and RO membranes. If chloramine is used instead of hypochlorite, can react to create amines, which are hard to remove; requires strong cation exchanger
Pretreatment	Metabisulfite injection	Chlorine Chloramines	Metabisulfite	RO DI	Softener pH adjustment	Neutralizes chlorine Bacteria growth problems less likely	
Purification	Reverse osmosis (RO)	Anions, cations, colloidal silica Bacteria Endotoxin Colloids Organics		Storage tank	Softener Chlorine removal pH adjustment to 8-8.5 to reduce carbon dioxide to bicarbonate Coarse and submicron filters	Reliability	Rate of production Storage tank may be needed Capital cost Maintenance Resistivity not as high as DI
Purification	Deionization (DI)[3,4]	Anions, cations Retards silicon Strong base deionizer can remove silica	Some bacteria and bead fines	Final purification process or ultrafilter	Chlorine removal Coarse filter	Rate of production Efficiency of ion removal High resistivity	Potential for silicon breakthrough Potential to magnify fluoride if resin becomes overloaded Microbial growth Endotoxin generation due to bacterial growth Need to exchange or regenerate resins
Purification	Cation exchange resin	Cations	Some bacteria and bead fines	Final purification processes or ultrafilter	Chlorine removal	Rate of production Efficiency of ion removal	
Purification	Anion exchange resin	Anions, cations Retards silicon Strong base deionizer can remove silica	Some bacteria and bead fines	Final purification process or ultrafilter	Chlorine removal	Rate of production Efficiency of ion removal High resistivity	Reacts with chlorine to produce trimethylamines
Purification	Distillation	Anions, cations Bacteria Endotoxin Organics	n/a	Storage tank	Softener	Simple operation	Rate of production low for the dollar cost Energy input high
Purification	Ultrafiltration	Anything larger than the molecular weight cutoff of the membrane	n/a		All other purification needs (where needed to remove bacteria and endotoxin)	Bacteria and endotoxin removal	Cost Can mask upstream purification problems Microbial breakthrough
Distribution	UV	Kills bacteria	Inactivated bacteria becomes endotoxin	Used following a component that has high bacterial counts			Must be followed by an ultrafilter due to endotoxin generation
Distribution	Ozone	Kills bacteria			Used to disinfect the water system during routine disinfection steps	Very effective antimicrobial	Must monitor ambient levels
Distribution	Steam/hot water	Kills bacteria			Used to disinfect the water system during routine disinfection steps	If designed into the water system, a very easy-to-use method of disinfecting the distribution loop	
Distribution	Chemical disinfection	Kills bacteria			Used to disinfect the water system during routine disinfection steps		Requires rinsing of the distribution system prior to use

Annex F - Water Treatment System Design

Figure F.1 is an example of a general water treatment process for incoming water to produce water that is acceptable for use in medical device processing.

