

Is that Scope Safe?

Are Your Scopes Dirty? Challenges of Testing Verification

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Company Mission

To provide innovative and cost effective products that aid our Healthcare Industry customers in meeting their sterilization, decontamination, storage, distribution and security needs.



www.hmark.com

Healthmark Policy

Healthmark's Policy is to provide our customers and the healthcare community with the highest quality, state of the art medical products and support services in a timely and cost effective manner.

This goal is supported by a staff committed to individual accountability, professionalism, mutual respect, collaboration and service excellence. **This webinar is part of that commitment, educating our customers.**

Objectives

- Review the latest information from various organizations on flexible endoscopes in the last year
- Discuss the key provisions and competency recommendations of the standard ST91
- Review the ongoing updating of the document to keep information current
- Define best practices for processing flexible endoscopes

Breaking News

- **A Seattle Hospital has issue again with dirty scopes**
 - 8/20/15
 - www.seattletimes.com
- **California hospital says endoscope was cleaned improperly for 7 years**
 - 10/16/15
 - www.beckershospitalreview.com
- **ECRI puts out new List of technology Hazards**
 - 11/11/15
- **FDA sends out Warning Letter of recall on popular AER**
 - 11/13/15

Friday the 13th Nov. 2015

FDA Recommends Health Care Facilities Transition from Custom Ultrasonic Endoscope Washer/Disinfectors to Alternate Reprocessing Methods: FDA Safety Communication.

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm472462.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Since August 10th, FDA has received 21 complaints on Custom Ultrasonics. FDA recommends that health care facilities currently using Custom Ultrasonic AERs transition to alternative re-processing methods as soon as possible.

FDA orders recall of 2,800 scope-washing machines, citing infection risk.
Custom Ultrasonic Endoscope Washer/Disinfectors

<http://www.latimes.com/business/la-fi-fda-recall-scope-washers-20151113-story.html>

ECRI 2016 Top Ten Technology Hazards

1: Inadequate cleaning of flexible endoscopes before disinfection can spread deadly pathogens

5: Insufficient training of clinicians on operating room technologies puts patients at increased risk of harm

Dirty Scopes #1 Issue, Again



Inadequate Cleaning of Flexible Endoscopes before Disinfection Can Spread Deadly Pathogens **1**

The failure to adequately reprocess contaminated instruments—that is, to clean and disinfect or sterilize them—before using them on subsequent patients can lead to the spread of deadly pathogens.

A key aspect of effective reprocessing is cleaning biologic debris and other foreign material from instruments before the disinfection or sterilization step. If this pre-cleaning is not carried out effectively, the disinfection or sterilization step may not be effective.

Flexible endoscopes, in general, and duodenoscopes, in particular, are of specific concern because their complex design and long, narrow channels can make effective cleaning difficult. A series of fatal carbapenem-resistant Enterobacteriaceae (CRE) infections that attracted a lot of attention in 2014 and 2015 illustrates this concern. The deaths were associated with the use of duodenoscopes that had not been successfully disinfected between uses.

Facilities need to emphasize to their reprocessing staff that inattention to the cleaning steps within the reprocessing protocol can lead to deadly infections.

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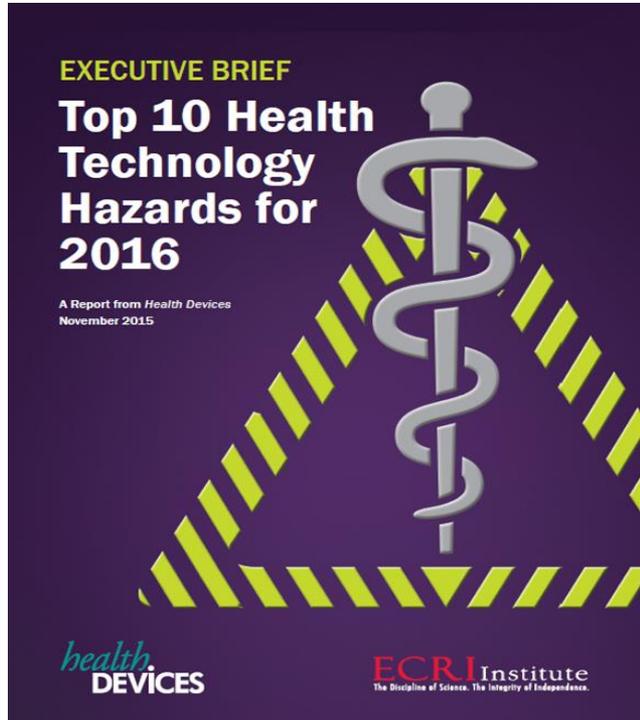
Adapted from: Health Devices 2015 November. ©2015 ECRI Institute. www.ecri.org/2015hazards
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#1 Issue ECRI – 2016 – Dirty scopes

