Enhanced Visual Inspection of Flexible Endoscopes

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Objectives

- Define visually clean and enhanced visual inspection for endoscopes
- Review the latest information from various organizations on enhanced visual inspection using a borescope
- Define best practices for enhanced visual inspection of medical devices
Overview of the Levels of Inspection

- All scopes must be visually inspected after manual cleaning: Look for debris and damage.
- Standards and professional guidelines also call for lighted magnification to be used for this step.
- Cleaning verification tests are used to check for internal retained patient debris.
- AAMI and AORN recommend use of a borescope for internal inspection.
Inspection of Flexible Endoscopes

- CSA
- PHAC
- AAMI - ST 79 and ST 91
- AORN
- SGNA

All support the practice of using some type of visual inspection to unaided eye.
Basic visual inspection – Unaided Eye

- The most basic verification of the performance of a cleaning process is by carefully inspecting the cleanliness of instruments and materials with your eyes.

- All objects should be free of any remaining soils, deposits, pitting etc.

- Duodenoscope IFU:
  - Olympus 180 duodenoscope:
    - “Inspect whether there is debris on the forceps elevator and in the forceps elevator recess while raising and lowering the forceps elevator, and repeat brushing and/or flushing the forceps elevator and the forceps elevator recess until no debris is observed upon the inspection.”

- Inspect all items for residual debris. **Should any debris remain, repeat the entire cleaning procedure until all debris is removed.**
• Equipment monitoring including visual inspection to identify conditions that may affect the cleaning or disinfecting process.

• During the manual cleaning process, trained personnel should inspect devices for functionality and damage.

• Visual inspections of equipment should be conducted to ensure that it is in proper working order in accordance with the endoscope manufacturer’s recommendations and to identify conditions that may affect the cleaning or disinfection processes.

• Visually inspect the scope to verify working properly.

• Source: PHAC 2011: Infection prevention and control guidelines for Flexible Gastrointestinal Endoscopy and Bronchoscopy
Remove damaged or defective scopes from service.

Routine visual inspection and preventative maintenance of each endoscope provides valuable info about the scope’s condition and can uncover the need for repair.

Use of damaged or unclean endoscopes is a risk to patient safety.

Identifying wear and tear, damage or deterioration is essential to good endoscope care.

Source: Z314.8-14: Feb 2014
A diligent inspection of the entire endoscopes shall be performed after each use shall include at minimum:

- An overall assessment of the cosmetic appearance
- No discoloration
- No cracks
- No sharp edges
- No holes or other degradation
CSA – Decontamination of Medical Devices

- Insertion tub should be assessed to determine if the outer surface is damaged or punctured.
- Distal end and cap should be round and smooth.
- Lens at distal end or objective lens should not be cracked or dirty.
- Biopsy channel recessed hole should be round, smooth and not impacted or cracked.
CSA – Decontamination of Medical Devices

- Water resistant cap should be watertight
  - If fluid is present after the disinfection process, the leak test should be re-done.
  - If leak test is negative, then likely the cap is not water resistant
  - The integrity of the cap should be assessed for missing, damaged or stretched o-rings
  - Light guide connector prong should be checked to ensure that it is tight
CSA – Decontamination of Medical Devices

- Knobs should not be cracked, looks, leak or have a grinding feeling when turned.
- Endoscope should angulate smoothly without tightness or play.
- Bending section should not bend irregularly.
- Degree of angulations should be checked.
  - Refer to scope IFU for angulation charts.
US Guidelines - Enhanced Visual Inspection

- Inspection with **lighted magnification** supported by:
  - AAMI ST91: Inspection using magnification and additional illumination might identify residues more readily than the unaided eye.
  - AORN: An endoscope that appears clean may harbor debris that cannot be seen without magnification.
  - Lighted magnification may increase the ability to identify residual soil or damage.
SGNA – Endoscope Inspection

- Treat as a safety stop or “time out” to ensure the endoscope is visually clean before proceeding to the next step of HLD.

- Visually inspect for conditions that could affect the disinfection process (e.g., cracks, corrosion, discoloration, retained debris).

- Repeat manual cleaning step(s) if not clean.

- Minimum standard for cleaning assessment of scopes.

- Need adequate lighting
AORN visual inspection

- Visually inspect with lighted magnification for cleanliness, integrity, and function before use, during the procedure, after the procedure, after cleaning, and before disinfection or sterilization.

- Inspection helps to identify residual organic material and defective items and remove from service soiled / defective items that might put patients at risk for infection or injury.
• Careful visual inspection should be conducted to detect the presence of any residual soil.

• Users should inspect every device for visible organic soil and contamination in a simple functionality test.

• Direct visual inspection is not always possible for the inner components of medical devices that have lumens.

• Use lighted magnification and inspect throughout process

ST91 Visual inspection
Because duodenoscopes are more complex than other endoscope instruments, it requires **meticulous attention to detail and step-by-step precision** to render them safe for re-use.

**After observing the cleaning** and disinfecting processes and asking questions so that each step of the process is understood, the IP or HE may visit the department regularly to observe scope cleaning practices and reinforce the importance of the work being done.

The IP or HE will evaluate human factors, including ensuring that the cleaning area is set up with a **bright light** and **magnification** so all sections of the scope being cleaned can be well visualized.

CDC Visual Inspection

- Ensure that the elevator mechanism is thoroughly cleaned and free of all visible debris.
  - Visual inspection is to be done with the elevator in the “open/raised” position and “closed/lowered” position to ensure there is no visible debris above or below the elevator mechanism.

- Consideration should be given to use of a magnifying glass (e.g., 10x) to improve detection of residual debris around the elevator mechanism.

- APIC: The IP will evaluate human factors, including ensuring that the cleaning area is set up with a bright light and magnification so all sections of the scope being cleaned can be well visualized.
H. Visual Inspection - All routine cleaning instructions should include instructions for visual inspection, which may include use of magnification and adequate lighting. The instructions should advise the user that if the device is determined not to be visually clean at the end of the cleaning step, the user should either repeat the relevant previous cleaning steps or safely dispose of the device. Additionally, the visual inspection instructions should identify acceptance or failure criteria related to device performance (e.g., unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals), as well as instructions to properly dispose of devices that fail.
Endoscope borescopic inspection

- Not required in any endoscope IFUs at this time
- Suggested in the standards and guidelines
  - Tougher wording presently in draft standards
- Used in all major research papers (Healthmark FIS)

New biopsy area
Inspection with a borescope
Inspection entails all of the scope
Where to inspect in a scope

- Instrument/suction channel
- Valve openings
- Biopsy
- Distal tip
- Connection points within scope
- Forceps elevator
- Around control knobs
- Accessories
Where to inspect in a scope:

- Inspect down the Instrument/suction channel and biopsy port
- Material changes from metal to plastic
- Inspect up the scope from the distal tip into the bending section
- Material changes in bending section
- Bifurcation
When to inspect with a borescope?

- Two options that facilities are currently employing based on their logistics and workflow:
  - After manual cleaning prior to disinfection
  - After reprocessing is complete and the scope is in storage
When to inspect with a borescope

- After manual cleaning prior to disinfection
  - Dirty procedure
- Borescope must be processed between uses in accordance with the IFU
  - Wipe with surface disinfectant wipes
  - Can disinfect or sterilize dependent on model.
When to inspect with a borescope

- After disinfection and endoscope is in storage
  - Clean procedure
- Borescope must be reprocessed after use
- Endoscopes must be completely reprocessed after inspection (rerun through cleaning and disinfection)
- Used as a quality tool to inspect endoscopes on a periodic interval established by the facility
- Looking for retained debris, damage and moisture
  - Endoscopes should be dry at this point since they are in storage!
Many different types of borescopes are available
Various sizes
Make sure to know inventory to pick the correct size borescope
Video and fiber scopes available
Different manufacturers
Different chemical compatibilities
Disinfection
Sterilization
Supporting research and documents
December 8, 2017

Re: Use of borescopes for cleaning verification of Olympus flexible endoscopes

Dear Health Care Professional,

This letter is in response to your recent inquiry on the use of borescopes for cleaning verification of Olympus flexible endoscopes.

Olympus does not currently have an official stance on the use of borescopes as a tool for visualization of flexible endoscope channels after manual cleaning. We are aware that several industry guidelines have a recommendation regarding the use of borescopes. However, as the endoscope manufacturer, Olympus neither requires nor prohibits the use of borescopes. Please refer to the Instructions for Use of the specific endoscope model for validated reprocessing instructions.

