Automated Medical Instrument Washers: To Clean...or “Not Too Clean”

Dr. Michelle J. Alfa, Ph.D., FCCM
Medical Director, Clinical Microbiology, Diagnostic Services of Manitoba, Winnipeg, Canada
St. Boniface General Hospital
Winnipeg, Manitoba, Canada

Acknowledgements:
Nancy Olson
Iram Fatima
Pat DeGagne
Louise Buelow-Smith
Objectives:

- Outline the issues related to cleaning of medical devices using automated washers
- Analyze data on surgical instrument residuals - Pre and Post automated cleaning
- Review the impact of inadequate water quality on patients
- Discuss the importance of instrument washer monitoring in Healthcare Facilities
Automated washers: Assessment of cleaning efficacy in N. America

- **Installation testing:**
  No requirements to assess cleaning efficacy

- **Ongoing performance testing:**
  No requirements to assess cleaning efficacy

- **Qualified personnel to do testing:**
  In N. America healthcare facilities do not have infrastructure to perform ISO cleaning testing

ISO/TS 15883:2005 *Washer-disinfectors (parts 1-5)*
Automated Washers

- Feedwater: tap water
- Wash cycle: alkaline wash (may also have enzymatic wash)
- Final rinse: may be deionized water or may be tap water
- Measure of ongoing efficacy: visibly clean instruments

Most North American healthcare facilities struggling with what water quality is needed.

AAMI TIR34:2008 Water for reprocessing medical devices
**Inadequate Water Quality**

- **Impact on Medical Devices:**
  - Damage: pitting, corrosion, $\rightarrow$ loss of function
  - Reduction in cleaning efficacy
  - Interference with disinfection/sterilization efficacy

- **Impact on patient:**
  - Infection transmission
  - Adverse reaction; inflammation, fever
Residual Organic Material: Patient Ready medical devices

- D. Miller et al Anaesthesia 2001;56:1069-72
  [erythrosin B dye stained protein]
  **Protein residuals:**
  - laryngeal mask airways: 20/20 (100%)
  - laryngoscope blades 34/44(77%)

  [SYPRO Ruby fluorescent stained protein]
  **Protein residuals:**
  - surgical instruments: 56% severe residuals
Study to evaluate instrument residuals after patient-use and post cleaning

- Five instruments (most commonly used)
- Total of 10 patient procedures evaluated
  - 5 pre-clean
  - 5 post-clean
- Surface area swabbed: 1cm²
- Protein, Hg, Carb, LPS

## Residuals on Patient-used instruments before and after cleaning: Automated washer

<table>
<thead>
<tr>
<th>Instrument type: (visible soil after use)</th>
<th>Protein: (µg/cm²) Average for 5 devices</th>
<th>Hemoglobin: (µg/cm²) Average for 5 devices</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before cleaning</td>
<td>After cleaning</td>
</tr>
<tr>
<td>1. Curved Mosquito forcep</td>
<td>7.04</td>
<td>0.18</td>
</tr>
<tr>
<td>1/5 visibly soiled: (1 device; 1+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Fine Needle Driver</td>
<td>49.96</td>
<td>0.00</td>
</tr>
<tr>
<td>5/5 visibly soiled: (2 devices; 1+, 3 devices; 3+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Curved Iris Scissors</td>
<td>373.78</td>
<td>0.14</td>
</tr>
<tr>
<td>2/5 visibly soiled: (2 devices; 3+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Toothed Adson forcep (fine)</td>
<td>55.38</td>
<td>1.04</td>
</tr>
<tr>
<td>4/5 visibly soiled: (2 devices; 1+, 2 devices; 2+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Skin Hook</td>
<td>3.36</td>
<td>3.16</td>
</tr>
<tr>
<td>1/5 visibly soiled: (1 device; 1+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Average:</strong></td>
<td><strong>97.90</strong></td>
<td><strong>0.90</strong></td>
</tr>
</tbody>
</table>
### Residuals on Patient-used instruments before and after cleaning: Automated washer

<table>
<thead>
<tr>
<th>Instrument Type</th>
<th>Carbohydrate: (μg/cm²)</th>
<th>Endotoxin: (EU/cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before cleaning</td>
<td>After cleaning</td>
</tr>
<tr>
<td>1. Curved Mosquito forcep</td>
<td>120.52</td>
<td>301.16</td>
</tr>
<tr>
<td>1/5 visibly soiled:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(1 device; 1+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Fine Needle Driver</td>
<td>116.86</td>
<td>336.86</td>
</tr>
<tr>
<td>5/5 visibly soiled:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2 devices; 1+, 3 devices; 3+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Curved Iris Scissors</td>
<td>146.68</td>
<td>352.10</td>
</tr>
<tr>
<td>2/5 visibly soiled:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2 devices; 3+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Toothed Adson forcep (fine)</td>
<td>169.40</td>
<td>138.76</td>
</tr>
<tr>
<td>4/5 visibly soiled:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(2 devices; 1+, 2 devices; 2+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Skin Hook</td>
<td>141.14</td>
<td>193.46</td>
</tr>
<tr>
<td>1/5 visibly soiled:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(1 device; 1+)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Average:</td>
<td>138.92</td>
<td>264.47</td>
</tr>
</tbody>
</table>
Conclusions from Study:

- Not all WD cycles had this problem (84% of instruments had higher Carb and 60% had higher Carb & LPS residuals post cleaning vs pre-cleaning Avg level)

- Likely reflected inadequate water quality → ? Final rinse water

- ? Biofilm in lines/water holding tank?