The failure to adequately reprocess contaminated instruments—that is, to clean and disinfect or sterilize them—before using them on subsequent patients can lead to the spread of deadly pathogens. **A key aspect of effective reprocessing is cleaning biologic debris and other foreign material from instruments before the disinfection or sterilization step.** If this pre-cleaning is not carried out effectively, the disinfection or sterilization step may not be effective. Flexible endoscopes in general, and duodenoscopes in particular, are of specific concern because their complex design and long, narrow channels can make effective cleaning difficult.

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#5 – Training and IFU



The graphic shows a white surgical robot arm positioned next to a large, 3D yellow question mark. The background is a gradient of brown and orange.

Insufficient Training of Clinicians on Operating Room Technologies Puts Patients at Increased Risk of Harm

5

Insufficient training of clinicians on operating room (OR) technologies can result in use errors that lead to prolonged surgery, complications that require additional treatment, and even serious patient injury or death.

Errors can result if training:

- It is not provided or is insufficient or ineffective (e.g., if it does not provide an assurance of competency)
- Does not include all relevant team members, including physicians, per diem staff, and new hires, as well as regular staff
- Is not completed by all relevant team members before they use a device in clinical practice

ECRI Institute estimates that approximately 70% of incidents involving a medical device can be attributed to user error or the technique of use. Many of these incidents could have been avoided if users had a better understanding of the instructions for use and device operation.

Facilities should make training a key part of the acquisition process for new OR technologies, as well as an ongoing consideration for existing technologies.

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Compliance with standards is poor

- Recently, Becker's Clinical Quality and Infection Control update reported:
 - The Joint Commission has identified the five most challenging hospital accreditation standards in the first half of 2013.
 - Five standards that were most frequently deemed not compliant for hospitals in the first half of the year, along with their noncompliance rates.
 - Number 3 out of 5
 - **The hospital reduces the risk of infections associated with medical equipment, devices and supplies (IC.02.02.01)**
 - Rates are going up:
 - » 47% in 2013
 - » 42 % in 2012
 - » 36% in 2011

Why Endoscopes? Why Now?

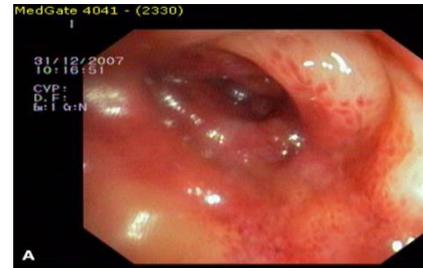
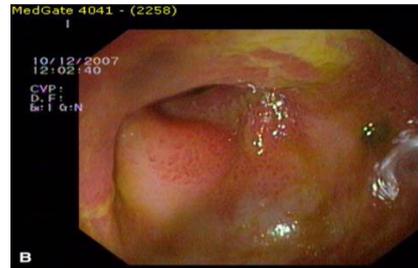
- Approximately **12 million** gastrointestinal endoscopies are performed annually in the United States
- Contaminated endoscopes have been linked to **more health care-associated infections than any other medical device**
- Several guideline-issuing organizations estimated that the risk of endoscopy-associated infection (EAI) is only 1 in 1.8 million procedures
- However...
 - Most outbreaks are not published
 - Most outbreaks are not investigated
 - Difficult to link infections to contaminated endoscopes
 - Reviews of reprocessing practices show widespread lapses in essential steps
 - Risks are greater than just infections (e.g., toxicity with aldehydes)
 - Deaths have been associated with poor reprocessing of flexible endoscopes

What you know about scopes

- You've been told:
 - Not a big deal when it comes to infections
 - Risk of infection is low
 - We (the facility) has no issues. We are doing it all correctly.
 - Information has been out there but we have failed to “connect the dots”.
 - Peer-reviewed & Non-peer reviewed information
 - These do not always match
- Focus is on ERCP. Tip of the iceberg?
 - Bronchoscopes? Others?
- Our patients (customers) are getting their information from:
 - TV, Internet, word of mouth
- Quick review of what has been going on

Device Processing Risks

Device Damage - Toxic Substances - Infections



Transmission of Infection by Flexible Gastrointestinal Endoscopy and Bronchoscopy

Julia Kovaleva,^a Frans T. M. Peters,^b Henny C. van der Mei,^c John E. Degener^a

April 2013 Volume 26 Number 2

Clinical Microbiology Reviews p. 231–254

CBS NEWS / January 22, 2015, 12:29 PM

Deadly superbug infected patients at Seattle hospital

'Superbug' linked to 2 deaths at UCLA hospital



Doug Stanglin, USA TODAY

11:09 a.m. EST February 19, 2015

Superbug outbreak extends to Cedars-Sinai hospital, linked to scope

281 Hartford Hospital Patients Exposed to Drug-Resistant E. Coli

Medical scope now tied to Wisconsin superbug outbreak

Scope disinfection failure suspected in superbug cluster, leads UPMC to alter methods

Endoscope Processing Failures Resulting in Patient Notifications - Consumer Pressure

Location	Year	Reprocessing Failure	Patient notifications
Sacramento, CA	2002	Failure to clean auxiliary channel	750
Toronto, Canada	2003	Soap used to disinfect	146
Seattle, WA	2004	Inadequate LCG soak time	600
Sacramento, CA	2004	AER malfunction	1331
Long Island, NY	2004	Failure to test MEC of LCG	177
Redwood City, CA	2004	AER Malfunction	2000
Charleston, WV	2004	Improper LCG use	1383
Pittsburg, PA	2005	Auxiliary channel	200
Leesburg, VA	2005	Inadequate LCG soak time	144
San Diego, CA	2006	Failure to disinfect	299
Beaumont, TX	2006	Improper adapter	320

Endoscopes Poster - IAHCSSMM*

- 57 % did not brush all channels and components
 - 55% did not dry with forced air
 - 22% leaked tested with sudsy water
 - 10% skipped final wipe down
 - 45% missed multiple steps
 - 99% missed 1 or more steps or done incorrectly
 - 1% all steps completed correctly
- Hawthorne Effect

* Information taken from a poster presentation at IAHCSSMM Annual Conference May 5-8, 2013 Ofstead & Associates – Endoscope Reprocessing: Evaluating Guideline Adherence

Regulations/Standards/Guidelines

- Regulations
 - A rule or directive made and maintained by an authority
 - Mandatory
- Standards
 - Requirements and specifications to ensure consistency and fit for purpose
 - Voluntary, but can become mandatory
- Guidelines, Recommended Practices, Technical Information Reports
 - Technical guidance, information or preferred procedures regarding a given topic
 - Voluntary but with interpretation



Endoscopy - Healthcare Facilities

- Guidelines
 - CDC Guideline for Decontamination and Sterilization in Healthcare Facilities (2008)
 - ASGE/SHEA/SGNA/APIC: Multi-society guideline on reprocessing flexible gastrointestinal endoscopes (2011)
 - SGNA: Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes (2012)
 - SGNA: Guideline for Use of High Level Disinfectants & Sterilants for Reprocessing Flexible Gastrointestinal Endoscopes (2013)
 - AAMI TIR34 Water for the reprocessing of medical devices (2014)
 - AORN Recommended practices for cleaning and processing flexible endoscopes and endoscope accessories (2014)



Endoscopy - Healthcare Facilities

- Standards

- AAMI/ANSI ST79. Steam sterilization, 2nd edition (Incorporates Amendment 1:2010, A2,2011, A3:2012, and A4:2013)
- AAMI/ANSI ST 58. Chemical sterilization and high-level disinfection. 3rd edition (2013)
- AAMI/ANSI ST 41. Ethylene oxide sterilization 4th edition (2010)
- **AAMI/ANSI ST91**. Comprehensive guide to flexible and semi-rigid endoscope reprocessing in health care facilities (2015)



American
National
Standard

A graphic consisting of two overlapping trapezoidal shapes. The bottom-left shape is blue and the top-right shape is green, together forming a larger, irregular shape that points towards the top-right.

ANSI/AAMI
ST91:2015
Flexible and semi-rigid
endoscope processing in
health care facilities

What is ANSI/AAMI ST 91?

- Flexible and semi-rigid endoscope reprocessing in health care facilities
- Contains best practices for scope reprocessing in ANY setting

AAMI ST 91: Scopes

- Guidelines for processing of flexible endoscopes
 - Includes pre-cleaning, leak-testing, cleaning, packaging (where indicated), storage, high level disinfection, and/or sterilization
- Include flexible gastrointestinal (GI) endoscopes; flexible bronchoscopes; flexible ear, nose, and throat endoscopes; surgical flexible endoscopes (e.g., flexible ureteroscopes); and semi-rigid operative endoscopes (e.g., choledochoscopes)
- Exclusions
 - Rigid endoscopes
 - Rigid probes (e.g., TEE probes)

What Information is in ST 91?

- Definitions
- Design of endoscope processing areas
- Personnel considerations
- Cleaning
- High level disinfection
- Automated endoscope reprocessors (AERS)
- Liquid chemical sterilization
- Gaseous chemical sterilization
- Processing accessories
- Storage and Transportation to site of use
- Quality Control
- Quality Process Improvement
- Informational Annexes
- We will review just a few of these sections due to time

Recommendation

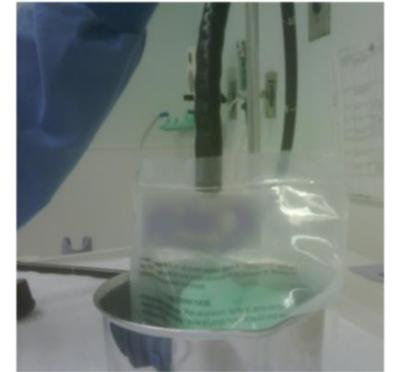
- Pre-cleaning
- Leak Testing
- Cleaning with approved detergent solution
- Rinsing
- **Monitor the cleaning process (added this step)**
- Disinfectant/Sterilant
- Rinsing
- Drying & Alcohol Flush
- Storage

Highlights of ST 91

- Gives recommendations for:
 - Certifications for technicians performing reprocessing
 - Monitoring the manual cleaning process
 - Monitoring the automatic cleaning process
 - Monitor water quality
 - Monitor temperature
 - After cleaning, all detachable valves should be kept together with the same endoscope as a unique set
- Risk Assessment
- Proper documentation and quality assurance parameters

Precleaning at the Point of Use

- ‘Bedside’ procedure
- Purpose: Reduce levels of microorganisms and soil (blood, other patient materials), prevent soil drying and reduce risk of biofilm development
- Steps
 - Appropriate PPE
 - Immediately after removing insertion tube from patient – before detaching scope from light source
 - Cleaning solution (or water)
 - External wipe/sponge (non- to low-linting)
 - Suction solution through suction lumen
 - Flush all channels



Remember Device Manufacturer's Instructions!

Contaminated Transport

Closed, Labeled Transport Containers



Transport Trolley



The 2220 Trolley is perfectly suited to transport Healthmark's 2220 round bins, and has the capability to hold up to 5 bins simultaneously.

The stainless steel frame is sturdy enough to address the rigors of daily use.

By adding Healthmark's green and red tamper evident seals it becomes an excellent process control system for both Clean (green) and Dirty (red) Flexible Endoscopes.

Locking casters insure no unwanted movement. This cart and tray system is ideal for transporting clean and dirty scopes to and from reprocessing.

Transportation



The above picture shows a returned patient-used scope in an unmarked container/bag.



Maybe a better way to meet the standards found in ANSI/AAMI ST 79; page 38; section 6.

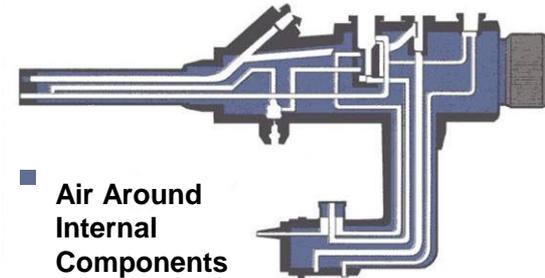
Transportation

- Getting from point of use to cleaning
- Must be clearly marked
- AAMI ST 79
- AAMI ST 91



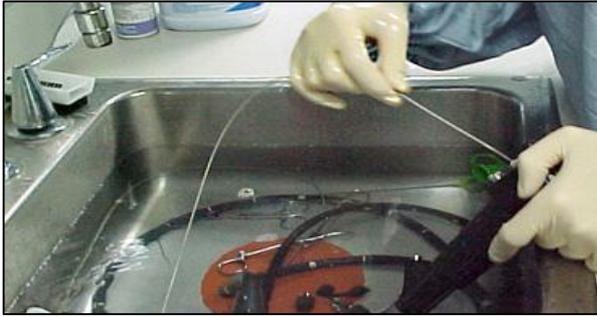
Leak Testing

- Detects damage to interior and exterior of scopes
- Done before immersion of endoscopes to minimize damage
- Both manual and computerized leak testing
 - Inspect carefully and over time
 - Manipulate the device
- Leak testing is specific to each endoscope – follow manufacturer's instructions





Why you leak test .



Manual Cleaning

- Scope and accessories
- Submerge scope to prevent splashing contaminated fluids
- Video caps must be in place if applicable
- External surfaces cleaned with soft, lint-free cloth or appropriate sponge
- Brushing, when specified
 - Appropriate size for scope and valves
 - Must be in good condition
 - Should be single use or if reusable, disinfected or sterilized between uses
- Flush all channels with detergent
- Additional automated washing/cleaning may be used

Must use the right size brush

- It's absolutely necessary to use the appropriately sized brush - diameter of the brush is critical to letting bristles create friction against the walls of the lumen.
- If you use one that's too big, the bristles will bend back and won't scrub debris away, and you risk scratching the inside of the cannula.
- Too small, and you won't create any (or at least not enough) friction between the bristles and the inner walls.

Improper Fit

Brush diameter is too small for the channel



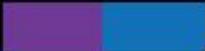
Brush diameter is too large for the channel and does not create proper friction



Proper Fit:

Brush diameter is adapted to the channel and creates proper friction to clean inner channel



ITEM NUMBER	CHANNEL DIAMETER	SCOPE COLOR
CC-110	1.2 mm	
CC-172	1.7 -2.2 mm	
CC-250	2.6 -3.2 mm	
CC-374	3.7-4.3 mm	
CC-601	5.5 mm	
CC-603	7.4-10.0 mm	uncolored
3770/Valve Brush	6.37 mm & 1 mm	uncolored



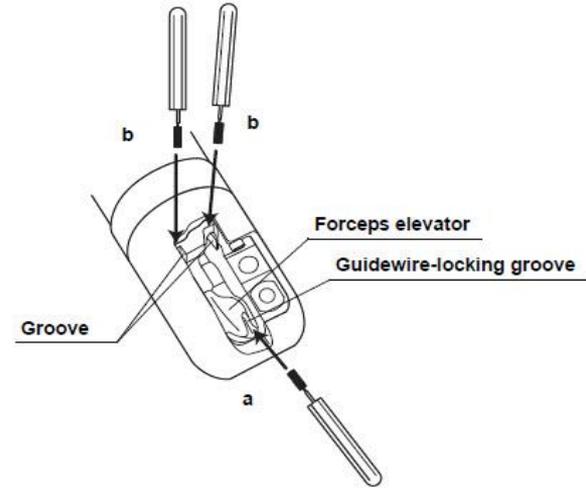
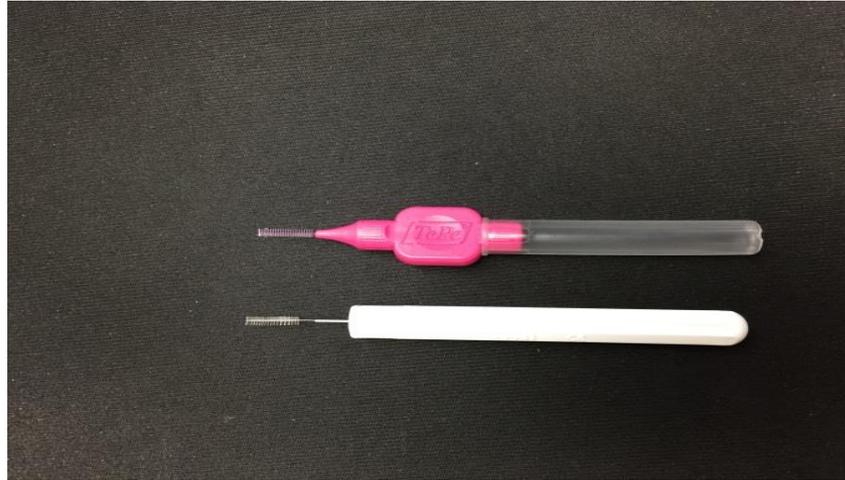
The color on your Endo Brush bag will correspond to the color located here on your Olympus scope.

Please Note: Some brush sizes will correspond to two Olympus colors rather than one. In which case, this brush size may be used for either color scope.

Elevator Area of an ERCP Scope Needs a Special Brush

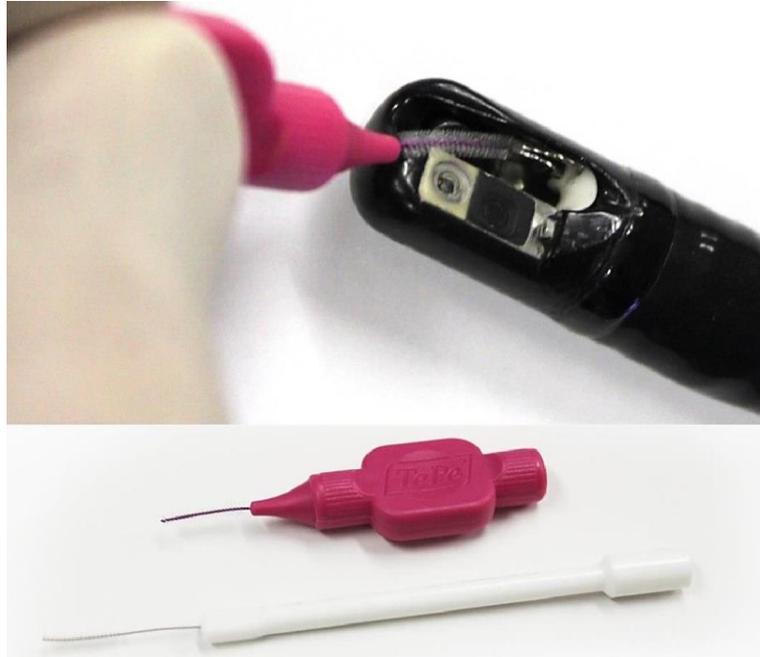


Additional ERCP Cleaning Steps



Revised cleaning procedure requires brushing of the forceps elevator recess with two different size brushes. In addition to the brush that is in the old IFU for cleaning the elevator recess area, **the MAJ-1888 brush, or equivalent is recommended for further cleaning of this area.**

MAJ-1888 brush, or equivalent is recommended for further cleaning of this area.



Remember to Rinse!

- Rinsing is often underestimated
 - Removal of chemicals and residual soil such as protein (e.g., enzymes used during cleaning)
 - Devices should not present a toxic risk to patients
 - Water quality/purity can impact this
 - Number of rinses and rinsing method



Verifying Clean

- Visual inspections and testing of the equipment
 - Use of lighted magnification – outside & inside of scope
 - 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
 - Swabbing method
 - Flushing method
 - Protein
 - Hemoglobin
 - Carbohydrates
 - Enzyme detection for Bacteria
 - ATP
 - Other test in the future
- Lots of information on all of these methods
- Pick what fits for your facility

Lighted Visual Inspection Tools



What markers should be utilized for user cleaning verification?

- Literature supports using the three most predominant contaminants that are the main components of bodily fluids are protein, hemoglobin, and carbohydrates as markers.*
- Regulatory authorities (like the FDA) look for results from device manufactures for two markers of the test soil chosen (for example, protein, hemoglobin, mucus).*
- Alfa has shown that for flexible scopes: Protein; < 6.4 µg/cm², Carbohydrate; < 1.8 µg/cm², Hemoglobin; < 2.2 µg/cm², are excellent markers for cleaning validation and verification.**
- Users should look at testing for the same markers to verify their process as the manufacturer of the device
- Users should understand not only what a test tells you when it passes, but also when it fails.