WARRANTY
Nothing contained in this letter alters, extends, or modifies in any way the authorized Olympus warranty applicable to each device or instrument.

If you have any additional questions, please contact your local Olympus sales representative or the Olympus Technical Assistance Center at 1-800-848-9024 (United States) or 1-800-387-0437 (Canada).

Sincerely,

Olympus
BACKGROUND

Visual inspection is the most common technique for inspecting medical devices. Standards, guidelines, and articles all support the use of visual inspection to ensure medical devices are clean and functional before they are re-used, sterilized, or discarded. Visual inspection is a crucial step in maintaining the cleanliness and safety of medical devices.

DISCUSSION

Who is taking medical device reprocessing professionals to visually inspect instruments? The manufacturer of the instrument with their IFU (instructions for use) identifies the operators that must perform visual inspection. The facility must train all medical device users and provide written instructions on how to perform visual inspection.

The visual inspection process involves examining the medical device for any visible defects, as well as checking for any unusual colors, textures, or odors. The inspection should be performed using good light sources and magnification, if necessary.

SOLUTIONS

Who is taking medical device reprocessing professionals to visually inspect instruments? The manufacturer of the instrument with their IFU (instructions for use) identifies the operators that must perform visual inspection. The facility must train all medical device users and provide written instructions on how to perform visual inspection.

Examples of enhanced optical inspection tools include:

- Surface inspection: Use enhanced optical inspection tools to identify any surface defects or scratches.
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Examples of surface test methods include:

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Key areas to examine with a flexible inspection scope include:

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Support for using enhanced visual inspection – Poster at AORN 2017

Multisite study on ureteroscope reprocessing effectiveness

Cori L. Ofstead, MSPH\(^1\); John E. Eiland, RN, MS\(^2\); Otis L. Heymann, BA\(^3\); Mariah R. Quick, MPH\(^4\); Harry P. Wetzel, MD, MSPH\(^1\)

\(^1\)Ofstead & Associates, Inc., Saint Paul, MN, USA

Introduction and purpose
- Contaminated endoscopes, gastrosopes, bronchoscopes, and cystoscopes have been linked to outbreaks\(^1\)\(^2\)
- Damaged or contaminated endoscopes have also caused injuries and infections\(^3\)\(^4\)
- Functional failures discovered during processing or reprocessing lead to frequent repairs\(^5\)
- Current guidelines recommend careful visual inspection during reprocessing\(^6\)
- This study sought to answer the following research questions:
  - How much contamination can be detected in sterile flexible ureteroscopes?
  - How much damage or debris is visible when using uIghted magnification?

Methods
- Prospective study conducted in two large institutions
- The research team:
  - Audited reprocessing revaluations
  - Obtained samples using surface swabs and a brush brush flush technique
  - Performed tests for microbial contamination:
    - Protein, hemoglobin, and adenovirid triphosphate (ATP)*
    - Microbial cultures
- Conducted visual inspections of:
  - External surfaces using lighted magnification and a digital camera
  - Channels and ports using a 0.3 mm fiber optic borescope

Results
- Flexible ureteroscope characteristics (N=17):
  - Average age 2.1 years
  - Repairs required after an average of 19 uses due to:
    - Failed light tests
    - Inadequate image quality
    - Broken fibers
    - Punctured insertion tubes

Table 1. Results of visual inspections, biochemical tests, and microbial cultures (N=17)

<table>
<thead>
<tr>
<th>Test</th>
<th>Benchmark</th>
<th>Number (%) above benchmark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visual Inspection</td>
<td>No damage or debris</td>
<td>36 (100%)</td>
</tr>
<tr>
<td>Protein</td>
<td>6-4 mg/mL</td>
<td>36 (100%)</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>2.2 mg/dL</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>ATP</td>
<td>200 RLU</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>Microbial cultures</td>
<td>No growth</td>
<td>3 (15%)</td>
</tr>
</tbody>
</table>

*One ureteroscope was put up for repair during the study.** No relative light sources

![Image of ureteroscope with visible damage and debris](http://www.ofsteadinsights.com/?p=2303)

Summary and next steps
Sterilized ureteroscopes had high contamination levels, visible damage, and debris

