Flexible Endoscopes: The “A,B,C’s” of Monitoring Manual Cleaning Efficacy!

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Disclosure:

Sponsored to give invited presentations at various National and International conferences by:
STERIS, 3M, J&J, Healthmark, APIC, CACMID, Virox, Medisafe, Ontario Hospital Association, CHICA, and multiple conference associations.

The University of Manitoba has licensed Dr. Alfa’s patent for Artificial Test Soil to Healthmark.

Opinion Leader Panel participation or Consulting Services for: 3M, J&J, STERIS, Olympus, bioMerieux, Serim, Borden Ladner Gervais LLP, various Canadian Healthcare facilities.

Research projects for:
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Objectives:

- Quality Process: Flexible Endoscopes
  Monitoring of manual cleaning
  - Sample collection
  - Test Methods: ATP, Organic residuals, Bioburden?
  - Validation of methods

Summary
Recent Endoscope reprocessing Issues in Canada and the USA:

- 500 Vancouver patients were alerted to potential exposure of blood-born virus infections due to improperly reprocessed endoscopes (April 2010)
- Approximately 10,000 former Veterans Affairs patients in Georgia, Tennessee, and Florida warned of potential exposure to infections (Feb. 2009)
- The VA said the problems were caused by human error in the cleaning and operation of endoscopic equipment
Older Flexible Endoscopes pose greatest problems

“...the number of times an individual endoscope was contaminated was directly proportional to the number of occasions that the instrument was used.”

_Bisset et al Am J Infect Control 2006;34:274-80_
What are the issues?

- Endoscopes stored wet → biofilm
- Design flaws
- Human errors in reprocessing
- Automated Endoscope Reprocessor errors

**Visual inspection is inadequate:** you cannot see inside the channels that range from 2mm – 4.2mm

Infection Prevention and Control Guideline for Flexible GI endoscopes and Bronchoscopes. Public Health Agency of Canada 2010
Guidelines: What do they say?

- Decontamination of reusable medical devices. CSA guideline Z314.8-08
- Standards of Infection Control in Reprocessing of Flexible Gastrointestinal endoscopes SGNA 2011.
- Provincial Infectious Diseases Advisory Committee (PIDAC) – MOHLTC Best Practice Practices for Cleaning, Disinfection and Sterilization – In all Health Care Settings. April 30, 2006

No specific recommendations for how to monitor manual cleaning.
Validation of Manual Cleaning Monitors

Channel Chek: Healthmark

Clean-trace: 3M

Endoscope Channel Sample

Carbohydrate, protein, hemoglobin

Detects ATP

Tests assess how well the manual cleaning is being done by staff

Pictures from company websites
Manufacturer Validation of Manual Cleaning Monitors for Flexible Endoscopes

- **Which channels to monitor?**
- **How should channel sample be collected:**
  - realistic in busy clinic
  - volume, type of liquid used for sampling
- **Limit of detection of method**
  - relate to benchmarks to be achieved
Channel-Chek Prototype Test:
protein, blood, carbohydrate

- How to collect Sample?
- Benchmark for Clean?
- In hospital clinics is it feasible?

Manuscript accepted Sept 2011 in American Journal of Infection Control
Endoscope Channel: sample collection

10 mL sterile RO water flushed into biopsy port

10 mL sample collected
Flush-brush-Flush Vs: Flush for Endoscope Sample collection

Average of three replicate experiments

Residual Organic Residue

Channel Sample Residue (µg/mL)

Protein  Hemoglobin  Carbohydrate

Flush-brush-flush  Flush

Manuscript accepted Sept 2011 in American Journal of Infection Control
Validation of Rapid Organic Test Strips using Research studies

- **All pads negative** complies with benchmarks:
  - < 6.4 ug/cm² protein,
  - < 500 ug/cm² carbohydrate
  - < .25 ug/cm² hemoglobin

- **Result interpretation:** If ANY of the 3 pads flags as positive → re-clean entire scope and retest S/B channel