*The source for all of this information is taken from : A White Paper ;The New Scope of Reusable Device Cleaning Validations-By: Patrick Kenny;Microtest-2011

**Alfa MJ et al A Survey of reprocessing methods, residual viable bioburden and soil levels in patient-ready ERCP duodenoscopes used in Canadian centers. Infect Control Hosp Epidemiol 2002;23:198-206

Endoscope Lumens: Manual Cleaning Monitors



Channel Sample

Carbohydrate, Protein, Hemoglobin



ChannelCheck

Blood or Protein



ATP



Detects ATP

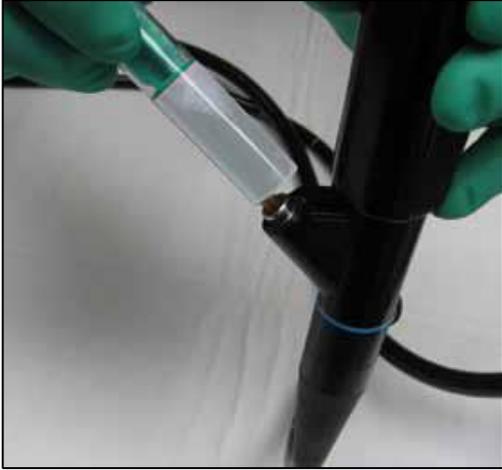
Tests assess how well the manual cleaning is being done by staff



EndoCheck

- Test kits for detection of blood or protein residues inside the scopes various channels
- Prepackaged test easy to use
- Detection limit of $0.1\mu\text{g}$ within seconds for blood
- Detection limit of $1.0\mu\text{g}$ within minutes for protein

Channel Check



- ChannelCheck™ is capable of testing virtually any lumened instrument for residual organic soils, including flexible endoscopes, no matter the channel size because it is a flush method.
- ChannelCheck™ tests for three common organic soils at once: blood, protein and carbohydrates.
- Science & Method were developed by Microbiologist, Dr. Michele Alfa, University of Manitoba
- Conducted an extensive study
 - 25 sites - 1100 plus tests.
- Demonstrated that 17% of scopes are still dirty after initial cleaning

ATP

- Testing Methods
 - Flush
 - Swabbing
 - Surfaces & Lumens
- Many, many articles on ATP
 - Positive
 - Monitoring the effectiveness of cleaning in four British hospitals; JIC, June 2007
 - Negative
 - Evaluation of ATP Bioluminescence Assays for Potential Use in a Hospital Setting **

**Infection control and hospital epidemiology May 2011, vol. 32, no. 5

Key Points with Disinfection

- Label claims can vary
 - Safety, preparation, contact time, numbers or rinsing etc
 - Request specifics from manufacturers (e.g., ‘rinse thoroughly’)
- Single use or multiple use
 - Use of solution test strips to verify minimum recommended concentration (MRC)
- Multiple use disinfectants
 - Closely reuse label claims, including maximum reuse life
 - ‘Topping off’ of solutions
- All parts of the device should be contacted
- Importance of rinsing
 - Correct water quality (bacteria-free; AAMI TIR34)
 - Fresh water for every rinse (by immersion)
 - Correct number of rinses
- Device inspection prior to use

Storage issues & moisture in endoscopes can contribute to Biofilm formation and promote growth of organisms

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 follow proper reprocessing practices and store scopes properly, biofilm might not be an issue.



Storage of Flexible Scopes



- Improper Storage
 - Coiled scopes
 - Touching the base of the cabinet
- Can allow for microbial growth if not completely dry
- Present testing methods for a scope in storage
 - Traditional culture plating at least 2 days

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 should be stored together with the scope**
 - a small bag or similar device can be used to attach the parts to the scope.
 - **New AAMI ST91 standard**

