Case Studies of Problems in Reprocessing Instruments
Agenda

Analytical tools
- FTIR
- EDS

Case studies
- Six real-life instrument mysteries

Water quality
- Problems in water quality
- Solutions for water quality
- AAMI TIR 34 Water Categories
Analytical Tools

- Fourier Transform Infrared Spectroscopy (FTIR)
  - Organic analysis
Analytical Tools

- Energy Dispersive X-Ray Spectrometry (EDS)
  - Inorganic Analysis
The Case of the Green Light Handle
Problem

- Green OR Light Handle from Baltimore, MD
- Reprocessed according to IFU
- Aluminum trays also had a green hue
- Hot water sample was taken
Analysis

- Fourier Transform Infrared Spectroscopy (FTIR)
  - No organic components

- Energy Dispersive X-Ray Spectrometry (EDS)
  - 22.5% copper on the surface, 9.22% aluminum

- Water Analysis

<table>
<thead>
<tr>
<th></th>
<th>Hot Water</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hardness (gpg)</td>
<td>5.0</td>
</tr>
<tr>
<td>pH</td>
<td>7.8</td>
</tr>
<tr>
<td>Total Dissolved Solids (ppm)</td>
<td>171</td>
</tr>
<tr>
<td>Total Alkalinity (ppm)</td>
<td>48</td>
</tr>
<tr>
<td>Iron (ppm)</td>
<td>Not Detected</td>
</tr>
<tr>
<td>Copper (ppm)</td>
<td>0.56</td>
</tr>
<tr>
<td>Manganese (ppm)</td>
<td>Not Detected</td>
</tr>
</tbody>
</table>

- Copper is the culprit …
Recommendations

- Determine the source of high levels of copper in water
  - Copper can cause staining at 0.2 ppm and above
  - Reduce copper levels in water
  - Use chelating detergents and adjust concentrations accordingly

- Use mildly acidic stain remover to reclaim instruments
  - Manually scrubbing after the acid soak may be necessary to completely remove discolorations
The Case of the Corroded Codman Scissors
Problem

- Discolored Codman brand curved scissors from Santa Monica, CA
- Red/brown and iridescent discolorations
- Corrosion suspected
- Reprocessing practice unknown
Analysis

Microscopic Analysis

- Significant corrosion
  - Pits
  - Fretting (mechanical chafing)

Chemical Analysis

- Iron around discolorations
- Protein

Digital images showing examples of apparent corrosion on the scissors under microscope magnification.

Digital images showing an apparent corrosion pit (left) and apparent fretting corrosion (right) on the scissors under microscope magnification.

Digital images showing apparent soils on the blade (left) and shaft (right) of the scissors.
Recommendations

- Investigated reprocessing practices
  - Instruments were not always manually cleaned
  - Hinged instruments were not processed in an open position

- Surface stains
  - Red/brown and iridescent discoloration removed with a 10 minute soak in mildly acidic stain removal solution followed by manual scrubbing

- Corrosion (not removable)
  - Caused by chloride ions (in blood and tissue)
    - Prevent by immediate treatment after surgery, manual cleaning
  - Caused by insufficient drying
    - Prevent by avoiding overloading and programming sufficient dry time
  - Caused by fretting
    - Prevent by lubrication
The Case of the Disappearing Black Finish
Problem

- Discolored Gyrus ACMI Ear Speculum from Kansas City, MO

- Reprocessed in washer/decontaminator with other instruments

- Ebonized (protective) finish was removed

- Brass is not chemically resistant to strong chlorine sources or acids
Analysis

Energy Dispersive X-ray Analysis (EDS)

- Brass Alloy

<table>
<thead>
<tr>
<th>Sample</th>
<th>EDS Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ear Speculum</td>
<td>Copper (~44.63%)</td>
</tr>
<tr>
<td></td>
<td>Zinc (~34.98%)</td>
</tr>
<tr>
<td></td>
<td>Chlorine (~13.14%)</td>
</tr>
<tr>
<td></td>
<td>Aluminum (~2.997%)</td>
</tr>
<tr>
<td></td>
<td>Nickel (~2.17%)</td>
</tr>
<tr>
<td></td>
<td>Iron (~2.12%)</td>
</tr>
</tbody>
</table>

Ebonized Finish

- Typically achieved through chemical oxidation
- Some copper, nickel and iron oxides appear black, zinc oxides appear white, aluminum oxides vary in color
- Other forms use pigments or carbon black (carbon was not detected on this instrument)
Recommendations

Follow manufacturer’s instructions for use

- Cleaning process
- Product recommendations
- Tool recommendations

Gyrus ACMI IFU Recommendations

- Soak for a minimum of two (2) minutes in enzyme solution
- Rinse thoroughly under lukewarm water
- Manually clean with a soft bristled brush while immersed in a detergent solution, paying close attention to crevices and hard-to-clean areas
- Rinse thoroughly under lukewarm water
- Dry the instrument with a clean, soft cloth
- Visibly examine the instrument for cleanliness

Contact Gyrus to see if instruments can be reclaimed
The Case of the Corroded Wrapped Instruments
Problem

- Corroded instruments in Passaic, NJ
- Returning from surgery wrapped in a wet fabric towel
- Source of “wetness” was unknown
- Wet towel was submitted
Analysis

Fourier Transform Infrared Spectroscopy (FTIR)
- Cellulose found (consistent with cotton/rayon)

Energy Dispersive X-ray Analysis (EDS)
- Chloride found

<table>
<thead>
<tr>
<th>Sample</th>
<th>FTIR Analysis (Organic Components)</th>
<th>EDS Analysis (Inorganic Components)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Extract</td>
<td>• Cellulose</td>
<td>• Oxygen</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Sodium</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Chloride</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Potassium</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Silicon</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Sulfur</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Potassium</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Aluminum</td>
</tr>
</tbody>
</table>

Chloride ions
- Found in blood, tissue
- Sodium hypochlorite (chlorine bleach)
- Saline solution
Recommendations

- Only use water or approved products to keep instruments wet
- Re-usable textiles may retain some residual chemistries
The Case of the Tarnished Retractor
Problem

- Tarnished retractor handle from Jackson, MS

- Original state of handle was unknown
  - Brass?
  - Surface plating?

- Tarnishing was not widespread
Analysis

Metal identification
- Shaft (untarnished) was 400 series stainless steel
- Handle was a different metal (non-magnetic), but unable to identify (needed to destroy the instrument for EDS)

Microscopic examination
- Corrosion on shaft and handle
Recommendations

- Corrosion and corrosion pits were not removable
  - Don’t let debris dry onto instruments
  - Minimize contact with aggressive chemistries

- Don’t put plated instruments in the ultrasonic; plating is damaged by cavitation

- Remove tarnish by soaking in mildly acidic solution for 10 minutes followed by manual scrubbing

Digital images of the retractor handle as submitted (left) and after reclaim procedures (right), magnified 10x.
The Case of the Disappearing Numbers
Problem

Black numbers removed over time on Elekta Leksell® Multi Purpose Stereotactic Arc system from New York, NY and Elekta Headquarters, Stockholm, Sweden

Three Coordinate Setting Axis samples (right in each set of 2) and three Arc support samples (left in each set of 2) as received
Analysis

Simulated conditions in facility

- Water condition
- Washer cycles
- Chemistry

Residue and discoloration observed with soft water

- Aluminum oxide

The arc setting axis and arc support both developed an overall white deposit during cycle testing. This deposit thickened with repeat cycle exposure and resulted in a muting of the original color of the device (the removable ring of the Coordinate Setting Axis was retained for color comparison purposes). The pictures shown here are after 20 cycles.
Recommendations

- Removal of black print could not be reproduced
  - Possible lot-specific defect in manufacturing (further investigated by Elekta)
  - Possible unknown customer procedural impact

Water quality makes a difference!

- Use of soft water during thermal disinfection led to residue and discoloration
  - Removed with a wet paper towel
- Use of purified water during thermal disinfection phase did not lead to residue or discoloration, and did not remove the black print.
Water Quality
Why Is Water Quality Important?

Water is involved in nearly every part of instrument reprocessing
- Pre-cleaning
- Manual cleaning
- Ultrasonic
- Washer/Disinfector

Water spotting and staining cause questions about instrument cleanliness resulting in re-work and in severe cases, postponed surgeries

Mineral deposits can hinder sterilization effectiveness

Water quality can affect instrument longevity and function

Recognized by AAMI
AAMI TIR 34

Water for the Reprocessing of Medical Devices
TIR 34

Approved in October of 2007

Objectives of this Technical Information Report

- Provide guidance on the selection of the appropriate water quality for each stage of medical device reprocessing for each category of medical device
- Provide technical information to guide the set up and monitoring of water treatment systems
- Provide a common language around water
Establishes four categories for water quality

These categories are defined with regard to the waters’:

- Ionic Contaminants (Copper, Chloride, Iron, Manganese)
- Hardness
- TDS
- Bacteria levels
- Endotoxin levels
- pH
- TOC (Total Organic Carbon)
- Resistivity

Steps in the decontamination process are then connected with these categories of water quality
Water Impurities
Hydrologic Cycle
Ionic Contamination