Manuscript accepted Sept 2011 in American Journal of Infection Control
Channel-Chek Prototype Test: Canadian Multi-centre testing

- Prototype kits sent to 44 clinics from 23 Healthcare facilities; 1499 scopes tested
- Sample: S/B → distal end using 10 ml sterile RO water
- Staff surveyed regarding test method

Manuscript accepted Sept 2011 in American Journal of Infection Control
Trans-Canada Survey: patient-ready flexible endoscopes

<table>
<thead>
<tr>
<th>Scope</th>
<th>No:</th>
<th>Pos:</th>
<th>Carbohydrate</th>
<th>Protein</th>
<th>Blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastroscope</td>
<td>543</td>
<td>50 (9.2%)</td>
<td>0</td>
<td>3</td>
<td>47</td>
</tr>
<tr>
<td>Colonoscope</td>
<td>463</td>
<td>32 (6.9%)</td>
<td>5</td>
<td>2</td>
<td>25</td>
</tr>
<tr>
<td>Bronchoscope</td>
<td>251</td>
<td>10 (4%)</td>
<td>0</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>ERCP scope</td>
<td>57</td>
<td>7 (12.3%)</td>
<td>0</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>[Elevator wire]</td>
<td>21</td>
<td>4 (19.1%)</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Sigmoidoscope</td>
<td>91</td>
<td>2 (2.2%)</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
</tbody>
</table>

Manuscript accepted Sept 2011 in American Journal of Infection Control
# Reprocessing Staff Questionnaire: Trans-Canada Survey

<table>
<thead>
<tr>
<th>Question</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>How important is it to confirm adequate cleaning of flexible endoscope channels?</td>
<td>4.86</td>
</tr>
<tr>
<td>Should test be done some scopes each day?</td>
<td>4.16</td>
</tr>
<tr>
<td>Should test be regular part of QA in endoscopy area?</td>
<td>4.47</td>
</tr>
<tr>
<td>Ease of ENTIRE Rapid test?</td>
<td>4.64</td>
</tr>
<tr>
<td>Is time of test (90 sec) realistic for endoscopy area test?</td>
<td>3.98</td>
</tr>
</tbody>
</table>

(1: lowest/worst…… 5: highest/best)

Manuscript accepted Sept 2011 in American Journal of Infection Control
ATP monitoring of Endoscope Channel Cleaning

- ATP is present in *living* cells: both human and bacterial cells
- ATP measured by assay that detects “relative light units” or RLUs

*Low level of RLUs*  
*High level of RLUs*  

Pictures from Google Images
ATP does not have a linear correlation with microbial numbers \([\sim 10^3 \text{ cfu/mL to be detected}]\)

- Various manufacturer’s kits have different limits of detection for bacteria \([\text{Aiken et al ICHE 2001}]\)
- Reflects total human cellular and bacterial cellular residuals
- Disinfectants inactivate ATP

Pictures from Google Images
ATP: Simulated-use testing

- Artificial Test Soil
  (containing $10^6$ cfu/mL *Pseudomonas aeruginosa*, *Enterococcus faecalis*)
- All channels inoculated, held 1 Hr at RT
- Flush method used to sample all channels

Channel sample collected

20 mLs sterile RO water
Simulated-use Evaluation

Duodenscope: triplicate testing

**CLEAN Benchmarks:**

Protein: \(< 6.4 \ \text{ug/cm}^2\)

Bioburden: \(< 4 \ \text{Log}_{10}/\text{cm}^2\)

*Sterile RO water to collect sample*

L1: Suction/biopsy channel (40 mL)

L2: Air/water channel (20 mL)

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**Simulated-use Evaluation**

**Duodenoscope: triplicate testing**

**Protein:**
- Total clean: range 0.06 – 0.46 ug/cm²
- Partial clean: range 45 – 356 ug/cm²

**Bioburden:**
- Total clean: range 2 – 3 Log₁₀/cm²
- Partial clean: range 5 – 6 Log₁₀/cm²

**ATP:**
- Total clean: range 16 – 183 RLUs
- Partial clean: range 8,000 – 46,000 RLUs

**CLEAN Benchmarks:**
- Protein: < 6.4 ug/cm²
- Bioburden: < 4 Log₁₀/cm²

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**Sterile RO water to collect sample**

