Cleaning: Recent advances in products and processes and Real-time monitoring

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Overview:

- **Medical Device Cleaning:**
  - Current Issues & Advances
    - Manufacturer validated protocols
    - Cleaning mechanics
    - Cleaning agents

- **Real-time monitoring**
  - Manufacturer/Research tests
  - Rapid User testing

- **Conclusions**
Manufacturer validated cleaning protocols

- Lack of validated manufacturer’s cleaning instructions for some devices:
  - “Clean as per usual hospital protocol”
  - “Clean the tips by aspirating distilled water through the tip to clear any debris from within the tip and prevent plugging of the suction port.”
- No indication whether disassembly is required
- No indication whether sonication is needed or could damage device
New Developments:
Manufacturer’s Instructions:

- AAMI ST81 and EN ISO 17664 Guidance documents now require medical device manufacturers provide at least one manual and one automated validated cleaning protocol

- USERS: refuse to order/pay for medical device until validated cleaning protocol provided by manufacturer
Automated preferred
(equipment must be maintained properly)

- Automated Endoscope Reprocessors (AERs)
  - cleaning cycles
    (many do not have FDA clearance for cleaning claims)
  - channel separators; flow monitoring (ISO 15883-4)

- Narrow lumen cleaners
  - ultrasonic combined with detergent and fluid flow
  - self-decontamination (thermal or other)**

- Washer/Disinfectors
  - validated for respiratory equipment; replace pasteurizers
    (spray vs immersion)
And What About the Water Quality??!!

- AAMI working on a “Water Quality” Guidance document for users
- ISO 15883-1; Viable count of final rinse water and/or other methods that are equivalent (e.g. ATP method)
Cleaning Agents:

- Chemical detergents: Alkaline, Acid, Neutral
- Enzymatic detergents:
  - single or multi-enzyme
  - contact time
  - protein solution (rinsing important)
- Accelerated Hydrogen Peroxide agents

The *specific formulation* determines efficacy; cannot compare across class of agents (e.g. not all enzymatic detergents are equally effective)
Survival of bacteria in enzymatic detergent

**Enterococcus faecalis**

**Pseudomonas aeruginosa**

Soaking overnight at room temperature in enzymatic detergent will lead to biofilm formation!!
Enzymatic Detergent: Biofilm removal

Medical Device Cleaning; Real-time monitoring

- Monitor Washer function
- Monitor medical devices post-cleaning

It Looks Clean Enough to me!!!
Recent Advance: Guidelines encouraging rapid user test methods

- **CEN/ISO (15883-5):** working toward standardizing soils and test methods for users
- **AAMI:** guideline for manufacturer’s
  - recommending manufacturers provide rapid tests for users to verify in-use cleaning efficacy

How Clean is Clean Enough!!??
What parameter to monitor?

Guidelines: “Visibly Clean”

**Literature parameter benchmarks:**

**Stainless steel instruments:** 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)
- Hemoglobin strips: ? Limit of detection (Fengler)

**Flexible endoscope biopsy channel:** (Alfa et al 2002)
- Protein; < 6.4 µg/cm²
- Carbohydrate; < 1.8 µg/cm²
- Hemoglobin; < 2.2 µg/cm²

**WHAT IS REALISTIC FOR IN-USE TESTING??**
New Developments: Test Soil

ISO 15883-5: Multiple test soils:
- de Bruin (2005): compared soils and identified a universal standardized test soil for users (only for alkaline detergent cleaning in hot water)
  - visual assessment of cleaning
  - Washer monitoring; no correlation with in-use benchmarks
  - recommended German egg yolk test soil

deBruijn ACP, van Drongelen AW, Zentral Steril 2005;13
Device cleaning test methods:
Device immersed, or lumen filled with reagent

- **Bradford’s reagent:** detects protein by turning blue
- **TMB reagent:** detects hemoglobin by turning green:
- **Radioactive tracers:** labeled protein; if not removed, detected as residual radioactivity inside medical device

Specialized radioisotope imaging equipment
SYPRO Ruby Test for Protein on Medical devices

- Sensitive dye that stains any protein; detected using special epi-fluorescent microscope
- Surface testing of residual protein on medical devices after cleaning; LD of 85pg/mm²
- Not clear what would be an acceptable level of residual dye (ie. cutoff for residual protein)
- A good research tool but not readily adaptable to in-use testing for users

Lipscomb et al J Hosp Infect 2006;62:141-8
Washer Monitoring; in-hospital use

- **TOSI:** Protein/fibrin (PEREG, GmbH) QA device for washers; visual inspection post-cleaning.

- **Test soil:** colored paste brushed onto devices, test carriers, or inside washer on walls; visual inspection post-cleaning (e.g. Browne’s soil, Danish soil).

- **Lumen Test:**
  - Soil/stained/fixed inside tubing; clean then visualize
  - Biofilm; after cleaning, stain or do viable count to determine if biofilm removed

Orzechowski et al Zentr Steril 2003;11:165-178
Zuhlsdorf et al J Hosp Infect 2004;56:305-11
Rapid User Tests: for in-hospital cleaning assessment

- **Biuret reaction (5.5 µg/cm²):** Protein (Kruger 1997); swab device → assess colour development.

- **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)

**Surface testing only, not applicable to lumens**
REMEMBER: Rinse well after Cleaning

*Enzymatic detergents are proteins* and if not properly rinsed off can be detected by rapid user cleaning tests that detect protein!!
ATP: Flexible Endoscopes

- ATP is “energy source” in living cells (e.g. eukaryotes; human cells) and prokaryotes; bacterial cells)
- Rapid test methods for swab & fluid samples from flexible scopes (surfaces and lumens)
- Cutoff for adequate cleaning? - 500 RLU/sample suggested
- Organic material alone; no ATP (fecal protein, carbohydrate etc)

RLU (relative light units) measured
<table>
<thead>
<tr>
<th>Site sampled:</th>
<th>ATP RLU/sample</th>
<th>Unit A (N = 25)</th>
<th>Unit B (N = 38)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surface; swab, channel; brush</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scope: Biopsy channel</td>
<td></td>
<td>683 (16%)</td>
<td>1389 (45%)</td>
</tr>
<tr>
<td>(post-clean, pre-disinfection)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scope: Biopsy channel</td>
<td></td>
<td>82 (4%)</td>
<td>67 (0%)</td>
</tr>
<tr>
<td>(post-clean, post-disinfection)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scope: Exterior, tip</td>
<td></td>
<td>1387 (44%)</td>
<td>353 (16%)</td>
</tr>
<tr>
<td>(post-clean, post-disinfection)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endoscopy room: Video equipment switches</td>
<td></td>
<td>5322 (92%)</td>
<td>401 (13%)</td>
</tr>
</tbody>
</table>

(from: Obee et al 2005)
Value of Cleaning Verification tests for users

- **Washing Machine tests:**
  - confirm proper function (QA)

- **Medical device tests:**
  - confirm that cleaning protocol used in-hospital is effective
  - confirm staff training and document competency over time
SUMMARY:

- **Medical Device Cleaning:**
  - Current Issues & Advances
  - Manufacturer validated protocols
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- **Real-time monitoring by users:**
  - Washer efficacy**
  - Cleanliness of medical devices