Stage 1

Stage 2

Stage 3

Direction of Fluid Flow:

Biofilm

Continuously bathed in Fluid

Biofilm

→

Cyclic Build-up Biofilm

Cycle 1

Cycle 2

Cycle 50

Build-up Biofilm;

layers of dried organic matrix with embedded organisms

Cycle:

- post-patient: hydrated
- cleaning: hydrated
- disinfection: hydrated
- storage: dry

~300 - 500 μm thick

~10 - 50 μm thick
Survival of bacteria in enzymatic detergent at use-dilution

**Enterococcus faecalis**

Soaking overnight at room temperature in enzymatic detergent will lead to biofilm formation!!

**Pseudomonas aeruginosa**

Alfa MJ. Cleaning: Recent advances in products and processes and real-time monitoring. In: Disinfection, Sterilization and Antisepsis 2007
Automated Washer Cleaning Efficacy: How to assess?

- ISO guidelines; test soils to make → visibly clean (soil removed)
- Sample the processed instruments
- Place cleaning monitors in wash chamber:
Rapid User Tests: SURFACE TESTING
in-hospital cleaning assessment

- ProtTEST Check (unknown LD):
  Protein (MediSafe, UK) swab device → assess

- Protec Swab test (unknown LD):
  Protein or ATP (Biotrace) swab can be tested.
  (commercially available)

- Ninhydrin Swab test (2.5 µg/swab):
  Protein: ISO/CEN method evaluated for users; swab method (deBruin 2002)
What Cleaning monitors for Washers are available (Surface vs Lumen)?

- HealthMark USA, Medisafe UK, Steris/Browne UK, SteriTec, USA

- TOSI; Washer
- Browne soil
- Browne STF Load Check
- Steritec Wash-Checks

- Flexi check: Endoscope lumen
- Medisafe Lumen check: Laparoscopic device lumen
- TOSI Lumchek
- Steritec Lumen Wash-Checks

These represent some examples it is NOT an all-inclusive list.
Cutoff for adequate cleaning??

Protein
- OPA method: 0.01 µg/device; (Verjat 1999)
- Ninhydrin method: 2.5 µg/swab; (deBruin 2002)
- Biuret method: 5.5 µg/cm²; (Kruger 1997)
- BCA method: 6.4 ug/cm²; (Alfa 2002)

Still controversial – No International Standard

Correlation of Protein residuals unknown:
- clinical outcome
- commercial test methods
Toxic Anterior Segment Syndrome (TASS)

- After cataract surgery
- Outbreak of TASS in USA (2008-2009)
- Early onset (12-24 hrs post-surgery) inflammation → pain, blurred vision (limbus-to-limbus corneal edema)

http://www.eyenet.org/aaonews/eyenet/cataract/cataract_nov.htm

Toxic Anterior Segment Syndrome: Why Sterile Isn’t Clean Enough by Laura J. Rongé,
Non-infectious toxic material enters anterior segment of eye during surgery & causes inflammatory reaction

- Water contaminants
- Reprocessing chemical residuals
- Organic residuals

Reprocessing with sterile treated water is critical for ophthalmic surgery instruments
If water quality is so important in the cleaning of medical instruments........ What do Healthcare facilities need to do???
AMMI TIR34: Four Essential Steps

<table>
<thead>
<tr>
<th>Step</th>
<th>Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Assessment of potable water quality</td>
</tr>
<tr>
<td>2</td>
<td>Implementation of water treatment process (if needed)</td>
</tr>
<tr>
<td>3</td>
<td>Assurance of proper water quality for the various stages in medical device reprocessing</td>
</tr>
<tr>
<td>4</td>
<td>Ongoing monitoring of water quality</td>
</tr>
</tbody>
</table>
SUMMARY

- Buildup of organic residuals on surgical instruments may occur if water quality affected by biofilm in lines.
- Automated washers should be monitored to ensure cleaning efficacy.
- Water quality is important and should be assessed periodically.
Remember:
Not Everything related to Water Quality is Annoying!!

![Image of a child with swimming goggles, suggesting a positive attitude towards water quality.](image-url)
References

Reprocessing Instructions & Methods

- AAMI TIR12:2004 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers, 2ed
- ANSI/AAMI ST81:2004 Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices
- CDC (HICPAC) Guideline for Disinfection and Sterilization in Healthcare Facilities 2008
- Provincial Infectious Diseases Advisory Committee (PIDAC) – MOHLTC Best Practice Practices for Cleaning, Disinfection and Sterilization – In all Health Care Settings (April 30, 2006)
- Red brochure: Proper Maintenance of Instruments, 8ed.
  http://www.a-k-i.org/englisch/lit.htm

Cleaning

- AAMI TIR34:2008 Water for reprocessing medical devices
- AAMI TIR30:2003 A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices