

# Is that Scope Safe?

Flexible Endoscope Cleaning  
Stephen M. Kovach

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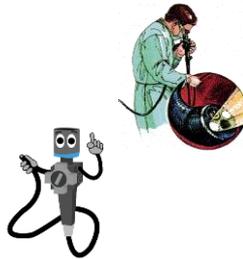
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## This Quote Sums up the Activity Going on Right Now with Flexible Scopes

“If you want to truly  
understand something, try  
to change it”

Kurt Lewis



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## Objectives

- To understand and make sure a scope is ready for your patient, you need some background information to make sure that **“the scope is clean enough to be used ?”**
  - We will review and help you understand:
    - What your customer knows about your process
    - The anatomy of flexible scopes
    - The literature on the issues with flexible scopes
    - The evidence-based clinically relevant products on monitoring flexible scopes
    - Possible quality improvement programs to help ensure your scope is patient ready.
- Remember our mantra
  - If it is not clean, it might not be able to be high-level disinfected or sterilized

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## What Your Customer Knows about Scopes

- Main source of news
  - Internet
  - Papers
  - TV
- Tipping point for dirty scopes
- Articles released on the same day: January 21, 2015
  - USA Today Article
  - Seattle Times Article
  - Gastroenterology Societies Discuss Patient Safety in Gastrointestinal Endoscopy
- Plus ECRI list

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## USA Today Front Page 1 - 21 - 2015



Read the article

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## The Seattle Times Local News

Home | News | Business & Tech | Sports | Entertainment | Food | Living | Homes | Travel | Opinion

Originally published January 21, 2015 at 9:24 PM | Page modified January 22, 2015 at 4:58 PM

### Undisclosed superbug sickened dozens at Virginia Mason

An outbreak of multidrug-resistant superbugs spread by contaminated endoscopes infected at least 32 patients at Virginia Mason Medical Center between 2012 and 2014. Neither the hospital nor health officials notified patients or the public.

By Julie Aveson  
Seattle Times health reporter

An outbreak of drug-resistant superbugs spread by contaminated medical scopes infected at least 32 patients at Virginia Mason Medical Center in Seattle between 2012 and 2014, new reports show.

Even of those patients died, but it's not clear what role, if any, the infections played, doctors said.

The rare bacteria likely were transmitted from patient to patient by specialized endoscopes, flexible tools used to treat pancreatic cancer and other gut problems, which had been cleaned according to manufacturers' directions but still harbored the potentially deadly germs.

#### READER COMMENTS

HIDE / SHOW COMMENTS

"We didn't feel like it was a new issue that warranted emergency notification." This sounds like not only a bad... (January 22, 2015) [more](#)

Che more item, I read a comment that the people were old and sick. This is not the point, the point is that they were... (January 22, 2015) [more](#)

That is absolute bull. Doctors care about doing a good job and patient's having good outcomes. I don't believe that... (January 22, 2015) [more](#)

Read all 86 comments • Post a comment •

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## Gram Positive and Gram Negative Bacteria

2 Classes of Bacteria Based on Differences in the Cell Structure

### Gram Positive Examples

- Skin flora
- Non pathogenic
- *S. epidermidis*
- *S. salivarius*

### Gram Negative Examples

- *E. coli*
- *Legionella*
- *Pseudomonas*
- *Salmonella*
- *Serratia*
- *Helicobacter*



Image courtesy: pipereport.com

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## Impact of Gram Negative Bacteria

- Frequently reported in endoscope acquired infections
- Replicate more easily in moisture
- Indicators for bacterial contamination in endoscopes
- Reduce the risk of false positives associated with the gram positive bacteria normally occurring as skin flora

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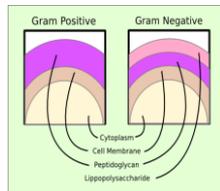
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## The Problem with Gram Negative Bacteria

- Presence of double membrane surrounding bacterial cell
- The outer membrane excludes certain drugs from penetrating the cell
- Confers more antibiotic-resistance than gram positive bacteria




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## CRE Bacteria

- Family of gram negative bacteria
- Multidrug resistant
- Nearly immune to the 'Carbapenem' class of antibiotics, considered the last line of defense against gram negative infections
- Recent outbreaks of the deadly CRE bacteria in Chicago, Seattle, and Pittsburgh - linked to Duodenoscopes/ERCP endoscopes



Image courtesy: [www.dailymail.co.uk/news/article-2285729/Rare-antibiotic-resistant-superbug-outbreak-U-S-health-officials-high-alert.html](http://www.dailymail.co.uk/news/article-2285729/Rare-antibiotic-resistant-superbug-outbreak-U-S-health-officials-high-alert.html)

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## Duodenoscopes and CRE

- The design of the ERCP endoscopes might pose a particular challenge for cleaning and disinfection
- Endoscopic retrograde cholangiopancreatography (ERCP) is an effective technique for diagnosing and treating problems in the liver, gallbladder, and pancreas.
- To prevent risk of disease transmission during ERCP, the duodenoscope's complex internal surfaces, including its long and narrow elevator-wire channel — require special attention and thorough reprocessing.



Image Courtesy: [www.gastrohep.com/ebooks/thumbnails.asp?book=1405120762&ci=4](http://www.gastrohep.com/ebooks/thumbnails.asp?book=1405120762&ci=4)

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*"Your infection may be antibiotic-resistant, but let's see how it responds to intensive litigation."*

Image courtesy: [Cartoonbank.com](http://Cartoonbank.com)

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### What's Hiding inside the Endoscope Lumen?

- Is there any residual bioburden in the lumen that we cannot visualize?
- Do we need periodic surveillance to monitor this?
  - After cleaning
  - After disinfection
  - In storage
- What do you think ?



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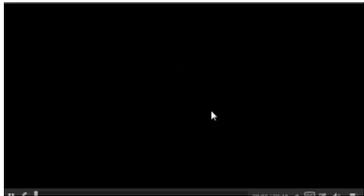
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### Public Knowledge

Comes from the TV, radio, newspaper, internet research, and word of mouth from employees about their facility.



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### How Would You Answer This Question ?

- Do you have protocols that ensure the staff can readily identify whether an endoscope is contaminated or is ready for patient use?
- Are you conducting competency testing of personnel reprocessing endoscopes on a regular basis?
- Although vague, present guidelines support these two statements.

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Flexible endoscopes have topped the list of the biggest health hazards for many years.

Decontamination of this particular equipment requires a very specific multi-step process, and failure to adhere to any step could jeopardize patients.\*

\* [http://blogs.hcpro.com/osh/2010/09/flexible-endoscopes-a-top-hazard-according-to-ecri/?utm\\_source=icwm&utm\\_medium=eNL&utm\\_campaign=20100901](http://blogs.hcpro.com/osh/2010/09/flexible-endoscopes-a-top-hazard-according-to-ecri/?utm_source=icwm&utm_medium=eNL&utm_campaign=20100901)

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A comment from a major repair facility staff member... "The biggest horror story we see are facilities not brushing the biopsy channels and pre-cleaning them before they send them in for repair," he expounds. "There's nothing more disgusting than to open up a case and find fecal matter because they didn't brush out the biopsy or suction channels. That's more common that we would like to see."

<http://www.surgicenteronline.com/articles/5a1cover.html>



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### The Anatomy of a Flexible Scope



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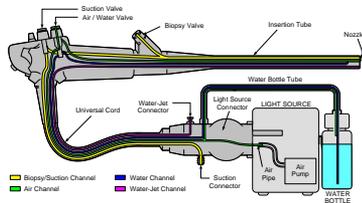
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## Flexible Endoscope's Anatomy



- Endoscopes are complex medical instruments having long and narrow working channels that are subjected to torque and angulation forces
- These forces require special materials and engineering
- Endoscopes have state of the art electronics, including fiber optics and imaging technology

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## Flexible Endoscopes

- There are a variety of flexible endoscopes types with differing channel sizes and configurations.



Bronchoscopes

Colonoscopes

Intubation Scopes

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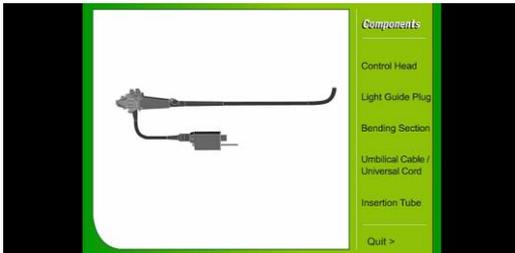
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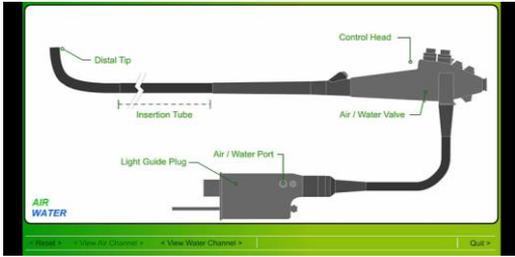
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# Air Water Channel



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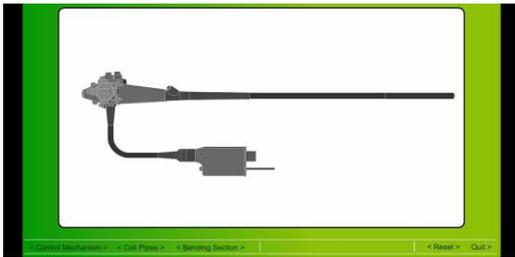
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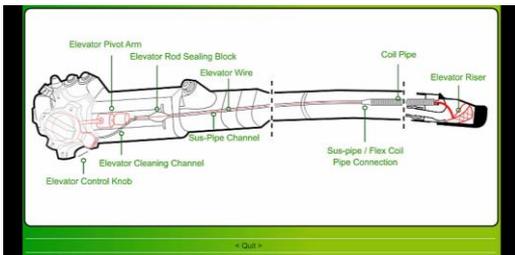
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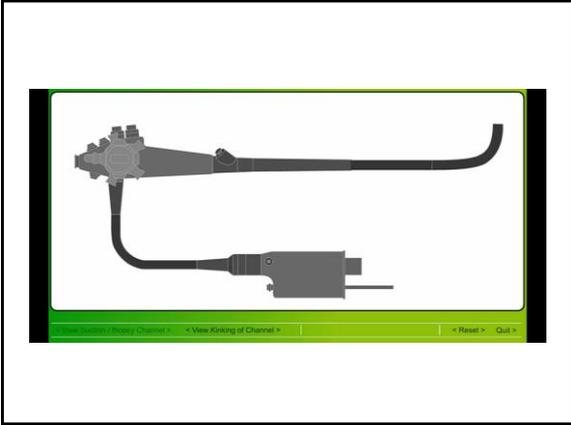
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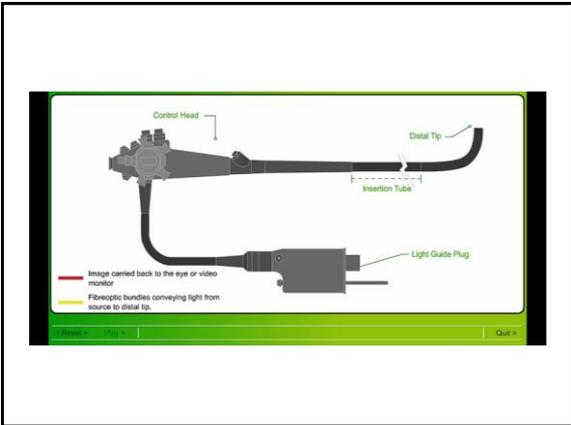
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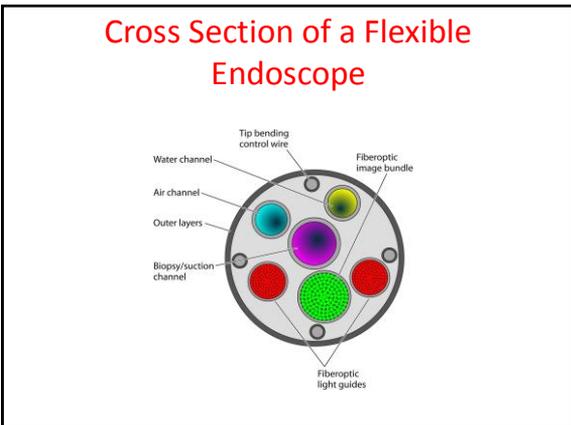
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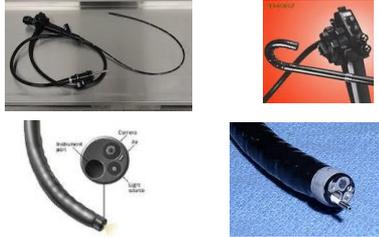
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### Flexible Endoscopes: Complex Narrow Lumens



Staff may not know which channels require cleaning

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### Cleaning Concerns

Any organic matter that remains after manual cleaning lowers the effectiveness of the disinfectant, but the complex nature of endoscopes makes them very difficult to thoroughly decontaminate. With imperfect cleaning, bacteria could survive the disinfection process and infect the next patient.

Spach D, Silverstein F, & Stamm W. Transmission of infection by gastrointestinal endoscopy and bronchoscopy. *Annals of Internal Medicine* 118, 117-128 (1993).

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Articles and Literature  
along with  
and  
Evidence-based Products  
Applying the Principles to Product

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## Review of the Research

- Scientific Research
  - Residual soils in flexible endoscopes
  - Cleaning of flexible endoscopes
  - Organic & Microbial residuals
  - Organic & Bioburden markers to assess cleaning
  - Benchmarks for cleaning
- Clinical application of research to audit cleaning

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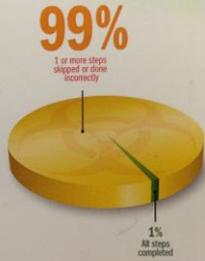
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### Direct observation found guideline nonadherence with manual cleaning of GI endoscopes (69 total)

- 57% did not brush all channels & components
- 55% did not dry with forced air
- 22% leak tested with sudsy water
- 16% skipped air purge after detergent flush
- 14% did not flush with alcohol
- 10% skipped final wipe down



**Multiple steps skipped  
45% of the time**

Information taken from a poster presentation at IAHCSBM Annual Conference May5-8,2013 Orlahead & Associates - Endoscope Reprocessing : evaluating Guideline Adherence

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### ***RUST Prototype Test:***

protein, blood, carbohydrate

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




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## What Organic Parameter to Monitor?

Guidelines: "Visibly Clean" is the standard; is it enough?

### Flexible endoscope biopsy channel: (Alfa et al 2002)

- Protein; < 6.4 µg/cm<sup>2</sup>
- Carbohydrate; < 1.8 µg/cm<sup>2</sup>
- Hemoglobin; < 2.2 µg/cm<sup>2</sup>
- Endotoxin; <2.2 EU/cm<sup>2</sup>

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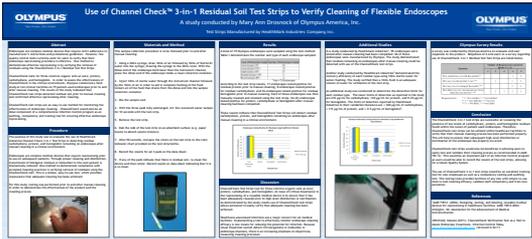
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## Olympus Study on the ChannelCheck™




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## ChannelCheck™ Verification Test as a Tool to Assess Endoscope Cleanliness

- ICT 1/2011 published
- The purpose of this study was to determine the real-world effectiveness of healthcare facilities' flexible endoscope cleaning procedures by utilizing the ChannelCheck™ residual soil test.
- A total of twelve health care facilities were recruited to participate in this study.
- The ChannelCheck™ is an easy to use and effective tool for monitoring the endoscope cleaning process and demonstrating competency of facility reprocessing staff.

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## HemoCheck Study



What did you leave behind? – Poster – IAHCSSM Annual Meeting – May 2014

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## Flexible Endoscope Study

- Infection Control Today – 11/2006
  - Kovach & Humphries
    - Looked at 24 scopes
      - Pre and post cleaning
      - Used EndoCheck Hemoglobin
    - Three scopes remained positive for blood soil after the first cleaning and were again positive after a second cleaning
    - One scope needed a 4<sup>th</sup> cleaning
  - Testing helped them improve the process and let data help them make improvements

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## ATP Studies

- 100 of article
  - Peer reviewed and non peer reviewed
    - Monitoring the Effectiveness of Hospital Cleaning Practices by Use of an Adenosine Triphosphate Bioluminescence Assay; Infection Control Hospital Epidemiology 2009; 30:678-684
    - Monitoring the effectiveness of cleaning in four British hospitals; AJIC, June 2007
    - Establishing a clinically relevant bioburden benchmark: A quality indicator for adequate reprocessing and storage of flexible gastrointestinal endoscopes; American Journal of Infection Control 40 (2012) 233-6

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### Other Articles

- 53% of Biopsy Port valves after cleaning exhibited some form of debris or potential contamination; Endonurse 12/6
- 57% of centers that process scopes were not in compliance with basic national standards; Infection Control and Hospital Epidemiology Volume 23;2002
- The question is, “Are you sure your scopes are safe and clean???? What are you doing?”

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### What Does All of This Data Suggest ?

- All of the studies support a need for a QA program
- Residual bio-burden is a concern on scopes after cleaning
- All the studies then raise at least these 3 questions:
  - What do we test for ?
  - Organic residue or something else ?
  - What can be done to improve the process of monitoring the cleaning process of flexible and all scopes in general ?
- If staff followed the IFU all the time, we should not have any issues.
  - We know that is not happening

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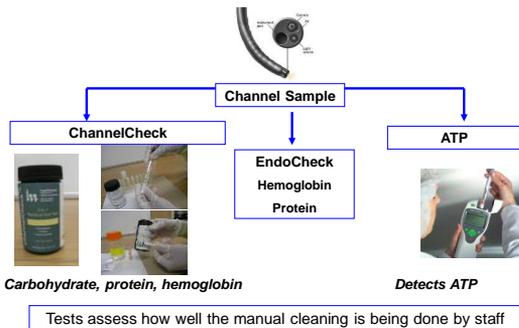
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Endoscope Lumens: Manual Cleaning Monitors  
Presently No Standard States You “Must” Monitor




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Storage Issues  
and  
Moisture in Scopes  
Start  
Biofilm Formation  
and Promote Growth

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Keep the Scope Dry

- From a microbiology perspective, an absence of moisture means bacteria can't replicate and biofilm can't form. That's a pivotal point. Flexible endoscopes are supposed to be stored dry. If staff follows proper reprocessing practices and stores scopes properly, biofilm might not be an issue.



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Storage of Flexible Scopes



- Improper storage
  - Coiled scopes
  - Touching the base of the cabinet
- Can cause microbial growth
- Present testing methods for a scope in storage
  - Traditional culture plating
    - (2 days)
  - Enzyme detection for bacteria
    - (10 minutes)
      - o Specific to gram negative bacteria

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## Storage of Reprocessed Endoscopes

- Hung vertically with the distal tip hanging freely in a well-ventilated, clean area
- Scopes should not be touching each other
- All removable parts (e.g., valves and caps) should be detached from the endoscope
- Detachable parts stored together with the scope; a small bag or similar device can be used to attach the parts to the scope




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## Storage of Reprocessed Endoscopes

- Identification of Patient Ready Scope
- The tag or label is affixed to the endoscope after it has been reprocessed and before it is placed in the storage cabinet
- The tag should be labeled with the following information:
  - a) Date of cleaning
  - b) Name of person who performed the cleaning
  - c) Date of high-level disinfection




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## Green is Clean




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## Quality Improvement and the Guidelines and Standards

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## Just Some of Our Groups



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## What Are These Based On?

- Clinically relevant & evidence-based practices
- Peer reviewed literature
- Other articles
- Manufactures' research and guidance
- Research and science
- Unfortunately, some practices do not have the evidence to support the practice
- Dynamic process
- All the major groups support in principal
  - Quality improvement
  - Quality assurance
  - Monitoring of your process

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### AAMI

*“A problem analysis should be completed for any problem with any aspect of decontamination that can pose a risk to personnel or patients. The problem analysis should define and resolve the problem and the system should be monitored to ensure that the problem has been corrected. (AAMI ST 79)”*

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### Quality Improvement Program Monitoring the Process

Currently most just respond to problems after they occur... not the best way to prevent or reduce the concern of dirty scopes.



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### Suggestions for a Quality Improvement Program

Put in a proactive preventive maintenance program for all scopes.

Monitor the critical steps in the process.

What are they?



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## Monitoring Steps in Your Process

- Look at your process
- Create an audit tool
  - Pre-cleaning
  - Leak testing
  - Cleaning with enzymatic detergent solution
  - Rinsing
  - Monitor the cleaning process
    - Manual
    - Automatic
  - Disinfectant/Sterilant
  - Rinsing
  - Drying & Alcohol Flush
  - Storage
  - Transport

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## Leak Testing

### Best Practices:

- Visualize bending section inflation before immersing
- Fully angulate distal tip in all directions
  - Document all results
- Follow OEM instructions for reprocessing a leaking endoscope
- Use same water-resistant cap throughout procedure

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**LEAVE YOU WITH THESE FEW  
THOUGHTS**

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Remember That Endoscope Leak Testers Give Hospitals Some of the Most Value in Reducing Repair Costs