- Tests conducted on sterilized flexible ureteroscopes found:
  - All had visible irregularities
  - All had contamination above benchmarks for clean GI endoscopes
  - Two (13%) had positive microbial cultures
  - Results highlight the need for:
    - Improvement in adherence to guidelines, including:
      - Revisiting pre-cleaning by ER staff to prevent buildup of mold
      - Implementation of an effective verification process
    - Visual inspections with lighted magnification to identify irregularities
    - More frequent preventive maintenance
    - Reprocessing methods that are proven effective to ensure patient safety

Disclosures and acknowledgements
The study was conducted independently by researchers from Ofstead & Associates, Inc. and personnel from two study sites. Boston Scientific Corporation provided a wash assist, and F.H. Wei et al. provided study materials. The study sponsors did not have access to the data or participate in the development of the content of this poster.

References
1. AORN. Guideline for processing flexible endoscopes, 2016.
Support for using enhanced visual inspection – Poster at AORN 2016

Residual contamination found on endoscopes in an ambulatory surgery center

Cori L. Ofstead, MSPH1, John E. Eiland, RN, MS1, Miriam R. Amelang, BA1, Otis L. Heymann, BA1, Sarah B. Held, RN, MBA2, Michael J. Shaw, MD3

1Ofstead & Associates, Inc., Saint Paul, MN, USA; 2Fairview Maple Grove Medical Center, Maple Grove, MN, USA; 3Division of Gastroenterology, Department of Medicine, University of Minnesota Medical School, Minneapolis, MN, USA

Introduction
- Contaminated endoscopes have caused outbreaks of multi-drug resistant organisms.
- During an outbreak investigation, endoscopes identified as contaminated were examined.
  - Brown staining, scale, and a small crack in the distal tip
  - Pseudomonas aeruginosa identified as the etiologic strain
- In another outbreak investigation:
  - Infection was linked to contaminated endoscopes
  - The manufacturer found critical defects in every duodenoscope
- This study was designed to answer two questions:
  - How much do damage and debris accumulate in endoscopes over time?
  - Is it possible to get old endoscopes clean?

Methods
- Longitudinal study in an ambulatory surgery center
- Three assessments conducted over a 7-month period
- Baseline data collection in April 2015
- Auditing reprocessing practices
- Compiling data on endoscope age, usage, and repair history
- Evaluating 17 clinically-used endoscopes:
  - Rapid indicator tests for ATP and protein
  - Medical cultures
  - Bronchoscope examinations of interior components
  - Implementation of more rigorous reprocessing methods (beginning in May 2015)*

Results
- At baseline assessment:
  - 6 endoscopes were > 2.5 years old
  - Endoscopes had been used 36-541 times
  - Nine endoscopes had been repaired
  - There was good adherence to reprocessing policies
  - 16 of 17 endoscopes were still contaminated after manual cleaning
  - Contamination levels were higher for gastroscope than colonoscopes

Looking inside reprocessed endoscopes revealed damage and debris

- During the baseline assessment, researchers found:
  - Damage and debris inside channels
  - Contamination levels exceeding benchmarks
  - Residual fluid in channels and ports
  - Finding that current reprocessing methods were not sufficient
- Interventions included:
  - Sending endoscopes out for repair
  - Adopting more rigorous reprocessing practices
  - Implementing manual ATP monitoring of cleaning effectiveness
  - Increasing enzyme air drying times
- Results from the interim and final assessments are forthcoming
- Observations from an annual audit of reprocessing practices
- Impact of interventions designed to improve reprocessing
- Changes in contamination levels and visual appearance over a 7-month period

Summary and next steps

Figure 1. ATP test results after manual cleaning

Figure 2. ATP test results after manual cleaning

Figure 3. Protein test results after manual cleaning

Figure 4. Tobacco, non-tobacco, and brown staining inside the distal end of colonoscopes

Figure 5. Tobacco, non-tobacco, and brown staining inside the distal end section of colonoscopes

Disclosures and acknowledgements
The study was conducted independently by researchers from Ofstead & Associates, Inc., the University of Minnesota, and Fairview-Maple Grove Medical Center. The study was supported in part by research grants from 3M Health Care, Medtronic, Inc., and HealthMark Industries. Study sponsors did not have access to the data nor participate in developing the content of this poster.