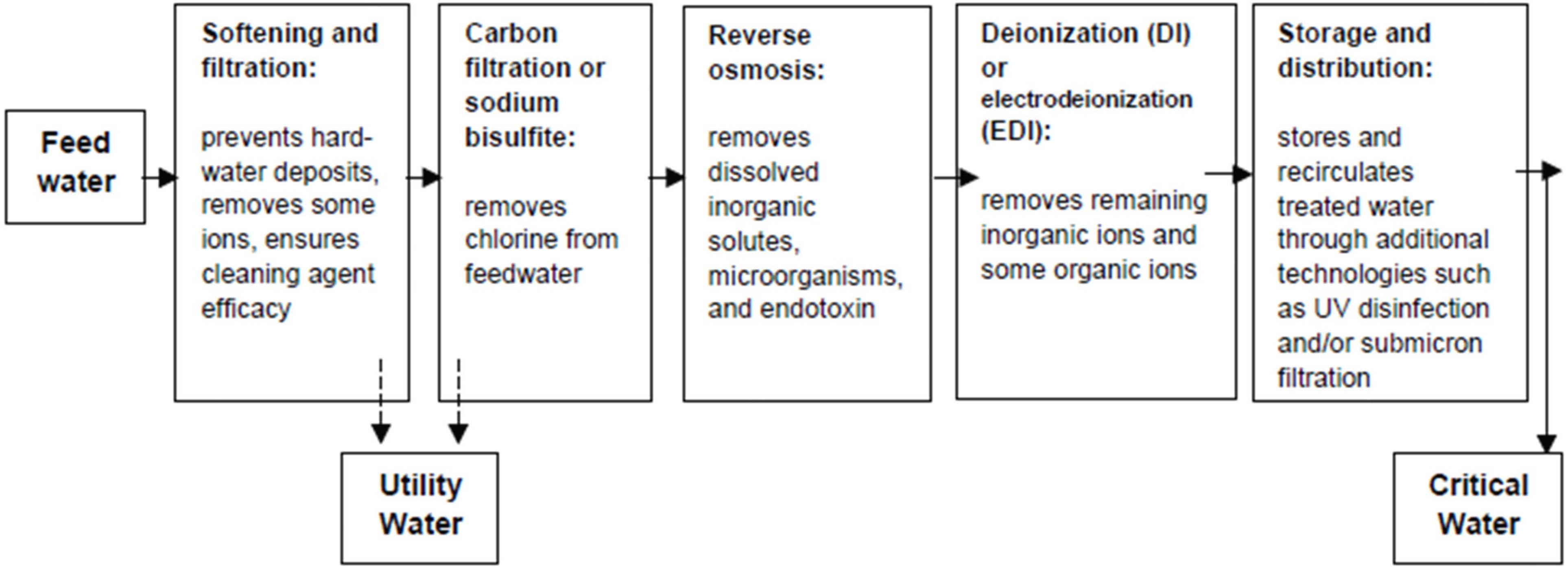


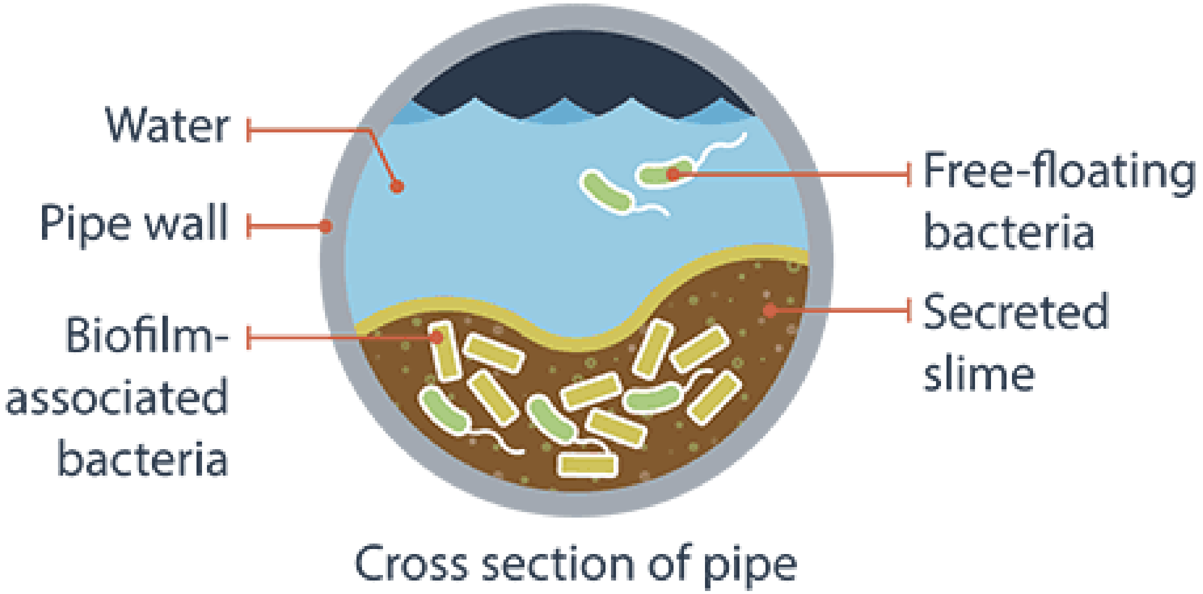
Figure F.1—Example process flow diagram (PFD)

Annex G - Routine Monitoring of Water Treatment Equipment & Produced Water Quality

- Pretreatment equipment monitoring
- Primary Treatment Equipment Monitoring
- Storage Tanks, Distribution Equipment, and Piping Monitoring
- Bacterial Control Equipment

Distribution Loops Must be in Control

- Microbial Load can be variable if biofilms are present



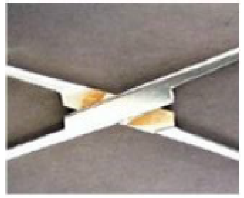
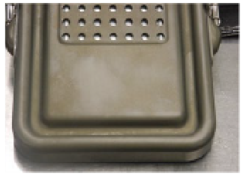
- Regular Disinfection
- Routine Monitoring Program w/ Point of Use Test Locations

Annex H – Maintaining Microbiological Quality

- Microbiological Quality
  - Bioburden by colony forming unit (CFU)
  - Bacterial Endotoxin Test
- How to Perform Water Sampling
- Results Exceeding Specification

Annex I – Typical Presentation of Water Quality Issues During the Processing of Medical Devices

Table I.1—Examples of observed problems during medical device processing that can be caused by poor water quality

	Observed problem	Possible causes	Recommendations
	Ineffective cleaning or residual soil	— Soil allowed to dry on medical devices before cleaning; — Cleaning process not efficient; — Quality of water affects cleaning chemistry; — Medical devices difficult to clean; — Medical devices not fully opened or not disassembled and; — Medical device not loaded into a washer correctly.	— Review the handling of medical devices during clinical use and processing — Check the cleaning chemistry can handle certain water qualities (e.g., high water hardness) — Conduct water quality testing (particularly hardness) and consult with expert to assist in problem remediation
	Surface damages include: — Corrosion; — Pitting; — Rusting; — Stress cracking.	— Quality of medical devices and materials of construction — Physical damage during handling of the medical device — Allowing soil to dry on medical devices before cleaning — Exposure to some chemicals (e.g., saline solutions, chlorine, iodine, chlorinated water (especially when heated) — Incompatible water of cleaning chemistries (e.g., pH too high/low)	— Repair or discard damaged medical devices — Review the handling of medical devices during clinical use and processing — Monitor water quality — Testing (particularly pH, chlorine, and silicates) — Consult with expert to assist in problem remediation
	Loss of color	— Bleaching of colors over time, especially with colored anodized aluminum — Chlorinated water (especially, when heated) — Incompatible water, cleaning chemistries (e.g., pH too high/low),	— Review the handling of medical devices during clinical use and processing — Conduct water quality testing (particularly pH, chlorine, and silicates)

Situation 1: Manual Pre-Cleaning

- Utility Water – Hardness <150mg/L
- Salts in hard water may deposit on instruments
- Salts may impact detergent effectiveness

Situation 2: Automated Cleaning

- Critical Water (final rinse) – Conductivity < 10µS/cm
- Excessive Ions can damage device surfaces
- Ions can discolor devices when exposed to heat

Situation 3: Device Inspection

Questions?