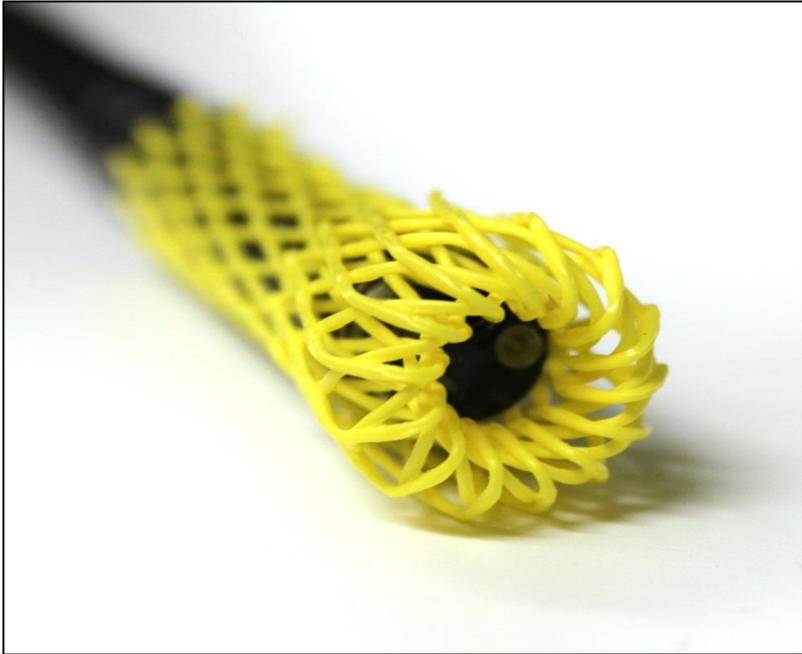


Storage of reprocessed endoscopes

- 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



Protecting the Distal Tip



Keep Valves & Scope Together



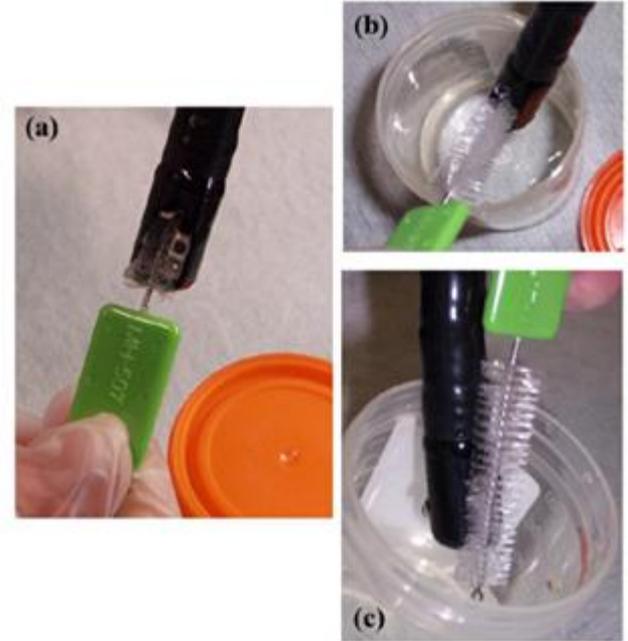
- Single-use valve cage for the safe storage of endoscope valves and to ensure that they remain as part of a unique set with the parent endoscope.
- Meet the requirement of the standard
 - options

New guidelines released in AAMI ST91 focus on safety and traceability of endoscopes parts and valves. The parent endoscope and its associated valves and air/water channel cleaning adapter should remain together as a unique set. This would aid in the investigation of an infection control outbreak by allowing for all parts used in a suspected case to be identified easily and pulled out of use.



CDC Interim Guidance on culturing 4/3/15

- What sites of the duodenoscope should be cultured?
 - Instrument channel (suction/biopsy channel)
 - Distal end (elevator mechanism, elevator recess)
 - Elevator channel (on older, unsealed)



Quality Process Improvement

- This section identifies performance measures and process monitors used for continuous quality improvement (CQI) programs.
 - Effective means of improving the performance of any process
 - CQI looks at the entire process including decontamination, preparation, packaging, HLD, sterilization, quality control, etc.
- A procedure for performing a risk analysis in facilities is outlined

No Silver Bullet

An ounce of prevention can yield enormous return for your patient.

1 oz Silver Bullet - .45 Caliber ACP



It must also be understood that implementation of any quality improvement or risk-based program does not always prevent incidences from happening but they will help you reduce and understand those incidences better if they do occur.

We hope this program will help you
achieve “Best Practice”



Closing

- We have only talked about a few of the highlights of ST 91
 - Purchase ST 91 at www.aami.org
- A policy should be based on the various standards and recommendations for flexible scope along with data from scientific data
- Users verify and manufacturers validate process
- Training of staff is so important
 - Wall charts
 - Certification
- Make a check sheet of what you need to monitor
- Each facility needs to adapt a policy to their own situation



Questions



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AAMI ST91: Flexible Endoscope Processing

What you need to know

Hosted By
Becker's Hospital Review

Presented By
Healthmark Industries
Fraser, Michigan