- Electrically charged atoms or molecules dissolved in water
- Units: mg/L (milligrams of metal per liters of solution)
- Metals like (Copper, Iron, Manganese)
- Chlorine ion is of special concern

Impact on the process
- Surface staining
- Corrosion
Examples of Staining
Examples of Staining

Surface staining can be removed by an eraser or acid stain remover
Chloride Induced Corrosion

Chloride Sources
- Blood
- Tissue
- Some water supplies
- Saline Solution
Most Common Chloride Source
Corrosion Pits

Corrosion pits are permanent changes to the material and can:

- Increase the difficulty of soil removal
- Decrease the effectiveness of disinfection and sterilization
- Compromise instrument functionality
Hardness

- Typically defined by the level of calcium or magnesium in the water
- Units: ppm of CaCO₃ (also expressed in gpg = ppm/17.1)
- Can form insoluble compounds

Impact on the Process
- Scale can impede cleaning and sterilization (Water insoluble)
- Reduce washer efficiency
- Reduce detergent efficiency
- Decrease the lifespan of instrumentation and equipment
Hard Water Scale
TDS (Total Dissolved Solids)

- Sum of all ions in solution
- Units: ppm
- Usually measured by resistivity
- Impact on the process
  - Water Soluble Spots and films
# Dissolved Ions

<table>
<thead>
<tr>
<th>Dissolved Ion</th>
<th>Name</th>
<th>Measured as...</th>
<th>Concentration (ppm CaCO₃)</th>
<th>Potential Problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ca²⁺</td>
<td>Calcium</td>
<td>Hardness</td>
<td>150</td>
<td>Scale</td>
</tr>
<tr>
<td>Mg²⁺</td>
<td>Magnesium</td>
<td>Hardness</td>
<td>30</td>
<td>Scale</td>
</tr>
<tr>
<td>Na⁺</td>
<td>Sodium</td>
<td></td>
<td>110</td>
<td></td>
</tr>
<tr>
<td>K⁺</td>
<td>Potassium</td>
<td></td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Fe²⁺</td>
<td>Iron</td>
<td></td>
<td>&lt;1</td>
<td>Rust</td>
</tr>
<tr>
<td>Cu²⁺</td>
<td>Copper</td>
<td></td>
<td>&lt;1</td>
<td>Green Film</td>
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</tbody>
</table>

*Total Cation* 300

<table>
<thead>
<tr>
<th>Ion</th>
<th>Name</th>
<th>Measured as...</th>
<th>Concentration (ppm CaCO₃)</th>
<th>Potential Problem</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCO₃⁻</td>
<td>Bicarbonate</td>
<td>Alkalinity</td>
<td>150</td>
<td>Scale</td>
</tr>
<tr>
<td>CO₃²⁻</td>
<td>Carbonate</td>
<td>Alkalinity</td>
<td>&lt;1</td>
<td>Scale</td>
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<tr>
<td>SO₄²⁻</td>
<td>Sulfate</td>
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<td>56</td>
<td></td>
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<tr>
<td>Cl⁻</td>
<td>Chloride</td>
<td></td>
<td>90</td>
<td></td>
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<tr>
<td>NO₃⁻</td>
<td>Nitrate</td>
<td></td>
<td>2</td>
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<tr>
<td>PO₄⁻</td>
<td>Phosphate</td>
<td></td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

*Total Anion* 300

*Total Dissolved Solids* 300

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Bacteria Levels

Microorganisms exist in water

Units: cfu/mL (colony forming units per milliliter of solution)

Chlorine is used to reduce replication, but not eliminate microorganisms from potable water

Water used in cleaning should have a lower level of microorganisms than the soil the cleaning process is removing

Impact on the Process:
- Microorganisms can be a source of contamination
Endotoxin Levels

- Fragments of the cellular wall of bacteria left after the death of the organism
- Units: EU/mL (Endotoxin units per milliliter of solution)
- These fragments are not destroyed during disinfection or sterilization
- Reducing their level in final rinse water is required

Impact on the Process:
- When introduced into the body they can cause adverse reactions
- The issue is a special concern for instrumentation used in the eye, bloodstream or cerebrospinal fluid
Water pH

- A measure of the waters acidic or alkaline nature
- Logarithmic scale
- 1 – 6 (Acid), 7 (Neutral), 8-14 (Alkaline)
- Potable water should have a range of 6.5 - 8.5

Impact on the Process:
- The pH of water can cause/influence corrosion
- Affects the performance of detergents, disinfectants and sterilants
TOC (Total Organic Carbon)

- A combination of natural and synthetic compounds in the water that contain the element carbon (C)

- Units: mg / L (milligrams of liters of solution)

- These compounds can be the result of:
  - Plant and Animal decay
  - Microorganisms
  - Agricultural chemicals
  - Insecticides
  - Herbicides

- Impact on the process
  - Can cause instrument staining
  - Decrease detergent, disinfectant, or sterilant effectiveness
  - Food source for microorganisms
Resistivity

- Is a measure of how strongly a material opposes the flow of electricity.