Slide courtesy of Lighthouse Imaging LLC (Portland, ME)

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Why you leak test

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## Endoscope Reprocessing: Quality Improvement Program

- **Ensure staff competency:**
  - Initial training verification
  - Updated for new scopes
  - Yearly competency assessment needed
- **Ensure ongoing adequacy of reprocessing:**
  - Visible inspection inadequate for scope lumens
  - **Audit tool:**
    - Monitor scope lumens
    - Monitor AER cleaning adequacy (if used)
- Pick a product and base your policy on the information




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## Verifying Clean

Visual inspections and testing of the equipment

- Inspecting organic residues
- Testing for any cracks in the devices
- Checking integrity of fiber optic bundles

Methods to measure organic and other residues found on scopes

- Protein
- Hemoglobin
- Carbohydrates
- Enzyme detection for bacteria
- ATP
- Other tests in the future

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## Closing

- A policy should be based on the various standards and recommendations for flexible scopes, along with data from scientific data
- Users verify and manufacturers validate process
- Training, training of staff is so important
  - Wall charts
  - Certification
- Make a check sheet of what you need to monitor
- Each hospital needs to adapt a policy to their own situation
- Remember this...

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### Closing

- It is in the patient’s best interest for a hospital to do the best it can each and every time. Testing scopes for cleanliness as part of a quality improvement program is part of that commitment to quality and to the patient.
- Which Headline would you like to see for your hospital...

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### Example of a Headline in a Newspaper

- |   |  |
|---|--|
| <ul style="list-style-type: none"> <li>• St. Stephens Hospital has to call 700 patients because a flexible scope might not have been cleaned properly between patients</li> </ul> | <ul style="list-style-type: none"> <li>• St. Stephens Hospital improves patient outcome by implementing a quality improvement process for the cleaning of flexible scopes</li> </ul> |
|---|--|

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### Think of Your Medical Facility

*“Hospitals that eventually demonstrate a sustainable link between quality investments and better clinical outcomes will likely gain competitive advantage, thereby improving financial performance and possibly their bond ratings”*

<http://www.jhi.org/Hi/Topics/PatientSafety/SafetyGeneral/Literature/ImprovingClinicalQualitySafetyImportanceNotforProfitHospitals.htm>

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4. Pineau L et al Endoscope drying/storage cabinet: interest and efficacy. J Hosp Infect 2007;doi:10.1016/j.jhin.2007.10.012
5. Sciortina CV, E L Xia, A Moeze Assessment of a novel approach to evaluate the outcome of endoscope reprocessing. Infect Control and Hosp Epidemiol 2004;25:284-290
6. Orzechowski, ACP de Bruijn, C. Wassenaar Validation of a cleaning test for flexible endoscopes. Zentr Steril 2003;11:165-178
7. Mehta AC et al American College of Chest physicians and American Association for Bronchology consensus Statement: Prevention of Flexible Bronchoscopy-associated infection. 2005;128;1742-1755
8. [www.myendosite.com](http://www.myendosite.com)
9. As noted on slides

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## Flexible Endoscope Reprocessing is Changing

- Why do you need to do something now?
    - Consumer pressure for quality
    - Guidelines and Standards
    - Equipment failure
    - Staff training
    - Preventative maintenance program
  - What are ways to implement?
    - Look at your process
    - User testing
    - Equipment testing
  - Guidelines and standards support, in general, some type of quality improvement program for monitoring but are not specific at this time
- **AAMI TIR 54 / ST 91**




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## It Takes a Lot of Time to Properly Process Any Scope




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## When It Comes to Reprocessing Medical Devices, Patients' Lives Are In Your Hands



- ☐ Your commitment and responsibility to providing safe, efficient, and quality patient care should include testing scopes for cleanliness and proper reprocessing.
- ☐ Remember that most medical facilities do not have in place adequate quality monitoring programs for flexible scopes... you will very soon.

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### Some Things to Think about While Going Home

- We are what we repeatedly do. Excellence, then, is not an act, but a habit. ~ Aristotle
- We are all safety officers. ~ Rose Seavey
- Products and technologies may kill bugs, but people prevent healthcare associated infections.
- Knowledge is Power, but the real power is when you share your knowledge of what you know with others. ~ S.M. Kovach

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## Thank You

- Healthmark
- My Family
- Excellentia Advisory Group
- All of You for attending and wanting to share information
- Fill out the evaluation form
- Remember to "Keep it Clean"



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