References
Reprocessing effectiveness for gastroscopes and colonoscopes: Longitudinal comparison of two methods

Cori L. Ofstead, MSPH1, Harry P. Wetzler, MD, MSPH2, Miriam R. Amelang, BA1, Otis L. Heymann, BA1; John E. Eiland, RN, MS1, Sarah B. Held, RN, MBA2, Michael J. Shaw, MD3
1 Ofstead & Associates, Inc., Saint Paul, MN, USA; 2Fairview Maple Grove Medical Center, Maple Grove, MN, USA; 3Division of Gastroenterology, Department of Medicine, University of Minnesota Medical School, Minneapolis, MN, USA

1. Introduction
- Outbreaks have been linked to contaminated gastroscopes and colonoscopes.
- Investigators have identified endoscope defects during outbreaks.
- Study conducted to determine:
  - How much damage and debris accumulate over time?
  - Is it possible to get old endoscopes clean?
  - What is the effect of more rigorous reprocessing methods?

2. Methods
- Longitudinal study conducted over 7 months.
- Standard reprocessing (control) compared with more rigorous methods (intervention) (intervention).
- Baseline and interim data collection included:
  - Observation of reprocessing
  - ATP tests and cultures after cleaning and after HLD
  - Borescope examinations of channels

Table 1: Endoscope study groups

<table>
<thead>
<tr>
<th>Reprocessing Method</th>
<th>Control</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visible pre-cleaning</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Manual cleaning</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Verification of cleaning effectiveness using ATP</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Repeat cleaning and HLD when ATP ≤ 2,000 RLU</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Automated cleaning in AER</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>HLD with presoak in AER</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Alcohol flush and forward air in AER</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Visible oropharynx in withdraw cabinets</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

3. Results
- Baseline:
  - Manual cleaning and HLD commonly ineffective (Table 2).
  - Gastroscopes more contaminated than colonoscopes.
  - Visible irregularities and residual fluid identified (Figures 1, 2).
- Interim:
  - Contamination and defects worsened over time.
  - Discoloration reduced in intervention group (Figures 3, 4).
  - Cleaning verification tests exceeded benchmarks:
    - 1% of colonoscope encounters (n=304)
    - 52% of gastroscopes encounters (n=143) (figure 5).

Table 2: Results for baseline and interim comparisons

<table>
<thead>
<tr>
<th>Method</th>
<th>Baseline (N=35)</th>
<th>Interim (N=35)</th>
<th>Interim results by group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-cleaning ATP ≥ 2,000 RLU</td>
<td>29%</td>
<td>37%</td>
<td>30%</td>
</tr>
<tr>
<td>Highest post-cleaning ATP ≥ 10,000 RLU</td>
<td>84%</td>
<td>75%</td>
<td>75%</td>
</tr>
<tr>
<td>Positive cultures post HLD</td>
<td>47%</td>
<td>58%</td>
<td>67%</td>
</tr>
<tr>
<td>Number sent for repair*</td>
<td>2</td>
<td>4</td>
<td>2</td>
</tr>
</tbody>
</table>

4. Summary

Endoscope contamination accumulated over time
- Borescope examinations identified six endoscopes requiring repair.
- Routine ATP tests detected endoscopes needing re-cleaning before HLD.
- More rigorous reprocessing methods reduced discoloration.

References

Disclosures and acknowledgments

Support for using enhanced visual inspection

- Fluid and Simethicone residual identified in a scope after processing in 19 of 20 scopes inspected

Reference: Ofstead and associates, AJIC 2016, article in press
Support for using enhanced visual inspection

- Borescope inspection identified scratches, discoloration, debris, & fluid
- These changed over time
- Allowed damaged and contaminated scopes to be identified and reprocessed and sent for repair
- When went for repair, manufacturer determined

Reference; Ofstead and associates, AJIC 2016. Article in press.
Photos taken with a borescope
Borescope Examination
Showing a Cracked Water Jet

The crack in the weld at the water jet nozzle not picked up by a leak test

Inside a biopsy port channel of an endoscope
Examples of Debris and Damage Found in Endoscopes.
Borescope Examination Photos using the FIS

- Fluid in Channel of “DRY” scope
- Debris inside a channel
Shredding of the Channel
Moisture in the Channel
Staining and debris in channel
Visual Inspection Products
Helping you see where the naked eye cannot
Mary Ann DRosnock
Senior manager of Clinical education and Co-chair of AAMI ST91
mdrosnock@hmark.com

- Thank you! Questions?