- The larger the number, the greater resistance the material provides \((\Omega \cdot m)\) at 20 °C
  - Copper \(1.7 \times 10^{-8}\)
  - Carbon \(1.5 \times 10^{-5}\)
  - Hard Rubber \(1 \times 10^{13}\)
  - Pure Water \(2.5 \times 10^5\)

- Pure water has a strong resistivity until impurities are added.
  - Hardness and metal ions significantly increase the ability for water to conduct electricity

- Impact on the process
  - Changes in Resistivity can impact product dosing systems and water purification monitoring systems
Water Treatment and Purification Systems

- Water Softening
- Deionization (DI)
- Distillation
- Reverse Osmosis (RO)
Water Softener

- **Ion Exchange**

- Removes hard water ions (calcium and magnesium) and replaces them with sodium ions

- Sodium is supplied by salt

- **Benefits of using softened water in the decontamination process**
  - Removes scale forming material
  - Improves detergent efficiency

- **Areas of concern**
  - Maintenance (Salt addition)
  - Regeneration schedule
Water Softener (Ion Exchange)
Deionization

Ion Removal

Removes charged ions (cations + and anions -)
- Hard water ions
- Metal ions
- Removes TDS

Benefits when using DI water in the decontamination process (Rinsing)
- Prevents staining and spotting
- Improves rinsing effectiveness

Areas of concern
- Tank (resin) replacement
Deionization System (Ion Removal)
Distillation (Removal by evaporation)

The most effective water purification system

Removes:
- Hard water ions
- Metal ions
- TDS
- Particulate matter
- Microorganisms
- Some organic matter

Benefits when using distilled water in the decontamination process (Rinsing)
- Prevents staining and spotting
- Improves rinsing effectiveness
- Prevents microbial contamination

Areas of concern
- System maintenance
Reverse Osmosis

- Reduces the level of contamination using a semi-permeable membrane

- Effective at reducing: (90-95% reduction is typical)
  - Hard water ions
  - Metal ions
  - Removes TDS
  - Particulate matter
  - Microorganisms
  - Organic matter

- Benefits when using RO water in the decontamination process (Rinsing)
  - Prevents staining and spotting
  - Improves rinsing effectiveness

- Areas of concern
  - Membrane fouling
  - Microbial contamination in the holding tank
  - Space requirements
Reverse Osmosis System

City Water

Semipermeable Membrane

Pure Water

Na⁺, Cl⁻, Ca²⁺, Mg²⁺, Microbes
AAMI TIR 34 Water Categories

- High Purity Water
  - Highly Treated (RO or Distilled)
  - Used as a final rinse before sterilization for devices that will contact the bloodstream

- Deionized
  - Limited treatment to remove inorganic material
  - Can be used in precleaning, cleaning and the final rinse for all medical devices with the exception of critical devices that will contact the bloodstream

- Softened
  - Limited treatment to remove scale forming material
  - Used in precleaning and cleaning

- Potable
  - Not treated (Potable)
  - Used in precleaning and cleaning
## Water Types Used in the CS for Critical Devices

<table>
<thead>
<tr>
<th></th>
<th>Manual Prewash</th>
<th>Prewash</th>
<th>Wash</th>
<th>Thermal Rinse</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Softened</td>
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<td>![Checkmark]</td>
<td>![Checkmark]</td>
<td>![Checkmark]</td>
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<tr>
<td>Deionized</td>
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<td>![Checkmark]</td>
<td>![Checkmark]</td>
</tr>
<tr>
<td>RO and Distilled</td>
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<td></td>
<td>![Checkmark]</td>
<td>![Checkmark]</td>
</tr>
</tbody>
</table>

- If used with filtration to remove organics.
## Water Types Used in the CS

<table>
<thead>
<tr>
<th></th>
<th>Manual Prewash</th>
<th>Prewash</th>
<th>Wash</th>
<th>Rinse</th>
<th>Thermal Rinse</th>
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<tbody>
<tr>
<td>Hot Water</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Cold Water</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DI or RO Water</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>
Summary

Ask for Help
- Contact representatives from manufacturers to help solve your mysteries
- Include as much information as possible

Avoid Reprocessing Problems
- Follow instrument manufacturer’s IFU for reprocessing
- Know how your instruments are coming down from surgery
- Reprocess as soon as possible

Know Your Water Quality
- AAMI TIR34 recommendations
- Water treatment options
Questions?