L1: Suction/biopsy channel (40 mL)
L2: Air/water channel (20 mL)

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**ATP Clinical Study: One hospital**

**Benchmark for clean < 200 RLUs**

30 colonoscopes and 30 duodenoscopes post manual cleaning

1. Duodenoscopes more difficult to clean than Colonoscopes

2. Duodenoscopes Post manual cleaning:

<table>
<thead>
<tr>
<th>Channel Type</th>
<th>% &gt; 200 RLUs</th>
<th>All RLUs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surface 1</td>
<td>10%</td>
<td>&lt; 750 RLUs</td>
</tr>
<tr>
<td>Suction/Biopsy channel</td>
<td>0%</td>
<td>&gt; 200 RLUs</td>
</tr>
<tr>
<td>Air/water channel</td>
<td>0%</td>
<td>&gt; 200 RLUs</td>
</tr>
<tr>
<td>Elevator G-wire channel</td>
<td>20%</td>
<td>&lt; 700 RLUs</td>
</tr>
</tbody>
</table>

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Summary: ATP Assay Validation

- Each manufacturer needs to validate benchmark RLU that correlates with adequate manual cleaning.

- **ATP Assay (3M):** < 200 RLUs ensures entire channel meets benchmarks (i.e. < 6.4 ug/cm² & < 4 Log₁₀ cfu/cm²).

- **ATP Assay:**
  - not applicable after HLD.
Monitoring Cleaning at What stage?

Endoscope Cleaning and Disinfection Process:

**PROCEDURE ROOM**

1. **1 CLEANING**
   - IPRECLEAN
   - LEAK TEST
   - PASS
   - REMOVE ALL DETACHABLE PARTS
   - CLEAN
   - RINSE

2. **SET ASIDE FOR REPAIR**

3. **REPLACE ALL DETACHABLE PARTS**

**REPROCESSING AREA**

4. **4 STORAGE**
   - HANG TO STORE

5. **3 DRYING**
   - PURGE ALL CHANNELS WITH AIR UNTIL DRY
   - ALCOHOL RINSE

**STORAGE**

Some AERs: cleaning cycle replaces manual clean

**Manual cleaning**

**HLD**

CSAO Endoscope Reprocessing
When to Monitor Cleaning??

Quality Assurance Program: Staff

- **New staff**: QA for training adequacy [all channels for each scope type]
- **New endoscopes**: QA for training adequacy [all channels for each scope type]
- **Ongoing (yearly)**: QA for maintenance of staff competency [all channels for each scope type]
Quality Assurance Program: Endoscopes

- **Site Verification:**
  - Establish reproducible baseline by testing all scopes all channels for a short period of time

- **Ongoing Monitoring:**
  - Each scope used tested ~1/week
  - Problem persists in S/B channel → test all channels

Pictures from Google Images
SUMMARY:

- **Quality Process: Flexible endoscopes**
  - Monitor cleaning process, not just disinfection stage

- **Ongoing Rapid Monitoring of manual cleaning**:
  - Select a [Validated] test method: ATP, Organic residuals
  - Users to [Verify] site can reliably meet validated cutoffs
  - Ensure test used at the correct stage of reprocessing

- **Guidelines:**
  - What frequency of testing?
References

General Reprocessing

- AAMI TIR12:2004 Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers, 2ed
- Provincial Infectious Diseases Advisory Committee (PIDAC) – MOHLTC Best Practice Practices for Cleaning, Disinfection and Sterilization – In all Health Care Settings (April 30, 2006)
- CDC (HICPAC) Guideline for Disinfection and Sterilization in Healthcare Facilities 2008
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
- ANSI/AAMI ST79:2006 Comprehensive guide to steam sterilization and sterility assurance in health care facilities

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